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, 2025**

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, 2025, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $328 million based on the closing sale price as reported on the Nasdaq Capital Market.

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

Class	Outstanding at March 6, 2026
Common Stock, $0.01 par value per share	29,663,875 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, 2025, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the 2026 annual meeting of stockholders.

CLEARPOINT NEURO, INC.

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Trademarks, Trade Names and Service Marks

ClearPoint Neuro®, *ClearPoint®*, *SmartFlow®, SmartFrame®, SmartGrid®, Inflexion®*, *ClearPoint Maestro®*, *SmartFrame Array®*, *SmartFrame OR®*, *ClearPoint Neuro Orchestra®, ClearPoint Prism®, ClearPointer®, When Your Path is Unclear, We Point The Way®*, *ClearPoint Advanced Laboratories™, IRRAS®, and IRRAFLOW®* are all trademarks of ClearPoint Neuro, Inc. and its affiliates. 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. All statements, other than statements of historical fact, in this Annual Report, including statements relating 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, are forward-looking statements. Forward-looking 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. We caution you that the forward-looking statements in this report are based on a combination of facts, factors currently known by us and our projections of the future, about which we cannot be certain. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

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.
- We may fail to realize the anticipated benefits of our acquisition of IRRAS, and the combined company may not perform as we or the market expect, which could adversely affect our business, results of operations, and the price of our common stock.
- 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 and our IRRA*flow* system may not achieve broad market adoption.
- Future business growth is dependent on our ability to market and sell both the ClearPoint system and the IRRA*flow* system, and on our ability to integrate and effectively manage a combined commercial team that must support two distinct product platforms.
- 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.
- Limitations in the existing clinical evidence for the IRRA*flow* system may affect clinical and commercial adoption.
- 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.
- We rely on single facilities for manufacturing and performance of services, which exposes us to significant risk of disruption.
- Our reliance on single-source suppliers could harm our ability to meet demand for our products.

- Our use of hazardous materials in manufacturing and in the conduct of services may expose us to significant health, safety, environmental, and regulatory risks.
- 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.
- Our role in current and future clinical trials requires significant resources, and in some cases, may limit our ability to control the conduct and outcomes of these studies. Negative or unfavorable results could adversely impact adoption of our products.
- 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.
- Our acquisition activities, including our recent acquisition of IRRAS, may expose us to heightened cybersecurity risks that could adversely affect our business, financial condition, and results of operations.
- 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.
- 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 currently have significant debt and may incur additional debt. Failure by us to fulfill our obligations under the applicable debt agreements may cause repayment obligations to accelerate. These agreements also contain certain covenants that restrict our operational and financial flexibility.
- 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. Failure to obtain necessary funding may delay, reduce or eliminate business activities and initiatives.
- Raising additional funds may cause dilution to existing stockholders, 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.
- The success of our biologics and drug delivery business is dependent on timely regulatory approval and commercialization of cell and gene therapies.
- A government shutdown or prolonged lapse in federal appropriations could materially delay or disrupt FDA review and approval processes critical to our business, which could have a material adverse effect on our financial condition and results of operations.
- 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 integrated systems used in minimally invasive neurosurgical 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.

In 2025, through our acquisition of IRRAS Holdings, Inc. ("IRRAS"), we expanded our portfolio into neurocritical care. IRRAS is a commercial-stage medical technology company focused on treatments for intracerebral hemorrhage, intraventricular hemorrhage, and other conditions requiring intracranial fluid management.

The IRRAS products complement our existing neurosurgical technologies and broaden our reach into acute care settings, enabling us to offer an expanded set of solutions spanning functional neurosurgery, neurocritical care, and intracranial drug delivery.

Our business consists of two integrated 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 2025, we released the ClearPoint Navigation Software Version 3.0, which allows for the ClearPoint system navigation software to support end-to-end procedures 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.

In 2025, through the acquisition of IRRAS, we added the IRRA*flow* Active Fluid Exchange System (the "IRRA*flow* system") to our portfolio of medical devices. The IRRA*flow* system integrates continuous irrigation, drainage, and real-time intracranial pressure monitoring to provide controlled, automated intracranial fluid management within neurocritical care and operating room settings.

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; 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, such customers achieving success in completion of clinical trials and subsequent regulatory approvals of their drugs and biologics, and such customers' realization of commercial success for their therapies, including overcoming barriers in reimbursement, physician adoption, and patient access to their therapies. In 2024, the U.S. Food and Drug Administration (the "FDA") granted marketing authorization for our SmartFlow Neuro 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 series of SmartFrame trajectory device, a hand controller and related accessories, and our SmartFlow Neuro cannula. Our SmartFrame devices are an adjustable trajectory guide that attaches to the patient's skull and holds the targeting cannula. In the MRI, a 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 image-guided neurosurgical procedures, 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 Neuro 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 Prism Neuro Laser Therapy System

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 1.5T and 3.0T MRI guidance. The laser system can be used in conjunction with the ClearPoint navigation platform or other third party cranial navigation platforms 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.

The IRRAflow System

Our IRRA*flow* system is an active fluid exchange platform designed for use in neurocritical care and neurosurgical operating room environments. The system integrates continuous irrigation, drainage, and real time intracranial pressure monitoring to actively manage intracranial fluid in patients with conditions such as intracranial hemorrhage and intraventricular hemorrhage. The use of IRRA*flow* Active Fluid Exchange System is indicated when intracranial pressure monitoring is required, and for externally draining intracranial fluid, as a means of reducing intracranial pressure in patients where an external drainage and monitoring system is needed.

The IRRA*flow* system consists of a control unit, proprietary dual-lumen catheters, and procedure-specific disposables. The control unit enables automated modulation of irrigation and drainage parameters, while the dual-lumen catheter design allows for infusion and drainage. The system's disposables include tubing sets and sterile collection components required for each procedure.

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 nonclinical contract research services in large and small research models to assist our customers with establishing drug safety prior to and in support of human clinical trials. In 2025, we expanded our preclinical services business through the lease of a facility to enable increased operational capabilities and service capacity.

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, and Brazil, our approval carries a similar indication for use.

In the United States, our SmartFlow Neuro 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 Neuro Cannula is investigational. The SmartFlow Neuro Cannula is also registered in Brazil, Canada, Turkey, and Taiwan. The device is a disposable 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 1.5T and 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 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.

Our ClearPoint Navigation Software Version 3.0 received 510(k) clearance in 2025. When used in conjunction with the SmartFrame disposable stereotactic frame, it is intended to provide precise stereotactic guidance when placing instruments or devices during neurosurgical procedures. These procedures include biopsies, catheter and electrode insertion including deep brain stimulation (asleep or awake) lead placement.

Our IRRA*flow* system has received 510(k) clearance from the FDA and is indicated for use when intracranial pressure monitoring is required and for externally draining intracranial fluid, as a means of reducing intracranial pressure in patients where an external drainage and monitoring system is needed. The system facilitates active fluid management, including controlled irrigation and drainage, within the intracranial space. The IRRA*flow* system has also obtained CE mark certification in the European Union for similar indications related to controlled fluid exchange and intracranial drainage. We may in the future seek new or expanded indications for use of the IRRA*flow* system, including indications related to subdural hematomas, extended-duration infusions, oncology, or intracranial drug delivery.

Market Discussion

Medical Devices for Neurosurgical Application

ClearPoint Navigational Platform and Therapy Applications

We believe there are a significant number of potential neurosurgical procedures in the U.S. in which our ClearPoint products could be used as a navigational platform for functional stereotactic neurosurgery in FDA-cleared indications 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. Multiple manufacturers have received FDA clearances for DBS systems, including Medtronic, Boston Scientific and Abbott Laboratories. These systems are indicated for Parkinson's disease and essential tremor. DBS is used to treat the symptoms of Parkinson's Disease, a degenerative condition that affects a substantial population in the U.S. and 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 believe a meaningful number of Parkinson's disease and essential tremor patients each year may be 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 focal 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 networks that propagate seizure activity. A substantial number of patients with brain tumors or drug-resistant epilepsy may be candidates for LITT. Historically, manufacturers with FDA cleared laser therapy systems in North America have included 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 believe brain tumor applications represent a meaningful potential procedural opportunity for our platform.

IRRAflow Neurocritical Care and Intracranial Fluid Management Applications

With the addition of the IRRA*flow* system to our product portfolio, we participate in the neurocritical care market focused on the active management of intracranial fluid and intracranial pressure. This market includes patients who require external drainage and monitoring systems in intensive care units or neurosurgical operating rooms.

Conditions commonly requiring external ventricular drainage or other forms of intracranial fluid management include intraventricular hemorrhage, intracerebral hemorrhage, subarachnoid hemorrhage, and other acute neurologic conditions associated with elevated intracranial pressure. We believe there are a substantial number of procedures in the United States each year involving external ventricular drainage or intracranial pressure monitoring in which a system such as IRRA*flow* may be used; however, actual utilization may vary based on physician preference, institutional protocols, and patient-specific factors. The IRRA*flow* system is designed to provide controlled irrigation, drainage, and continuous monitoring, offering what we believe to be an active alternative to traditional passive drainage methods. Subdural hematomas, extended-duration infusions, oncology, and intracranial drug delivery represent additional conditions that may benefit from active intracranial fluid management; however, the IRRA*flow* system is not currently cleared or approved for use in the treatment of those conditions, and we may in the future seek regulatory clearance or approval for such conditions from the FDA and applicable foreign regulatory authorities. See the risk factor titled, *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*, below.

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 Neuro 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 Neuro cannula, preclinical, development and consulting services, and other partnership arrangements. In 2024, the SmartFlow Neuro 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, for a rental fee, or for an agreed-upon period of time for a placement fee bundled into the price of a disposable products stocking order. 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.

With the acquisition of IRRAS, we have expanded our commercial reach into the neurocritical care and acute intracranial fluid management market. Commercializing the IRRA*flow* system involves marketing directly to neurosurgeons, neuro-intensivists, critical care physicians, and hospital based neurocritical care teams responsible for the management of intracranial pressure and intracranial fluid drainage. Similar to our ClearPoint model, the IRRA*flow* system generates recurring revenue primarily through disposable catheters and procedure-specific consumables, while the control unit serves as the durable capital equipment placed within hospitals. We believe that the integration of the IRRAS commercial team with our team will increase our commercial reach and scale, support the growth of the combined installed base, and strengthen our ability to serve both neurosurgical and neurocritical care customers.

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 Neuro 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 material long-term contracts with our suppliers for our ClearPoint system or SmartFlow Neuro Cannula.

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

Our IRRA*flow* system includes a reusable control unit and related hardware accessories, which are manufactured at our San Diego, California facility. We rely on third-party manufacturers for the catheter and other procedure-specific disposables used with the IRRA*flow* system. We currently source these disposables from single-source suppliers due to their specialized expertise, quality considerations, cost efficiencies, and regulatory requirements. However, we have identified alternative supply sources for these disposables if needed. Our primary contract manufacturers for IRRA*flow* disposables operate under master service agreements that govern the terms of our supply relationships.

Our facilities are structured to complete component processing, final assembly, packaging and distribution activities for our products which are manufactured in-house. 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 audits 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 System products and IRRA*flow* system products. Our five largest hospital customers accounted for approximately 21% of our neurosurgery navigation disposable product revenues in 2025. The addition of the IRRA*flow* business is expected to continue to reflect a similar concentration of revenue among a limited number of hospital sites.

Biologics and Drug Delivery

As of March 6, 2026, we had commercial relationships with over 60 pharma/biotech, academic, and contract research organization partners who have either evaluated or used our SmartFlow Neuro cannula or our consulting services.

One of these companies, PTC Therapeutics, Inc. and its affiliates ("PTC"), accounted for approximately 15% of our biologics and drug delivery revenues in 2025. One of our directors is PTC's Chief Executive Officer and President. 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 the PTC Supply Agreement was further amended and restated to allow us 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 will continue for the term of the PTC Supply Agreement, subject to certain early termination rights.

Intellectual Property

To maintain a competitive advantage in the marketplace, we seek to develop, maintain and protect 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. The acquisition of IRRAS added ten additional patent families with patents in the field of fluid exchange systems, neuromonitoring, and processes. As of March 6, 2026, we own or license over 130 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, Japan, 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, we entered into a license and collaboration agreement and a distribution agreement with CLS, which as amended in August 2020, 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 Neuro cannula, and for which we are committed to pay royalties based on our sales of the SmartFlow Neuro cannula.

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 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. Many of our competitors have substantially greater financial, manufacturing, marketing, and technical resources than we have.

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 navigation and therapy methods.

Following our acquisition of IRRAS, we also participate in the neurocritical care market for intracranial fluid management and intracranial pressure monitoring. In this market, we compete with manufacturers of traditional external ventricular drainage ("EVD") systems and related monitoring platforms. Key competitors in the EVD market include Medtronic plc, Spiegelberg GmbH & Co. KG, Sophysa, B. Braun, and Integra LifeSciences. While the IRRA*flow* system is differentiated by its active fluid exchange capabilities, irrigation and drainage features, and continuous monitoring functionalities, these competitors established EVD solutions present a competitive landscape that requires us to drive adoption and differentiate on clinical outcomes, workflow efficiency, and value propositions.

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 our 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 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 own 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 March 6, 2026, we had 172 full-time employees, including the 37 employees who joined us in connection with the IRRAS acquisition. 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. The matters described below reflect our beliefs and views as to factors, events or contingencies that could materially and adversely affect our business, financial condition, results of operations, and growth prospects, and/or the price of our common shares in the future. References in this section to past events or conditions are provided by way of example only and are not intended to be a complete listing or a representation as to whether or not the factors,events or contingencies discussed below have occurred in the past or their likelihood of occurring in the future.

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 persistent inflationary pressure, higher interest rates, changes in monetary policy, declining consumer and business confidence and spending, supply chain disruptions, the introduction of or changes in tariffs or trade barriers, and the potential for 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, including reduced liquidity and access to credit, increased borrowing costs, foreign currency fluctuations, and volatility in the valuations of securities generally. As a result, our ability to access capital markets or other funding sources in the future may be limited or may not be available on commercially reasonable terms, if at all.

Inflationary pressures and elevated interest rates could increase our costs for research and development, supply chain, labor, and other administrative expenses, which could in turn raise the cost of producing and distributing our products and services. In such environments, we may be unable to increase prices sufficiently to offset these higher costs. These impacts could be more pronounced in areas of our business where pricing is governed by long-term contractual arrangements, as we may not be able to quickly or easily adjust pricing, reduce costs, or implement countermeasures.

In addition, our hospital, pharmaceutical, and biotechnology customers may experience heightened financial and operational pressures as a result of macroeconomic conditions. Such pressures may include increased cost of funding, reduced access to capital markets, cash flow challenges, or difficulties complying with debt covenants. These conditions could, in turn, impede our hospital customers' ability to provide patient care or reduce budgets for new capital equipment and technologies. Government funding cuts have further constrained hospital and healthcare system budgets, which may limit their ability to invest in new technologies and slow adoption of our products. Our pharmaceutical and biotechnology customers who are engaged in gene and cell therapy development, may face reduced availability of research and development funding, which could slow the pace of innovation, delay clinical trials, or constrain commercialization efforts. Any such customer constraints may adversely affect their willingness or ability to purchase our products and services, or may impair their ability to make timely payments, either of which could negatively impact our business, financial condition, and results of operations. Moreover, broader economic uncertainty, elevated unemployment levels, and rising health insurance premiums, co-payments, and deductibles may lead to cost-conscious consumers pursuing fewer elective or advanced medical treatments, which could reduce procedure volumes and demand for our products and services.

Geopolitical changes and trends such as populism, protectionism, economic nationalism, as well as tariffs, sanctions, and other trade restrictions may become disruptive and costly to our business. The global economy has been, and may continue to be, negatively affected by ongoing conflicts, including Russia's invasion of Ukraine, instability in the Middle East, and heightened tensions in the Asia-Pacific region, particularly with respect to China and Taiwan. These developments may interfere with our supply chain, manufacturing costs, access to raw materials, and customer relationships. In addition, market uncertainty and volatility in various geographies may be magnified as a result of shifts in U.S. and foreign trade, economic, and regulatory policies following recent elections. Geopolitical uncertainty has also prompted many pharmaceutical and biotechnology companies to prefer sourcing from suppliers located closer to their manufacturing and research operations, or within their home markets, as a strategy to reduce exposure to security risks and cross-border disruptions. If we are unable to align with these preferences or establish sufficient local presence in key markets, our competitiveness with respect to certain international customers may be diminished. Although the majority of our operations are based in the United States, further escalation of geopolitical tensions could make it more costly or difficult to maintain our current international business or expand into additional markets, which could adversely affect our business, financial condition, and results of operations.

We may fail to realize the anticipated benefits of our acquisition of IRRAS, and the combined company may not perform as we or the market expect, which could adversely affect our business, results of operations, and the price of our common stock.

On November 6, 2025, we entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") with IRRAS Holdings, Inc. ("IRRAS"), a medical technology company focused on products used in neurocritical care, including treatments for intracerebral hemorrhage, intraventricular hemorrhage, and other conditions requiring intracranial fluid management. The transaction closed in the fourth quarter of 2025.

We pursued the acquisition based on expectations that the transaction would enhance our commercial scale, expand our presence into neurocritical care, drive operational efficiencies, and support our long term strategy of central nervous system drug delivery innovation. These anticipated benefits are inherently subject to uncertainties and are based on assumptions regarding the performance of the combined businesses. There can be no assurance that the expected synergies, growth opportunities, or operating efficiencies will be realized on the timeline anticipated, or at all. If we do not achieve these anticipated benefits, our financial condition, results of operations, and the market price of our common stock could be adversely affected.

The combined company may not perform as we or the market expect. Risks associated with integrating IRRAS into our business include:

- integrating the operations, systems, technologies, and personnel of IRRAS is a complex, costly, and time-consuming process, and any failure to do so effectively could adversely affect our financial condition and operating results;
- differences in corporate cultures, policies, procedures, internal controls, and operating practices may be more difficult or take longer to harmonize than anticipated;
- key employees of either company may choose not to remain with the combined company, and the loss of such personnel could adversely affect our operations, technical capabilities, or commercial execution;
- the success of the combined company depends in part on the retention of key customer and supplier relationships, and the merger may cause disruptions or changes in these relationships and behavior that negatively affect revenue;
- we may incur significant integration related costs, including costs related to aligning systems, processes, facilities, and commercial organizations;
- we may not have identified, or may have underestimated, liabilities or obligations assumed in the merger, which could result in unexpected litigation, regulatory exposure, accounting charges, increased tax liabilities, or other adverse effects;
- management's attention may be diverted from other strategic or operational matters due to the integration process;
- challenges in modifying, redesigning, or further developing IRRA*flow* technology for additional therapeutic applications, including longer duration infusions or oncology and drug delivery uses, which may require substantial engineering work, clinical evaluation, and additional regulatory clearances or approvals; and
- the risk that we may be unable to expand the indications for use of IRRA*flow* beyond its current FDA-cleared labeling due to technical, clinical, regulatory, or market constraints.

The occurrence of any of these factors, individually or in the aggregate, could materially and adversely affect our business, results of operations, financial condition, and the market price of our common stock.

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 our customer's satisfaction with our performance of services and our products, force majeure, regulatory approval, perceptions in connection with the safety of therapies or delivery mechanisms, our customers' ability to access adequate and sustainable financing, our customers' ability to achieve commercial success for their therapies, including overcoming barriers in reimbursement, physician adoption, and patient access to their therapies, and other factors that may be beyond our control. 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. Cancellation or renegotiation of a large agreement could adversely affect our business and, therefore, may adversely affect our operating results. In addition, 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. Any such events could have an adverse effect on our business, results of operations, financial condition and cash flows.

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 commercial 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 and our IRRAflow 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, and the IRRA*flow* system has also historically been used by a relatively small group of neurocritical care centers. Our future growth depends on our ability to increase physician and hospital awareness of both products and on the willingness of hospitals to adopt our technologies for their neurosurgical and neurocritical care procedures. Neither the ClearPoint system nor the IRRA*flow* system may gain broad market adoption unless we continue to convince physicians and hospitals of their respective benefits.

Moreover, even if physicians and hospitals understand the potential benefits of our systems, they may still elect not to use them for a variety of reasons, such as:

- the familiarity of physicians with other devices, drainage systems, or established surgical approaches;
- lack of exposure to the ClearPoint system or the IRRA*flow* system during residency or fellowship training, when preferences for surgical and critical care methods are formed;
- perceptions that there are insufficient clinical benefits of our systems compared to competing technologies or traditional approaches;

- budgetary constraints with respect to the purchase or placement of our ClearPoint system hardware or the IRRA*flow* control unit;
- the pricing of our disposable products, which may be higher than devices used with alternative approaches; and
- physician perceptions that additional clinical data or real-world evidence is needed to support broader adoption of our technologies.

Our ability to execute our growth strategy and become profitable depends on increased adoption of both the ClearPoint system and the IRRA*flow* system. Historically, a substantial portion of our revenue has been generated from sales of disposable products used with the ClearPoint system, and the IRRA*flow* system similarly relies on utilization driven sales of its disposable catheters and consumables. We are therefore highly dependent on growing the installed base and procedure volumes for both systems. We cannot provide assurance that either system will achieve broad market acceptance among hospitals and physicians. Any failure of the ClearPoint system or the IRRA*flow* system to achieve meaningful market acceptance and penetration would harm our future prospects and have a material adverse effect on our business, financial condition, and results of operations.

Our future business growth is dependent on our ability to market and sell both the ClearPoint system and the IRRAflow system, and on our ability to integrate and effectively manage a combined commercial team that must support two distinct product platforms; our limited experience selling the ClearPoint system in the operating room may further increase these challenges.

Historically, our commercial efforts have been focused on selling and supporting the ClearPoint system for neurosurgical procedures performed in the MRI suite. Although we recently expanded our ClearPoint navigation technology for use in the operating room through the launches of the SmartFrame Array Neuro Navigation System and Software, the SmartFrame OR Stereotactic System, and ClearPoint Navigation Software Version 3.0, we have relatively limited experience marketing and selling the ClearPoint system in the operating room environment, and our limited experience in this setting may make adoption more difficult, slower, or more costly than we anticipate.

Following our acquisition of IRRAS, our combined commercial organization is also responsible for promoting the IRRA*flow* system within neurocritical care units. Successfully commercializing both the ClearPoint system and the IRRA*flow* system requires coordinated and effective sales, marketing, and clinical support across two distinct clinical settings with different decision-makers, clinical priorities, and procurement pathways. The need to grow adoption of two systems in two different hospital environments amplifies the commercial complexity that we must now manage.

Integrating and managing the combined commercial organization presents additional risks, including:

- aligning sales and clinical support teams that previously operated under different commercial strategies, product expertise, and customer bases;
- training personnel to effectively promote both stereotactic navigation products and ICU-based fluid management technologies;
- addressing differing decision makers, sales cycles, reimbursement dynamics, and capital and disposable purchasing processes in the operating room and in neurocritical care units;
- retaining key sales and clinical specialists from both organizations and maintaining productivity during integration;
- harmonizing systems and processes, including customer relationship management tools, forecasting, performance metrics, and compensation structures; and
- allocating sales and clinical resources efficiently across two markets with different competitive landscapes and adoption curves.

Our ability to achieve our business objectives depends on expanding the installed base and procedure volumes for both the ClearPoint system and the IRRA*flow* system. If we are unable to overcome the challenges associated with our limited operating room experience, or if we cannot integrate the combined commercial teams effectively to support both platforms, we may fail to achieve anticipated growth. Any such failure could have a material adverse effect on our business, financial condition, and results of operations.

Our long-term growth depends on our ability to compete effectively in the neurosurgery and neurocritical care markets by developing and commercializing new products and services through our research and development efforts, independently and through third-party collaborations, including key development work required to support broader adoption of the IRRAflow system.

Our future business prospects depend in part on our ability to develop and commercialize new products and services, such as the Company's proprietary robotic neuro-navigation system. Following our acquisition of IRRAS, our growth also depends on our ability to complete certain research and development initiatives related to the IRRA*flow* system, including enhancements to its workflow,

expansion of its labelling, as well as potential design modifications or product improvements that may be necessary to expand clinical use or improve adoption in neurocritical care settings. If we are unable to complete these development efforts successfully, or if they take longer or cost more than anticipated, adoption of the IRRA*flow* system may be limited.

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, including enhancements or next generation versions of the IRRAflow system, will depend on numerous factors, including our ability to:

- properly identify and anticipate customer needs across neurosurgery and neurocritical care;
- identify, retain, and manage third-party design and development firms, where appropriate, to accelerate development;
- develop and introduce new products, enhancements, or modifications 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, including any enhancements or expanded indications for the IRRA*flow* system;
- 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 demand for these products, including future versions or enhancements of the IRRA*flow* system, does not materialize as expected, our results of operations will suffer. Our internal research and development efforts and our outsourced design and development initiatives may require substantial investment of time and resources before we can determine the commercial viability of a new product, technology, or modification. Even if we are able to develop enhancements or new generations of our products successfully, they may not produce sales that exceed the costs of development, and they may be rendered obsolete by changing customer preferences or the introduction of competing technologies.

Limitations in the existing clinical evidence for the IRRAflow system may affect clinical and commercial adoption.

The existing clinical literature regarding the IRRA*flow* system has significant limitations, and further clinical studies may be required to demonstrate safety and effectiveness of the device. If additional supportive data is not generated, clinical acceptance and broader commercial adoption of the IRRA*flow* system could be adversely affected.

The clinical evidence currently available regarding the IRRA*flow* system consists primarily of retrospective studies, small case series, single-center experiences, feasibility studies, and other observational analyses, many of which involve limited patient populations, lack randomization or control groups, and may not be powered to demonstrate statistically significant differences in clinical outcomes. As a result, their findings may be subject to bias and other methodological limitations inherent in non-randomized and small-scale research.

Because the majority of available clinical data is derived from retrospective or observational analyses, it may not provide the same level of evidentiary support as large scale prospective, randomized controlled trials. In addition, the differences in study design, patient selection, treatment protocols, and endpoints may limit the comparability and generalizability of the outcomes reported in the clinical data. These factors may make it more difficult to draw definitive conclusions regarding the safety, efficacy, or clinical benefit of the IRRA*flow* system based on the current available data.

Regulatory authorities, healthcare providers, payors, and other stakeholders may require more robust clinical evidence, including larger, well controlled prospective studies, before supporting broader adoption, reimbursement or expanded indications for the IRRA*flow* system. Future clinical studies may not produce favorable results, or they may not confirm the findings of the earlier reported data. If future data fails to demonstrate the safety and efficacy of the IRRA*flow* system, or if additional studies are required and we cannot complete them in a timely or cost-effective manner, our ability to commercialize the IRRA*flow* system could be adversely impacted.

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 2025, 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 8% of our total revenues, and 15% of our biologics and drug delivery revenue. Our five largest hospital customers account for approximately 21% of our revenues from selling medical devices for neurosurgical applications. 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.

We rely on single facilities for manufacturing and performance of services, which exposes us to significant risk of disruption.

Our internal manufacturing operations are generally conducted at single locations, which may limit our ability to provide an adequate supply of our products, and any disruption at these facilities could render us unable to produce our products, increase our expenses and decrease our revenue. Currently, final assembly of many of our products' components for our ClearPoint System 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. Following our acquisition of IRRAS, we also relied on IRRAS's manufacturing facility in San Diego, California, where the manufacturing of the reusable control unit and hardware for the IRRA*flow* system is performed. This San Diego facility is similarly exposed to regional risks, including wildfires, seismic activity, and potential utility interruptions. In addition, we may face additional risks associated with integrating and maintaining manufacturing operations acquired from IRRAS.

If either our Carlsbad or San Diego facility experiences a disruption, we would have no other means of assembling our products 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 backup manufacturing facilities for these operations, making us highly dependent on the continued availability and performance of our Carlsbad and San Diego sites.

In addition, our biologics and drug delivery research and development service capabilities are performed at a single facility in San Diego, California. We do not maintain a backup site for performance of these services, which makes us vulnerable to disruption. If our San Diego facility were to become unavailable due to natural disasters, power outages, fires, earthquakes, or other unforeseen events, we would be unable to continue providing research and development services to our customers until operations could be restored or replicated at another facility, which could delay our service activities and negatively impact our business and our future relationships with customers.

A disaster or disruption could damage, destroy, or delay our manufacturing or service operations, which could lead to additional expenses and decreased revenue due to our inability to supply products and services. 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 facilities 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. This includes the catheter and other procedure-specific disposables used with the IRRA*flow* system, which we currently source from third-party manufacturers with specialized expertise and established quality systems. These manufacturers supply IRRA*flow* disposables under master service agreements that govern the terms of our supply relationships. While we have identified alternative sources for certain IRRA*flow* disposables, we do not currently maintain multiple qualified suppliers for all of these products.

The ClearPoint Prism Neuro Laser Therapy System is supplied to us by CLS, and we rely on CLS as a single-source supplier for this product. CLS may itself rely on single source suppliers for certain components, subassemblies, or materials used in the manufacture of the ClearPoint Prism Neuro Laser Therapy System. Any disruption or delays in CLS's supply chain, including disruptions affecting their own single-source suppliers, could adversely impact the availability, cost, or performance of the product and, in turn, our ability to support customer demand.

We generally purchase components and component assemblies for the ClearPoint System 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 for the ClearPoint System. While alternative suppliers exist and have been identified for substantially all components of the ClearPoint System, 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 need to produce our products.

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 products 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.

Our use of hazardous materials in manufacturing and in the conduct of services may exposes us to significant health, safety, environmental, and regulatory risks.

We may use, store, generate, handle, and dispose of hazardous materials, including but not limited to chemicals, solvents, reagents, and radioactive isotopes used for biomarkers in testing, in our operations and services. These types of activities are subject to an extensive, evolving framework of environmental, health, safety, nuclear-materials, and transportation laws and regulations in the jurisdictions where we operate, which may include licensing and permit requirements, employee exposure limits, monitoring and reporting obligations, and strict rules governing storage, transport, and waste disposal. Despite our policies and training, hazardous materials incidents may occur, including spills, releases, contamination, accidental exposures, or improper handling or disposal.

Any such incident or any failure to obtain, maintain, or comply with applicable permits and licenses could result in enforcement actions; civil, criminal, or administrative penalties; remediation and decontamination obligations; shutdowns or restrictions on use of our facilities; product or service delays; and claims for personal injury, property damage, or environmental harm. Certain environmental laws can impose strict, joint and several liability for contamination, which could make us responsible for costs regardless of fault. Radioactive materials carry additional requirements for specialized facilities, training, monitoring, recordkeeping, waste management, and decommissioning. We also may depend on third parties to handle hazardous and radioactive materials safely, and their non-compliance or incidents could disrupt our operations, expose us to liability, or damage our reputation.

Compliance costs can be significant and may increase over time due to more stringent standards, expanded enforcement priorities (including with respect to emerging contaminants), or changes in how hazardous and radioactive materials are classified, transported, or disposed. We may incur capital or operating expenditures to achieve or maintain compliance, to obtain or renew licenses, or to complete decommissioning and site-closure activities.

Although we maintain insurance that we believe to be customary for our industry, such insurance may not be available on commercially acceptable terms, may contain significant exclusions (including for radiation-related losses), retentions, or limits, and may not cover all potential liabilities, costs, or damages arising from hazardous or radioactive materials. We may be unable to obtain or maintain adequate insurance coverage in the future, premiums could increase materially, and losses could exceed our policy limits. Any uninsured or under-insured liability, as well as any significant increase in insurance costs, could materially and adversely affect our business, financial condition, results of operations, and reputation.

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 Neuro 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 Neuro 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 Neuro 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 Neuro cannula for delivery of their therapeutic agent, and/or our ability to expand the cleared indications for our SmartFlow Neuro 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 Neuro cannula, we may not be able to grow our business.

Following our acquisition of IRRAS, we may also seek new or expanded indications for use of the IRRA*flow* system, including indications related to subdural hematomas, extended-duration infusions, oncology, intracranial drug delivery, or other therapeutic areas beyond the system's current cleared uses. Any such expanded indications or new claims for IRRA*flow* system may require additional 510(k) submissions or FDA approval of a PMA, depending on the nature and scope of the proposed indication. Certain expanded claims, particularly those involving new therapeutic modalities, extended treatment durations, or the delivery of pharmaceutical agents, may also require clinical trials to support FDA clearance or approval. If we pursue new indications or claims that we believe are important for broader clinical adoption or commercial success of IRRA*flow* system, the FDA may decline to grant

the requested clearance or approval. Likewise, to the extent clinical studies are required, we may not successfully complete these studies, or may lack the financial or operational resources necessary to initiate or support them. If we are unable to obtain expanded indications or new claims for the IRRA*flow* system, our ability to grow this part of our business may be limited.

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.

Our role as a collaborator, funder, and sponsor of current and future clinical studies in connection with the IRRAflow system requires significant resources, and in some cases, may limit our ability to control the conduct and outcomes of these studies. Negative or unfavorable results from these clinical studies could adversely impact adoption of our IRRAflow products.

We participate in a range of clinical research activities in connection with the IRRA*flow* system, including serving as a collaborator with third-party institutions, providing funding for investigator-initiated trials, and acting as the sponsor of company-initiated clinical studies. These activities require substantial financial, operational, and personnel resources. Our ability to initiate, manage, or continue these studies depends on the availability of internal resources, including qualified clinical, regulatory, and administrative personnel, as well as adequate funding. If we are unable to allocate sufficient resources, we may experience delays, interruptions, modifications, or terminations of ongoing or planned studies.

Where we support or collaborate on certain studies, we may have limited control over the design, timing, conduct, data collection, analyses, or publication of results. Investigators and institutions generally retain independent rights to publish study outcomes, and we may not be able to influence the nature, timing, or interpretation of such publications. Results from these studies, whether conducted by us or independently by third parties, may be negative, inconclusive, inconsistent with our expectations, or otherwise unfavorable.

Any current or future negative, inconclusive, or unexpected results, or the publication of data that is perceived as unfavorable, could reduce physician or patient confidence in the IRRA*flow* system, impair market acceptance, limit commercial adoption, or harm our reputation. In addition, delays or failures in our clinical research efforts could adversely affect our ability to obtain regulatory clearances or approvals for new indications for IRRA*flow*, expand market opportunities, or support reimbursement initiatives. Collectively, these risks could have a material adverse effect on our business, financial condition, and results of operations.

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.

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 and support 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.

Our acquisition activities, including our recent acquisition of IRRAS, may expose us to heightened cybersecurity risks that could adversely affect our business, financial condition, and results of operations.

We may engage in acquisition activity as part of our growth strategy, including our recent acquisition of IRRAS. Newly acquired companies may rely on information and operational technology systems that differ materially from our own and may not have cybersecurity protections comparable to those we have implemented. The integration of core systems and processes for such transactions often occurs after closing, which may create an elevated risk of cyber incidents during the intervening period. We may be subject to the data risks and cybersecurity vulnerabilities of an acquired company until we have had sufficient time to fully integrate the acquired company's customers, operations, and systems into our own infrastructure. Although we conduct due diligence with respect to the cybersecurity policies, procedures, and controls of our acquisition counterparties, there can be no assurance that such diligence will identify all material vulnerabilities, or that our policies, procedures, controls, and information security protocols will be sufficient to withstand a cyber-attack or other security breach with respect to the companies we acquire, particularly during the period between closing and final integration. Integrating newly acquired companies and implementing appropriate cybersecurity controls may be more resource-intensive and time-consuming than anticipated, and failure to appropriately integrate new acquisitions into our cybersecurity and information technology systems could lead to vulnerabilities and make our systems more complex to secure. In addition, if an acquired business's cybersecurity controls are materially weaker than ours, we may be exposed to existing cyber risks not identified prior to the acquisition that could impact our core operations until mitigated. Any such cybersecurity incident arising from or relating to an acquisition could result in significant business disruption, remediation costs, regulatory proceedings, private litigation, reputational damage, and loss of customer confidence, any of which could have a material adverse effect on our business, financial condition, and results of operations.

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 limited experience with acquiring or investing in other companies and 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 face additional risks related to acquisitions, now and in the future, that may divert our management's attention, result in dilution to our stockholders, and consume resources that are necessary to sustain and grow our existing business. In particular:

- we may become subject to litigation, investigations, proceedings, fines or penalties arising from or relating to the transaction or the acquired business, and any resulting liabilities may exceed our forecasts;
- we may acquire businesses with different revenue models, customer concentration risks, and contractual relationships that are difficult to integrate or manage;
- we may assume long-term contractual obligations, commitments or liabilities (for example, those relating to leased facilities), which could adversely impact our efforts to achieve and maintain profitability and impair our cash flow;

- we may not successfully evaluate or utilize the acquired technology and accurately forecast the financial impact of an acquisition transaction, including accounting charges;
- the acquisition may create a drag on our overall revenue growth rate, which could lead analysts and investors to reduce their valuation of our company;
- we may be exposed to existing cybersecurity risks not identified prior to an acquisition that could impact our core operations until mitigated; and
- if an acquired business's cybersecurity controls are materially weaker than ours, we may face heightened exposure to threats that compromise our core operations until such weaknesses are identified and remediated.

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. 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 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. 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. In addition, following our acquisition of IRRAS, we also have limited insight into the trends, operational challenges, and market dynamics associated with operating a business in the neurocritical care space. 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 currently have significant debt and may incur additional debt. Failure by us to fulfill our obligations under the applicable debt agreements may cause repayment obligations to accelerate. These agreements also contain certain covenants that restrict our operational and financial flexibility.

Under the 2025 NPA, the aggregate amount of our indebtedness, as of December 31, 2025 was $50.9 million.

Our indebtedness may:

- make it difficult for us to satisfy our financial obligations, including making scheduled principal and interest payments on our indebtedness;
- limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions or other general corporate purposes;
- limit our ability to use our cash flow or obtain additional financing for future working capital, capital expenditures, acquisitions, or other general business purposes;
- require us to use a portion of our cash flow from operations to make interest payments;
- limit our flexibility to plan for, or react to, changes in our business and industry;
- place us at a competitive disadvantage compared to our less leveraged competitors; and
- increase our vulnerability to the impact of adverse economic and industry conditions.

In addition, the 2025 NPA includes certain affirmative and negative covenants, that, among other things, may limit our ability to: create liens on assets; incur additional indebtedness; make investments; make acquisitions and other fundamental changes to our business; and sell and dispose of property or assets.

Further, in the event of default by us under the 2025 NPA, the lenders would be entitled to exercise their remedies thereunder, including the right to accelerate the debt, upon which we may be required to repay all amounts then outstanding under the 2025 NPA which would harm our financial condition.

Our ability to make payments on our existing or any future debt will depend on our future operating performance and ability to generate cash and may also depend on our ability to obtain additional debt or equity financing. It will also depend on financial, business or other factors affecting our operations, many of which are beyond our control. We will need to use cash to pay principal and interest on our debt, thereby reducing the funds available to fund operations, strategic initiatives and working capital requirements. If we are unable to generate sufficient cash to service our debt obligations, an event of default may occur under the 2025 NPA which could result in an acceleration of such debt upon which we may be required to repay all the amounts outstanding under our debt instruments. Such an acceleration of our debt obligations could harm our financial condition.

We expect to need additional funding for our combined business following the acquisition of IRRAS, and we may not be able to raise capital when needed or on terms that are acceptable to us. If we fail to obtain necessary financing, we may be forced to delay, reduce, or eliminate commercialization efforts, product development activities, integration initiatives, or other aspects of our operations.

The cumulative net loss of the combined company from our inception through December 31, 2025 was approximately $216.9 million, and net cash used in operations was $23.9 million for the year ended December 31, 2025. Since inception, we have financed our operations principally from the sale of equity securities and the issuance of notes payable. At December 31, 2025, we had cash and cash equivalents totaling $45.9 million, driven primarily by 2025 note issuances, a 2025 stock sale, and a 2024 public offering, as discussed in Notes 9 and 11 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 with Stifel, Nicolaus & Company, Incorporated, as sales agent, to sell shares of our common stock having aggregate sales proceeds of up to $50 million. As of December 31, 2025, we have not sold any shares of common stock under this agreement.

The acquisition of IRRAS has expanded our product portfolio and commercial footprint but has also increased our operating expenses and capital requirements. In addition to funding the ongoing commercialization of our ClearPoint platform, we must now support the IRRA*flow* system, integration-related activities, expanded sales and clinical support functions, and the continued development and adoption of both product lines. As a result, our future cash needs may be greater than previously anticipated.

In connection with the IRRAS acquisition, we also assumed certain known and unknown liabilities and obligations, including potential obligations relating to IRRAS's historical operations, existing contractual commitments, product warranties, product performance issues, regulatory compliance matters, clinical data or study obligations, intellectual property matters, and any pending or future claims or litigation. If these liabilities or obligations are greater than expected, or if additional obligations arise that were not identified at the time of the acquisition, we may be required to dedicate additional financial or managerial resources, which could increase our cash requirements and adversely affect our business, results of operations, or financial condition.

Our plans for the next twelve months reflect our expectation of increased revenues from sales of our hardware products and related disposable products, driven by greater utilization of the ClearPoint system and IRRA*flow* system at existing installed sites, and the installation of the ClearPoint system and IRRA*flow* system at new sites. We also expect continued payments from strategic partnerships, consulting services, and the sale of systems and disposables to our pharmaceutical partners for gene and stem cell therapy trials. We anticipate increases in operating expenses over the next twelve months to support these activities, with corresponding decreases in operating losses and cash used in operations. However, there can be no assurance that we will achieve these results.

As a result of the foregoing, it is uncertain whether we will need to seek additional funds through the sale of equity or debt securities, which would likely result in dilution to existing stockholders, the establishment of one or more credit facilities, or strategic partnerships or other collaborative arrangements. There is no assurance that we will be able to obtain additional financing on commercially reasonable terms, if at all, or that any financing we obtain will be sufficient to meet the needs of the combined company. If we are not able to obtain additional funding on a timely basis, we may be unable to achieve anticipated operational or financial results, satisfy our obligations as they become due, or fully execute our integration or growth strategies. An inability to raise a sufficient amount of additional capital would create substantial doubt about 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 and IRRA*flow* system products and services;
- the timing of approval, commercialization, and successful adoption of gene and cell therapies delivered using our ClearPoint platform;
- the scope, rate of progress, and cost of our ongoing product development activities relating to the ClearPoint system and the IRRA*flow* system;
- the cost and timing of integrating and expanding our sales, clinical support, marketing, and distribution capabilities and other corporate infrastructure, including those required for the combined ClearPoint system and IRRA*flow* product lines;
- the cost and timing of establishing inventories at levels sufficient to support our expanded product portfolio;
- the scope, rate of progress, and cost of 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 currently initiated and future clinical studies for both ClearPoint and IRRAflow technologies;
- the cost and timing of regulatory filings, clearances, and approvals across our combined product portfolio; and
- the cost of filing, prosecuting, defending, and enforcing 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.

Raising additional funds may cause dilution to existing stockholders, further 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. We have already entered into debt financing arrangements that restrict our ability to take certain actions, such as incurring additional debt, making certain capital expenditures or declaring dividends, and any future debt financing may impose similar or additional restrictions. 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.

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. The One Big Beautiful Bill Act includes significant reductions in Medicaid funding, which could impact demand and reimbursement for our products and the therapies of our pharmaceutical and biotech customers. 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.

The success of our biologics and drug delivery business is dependent on timely regulatory approval and commercialization of cell and gene therapies.

A significant portion of our growth strategy depends on the continued clinical progress, regulatory approval, and commercial launch of cell and gene therapies ("CGTs") that use our delivery-related medical devices and systems. The U.S. Food and Drug Administration ("FDA") maintains an evolving regulatory framework for CGTs and related delivery devices. Any material change in FDA policy, guidance, or review practices; adjustments in the agency's risk tolerance or evidentiary standards; reduced availability of expedited review pathways; or extended review timelines could delay or prevent approval of our customers' products and adversely affect our business.

The FDA may modify eligibility or evidentiary criteria for expedited programs, limit their use, or require additional data before or after approval. Even when such programs are granted, limited agency resources may reduce their impact on review timelines. The FDA's expectations for clinical trial design, long-term safety follow-up, manufacturing controls, labeling, and post-marketing obligations for CGTs continue to evolve and may result in additional studies, data requirements, or delays for our customers' programs. Similar developments relating to device-drug or device-biologic combinations may require new data or supplemental submissions by our customers and, in some cases, by us.

As sponsors pursue indications beyond rare or severe diseases, the FDA may apply more conservative benefit-risk standards, require larger or longer trials, or seek additional evidence of long-term efficacy and safety. In addition, periodic resource or staffing constraints at the FDA can extend review cycles, inspections, or regulatory correspondence. Any such changes or delays may postpone approvals or commercial launches of CGTs that rely on our products, which could result in lower utilization, deferred orders, and reduced revenues.

A government shutdown or prolonged lapse in federal appropriations could materially delay or disrupt FDA review and approval processes critical to our business, which could have a material adverse effect on our financial condition and results of operations.

Our business depends significantly on the timely review and clearance or approval of our products and our customers' products by the FDA. During a federal government shutdown or lapse in congressional appropriations, the FDA may furlough significant portions of its workforce, suspend or substantially delay the review of pending 510(k) submissions, de novo requests, PMA applications, and other regulatory submissions, and cease accepting new applications for the duration of the shutdown. Any such disruption could delay the clearance or approval of our products or our customers' products, including cell and gene therapies that rely on our delivery

devices and systems, and could postpone the commercial launch of products that are critical to our growth strategy. In addition, FDA inspections necessary to support product approvals or manufacturing compliance may be suspended or significantly delayed during a shutdown period, further extending regulatory timelines. Our drug delivery customers, whose programs depend on timely FDA action, may experience delays in clinical trial authorizations, combination product reviews, or approval decisions, which could reduce their demand for our products and services and adversely affect our revenues. Similarly, any expanded indications we may seek for our products could be subject to extended review timelines as a result of a shutdown. The recent government shutdown, between October 1, and November 12, 2025, was the longest in history and paused new fee applications and slowed review timelines for 43 days. The duration and frequency of future government shutdowns are inherently unpredictable, and a prolonged shutdown could have compounding effects on our regulatory pipeline and those of our customers. Any such delays or disruptions could have a material adverse effect on our business, financial condition, and results of operations.

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 ClearPoint manufacturing facilities were last subject to an ISO 13485 surveillance audit and MDSAP surveillance audit in January 2025. 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.

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;
- Risks, uncertainties, or unexpected developments related to our acquisition of IRRAS, including challenges with integration, realization of anticipated synergies, assumptions of liabilities, impacts on our financial results, or market perceptions of the acquisition and its success or failure; 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 29,663,875 shares outstanding as of March 6, 2026. As a result, our Board of Directors 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.

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.

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, IRRA*flow* 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 facilities 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 facilities, 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, performance of services, and product 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 facilities 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.

We place 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 Audit Committee oversees the cybersecurity risks we face. 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 our 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 our enterprise-wide cyber security and information security strategy, employee training and compliance, and managing policies and processes for our 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 hospital and research institutions in compliance with the extensive cybersecurity requirements of those institutions. In addition to our 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 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 us or our 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.

Our acquisition of IRRAS in November 2025 did not result in any changes to our cybersecurity governance structure, oversight responsibilities, or risk management framework. We expect to integrate IRRAS into our cybersecurity program during 2026.

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. In 2025, we entered into a lease of approximately 30,000 square feet of space within a life science building in San Diego, California to perform research and development services for our pharmaceutical and biotech customers. In connection with the IRRAS acquisition, we also assumed a lease for a facility located in San Diego, California, consisting of approximately 21,200 square feet used for manufacturing and office purposes. 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. Regardless of outcome, litigation and other legal proceedings can have an adverse impact on us because of defense and settlement costs, diversions of management resources and other factors. As of the date of filing this Annual Report, there is no material pending legal proceeding to which we are a party or to which any of our property is subject.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Market Information

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

Holders

As of March 6, 2026, we had 29,663,875 shares of common stock outstanding and no shares of preferred stock outstanding. As of March 6, 2026, we had approximately 184 stockholders of record. The approximate number of stockholders of record is based upon the actual number of holders registered in our records at such date and excludes holders in "street name" or persons, partnerships, associations, corporations, or other entities identified in security positions listings maintained by depository trust companies.

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.

Recent Sales of Unregistered Securities

We did not sell any unregistered securities during the period covered by this report that were not previously reported in a Quarterly Report on Form 10-Q or Current Report on Form 8-K.

Issuer Purchases of Equity Securities

The table below is a summary of purchases of our common stock we made during the quarter ended December 31, 2025. Other than as reported in the table below, we did not purchase any shares of our common stock during the quarter. We do not have any publicly announced repurchase plans or programs.

Period	Total Number of Shares Purchased [1]	Average Price Paid per Share
October 1 - October 31	7,480	$ 26.11
November 1 - November 30	-	$ -
December 1 - December 31	-	$ -

(1) These shares were surrendered to the Company to satisfy tax withholding obligations in connection with the vesting of restricted stock awards.

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 integrated systems used in minimally invasive neurosurgical 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. Over the past several years, we have expanded our capabilities beyond the MRI suite to include operating room based neurosurgical device products and a growing portfolio of services that support pharmaceutical and biotechnology partners developing gene and cell therapies. In 2025, with the acquisition of IRRAS, we expanded our portfolio into neurocritical care, focusing on treatments for intracerebral hemorrhage, intraventricular hemorrhage, and other conditions requiring intracranial fluid management.

Our business today consists of two integrated components: (i) a business providing medical devices for neurosurgical applications, and (ii) a business focused on partnerships in the biologics and drug delivery space.

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 2025, we released the ClearPoint Navigation Software Version 3.0, which allows for the ClearPoint system navigation software to support end-to-end procedures 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.

In 2025, through the acquisition of IRRAS, we added the IRRA*flow* system to our portfolio of medical devices. The IRRA*flow* system integrates continuous irrigation, drainage, and real-time intracranial pressure monitoring to provide controlled, automated intracranial fluid management within neurocritical care and operating room settings.

The second component of our business is focused on partnerships in the biologics drug and 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 has been 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 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 pharmaceutical company customers, such customers' continuation of research and product development plans, such customers achieving success in completion of clinical trials and subsequent regulatory approvals of their drugs and biologics, and such customers' realization of commercial success for their therapies, including overcoming barriers in reimbursement, physician adoption, and patient access to their therapies. 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 deficiency to regions of interest within the brain.

2025 Milestones and Developments

- Completed the acquisition of IRRAS, which brings the IRRA*flow* active fluid-exchange system into our product portfolio, a differentiated technology designed to modernize the management of intracranial bleeding.
- Entered into a debt financing arrangement with an affiliate of Oberland Capital Management under which we may borrow up to $105.0 million from time to time in tranches; we raised approximately $48.1 million in net proceeds under this arrangement during 2025.
- Raised approximately $3.3 million in net proceeds from the sale of shares of our common stock to an affiliate of Oberland Capital Management.
- Entered into a lease for the new preclinical research facility named ClearPoint Advanced Laboratories (CAL) located in San Diego, California, allowing for additional capacity to perform larger studies, and the ability to offer additional services to biopharma partners.
- Several of our partners advanced through preclinical and clinical review, with over ten pharmaceutical partners receiving expedited US FDA review designations.
- Received the following regulatory approvals:
    - FDA Clearance for the ClearPoint 3.0 Software which includes both operating room navigation capability and features enhanced for laser therapy applications;
    - FDA 510(k) clearance expanding compatibility of the ClearPoint PRISM Neuro Laser Therapy System with 1.5T scanners in addition to the previously cleared 3T compatible system;
    - European Medical Device Regulation (EU MDR) certification for the SmartFlow Neuro Cannula; and
    - Several expanded regulatory approvals for product use in Canada, Hong Kong, and Taiwan, bringing the total number of international clearances for key therapy delivery products to 34 countries worldwide.

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 Neuro 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 rights to commercialize, received 510(k) clearance through our Swedish partner, CLS. The Prism laser is 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. As a result of the IRRAS acquisition, revenue is expected to grow over the coming years due to a larger combined organization, expanded product offerings, and increased customer reach, both in the U.S. and internationally.

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 $23.9 million and $18.6 million for the years ended December 31, 2025 and 2024, respectively, and was almost entirely related to our ClearPoint system. Our service revenue was approximately $13.1 million and $12.8 million for the years ended December 31, 2025 and 2024, respectively, of which 89% and 92%, 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, 2025, we had more than 60 Partners, similar to the number of Partners as of the same date in 2024.

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 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. The IRRAS acquisition is expected to impact cost of revenue and reduce overall gross margins in the near term as IRRA*flow* currently operates at sub-scale production levels, resulting in higher per-unit manufacturing costs compared to the existing product portfolio.

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, (iii) expand the application of our technological platforms internationally, and (iv) invest in the IRRA*flow* product portfolio and clinical evidence.

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. We expect increases in our sales and marketing expenses as a result of the larger combined sales organization, primarily reflecting higher salary and personnel-related costs associated with the larger commercial team following the IRRAS acquisition.

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.

Business Combinations. The IRRAS acquisition has been accounted for under the acquisition method of accounting in accordance with ASC 805. Under the acquisition method of accounting, we record the assets acquired and liabilities assumed at their estimated fair values as of the acquisition date. The excess of the cost of the acquired business and the fair value of the assets acquired and liabilities assumed is recognized as goodwill. During the measurement period, which is up to one year from the acquisition date, we may adjust provisional amounts that were recognized at the acquisition date to reflect new information obtained about facts and circumstances that existed as of the acquisition date. See Note 3 to our consolidated financial statements included elsewhere in this Annual Report for additional information regarding the IRRAS acquisition.

Determining the fair value of assets acquired and liabilities assumed requires management to make significant estimates and assumptions used in estimating the fair value of acquired technology and other identifiable intangible assets. Although we believe that the assumptions and estimates we have made are reasonable and appropriate, they are inherently subjective. The assistance of an independent third-party valuation firm was used to determine the estimated fair values and useful lives of finite-lived intangible assets including developed technology, customer relationships, and trademarks. Valuation methods were based on the income-based approaches including the multi-period excess earnings method, distributor method, and relief-from-royalty method for developed technology, customer relationships, and trademarks, respectively. Critical estimates and assumptions used in valuing acquired intangible assets include the timing and amount of forecasted revenue, expenses, and cash flows, the life cycle of each asset, the potential regulatory and commercial success risk, competitive trends impacting the assets, and the discount rate reflecting the risk inherent in future cash flows. If the subsequent actual results and updated projections change compared with the assumptions and projections used to develop these values, we could record impairment charges. In addition, we have estimated the economic lives of certain acquired assets and these lives are used to calculate amortization expense. If our estimates of the economic lives change, amortization expenses could be accelerated or slowed.

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 capital equipment. 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.

Results of Operations

Comparison of the Year Ended December 31, 2025 to the Year Ended December 31, 2024

	Year Ended December 31,		Percentage
(Dollars in thousands)	**2025**	**2024**	**Change**
Product revenue	$ 23,859	$ 18,626	28%
Service and other revenue	13,112	$ 12,764	3%
Total revenue	36,971	31,390	18%
Cost of revenue	14,279	12,268	16%
Gross profit	22,692	19,122	19%
Research and development costs	13,897	12,392	12%
Sales and marketing expenses	16,461	14,478	14%
General and administrative expenses	16,498	11,986	38%
Other income (expense):			
Other expense, net	(146)	(40)	NM
Interest income	1,213	1,390	(13)%
Interest expense	(2,388)	(518)	361%
Net loss before income taxes	(25,485)	(18,902)	35%
Income tax expense	55	12	NM
Net loss	$ (25,540)	$ (18,914)	35%

NM - The percentage change is not meaningful.

Revenue. Total revenue was approximately $37.0 million and $31.4 million for the years ended December 31, 2025 and 2024, respectively.

	Year Ended December 31,		Percentage
(Dollars in thousands)	**2025**	**2024**	**Change**
Biologics and drug delivery			
Disposable products	$ 7,338	$ 5,606	31%
Services and license fees	11,702	11,704	(0)%
Subtotal – Biologics and drug delivery revenue	19,040	17,310	10%
Neurosurgery navigation and therapy			
Disposable products	14,831	10,285	44%
Subtotal – Neurosurgery navigation and therapy revenue	14,831	10,285	44%
Capital equipment and software			
Systems and software products	1,690	2,735	(38)%
Services	1,410	1,060	33%
Subtotal – Capital equipment and software revenue	3,100	3,795	(18)%
Total revenue	$ 36,971	$ 31,390	18%

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 10% to $19.0 million for the year ended December 31, 2025, from $17.3 million for the year ended December 31, 2024. This increase is attributable to $1.7 million of higher product revenue resulting from greater demand for disposables as multiple partners progress in their trials.

Neurosurgery navigation and therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 44% to $14.8 million during the year ended December 31, 2025, from $10.3 million for the year ended December 31, 2024. The increase is driven by an increased customer base, additional revenues due to sales of the IRRA*flow* product, and higher sales for new offerings of SmartFrame OR, Prism Laser Therapy, and introduction of our 3.0 operating room software, during the year ended December 31, 2025, compared to the year ended December 31, 2024.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software and related services, decreased 18% to $3.1 million for the year ended December 31, 2025, from $3.8 million for the year ended December 31, 2024, due to a decrease in the placements of ClearPoint navigation capital and software and Prism laser units.

Cost of Revenue and Gross Profit. Cost of revenue was $14.3 million, resulting in gross profit of $22.7 million for the year ended December 31, 2025, compared to $12.3 million, resulting in gross profit of $19.1 million for the year ended December 31, 2024. Gross margin was 61% for both the years ended December 31, 2025 and December 31, 2024.

Research and Development Costs. Research and development costs were $13.9 million for the year ended December 31, 2025, compared to $12.4 million for the year ended December 31, 2024, an increase of $1.5 million, or 12%. The increase was due to higher product and software development costs of $1.2 million, an increase in personnel costs, including share-based compensation expense, of $0.2 million, and additional costs due to the acquisition of IRRAS.

Sales and Marketing Expenses. Sales and marketing expenses were $16.5 million for the year ended December 31, 2025, compared to $14.5 million for the year ended December 31, 2024, an increase of $2.0 million, or 14%. This increase was due to higher personnel costs, including share-based compensation expense, of $1.4 million resulting from increases in headcount in our clinical team, as well as increased costs of $0.9 million due to the acquisition of IRRAS, partially offset by decreased marketing costs of $0.2 million and decreased travel costs of $0.2 million.

General and Administrative Expenses. General and administrative expenses were $16.5 million for the year ended December 31, 2025, compared to $12.0 million for the year ended December 31, 2024, an increase of $4.5 million, or 38%. This increase was due primarily to severance expense of $1.4 million in connection with the IRRAS acquisition, increased professional service fees of $1.0 million, higher personnel costs, including share-based compensation, of $0.9 million, higher information technology and software costs of $0.5 million, increased bad debt expense of $0.2 million, and additional costs of $0.2 million related to the IRRAS acquisition.

Interest Income. Interest income for the year ended December 31, 2025 was $1.2 million, compared with $1.4 million for the year ended December 31, 2024. The decrease in interest income is primarily due to decreased investment in U.S. Government securities due to lower cash balances in the first half of 2025.

Interest Expense. Interest expense for the year ended December 31, 2025 was $2.4 million compared with $0.5 million for the year ended December 31, 2024. The increase was due to the issuance of notes payable in May and November 2025. See Note 9 to the consolidated financial statements included elsewhere in this Annual Report for more information regarding the notes payable issued in May and November 2025.

Liquidity and Capital Resources

We have incurred net losses since our inception, which has resulted in a cumulative deficit at December 31, 2025 of $216.9 million. In addition, our use of cash from operations amounted to $23.9 million for the year ended December 31, 2025. Since inception, we have financed our operations principally from the sale of equity securities and the issuance of notes payable.

In May 2025, we entered into a Stock Purchase Agreement (the "2025 SPA") with TPC Investments III LP, an affiliate of Oberland Capital Management LLC (the "2025 Investor") relating to the purchase and sale in a registered direct offering of an aggregate of 275,808 shares of our common stock at a price of $12.69 per share, based on the trailing 30-trading day volume-weighted average price of our common stock. The aggregate net proceeds to us from the offering totaled approximately $3.3 million, after deducting offering expenses payable by us. See Note 11 to our consolidated financial statements included elsewhere in this Annual Report for more information regarding the 2025 SPA.

Contemporaneously with entering into the 2025 SPA, we entered into a note purchase agreement (the "2025 NPA") with the 2025 Investor and CALW SA, LLC, as purchaser agent, under which we may sell to the 2025 Investor tranches of notes ("Notes") in an

aggregate principal amount of up to $105.0 million. Under the terms of the 2025 NPA, (a) we sold a Note in the principal amount of $30.0 million (the "First Purchase Note") to the 2025 Investor upon signing of the 2025 NPA, (b) at our option, we may sell an additional $25.0 million in principal amount of Notes, in up to two increments of $12.5 million each, at any time prior to December 31, 2026, and (c) at our and 2025 Investor's option, we may sell up to $50.0 million in principal amount of Notes, at any time prior to December 31, 2026 (the "Third Tranche of Notes").

In connection with the signing of the merger agreement pursuant which we acquired IRRAS, we and the 2025 Investor entered into an amendment to the 2025 NPA pursuant to which the 2025 Investor agreed to purchase $20.0 million in principal amount of the Third Tranche of Notes under the 2025 NPA following the closing of the IRRAS acquisition (the "Third Tranche Note"). The Third Tranche Note was sold to the 2025 Investor in November 2025.

The net proceeds from the sale of the First Purchase Note, after deducting the debt discount and debt issuance costs of $0.6 million and $0.7 million, respectively, was approximately $28.7 million. The net proceeds from the sale of the Third Tranche Note, after deducting the debt discount and debt issuance costs, was approximately $19.4 million. See Note 9 to our consolidated financial statements included elsewhere in this Annual Report for more information regarding the 2025 NPA.

In March 2024, we completed a public offering of 2,653,848 shares of our common stock for net proceeds of approximately $16.2 million after deducting our payment of underwriting discounts and commissions and other offering expenses. See Note 11 to our consolidated financial statements included elsewhere in this Annual Report for more information.

In November 2024, we established an at-the-market equity offering program under which we may offer and sell, from time to time, shares of our common stock having aggregate sales proceeds of up to $50 million. As of December 31, 2025, we did not sell any shares of common stock under our at-the-market equity offering program. See Note 11 to our consolidated financial statements included elsewhere in this Annual Report for more information regarding our at-the-market equity offering program.

As a result of these transactions and our business operations, our cash and cash equivalents totaled $45.9 million at December 31, 2025. In management's opinion, based on our current forecasts, our existing cash and cash equivalent balances at December 31, 2025 are sufficient to support our operations and meet our obligations for at least the next twelve months from the date of issuance of the financial statements included elsewhere in this Annual Report.

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.

Cash Flows

Cash activity for the years ended December 31, 2025 and 2024 is summarized as follows:

	Year Ended December 31,	
(in thousands)	**2025**	**2024**
Net cash flows used in operating activities	$ (23,925)	$ (8,950)
Net cash provided by (used in) investing activities	615	(275)
Net cash provided by financing activities	50,179	6,189
Net change in cash and cash equivalents	$ 26,869	$ (3,036)

Net Cash Flows Used in Operating Activities. Net cash flows used in operating activities for the year ended December 31, 2025 was $23.9 million, an increase of $15.0 million from the year ended December 31, 2024. This increase was primarily due to a higher net loss of $6.6 million, and the paydown of accounts payable and accrued expenses of $10.6 million, the majority of which were liabilities assumed from the IRRAS acquisition. We do not expect to incur cash outflows for the payment of assumed liabilities of a similar magnitude in future periods, as the paydown of the liabilities assumed in connection with the IRRAS acquisition represents a non-recurring event.

Net Cash Flows Provided by (Used in) Investing Activities. Net cash flows provided by investing activities in 2025 were $0.6 million and related to cash acquired from the IRRAS acquisition, partially offset by equipment acquisitions.

Net cash flows used in investing activities in 2024 were $0.3 million and related to equipment acquisitions.

Net Cash Flows Provided by Financing Activities. Net cash provided by financing activities in 2025 consisted primarily of proceeds, net of financing costs and discount, of $48.1 million from the issuance of the notes payable; proceeds, net of offering costs, of $3.3 million from our common stock offering; partially offset by $1.9 million in payments for taxes related to shares withheld in connection with the vesting of restricted stock awards.

Net cash provided by financing activities in 2024 consisted of proceeds, net of offering costs, of $16.2 million from the public offering of our common stock and $0.4 million from the issuance of common stock under our employee stock purchase plan. These proceeds were partially offset by the repayment of the remaining $10 million outstanding under 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.

Operating Capital and Capital Expenditure Requirements

To date, we have not achieved profitability. We expect to 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.

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. The total undiscounted aggregate future operating lease obligations under all of our operating leases as of December 31, 2025 are $14.2 million. See Note 10 to the consolidated financial statements included elsewhere in this Annual Report.
- As of December 31, 2025, we had $50.9 million notes payable to the 2025 Investor due in 2031. Future interest payments associated with the notes are variable based on (i) the greater of the Term SOFR (as defined in the 2025 NPA) and 4.30%; and (ii) 3.95%, with a minimum rate of 8.25% and a cap of 9.50%. At current interest rates, we expect the interest payments (not including paid-in-kind) for the next 12 months to be approximately $2.5 million. See Note 9 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, 2025 for unfulfilled purchase orders and long-term purchase commitments was $9.0 million, of which approximately 55% is expected to be paid in 2026. See Note 10 to the consolidated financial statements included elsewhere in this Annual Report.

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 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 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 cost and timing of expanding our sales, clinical support, marketing and distribution capabilities, and other corporate infrastructure;
- 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;
- the cost and timing of establishing inventories at levels sufficient to support our sales;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the 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; and
- the effect of competing technological and market developments.

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

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this Item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The Report of Independent Registered Public Accounting Firm and Financial Statements are set forth beginning on page F-1 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, 2025, 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, 2025.

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, 2025, 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, 2025.

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 quarter ended December 31, 2025, 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.

(a) None.

(b) During our last fiscal quarter, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any Rule 10b5-1 trading arrangement (as defined in Item 408(a)(1)(i) of Regulation S-K) or any non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K), except as described below.

On November 26, 2025, Danilo D'Alessandro, our Chief Financial Officer, adopted a Rule 10b5-1 trading arrangement intended to satisfy the Rule 10b5-1 affirmative defense. The trading arrangement expires November 30, 2026, subject to earlier expiration if all transactions thereunder are completed before the scheduled expiration date. A total of 64,278 shares are subject to the plan.

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

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Except 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, 2025, pursuant to Regulation 14A under the Exchange Act, in connection with our 2026 annual meeting of stockholders (the "2026 Proxy Statement").

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 2026 Proxy Statement, except as to information disclosed in the Proxy Statement pursuant to Item 402(v) of Regulation S-K relating to pay versus performance.

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

The information required by this item is incorporated by reference from 2026 Proxy Statement.

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

The information required by this item is incorporated by reference from the 2026 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by this item is incorporated by reference from the 2026 Proxy Statement.

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
2.1	Agreement and Plan of Merger and Reorganization, dated November 6, 2025, by and among the Company, Ignite Merger Sub, Inc., ClearPoint Holdings, LLC, IRRAS Holdings, Inc. and the Seller Representative, incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 6, 2025	8-K	001-34822	10.1	November 6, 2025
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				

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
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
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(a)+	MRI Interventions, Inc. Amended and Restated 2013 Incentive Compensation Plan, incorporated by reference to Exhibit B to the Company's Proxy Statement on Schedule 14A filed on April 17, 2015	Schedule 14A	000-54575	B	April 17, 2015
10.1(b)+	Second Amended and Restated 2013 Incentive Compensation Plan, incorporated by reference to Exhibit A to the Company's Proxy Statement on Schedule 14A filed on September 5, 2017	Schedule 14A	001-34822	A	September 5, 2017
10.1(c)+	Third 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 20, 2020	DEF14A	001-34822	Appendix A	April 20, 2020
10.1(d)+	Fourth Amended and Restated 2013 Incentive Compensation Plan, incorporated by reference to Appendix A to the Company's Proxy Statement filed on April 11, 2022	DEF14A	001-34822	Appendix A	April 14, 2022
10.1(e)+	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	001-34822	Appendix A	April 5, 2024
10.1(f)+	ClearPoint Neuro, Inc. Sixth Amended and Restated 2013 Incentive Compensation Plan, incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 23, 2025	8-K	001-34822	10.1	May 23, 2025
10.1(g)+	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
10.1(h)+	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
10.1(i)+	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
10.1(j)+	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

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.1(k)+	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
10.2+	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
10.3+	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
10.4+	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
10.5+	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
10.6+	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
10.7+	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
10.8+	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
10.9+	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
10.10+	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
10.11+	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

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.12+	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
10.13†	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
10.14†	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
10.15†	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
10.16†	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
10.17	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 10.01 to the Company's Current Report on Form 8-K filed on November 7, 2022	8-K	001-34822	10.1	November 7, 2022
10.18	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
10.19	Form of Stock Purchase Agreement, incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 12, 2025	8-K	001-34822	10.1	May 12, 2025
10.20	Form of Note Purchase Agreement, incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on May 12, 2025	8-K	001-34822	10.2	May 12, 2025
10.21	ClearPoint Neuro, Inc. Non-Employee Director Compensation Plan, as amended and restated by the Board of Directors on May 18, 2025, incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 19, 2025	8-K	001-34822	10.1	May 19, 2025
10.22	Lease dated as of June 16, 2025, by and between BRE-BMR SCD LLC, a Delaware limited liability	8-K	001-34822	10.1	June 17, 2025

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
	company, and ClearPoint Neuro, Inc., incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 17, 2025				
10.23*	Consent and Amendment No. 1 to Note Purchase Agreement, dated November 5, 2025, by and among the Company, CALW SA LLC and the purchasers party thereto				
10.24*	Consent, dated December 29, 2025, by and among the Company, CALW SA LLC, and the purchasers party thereto				
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: March 17, 2026

/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)*	March 17, 2026
/s/ Danilo D'Alessandro **Danilo D'Alessandro**	*Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)*	March 17, 2026
/s/ R. John Fletcher **R. John Fletcher**	*Chairman and Director*	March 17, 2026
/s/ Lynnette C. Fallon **Lynnette C. Fallon**	*Director*	March 17, 2026
/s/ Pascal E.R. Girin **Pascal E.R. Girin**	*Director*	March 17, 2026
/s/ B. Kristine Johnson **B. Kristine Johnson**	*Director*	March 17, 2026
/s/ Matthew B. Klein **Matthew B. Klein**	*Director*	March 17, 2026
/s/ Linda M. Liau **Linda M. Liau**	*Director*	March 17, 2026
/s/ Timothy T. Richards **Timothy T. Richards**	*Director*	March 17, 2026

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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, 2025 and 2024, 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, 2025 and 2024, 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

As discussed in Note 3 to the consolidated financial statements, during the year ended December 31, 2025, the Company completed the acquisition of IRRAS Holdings, Inc., which was accounted for as a business combination. Accounting for the business combination required management to make significant judgements and estimates, particularly related to the determination of the fair values of the acquired intangible assets. We identified the accounting for the business combination as a critical audit matter because the valuation of the acquired intangible assets involved especially complex and subjective judgements, including the use of significant assumptions.

As a result, a high degree of auditor judgment was required in performing audit procedures to evaluate the reasonableness of management's estimates. Changes in these estimates can have a material effect on the amount of intangible assets and goodwill recognized in the business combination.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the accounting for the business combination included, among others:

- We obtained an understanding of the transaction and evaluated whether the acquisition was appropriately accounted for as a business combination.
- We assessed the competence and objectivity of management's valuation specialists involved in the fair value measurements.
- With the assistance of our valuation specialists, we evaluated the valuation methodologies used to estimate the fair values of the identifiable intangible assets and tested the significant assumptions used by comparing them to relevant and reliable information.
- We evaluated the reasonableness of the resulting purchase price allocation and assessed whether the related disclosures in the consolidated financial statements were appropriate and complete.

/s/ Cherry Bekaert LLP

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

Tampa, Florida
March 17, 2026

CLEARPOINT NEURO, INC.

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

	December 31,	
	2025	**2024**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 45,923	$ 20,104
Accounts receivable, net	6,549	4,713
Inventory, net	8,359	6,863
Prepaid expenses and other current assets	2,769	1,683
Total current assets	63,600	33,363
Property and equipment, net	2,621	2,005
Operating lease, right-of-use assets	8,430	3,086
Goodwill	7,472	—
Intangible assets, net	13,922	—
Other assets	1,702	735
Total assets	$ 97,747	$ 39,189
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,256	$ 1,340
Accrued compensation	4,360	4,885
Other accrued liabilities	2,786	1,450
Operating lease liabilities, current portion	694	557
Contract liabilities, current portion	1,669	2,121
Total current liabilities	10,765	10,353
Operating lease liabilities, net of current portion	8,461	3,011
Contract liabilities, net of current portion	581	436
Long-term notes payable, net	49,077	—
Deferred tax liabilities, net	354	—
Other long-term liabilities	489	—
Total liabilities	69,727	13,800
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized at December 31, 2025 and 2024; none issued and outstanding at December 31, 2025 and 2024	—	—
Common stock, $0.01 par value; 90,000,000 shares authorized at December 31, 2025 and 2024; 29,368,760 and 27,617,415 shares issued and outstanding at December 31, 2025 and 2024, respectively	294	276
Additional paid-in capital	238,995	216,483
Shares to be issued	5,641	—
Accumulated deficit	(216,910)	(191,370)
Total stockholders' equity	28,020	25,389
Total liabilities and stockholders' equity	$ 97,747	$ 39,189

See notes to Consolidated Financial Statements.

CLEARPOINT NEURO, INC.

Consolidated Statements of Operations

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

	Year Ended December 31,	
	2025	**2024**
Revenue:		
Product revenue	$ 23,859	$ 18,626
Service and other revenue	13,112	12,764
Total revenue	36,971	31,390
Cost of revenue	14,279	12,268
Gross profit	22,692	19,122
Research and development costs	13,897	12,392
Sales and marketing expenses	16,461	14,478
General and administrative expenses	16,498	11,986
Operating loss	(24,164)	(19,734)
Other income (expense):		
Other expense, net	(146)	(40)
Interest income	1,213	1,390
Interest expense	(2,388)	(518)
Net loss before income taxes	(25,485)	(18,902)
Income tax expense	55	12
Net loss	$ (25,540)	$ (18,914)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.90)	$ (0.70)
Weighted average shares outstanding:		
Basic and diluted	28,315,254	27,027,692

See Notes to Consolidated Financial Statements.

CLEARPOINT NEURO, INC.
Consolidated Statements of Stockholders' Equity
Years Ended December 31, 2025 and 2024
(Dollars in thousands)

	Common Stock		Additional Paid-in Capital	Shares to be issued	Accumulated Deficit	Total
	Shares	Amount				
Balances, January 1, 2024	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 period	—	—	—	—	(18,914)	(18,914)
Balances, December 31, 2024	27,617,415	$ 276	$ 216,483	$ —	$ (191,370)	$ 25,389
Issuances of common stock:						
Acquisition of IRRAS (see Note 3)	901,451	9	12,170	5,641	—	17,820
Registered direct offering of common stock	275,808	3	3,338	—	—	3,341
Share-based compensation	618,740	6	8,174	—	—	8,180
Option exercises (cash and cashless)	32,023	—	127	—	—	127
Payments for taxes related to net share settlement of equity awards	(133,212)	(1)	(1,855)	—	—	(1,856)
Issuance of common stock under employee stock purchase plan	56,535	1	558	—	—	559
Net loss for the period	—	—	—	—	(25,540)	(25,540)
Balances, December 31, 2025	29,368,760	$ 294	$ 238,995	$ 5,641	$ (216,910)	$ 28,020

See Notes to Consolidated Financial Statements.

CLEARPOINT NEURO, INC.

Consolidated Statements of Cash Flows
(Dollars in thousands)

	Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (25,540)	$ (18,914)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for credit losses (recoveries)	21	(296)
Depreciation and amortization	814	980
Amortization of intangible assets	168	—
Share-based compensation	8,180	6,907
Payment-in-kind interest	908	—
Amortization of debt issuance costs and original issue discounts	83	51
Amortization of lease right of use assets, net of accretion in lease liabilities	1,255	923
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(268)	(1,206)
Inventory, net	(103)	743
Prepaid expenses and other current assets	(397)	262
Other assets	(195)	(39)
Accounts payable and accrued expenses	(7,520)	3,105
Lease liabilities	(1,012)	(869)
Contract liabilities	(319)	(597)
Net cash flows from operating activities	(23,925)	(8,950)
Cash flows from investing activities:		
Cash acquired in business combination, net of cash paid	1,137	—
Purchases of property and equipment	(522)	(275)
Net cash flows from investing activities	615	(275)
Cash flows from financing activities:		
Proceeds from offerings of common stock, net of offering costs	3,263	16,149
Proceeds from issuance of notes payable, net of financing costs and discount	48,086	—
Repayment of 2020 senior secured convertible note	—	(10,000)
Proceeds from stock option exercises	127	21
Payments for taxes related to net share settlement of equity awards	(1,856)	(424)
Proceeds from issuance of common stock under employee stock purchase plan	559	443
Net cash flows from financing activities	50,179	6,189
Net change in cash, cash equivalents and restricted cash	26,869	(3,036)
Cash, cash equivalents and restricted cash, beginning of year	20,104	23,140
Cash, cash equivalents and restricted cash, end of year	$ 46,973	$ 20,104
Cash and cash equivalents	45,923	20,104
Restricted cash included in other current assets and other assets, non-current	1,050	—
Total cash, cash equivalents and restricted cash	$ 46,973	$ 20,104
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ 69	$ 62
Interest	$ 908	$ 480

CLEARPOINT NEURO, INC.
Consolidated Statements of Cash Flows

NON-CASH INVESTING AND FINANCING TRANSACTIONS:

- The Company had $0.3 million and $0.2 million in capital expenditures accrued but not yet paid in December 31, 2025 and 2024, respectively.
- During each of the years ended December 31, 2025 and 2024, the Company recorded net transfers of ClearPoint reusable components having an aggregate net book value of $0.4 million between loaned systems, which are included in property and equipment in the accompanying consolidated balance sheets, and inventory.
- As discussed in Note 3, the Company acquired all of the outstanding equity interests of IRRAS in November 2025, and in connection therewith paid the former equityholders of IRRAS cash consideration of $0.02 million and equity consideration of $17.8 million in the form of 1,319,010 shares of common stock.
- As discussed in Note 10, the Company entered into a lease for a building in San Diego, California in June 2025. 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 $3.3 million.

See 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. 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. Over the past several years, 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.

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 Neuro 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.

In 2025, through the acquisition of IRRAS, the Company expanded its portfolio into neurocritical care. IRRAS is a commercial-stage medical technology company focused on treatments for intracerebral hemorrhage, intraventricular hemorrhage, and other conditions requiring intracranial fluid management.

The Company has several foreign wholly owned subsidiaries, primarily established 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.

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, 2025 of $216.9 million. In addition, the Company's use of cash from operations amounted to $23.9 million for the year ended December 31, 2025. Since inception, the Company has financed its operations principally from the sale of equity securities and the issuance of notes payable.

In May 2025, the Company entered into the 2025 SPA (as such term is defined in Note 11) relating to the purchase and sale in a registered direct offering of an aggregate of 275,808 shares of the Company's common stock, for aggregate net proceeds totaling approximately $3.3 million after deducting offering expenses payable by the Company.

Contemporaneously with entering into the 2025 SPA, the Company entered into the 2025 NPA (as such term is defined in Note 9) under which the Company may sell to the 2025 Investor tranches of notes in an aggregate principal amount of up to $105.0 million. The Company sold the initial note thereunder upon signing the 2025 NPA and received net proceeds of approximately $28.7 million, after deducting the debt discount and debt issuance costs of $0.6 million and $0.7 million, respectively.

In connection with the signing of the merger agreement pursuant to which the Company acquired IRRAS Holdings, Inc., the Company and the 2025 Investor entered into an amendment to the 2025 NPA pursuant to which the 2025 Investor agreed to purchase a note in the principal amount of $20.0 million under the 2025 NPA. The Company issued such note in November 2025 and received net proceeds of approximately $19.4 million, after deducting debt discount and debt issuance costs.

In March 2024, the Company completed a follow-on public offering of 2,653,848 shares of its common stock for net proceeds of 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 $50.0 million, subject to the terms and conditions of the ATM Agreement. As of December 31, 2025, the Company had not sold any shares of common stock under the ATM Agreement.

Additional information with respect to the stock and debt offerings described above is found in Note 11 and 9, respectively.

As required by accounting principles generally accepted in the United States (“GAAP”), the Company has evaluated its ability to continue as a going concern for at least the next twelve months from the date of issuance of these financial statements. The Company has determined that based on its current forecasts, its existing cash and cash equivalent balances at December 31, 2025 are sufficient to support the Company’s operations and meet its obligations for at least the next twelve months from the date of issuance of these financial statements.

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, 2025, cash equivalents consisted predominantly of U.S. Government debt securities.

Restricted cash

The Company has restricted cash pledged as a security deposit and collateral related to its operating leases. Amounts related to the cash pledged as collateral expected to be released within twelve months of the accompanying consolidated balance sheet is classified in other current assets. The remaining noncurrent balance is presented in other assets in the accompanying consolidated balance sheet.

Inventory

Inventory, which consists of raw materials, work in process, and finished goods available for sale, 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. The Company periodically reviews its inventory for obsolete items and provides a reserve upon identification of potential obsolete items.

Business Combinations

Under the acquisition method of accounting, the Company allocates the fair value of the total consideration transferred to the tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values on the date of acquisition. These valuations require the Company to make estimates and assumptions, especially with respect to intangible assets. The excess consideration over the aggregate fair value of tangible and intangible assets, net of liabilities assumed, is recorded as goodwill. Costs incurred to complete a business combination, such as legal and other professional fees, are expensed as incurred.

If the initial accounting for a business combination is incomplete by the end of a reporting period that falls within the measurement period, the Company reports provisional amounts in the financial statements. During the measurement period, the Company adjusts the provisional amounts recognized at the acquisition date to reflect new information obtained about facts and circumstances that existed as of the acquisition date that, if known, would have affected the measurement of the amounts recognized as of that date. These adjustments to the provisional amounts are recorded with a corresponding offset to goodwill. Any adjustments identified after the measurement period are recorded in the consolidated statements of operations.

Goodwill, Intangible Assets and Other Long-Lived Asset

Assets acquired, including intangible assets, and liabilities assumed are measured at fair value as of the acquisition date. Goodwill, which has an indefinite useful life, represents the excess of cost over fair value of the net assets acquired.

Goodwill is not amortized; however, it is reviewed for impairment at least annually, or more frequently if an event occurs indicating the potential for impairment. Goodwill is considered to be impaired if the carrying value of the reporting unit exceeds its respective fair value.

The Company performs the goodwill impairment analysis at the reporting unit level, which aligns with its reporting and operating segment structure and availability of discrete financial information. During the goodwill impairment review, the Company assesses qualitative factors to determine whether it is more likely than not that the fair values of the reporting unit is less than the carrying amount, including goodwill. The qualitative factors include, but are not limited to, macroeconomic conditions, industry and market considerations, and the Company's overall financial performance. If this qualitative assessment indicates that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, the Company performs a quantitative goodwill impairment test. If the carrying amount of the reporting unit exceeds the fair value, the Company records an impairment loss based on the difference. The qualitative assessment for the reporting unit may be bypassed and instead the Company may proceed directly to the quantitative goodwill impairment test.

Intangible assets with finite lives are amortized using the straight-line method over the estimated economic lives of the assets, which range from one to ten years. The Company's intangible assets with finite lives are reviewed for impairment whenever events or change in circumstances indicate that the carrying amount of such assets may not be fully recoverable. The carrying value is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. An impairment loss is measured as the amount by which the carrying amount exceeds its fair value.

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.

Revenue Recognition

The Company’s revenue is comprised primarily of: (1) product revenue resulting from the sale of disposable products related to neurosurgery navigation, therapy, neurocritical care, and biologics and drug delivery, as well as ClearPoint and IRRA*flow* capital equipment and ClearPoint 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, therapy, neurocritical care, and biologics and drug delivery product sales:* Revenue from the sale of neurosurgery navigation products (consisting of disposable products sold commercially and related to cases utilizing the ClearPoint system), therapy products (consisting primarily of disposable laser-related products used in neurosurgical procedures), neurocritical care products (consisting of disposable products sold commercially and related to cases utilizing the IRRA*flow* system), biologics and drug delivery products (consisting primarily of disposable products related to customer-sponsored preclinical and clinical trials), is generally based on customer purchase orders, and is recognized at the point in which legal title, and risks and rewards of ownership, transfer to the customer.

- *Capital equipment and software sales:*

    - *Capital equipment and software sales preceded by evaluation periods:* Revenue for capital equipment and software sales (consisting of computer hardware and software that are integral components of the ClearPoint system or the IRRA*flow* system) which are preceded by customer evaluation periods is recognized at the point in time that the Company is in receipt of a purchase order and all related items have been shipped to the customer. During these evaluation periods, installation of the systems has been completed, if required, training of customer personnel has been completed, and the systems have been in operation.

    - *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, if required.

  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 Neuro 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 for 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 4 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, 2025 and 2024, the Company had no accrued interest or penalties related to uncertain tax positions.

See Note 13 for additional information regarding income taxes.

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 11, 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 each of the years ended December 31, 2025 and 2024, approximately 3 million 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 2025 or 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, 2025, the Company had approximately $0.8 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.

One pharmaceutical customer, a related party that is a former stockholder and former noteholder, and whose chief executive officer is a member of 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 8% of total revenue for the year ended December 31, 2025, and of 9% total revenue for the year ended December 31, 2024. There were no outstanding receivables from this customer at December 31, 2025 or December 31, 2024.

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, 2025 and 2024 was $1.2 million and $1.1 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

Beginning in its 2025 annual reporting, the Company adopted Accounting Standards Update ("ASU") No. 2023-09, "Improvements to Income Tax Disclosures," on a prospective basis. This standard requires the disclosure of 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 adoption of this new standard did not have a material impact on the consolidated financial statements. For additional information, see Note 13.

Recent Accounting Standards Not Yet Adopted

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.

In September 2025, the FASB issued ASU 2025-06, "Intangibles - Goodwill and Other - Internal Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software," which improves the operability of the accounting for internal-use software by removing all references to software development project stages so that the guidance is neutral to different software development methods. This standard is effective for annual periods beginning after December 15, 2027, including interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the potential impact of the new pronouncement.

In December 2025, the FASB issued ASU 2025-11, "Interim Reporting (Topic 270): Narrow-Scope Improvements," which clarifies the guidance in Topic 270 to improve the consistency of interim financial reporting. ASU 2025-11 provides a comprehensive list of required interim disclosures and introduces a disclosure principle requiring entities to disclose events since the end of the last annual reporting period that have a material impact on the entity. This standard is effective for fiscal years beginning December 15, 2027, including interim periods within those fiscal years, with early adopted permitted. The Company is currently evaluating the potential impact of the new pronouncement.

Reclassification

The accompanying consolidated statement of operations for the year ended December 31, 2025 contains income tax expense formerly classified as general and administrative expense as a separate line on the consolidated statement of operations. Additionally, the Company reports interest income and interest expense separately within the consolidated statement of operations. The accompanying consolidated statement of operations for the year ended December 31, 2024 has been adjusted to conform to the 2025 presentation.

3. Business Combination

On November 20, 2025, the Company acquired all of the outstanding equity interests of IRRAS Holdings, Inc., or IRRAS, a medical technology company focused on neurocritical care. The total consideration for the acquisition, payable as of closing, was $5.0 million in cash and 1,325,000 shares of the Company's common stock, subject to certain adjustments including for indebtedness, working capital, and the satisfaction of indemnification obligations. As described below, the former equityholders of IRRAS are also eligible for earnout cash payments.

Of the total consideration, payable as of closing, (i) the Company paid $5.0 million on behalf of IRRAS directly to third parties to satisfy IRRAS' outstanding liabilities, (ii) the Company paid the former equityholders of IRRAS cash consideration of $0.02 million, and (iii) the Company paid or will pay the former equityholders of IRRAS equity consideration of $17.8 million in the form of 1,319,010 shares of the Company's common stock, subject to adjustment for the satisfaction of indemnification obligations. As the cash paid on behalf of IRRAS to satisfy its outstanding liabilities was paid directly to third parties, such amount is not reflected as consideration transferred to the former equityholders of IRRAS for purposes of the purchase price allocation.

Of the $17.8 million of equity consideration, up to 0.4 million shares of the Company's common stock remain to be issued, consisting of (i) shares issuable to the extent not applied to satisfy the indemnification obligations of the former equityholders of IRRAS, which shares may be issued, in whole or in part, sixteen months following the closing of the acquisition, subject to the terms of the merger agreement, and (ii) shares that will be issued as soon as practicable following receipt of documentation required to complete the issuances from the parties entitled to such shares.

The Company also agreed to pay the former equityholders of IRRAS a contingent cash payment equal to 25% of that portion of net sales of IRRAS products that exceeds (a) $13.0 million in 2026, (b) $17.0 million in 2027, and (c) $22.0 million in 2028, in each case, within 90 days after the end of the applicable year. The Company determined that the fair value of the earnout liability is nominal as of the acquisition date of closing and as of December 31, 2025.

The Company recognized transaction costs related to legal fees, of $0.4 million in the year ended December 31, 2025. These costs are reported in general and administrative expenses in the consolidated statements of operations.

The components of preliminary fair value of consideration transferred are as follows (in thousands):

Consideration Transferred		
Cash consideration paid to the former equityholders of IRRAS	$	15
Stock consideration to the former equityholders of IRRAS		17,820
Total consideration transferred	**$**	**17,835**

The acquisition of IRRAS was accounted for as a business combination using the acquisition method of accounting. The acquisition method requires, among other things, that assets acquired, and liabilities assumed in a business combination be recognized at their fair values as of the acquisition date. The following table summarizes the preliminary purchase price allocation as of the acquisition date (in thousands):

Net Assets Acquired		**Fair Value**
Cash, cash equivalents, and restricted cash	$	1,152
Accounts receivable, net		1,588
Inventory, net		2,005
Prepaid expenses and other current assets		414
Property, plant, and equipment		50
Operating right-of-use asset		2,670
Intangible assets		14,090
Goodwill		7,472
Total assets acquired	**$**	**29,441**
Accounts payable		1,249
Accrued compensation		2,329
Other accrued liabilities		5,004
Operating lease liability, current portion		218
Operating lease liability		2,452
Deferred tax liabilities, net		354
Total liabilities acquired	**$**	**11,606**
Net assets acquired	**$**	**17,835**

Goodwill represents the excess of the purchase price over the identifiable tangible and intangible assets acquired in addition to liabilities assumed arising from the business combination. The Company believes the goodwill related to the acquisition was attributable to the expected synergies, value of the assembled workforce, and the collective experience of the management team with regards to its operations, customers, and industry.

The estimated fair values of identifiable intangible assets were determined using the “income approach” which is a valuation technique that provides an estimate of the fair value of an asset based on market participant expectations of the cash flows an asset would generate over its remaining useful life. Some of the more significant assumptions inherent in the development of these asset valuations include the estimated net cash flows for each year for each asset or product, the appropriate discount rate necessary to measure the risk inherent in each future cash flow stream, the life cycle of each asset, the potential regulatory and commercial success risk, and competitive trends impacting the assets.

The following table summarizes the preliminary valuation of acquired intangible assets and estimated useful lives as of the acquisition date ($ in thousands):

	Useful life (in years)		**Fair Value (in thousands)**
Developed Technology	10	$	11,890
Customer Relationships	6		1,650
Trademark/Trade Name	1		550
Total identifiable intangible assets		**$**	**14,090**

The Company's financial results for the year ended December 31, 2025 reflect inclusion of the business operations of IRRAS from the closing date of the acquisition, November 20, 2025. The Company's consolidated results of operations since the closing date include $1.2 million of revenue and $2.5 million in net loss attributable to IRRAS' operations.

Pro Forma Financial Information

The unaudited pro forma combined financial information was prepared using the acquisition method of accounting and was based on the historical financial information of the Company and the acquired assets of IRRAS. In order to reflect the occurrence of the acquisition on January 1, 2024 as required, the unaudited pro forma financial information includes adjustments to reflect (i) incremental amortization expense incurred based on the fair values of the identifiable intangible assets acquired, (ii) the additional interest expense associated with the issuance of debt to finance the acquisition, and (iii) the additional cost associated with the fair value adjustment to inventory.

The unaudited pro forma financial information is not necessarily indicative of what the consolidated results of operations would have been, had the acquisition been completed on January 1, 2024. In addition, the unaudited pro forma financial information is not a projection of future results of operations of the combined company nor does it reflect the expected realization of any synergies or cost savings associated with the acquisition.

The following table presents the unaudited pro forma combined results of the Company and the acquired assets of IRRAS for the years ended December 31, 2025 and 2024, as if the acquisition had occurred on January 1, 2024:

	December 31,	
(in thousands)	**2025**	**2024**
Net revenues	$ 44,457	$ 36,880
Net loss	$ 36,041	$ 30,574

4. Revenue Recognition

Revenue by Service Line

	Year Ended December 31,	
(in thousands)	**2025**	**2024**
Biologics and drug delivery		
Disposable products	$ 7,338	$ 5,606
Services and license fees	11,702	11,704
Subtotal – Biologics and drug delivery revenue	19,040	17,310
Neurosurgery navigation and therapy		
Disposable products	14,831	10,285
Subtotal – Neurosurgery navigation and therapy revenue	14,831	10,285
Capital equipment and software		
Systems and software products	1,690	2,735
Services	1,410	1,060
Subtotal – Capital equipment and software revenue	3,100	3,795
Total revenue	$ 36,971	$ 31,390

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, 2025, the Company recorded as a contract asset up-front costs for direct materials incurred to fulfill a customer contract.

(in thousands)	December 31, 2025	December 31, 2024	December 31, 2023
Accounts receivable, net	$ 6,549	$ 4,713	$ 3,211
Other contract assets			
Unbilled receivables	$ 714	$ 642	$ 733
Deferred contract costs	$ 150	$ —	$ —

- *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.

(in thousands)	December 31, 2025	December 31, 2024	December 31, 2023
Contract liabilities	$ 2,250	$ 2,557	$ 3,154

During the years ended December 31, 2025 and 2024, the Company recognized capital equipment and software-related service revenue of approximately $2.1 million and $2.3 million, respectively, which was previously included in contract liabilities in the accompanying consolidated balance sheets at December 31, 2024 and 2023, 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 $2.1 million at December 31, 2025. The Company expects to recognize approximately 72% of this revenue over the next twelve months and the remainder thereafter.

5. 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 $45.9 million and $20.1 million as of December 31, 2025, and December 31, 2024, 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.

6. Inventory

Inventory consists of the following as of December 31:

(in thousands)	2025	2024
Raw materials and work in process	$ 7,052	$ 5,503
Finished goods	4,813	3,619
Reserve for excess and obsolete inventory	(3,506)	(2,259)
	$ 8,359	$ 6,863

Inventory acquired in a business combination is recorded at acquisition date fair value and is recorded as a component of cost of goods sold as the inventory is sold.

7. Property and Equipment

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

(in thousands)	2025	2024
Equipment	$ 1,990	$ 1,558
Leasehold improvements	485	485
Loaned systems	1,863	1,305
	4,338	3,348
Less accumulated depreciation	(1,717)	(1,343)
Total property and equipment, net	$ 2,621	$ 2,005

Depreciation expense related to property and equipment for the years ended December 31, 2025 and 2024 was $0.4 million and $0.2 million, respectively. Loaned systems are ClearPoint systems that are in operation at customer sites on an evaluation basis.

8. Goodwill and Intangible Assets

Goodwill

On November 20, 2025, the Company acquired all outstanding equity interests of IRRAS. A goodwill balance of $7.5 million was recognized for the excess of the consideration transferred over the net assets acquired and represents the expected synergies, value of the assembled workforce, and the collective experience of the management team with regards to its operations, customers, and industry.

A summary of the activity impacting goodwill is presented below (in thousands):

Balance as of December 31, 2024	$ —
Goodwill acquired	7,472
Balance as of December 31, 2025	$ 7,472

Intangible Assets

The acquired intangible assets are amortized using the straight-line method over their estimated useful lives of one to ten years. The following table shows the cost, accumulated amortization, and weighted average remaining life for the acquired intangible assets as of December 31, 2025 (in thousands):

	Weighted average remaining life (in years)	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Developed Technology	10	$ 11,890	$ (99)	$ 11,791
Customer Relationships	6	1,650	(23)	1,627
Trademark/Trade Name	1	550	(46)	504
Total intangible assets	9.1	$ 14,090	$ (168)	$ 13,922

The table below sets forth amortization expense (in thousands):

		Year Ended December 31,	
Intangible asset	Location	2025	2024
Developed Technology	Cost of revenue	$ 99	$ -
Customer Relationships	Sales and marketing expenses	23	-
Trademark/Trade Name	Sales and marketing expenses	46	-
Total amortization expense		$ 168	$ -

The estimated future annual amortization of finite-lived intangible assets is shown in the following table. Actual amortization expense to be reported in future periods could differ from these estimates as a result of acquisitions, divestitures, and asset impairments, among other factors.

Year:		Amortization (in thousands)
2026	$	1,968
2027		1,464
2028		1,464
2029		1,464
2030		1,464
Thereafter		6,098
Total	$	13,922

9. Notes Payable

On May 12, 2025, the Company entered into a note purchase agreement (the "2025 NPA") with TPC Investments III, LP, an affiliate of Oberland Capital Management LLC (the "2025 Investor"), and CALW SA LLC, as purchaser agent, under which the Company may sell to the 2025 Investor tranches of notes ("Notes") in an aggregate principal amount of up to $105.0 million. Under the terms of the 2025 NPA, (a) the Company sold a Note in the principal amount of $30.0 million (the "First Purchase Note") to the 2025 Investor upon signing of the 2025 NPA, (b) at the option of the Company, the Company may sell an additional $25.0 million in principal amount of Notes, in up to two increments of $12.5 million each, at any time prior to December 31, 2026, and (c) at the option of the Company and the 2025 Investor, the Company may sell up to $50.0 million in principal amount of Notes, at any time prior to December 31, 2026 (the "Third Tranche of Notes").

In connection with the signing of the merger agreement pursuant which the Company acquired IRRAS, the Company and the 2025 Investor entered into an amendment to the 2025 NPA pursuant to which the 2025 Investor agreed to purchase $20.0 million in principal amount of the Third Tranche of Notes under the 2025 NPA following the closing of the IRRAS acquisition (the "Third Tranche Note"). The Third Tranche Note was sold to the 2025 Investor on November 20, 2025.

The purchase price of the Notes is, in each case, 98% of the principal amount thereof. The net proceeds from the sale of the First Purchase Note, after deducting the debt discount and debt issuance costs of $0.6 million and $0.7 million, respectively, was approximately $28.7 million. The net proceeds from the sale of the Third Tranche Note, after deducting the debt discount and debt issuance costs, was approximately $19.4 million.

The outstanding principal amount of the Notes bears interest at a rate per annum equal to the sum of: (i) the greater of the Term SOFR (as defined in the 2025 NPA) and 4.30%; and (ii) 3.95%, with a minimum rate of 8.25% and a cap of 9.50%, payable quarterly in arrears. For the first six quarters following the purchase date for each sale of Notes (each, a "Purchase Date"), 50% of the interest due shall be paid-in-kind and added to the then-outstanding principal balance of the Notes, which may be extended by two quarters at the Company's option.

The Notes mature on the sixth anniversary of their Purchase Date or the date on which all amounts owing to the 2025 Investor have been paid in full (the "Maturity Date"). Upon the occurrence and during the continuance of an Event of Default (as defined in the 2025 NPA) under the 2025 NPA, the then-applicable interest rate on all outstanding obligations will increase by 4.00%.

Beginning on January 1, 2027 and continuing until the Maturity Date of the First Purchase Note, the 2025 Investor will receive 0.375% of Net Revenue (as defined in the 2025 NPA) for any fiscal quarter (of up to $50,000,000 of Net Revenue for each fiscal year), payable quarterly. As a result of the sale of the Third Tranche Note, this percentage increased by 0.15% and is payable beginning on January 1, 2027 and continuing until the Maturity Date of the Third Tranche Note. The outstanding principal amount of the Notes, interest accrued thereon and any other amounts owing to the 2025 Investor under the 2025 NPA, will be due and payable on the applicable Maturity Date.

All of the Notes may be redeemed prior to the Maturity Date at the option of the Company, subject to payment of the Repayment Amount (as defined in the 2025 NPA). The 2025 Investor may demand redemption of the Notes prior to the Maturity Date in the event of a Change of Control (as defined in the 2025 NPA) of the Company or an Event of Default. The Repayment Amount will be: (a) if redemption occurs before the first anniversary of the date of issuance of a Note, 117.5% of the principal amount of such Note; (b) if redemption occurs after the first anniversary and prior to the second anniversary of the date of issuance of a Note, 125% of the principal amount of such Note; (c) if redemption occurs after the second anniversary and prior to the third anniversary of the date of issuance of a Note, 135% of the principal amount of such Note; (d) if redemption occurs after the third anniversary and prior to the fourth anniversary of date of issuance of a Note, an amount that would generate an internal rate of

return to the Purchasers of such Note of 11.50%; (e) if redemption occurs after the fourth anniversary of the date of issuance of a Note and prior to the sixth anniversary of the date of issuance of a Note, an amount that would generate an internal rate of return to the Purchasers of such Note of 10.50%; (f) if redemption occurs on the sixth anniversary of the date of issuance of a Note, an amount that would generate an internal rate of return to the Purchasers of such Note of 9.50%, minus, in each case, the sum of regularly scheduled interest paid in cash, payments of proceeds of insurance policies pursuant to the terms of the NPA, and payments of revenue participation in cash prior to such redemption date.

For the year ended December 31, 2025, the Company recognized interest expense of $2.4 million which is recorded in the consolidated statements of operations. The effective interest rate on the Notes is 11.3%.

The 2025 NPA contains no financial covenants. The Company's obligations under the 2025 NPA are subject to customary covenants, including limitations on the Company's ability to dispose of assets, undergo a change of control, merge with or acquire other entities, incur debt, incur liens, pay dividends or other distributions to holders of its capital stock, repurchase stock and make investments, in each case subject to certain exceptions. The Company's obligations under the 2025 NPA are secured by a security interest on substantially all of the Company's assets, including its intellectual property. The obligations of the 2025 Investor to purchase Notes are subject to certain customary conditions precedent.

The Company assessed the provisions of the 2025 NPA to determine if the agreement included any embedded derivative features by evaluating each feature against the nature of the host instrument. The only embedded feature which was determined to meet the characteristics of a derivative and require bifurcation and separate accounting was the 2025 Investor's right to demand redemption prior to the Maturity Date in the event of a Change of Control or an Event of Default. The fair value of the identified derivative was determined to be nominal as the probability of Change of Control or Event of Default was negligible at inception and December 31, 2025. For each subsequent reporting period, the Company will evaluate the probability of the Investor's right to demand redemption and record the applicable fair value as of the end of each reporting period.

Scheduled principal payments as of December 31, 2025 with respect to the Notes is summarized as follows:

Years ending December 31,	*(in thousands)*
2031	$ 50,908
Total scheduled principal payments	50,908
Less: unamortized discounts and financing costs	(1,831)
Total carrying amount	$ 49,077

The estimated fair value of the Notes, developed based on inputs classified as Level 3 within the fair value hierarchy, was approximately $48.8 million as of December 31, 2025.

10. 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.

On June 16, 2025, the Company entered into a lease agreement to expand into approximately 30,171 square feet within a life science building located in San Diego, California. The Company will use the facility for office, research and development, and laboratory purposes. The building will be occupied in three phases, the first of which (6,818 square feet) was made available upon lease signing. The next two phases (9,833 and 13,520 square feet, respectively) are expected to be made available by March 2026 and July 2026, respectively. The lease agreement expires 132 months (11 years) from the date on which the last phase is made available, subject to the Company's right to extend the lease term for one additional five-year period, at the then fair market rental value. The initial monthly base rent is $5.95 per square foot, subject to annual increases of 3%, with payment for the first and second phases to commence after occupation of the second phase and the payment for the third phase to commence after occupation of the third phase. The monthly base rent will be abated: (i) for the second through thirteenth months after the second phase occupation for the first and second phases; and (ii) for the first through twelfth months after the third phase occupation

solely for the third phase. The Company determined that the three phases of the lease agreement constitute separate lease components, and calculated the right-of-use asset and lease liability of the first phase of $3.3 million. Given the second and third phases of this lease have not yet commenced, the lease liability is excluded from the table below.

In connection with the IRRAS acquisition, the Company assumed an operating lease for 21,200 square feet used for manufacturing and office purposes located in San Diego, California. The lease is set to expire in April 2031, with the option to extend the lease for one additional five year term, at the then fair market rental rate.

The optional renewal periods for all 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 remaining leases. The weighted average remaining lease term of the Company's operating leases was 8.02 years and 6.81 years, and the weighted average discount rate used to determine the operating lease liability was 10.4% and 12.0%, as of December 31, 2025 and 2024, respectively.

The lease cost was $1.3 million and $0.9 million for the years ended December 31, 2025 and 2024, respectively.

As of December 31, 2025, future minimum lease payments are as follows:

Years ending December 31,	*(in thousands)*
2026	$ 1,616
2027	1,566
2028	1,716
2029	1,773
2030	1,833
Thereafter	5,706
Total minimum payments	14,210
Less: Discount to present value of lease payments	(5,055)
Discounted present value of lease payments	$ 9,155

Purchase Commitments

The Company is a party to various purchase arrangements related to its manufacturing and research and development activities. At December 31, 2025 there was approximately $4.8 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 four years.

Legal Contingencies

The Company previously disclosed that it 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 system was used. In August 2025, the Company settled this matter. The settlement amount was paid by insurance, and did not have a material impact on the Company's consolidated financial statements.

11. Stockholders' Equity

2025 Stock Purchase Agreement

On May 12, 2025, the Company entered into a Stock Purchase Agreement (the “2025 SPA”) with the 2025 Investor relating to the purchase and sale in a registered direct offering of an aggregate of 275,808 shares of the Company’s common stock at a price of $12.69 per share, based on the trailing 30-trading day volume-weighted average price of the Company’s common stock. The

aggregate net proceeds to the Company from the offering totaled approximately $3.3 million after deducting offering expenses payable by the Company.

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 At-The-Market Equity Offering Sales Agreement with Stifel, Nicolaus & Company, Incorporated, as sales agent (the "ATM Agreement") to, from time to time, sell shares of its common stock having aggregate sales proceeds of up to $50.0 million, subject to the terms and conditions of the ATM Agreement. As of December 31, 2025, the Company did not issue any shares of common stock under the ATM Agreement.

Equity Compensation Plans

The Sixth Amended and Restated 2013 Incentive Compensation Plan (the "2013 Plan") became effective in May 2025, which amended the previous plan to increase the number of shares of common stock available for awards by 700,000 shares. The plan permits the issuance of stock options, restricted stock awards ("RSAs"), restricted stock units ("RSUs") and other awards to selected employees, directors, and consultants of the Company. The total number of shares of the Company's common stock reserved for issuance under the 2013 Plan is 6,806,250 of which unvested awards covering 2,528,939 shares were outstanding as of December 31, 2025 and 1,340,527 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:

	Year Ended December 31,	
(in thousands)	**2025**	**2024**
Cost of revenue	$ 131	$ 112
Research and development	2,017	1,641
Sales and marketing	2,224	1,881
General and administrative	3,808	3,273
Share-based compensation expense	$ 8,180	$ 6,907

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

	Year Ended December 31,	
(in thousands)	**2025**	**2024**
Stock options	$ 272	$ 653
RSAs and RSUs	7,647	6,066
ESPP	261	188
	$ 8,180	$ 6,907

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, 2025	
	Unrecognized Expense	Remaining Weighted-Average Recognition Period (in years)
Stock options	$ 28	0.18
RSAs and RSUs	$ 8,479	1.72

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, 2025 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, 2024	1,376,396	$ 6.48		
Exercised	(38,013)	$ 5.98		
Forfeited or expired	(36,311)	$ 32.15		
Outstanding at December 31, 2025	1,302,072	$ 5.78	3.80	$ 10,809
Exercisable at December 31, 2025	1,259,605	$ 5.70	3.68	$ 10,572
Vested and expected to vest at December 31, 2025	1,302,072	$ 5.78	3.80	$ 10,809

(1) Intrinsic value is calculated as the estimated fair value of the Company's stock at December 31, 2025 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, 2025 is presented below:

	Non-vested Stock Options	Weighted-Average Grant Date Fair Value
Nonvested, December 31, 2024	123,987	$ 6.83
Vested	(81,520)	$ 7.26
Nonvested, December 31, 2025	42,467	$ 6.00

There were no stock options granted during 2025 or 2024.

The total intrinsic value of stock options exercised during the years ended December 31, 2025 and 2024 was $0.4 million and $0.1 million, respectively, and represents the difference between the exercise price of the option and the fair value of the common stock on the dates exercised. The total grant-date fair value of stock options vested during each of the years ended December 31, 2025 and 2024 was $0.6 million and $0.8 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.

Restricted Stock Activity

The Company issues RSAs and 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 award. 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.

RSUs are granted to the Company's non-employee directors on the day following an annual meeting of stockholders and they vest on the earlier of the first anniversary of the grant date or the day immediately preceding the next annual meeting of stockholders.

RSA activity as of and for the year ended December 31, 2025 is summarized below (no RSAs were granted in 2025 or 2024):

	Restricted Stock Awards	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2024	154,210	$ 11.12
Vested	(152,457)	$ 11.12
Forfeited or expired	(1,753)	$ 11.41
Outstanding at December 31, 2025	—	$ —

RSU activity as of and for the year ended December 31, 2025 is summarized below:

	Restricted Stock Units	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2024	1,657,760	$ 6.76
Granted	639,617	$ 13.34
Vested	(620,493)	$ 7.10
Forfeited or expired	(25,017)	$ 8.01
Outstanding at December 31, 2025	1,651,867	$ 9.16

The estimated fair value of both RSAs and RSUs 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 that vested during the years ended December 31, 2025 and 2024 was $6.1 million and $4.9 million, respectively.

Employee Stock Purchase Plan

In June 2021, the Company's stockholders adopted and approved the ClearPoint Neuro, Inc. Employee Stock Purchase Plan (the "ESPP"). In May 2025, the ESPP was amended to increase the number of shares of common stock reserved for issuance from 400,000 to 700,000 shares. 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. There are 382,463 shares remaining available for grant under the ESPP as of December 31, 2025.

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, 2025 and 2024.

During the year ended December 31, 2025, 56,535 shares were purchased under the ESPP at an average per share price of $9.88.

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:

	2025	2024
Risk-free interest rate	4.25% -4.29%	5.24% - 5.37%
Expected life (in years)	0.5	0.5
Estimated volatility	77.32% - 84.49%	64.5% - 67.33%
Expected dividends	None	None

The weighted-average fair value per ESPP purchase right during the years ended December 31, 2025 and 2024 was $5.02 per share and $2.10 per share, respectively.

12. Segment Disclosures

The Company is a medical device company offering precise navigation to the brain, and provides clinical products and preclinical development services for controlled drug and device delivery. Even with the acquisition of IRRAS, 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 4; 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.

13. Income Taxes

The Company adopted ASU 2023-09 "Income Taxes (Topic 740): Improvements to Income Tax Disclosures" on a prospective basis beginning with the year ended December 31, 2025. The following table presents required disclosures pursuant to ASU 2023-09 and reconciles the U.S. federal statutory tax amount to the actual global effective amount and rate for the year ended December 31, 2025.

	Year Ended December 31, 2025	
	Amount *(in thousands)*	**Percent**
U.S. Federal Statutory Rate	$ (5,378)	21.0%
State and local income taxes, net of federal income tax effect [(a)]	22	-0.1%
Foreign tax effects	33	-0.1%
Effects of changes in tax laws or rates enacted in the current period	—	—
Effects of cross-border tax laws	—	—
Tax credits	—	—
Changes in valuation allowance	5,124	20.0%
Nontaxable and nondeductible items		
Excess share-based compensation	(41)	0.2%
Other	295	-1.2%
Changes in unrecognized tax benefit	—	—
Other adjustments	—	—
Effective tax rate	$ 55	-0.2%

[(a)] State taxes in South Carolina, Massachusetts and New Jersey made up the majority (greater than 50%) of the tax effect in this category.

The following table presents the required disclosures prior to adoption of ASU 2023-09 and reconciles the U.S. federal statutory income tax rate to the actual global effective amount and rate for the year ended December 31, 2024.

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

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)	**2025**	**2024**
Deferred income tax assets:		
Net operating loss carryforwards	$ 64,837	$ 31,776
Share-based compensation	1,300	1,390
Accrued expenses	747	295
174 Capitalization	—	4,606
Unrealized FX (gain)/loss	5	—
Other	408	267
	67,297	38,334
Less valuation allowance	(64,155)	(38,333)
Total deferred income tax assets	3,142	1
Deferred tax liability - property and equipment	(117)	—
Deferred tax liability - intangibles	(3,379)	—
Deferred tax liability - unrealized FX (gain)/loss	—	(1)
Net deferred tax assets	$ (354)	$ —

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 $64.2 million has been established against deferred tax assets as of December 31, 2025, as management determined that it is more likely than not that sufficient taxable income will not be generated to realize those temporary differences.

The net deferred tax liability of $0.4 million as of December 31, 2025 relates to the acquisition of IRRAS, primarily related to book intangibles (with finite useful lives for book purposes and carryover tax basis) partially offset by tax net operating losses. As of December 31, 2024, the Company had no material net deferred tax liability and maintained a full valuation allowance against its net deferred income tax assets due to uncertainties surrounding their realization in future periods. Due to the timing of the acquisition late in 2025, any partial release of the valuation allowance would be reflected in the year ended December 31, 2025, and future periods as evidence of realizability evolves. The Company is subject to multiple state minimum income tax expenses for the years ended December 31, 2025 and 2024. 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.

At December 31, 2025, the Company had net operating loss carryforwards of approximately $258.2 million and $163.1 million available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. The federal net operating loss carryforwards begin expiring in 2026, and the state net operating loss carryforwards 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 2022 and subsequent years remain open for examination.