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

FORM 10-Q

(Mark One)

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

For the quarterly period ended **September 30, 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)	(IRS Employer Identification Number)
120 S. Sierra Ave., Suite 100 Solana Beach, California	**92075**
(Address of Principal Executive Offices)	(Zip Code)

(888) 287-9109
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files.) ☑ Yes ☐ No

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

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

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

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

As of October 27, 2025, there were 28,423,308 shares of common stock outstanding.

CLEARPOINT NEURO, INC.

TABLE OF CONTENTS

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®*, and *ClearPoint Advanced Laboratories™* are all trademarks of ClearPoint Neuro, Inc. Any other trademarks, trade names or service marks referred to in this Quarterly Report on Form 10-Q (this "Quarterly Report") are the property of their respective owners.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report contains “forward-looking statements” as defined under U.S. federal securities laws. These forward-looking statements relate to our expectations for performance, revenues and costs, and the adequacy of cash and cash equivalent balances and short-term investments to support operations and meet future obligations. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements, expressed or implied by the forward-looking statements.

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

In evaluating forward-looking statements, you should refer to: (i) the section titled “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, which we filed with the United States Securities and Exchange Commission (“SEC”) on February 26, 2025 (the “2024 Form 10-K”); (ii) Item 2 of this Quarterly Report, under the heading “Management's Discussion and Analysis of Financial Condition and Results of Operations -- Factors Which May Influence Future Results of Operations;” and (iii) Part II, Item 1.A of this Quarterly Report. As a result of these risk factors, we cannot assure you that the forward-looking statements in this Quarterly 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 Quarterly Report, except to the extent required by applicable securities laws.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CLEARPOINT NEURO, INC.
Condensed Consolidated Balance Sheets
(in thousands, except for share and per share data)

	September 30, 2025 (Unaudited)	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,221	$ 20,104
Accounts receivable, net	4,000	4,713
Inventory, net	6,583	6,863
Prepaid expenses and other current assets	2,525	1,683
Total current assets	51,329	33,363
Property and equipment, net	2,114	2,005
Operating lease, right-of-use assets	5,955	3,086
Other assets	959	735
Total assets	$ 60,357	$ 39,189
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 723	$ 1,340
Accrued compensation	3,516	4,885
Other accrued liabilities	1,748	1,450
Operating lease liabilities, current portion	347	557
Contract liabilities, current portion	1,719	2,121
Total current liabilities	8,053	10,353
Operating lease liabilities, net of current portion	6,195	3,011
Contract liabilities, net of current portion	769	436
Long-term note payable, net	29,203	—
Other long-term liabilities	263	—
Total liabilities	44,483	13,800
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized; none issued and outstanding at September 30, 2025 and December 31, 2024	—	—
Common stock, $0.01 par value; 90,000,000 shares authorized at September 30, 2025 and December 31, 2024; 28,428,176 and 27,617,415 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	284	276
Additional paid-in capital	224,714	216,483
Accumulated deficit	(209,124)	(191,370)
Total stockholders' equity	15,874	25,389
Total liabilities and stockholders' equity	$ 60,357	$ 39,189

See accompanying notes to Condensed Consolidated Financial Statements.

CLEARPOINT NEURO, INC.
Condensed Consolidated Statements of Operations
(Unaudited)
(in thousands, except for share and per share data)

	For the Three Months Ended September 30,	
	2025	**2024**
Revenue:		
Product revenue	$ 5,361	$ 5,474
Service and other revenue	3,500	2,648
Total revenue	8,861	8,122
Cost of revenue	3,261	3,275
Gross profit	5,600	4,847
Research and development costs	3,452	3,315
Sales and marketing expenses	3,838	3,549
General and administrative expenses	3,586	3,141
Operating loss	(5,276)	(5,158)
Other income (expense):		
Other expense, net	(64)	(11)
Interest (expense) income, net	(543)	209
Net loss before income taxes	(5,883)	(4,960)
Income tax expense	(8)	(14)
Net loss	$ (5,891)	$ (4,974)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.21)	$ (0.18)
Weighted average shares outstanding:		
Basic and diluted	28,427,574	27,591,623

	For the Nine Months Ended September 30,	
	2025	**2024**
Revenue:		
Product revenue	$ 16,649	$ 14,053
Service and other revenue	9,912	9,566
Total revenue	26,561	23,619
Cost of revenue	10,273	9,259
Gross profit	16,288	14,360
Research and development costs	10,660	9,060
Sales and marketing expenses	11,691	10,673
General and administrative expenses	11,056	8,725
Operating loss	(17,119)	(14,098)
Other income (expense):		
Other expense, net	(112)	(32)
Interest (expense) income, net	(472)	646
Net loss before income taxes	(17,703)	(13,484)
Income tax expense	(51)	(44)
Net loss	$ (17,754)	$ (13,528)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.63)	$ (0.50)
Weighted average shares outstanding:		
Basic and diluted	28,137,528	26,840,119

See accompanying notes to Condensed Consolidated Financial Statements.

CLEARPOINT NEURO, INC.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(Dollars in thousands)

For the Three and Nine Months Ended September 30, 2025

	Common Stock		Additional Paid-in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balances, January 1, 2025	27,617,415	$ 276	$ 216,483	$ (191,370)	$ 25,389
Issuances of common stock:					
Share-based compensation	453,832	5	1,903	—	1,908
Option exercises (cash and cashless)	7,851	—	21	—	21
Payments for taxes related to net share settlement of equity awards	(98,914)	(1)	(1,304)	—	(1,305)
Net loss for the period	—	—	—	(6,026)	(6,026)
Balances, March 31, 2025	27,980,184	$ 280	$ 217,103	$ (197,396)	$ 19,987
Issuances of common stock:					
Registered direct offering of common stock	275,808	3	3,338	—	3,341
Share-based compensation	157,827	1	2,268	—	2,269
Option exercises (cash)	6,000	—	28	—	28
Payments for taxes related to net share settlement of equity awards	(26,818)	—	(356)	—	(356)
Issuance of common stock under employee stock purchase plan	30,610	—	311	—	311
Net loss for the period	—	—	—	(5,837)	(5,837)
Balances, June 30, 2025	28,423,611	$ 284	$ 222,692	$ (203,233)	$ 19,743
Issuances of common stock:					
Share-based compensation	3,806	—	2,022	—	2,022
Option exercises (cashless)	759	—	—	—	—
Net loss for the period	—	—	—	(5,891)	(5,891)
Balances, September 30, 2025	28,428,176	$ 284	$ 224,714	$ (209,124)	$ 15,874

For the Three and Nine Months Ended September 30, 2024

	Common Stock		Additional Paid-in Capital	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	2,653,848	26	16,157	—	16,183
Share-based compensation	126,315	1	1,503	—	1,504
Option exercises (cash)	7,500	—	21	—	21
Payments for taxes related to net share settlement of equity awards	(24,047)	—	(151)	—	(151)
Net loss for the period	—	—	—	(4,146)	(4,146)
Balances, March 31, 2024	27,416,345	$ 274	$ 210,912	$ (176,602)	$ 34,584
Issuances of common stock:					
Share-based compensation	130,447	1	1,795	—	1,796
Option exercises (cashless)	1,373	—	—	—	—
Payments for taxes related to net share settlement of equity awards	(22,153)	—	(128)	—	(128)
Issuance of common stock under employee stock purchase plan	62,800	1	287	—	288
Net loss for the period	—	—	—	(4,408)	(4,408)
Balances, June 30, 2024	27,588,812	$ 276	$ 212,866	$ (181,010)	$ 32,132
Issuances of common stock:					
Share-based compensation	4,547	—	1,904	—	1,904
Option exercises (cashless)	860	—	—	—	—
Payments for taxes related to net share settlement of equity awards	(5,400)	—	(61)	—	(61)
Net loss for the period	—	—	—	(4,974)	(4,974)
Balances, September 30, 2024	27,588,819	$ 276	$ 214,709	$ (185,984)	$ 29,001

See accompanying notes to Condensed Consolidated Financial Statements.

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

	For the Nine Months Ended September 30, 2025	2024
Cash flows from operating activities:		
Net loss	$ (17,754)	$ (13,528)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for credit losses (recoveries)	217	(507)
Depreciation and amortization	565	740
Share-based compensation	6,199	5,204
Payment-in-kind interest	490	—
Amortization of debt issuance costs and original issue discounts	60	51
Amortization of lease right of use assets, net of accretion in lease liabilities	821	692
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	497	(157)
Inventory, net	(16)	434
Prepaid expenses and other current assets	(696)	88
Other assets	(192)	(40)
Accounts payable and accrued expenses	(1,251)	1,373
Lease liabilities	(716)	(635)
Contract liabilities	(69)	(1,422)
Net cash flows from operating activities	(11,845)	(7,707)
Cash flows from investing activities:		
Purchases of property and equipment	(473)	(12)
Net cash flows from investing activities	(473)	(12)
Cash flows from financing activities:		
Proceeds from offerings of common stock, net of offering costs	3,263	16,183
Proceeds from issuance of note payable, net of financing costs and discount	28,653	—
Repayment of 2020 senior secured convertible note	—	(10,000)
Proceeds from stock option exercises	49	21
Payments for taxes related to net share settlement of equity awards	(1,661)	(340)
Proceeds from issuance of common stock under employee stock purchase plan	311	288
Net cash flows from financing activities	30,615	6,152
Net change in cash, cash equivalents and restricted cash	18,297	(1,567)
Cash, cash equivalents and restricted cash, beginning of period	20,104	23,140
Cash, cash equivalents and restricted cash, end of period	$ 38,401	$ 21,573
Cash and cash equivalents	38,221	21,573
Restricted cash included in other assets, non-current	180	—
Total cash, cash equivalents and restricted cash	$ 38,401	$ 21,573
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ 69	$ 41
Interest	$ 490	$ 480

NON-CASH INVESTING AND FINANCING TRANSACTIONS:

•During the nine months ended September 30, 2025 and 2024, the Company recorded net transfers of ClearPoint reusable components having an aggregate net book value of $0.3 million and $0.4 million, respectively, between

loaned systems, which are included in property and equipment in the accompanying condensed consolidated balance sheets, and inventory.

•As discussed in Note 7, 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 $3.3 million.

See accompanying notes to Condensed Consolidated Financial Statements.

1. Description of the Business and Financial Condition

ClearPoint Neuro, Inc. (the "Company") is a commercial-stage medical device company focused on the development and commercialization of innovative platforms for performing minimally invasive surgical procedures in the brain. From the Company's inception in 1998, the Company has deployed significant resources to fund its efforts to develop the capabilities for enabling neurosurgery interventions, building an intellectual property portfolio, and identifying and building out commercial applications for the technologies it develops. In 2021, the Company's efforts expanded beyond the MRI suite to encompass development and commercialization of new neurosurgical device products for the operating room setting. In 2022, the Company commercialized the ClearPoint Prism Neuro Laser Therapy System as its first therapy product offering. The Company has exclusive global commercialization rights to the ClearPoint Prism Neuro Laser Therapy System through its Swedish partner, Clinical Laserthermia Systems ("CLS").

Since 2021, a growing part of the Company's revenue is derived from consulting services to pharmaceutical and biotech companies, academic institutions, and contract research organizations having a focus on biologics and drug delivery. The Company's services include protocol consultation and solutions for pre-clinical study design and execution for the delivery of pharmaceutical agents to the brain. Currently, the Company has more than 60 biologics and drug delivery customers who are evaluating or using its products and services in trials to inject gene and cell therapies directly into the brain. These relationships 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 the Company's business potentially represents the largest opportunity for growth; however, the Company's ability to grow in this market is dependent on its ability to maintain and establish new relationships with customers, such customers' continuation of research and product development plans, and such customers' achievement of success in completion of clinical trials and subsequent regulatory approvals of their biologics and drugs.

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 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 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 September 30, 2025 of $209.1 million. In addition, the Company's use of cash from operations amounted to $11.8 million for the nine months ended September 30, 2025, and $9.0 million for the year ended December 31, 2024. Since its inception, the Company has financed its operations principally from the sale of equity securities and the issuance of notes payable, however, there is no assurance any future sale of equity securities and/or issuance of notes payable will be at terms favorable to the Company or available at all. As required by generally accepted accounting principles in the U.S. ("GAAP"), the Company has evaluated its ability to continue as a going concern and has determined that based on

current forecasts, existing cash and cash equivalent balances at September 30, 2025 are sufficient to support the Company's operations and meet its obligations for at least the next twelve months.

In May 2025, the Company 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 the Company's common stock, par value $0.01 per share (the "common stock"), at a price of $12.69 per share, based on the trailing 30-trading day volume-weighted average price of the 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.

Contemporaneously with the 2025 SPA, the Company entered into a note purchase agreement (the "2025 NPA") under which the Company may sell to the 2025 Investor and the 2025 Investor may buy from the Company, tranches of notes in an aggregate principal amount of up to $105.0 million. The net proceeds to the Company in connection with the issuance of an initial sale of $30.0 million principal amount of notes under the 2025 NPA, after deducting the debt discount and debt issuance costs of $0.6 million and $0.7 million, respectively, was approximately $28.7 million.

Refer to footnotes 8 and 6, respectively, for more information regarding the 2025 SPA and 2025 NPA.

In March 2024, the Company completed a follow-on public offering of 2,653,848 shares of its common stock from which the net proceeds totaled approximately $16.2 million after deducting underwriting discounts and commissions, and other offering expenses paid by the Company. In November 2024, the Company entered into an At-the-Market Equity Offering Sales Agreement with an investment banking firm (the "ATM Agreement") pursuant to which it may offer and sell, from time to time, shares of its common stock, having aggregate sales proceeds of up to $50 million, subject to the terms and conditions of the ATM Agreement. The Company has not issued any shares of common stock under the ATM Agreement. See Note 8 below for additional information with respect to these offerings.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

In the opinion of management, the accompanying unaudited condensed consolidated financial statements have been prepared on a basis consistent with the Company's December 31, 2024 audited consolidated financial statements, and include all adjustments, consisting of only normal recurring adjustments, necessary to fairly state the information set forth therein. These condensed consolidated financial statements have been prepared in accordance with SEC rules for interim financial information, and, therefore, omit certain information and footnote disclosures necessary to present such statements in accordance with GAAP. The preparation of these condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses and the related disclosures at the date of the financial statements and during the reporting period. Actual results could materially differ from these estimates. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's 2024 Form 10-K. The accompanying condensed consolidated balance sheet as of December 31, 2024 has been derived from the audited consolidated financial statements at that date but does not include all information and footnotes required by GAAP for a complete set of financial statements. The results of operations for the three and nine months ended September 30, 2025, may not be indicative of the results to be expected for the entire year or any future periods.

Restricted cash

The Company has restricted cash pledged as a security deposit to comply with the terms of the San Diego lease entered into in June 2025. The Company arranged for its bank to issue a letter of credit in the amount of $0.2 million in favor of the landlord, in lieu of a security deposit. To support the letter of credit, the Company placed the funds in a restricted certificate of deposit, which is presented in other assets in the accompanying condensed consolidated balance sheets.

Inventory

Inventory is carried at the lower of cost or net realizable value. The costs of inventory are determined using the standard cost method, which approximates actual cost based on a first-in, first-out method. Items in inventory relate predominantly to the Company's ClearPoint system and related disposables. The Company periodically reviews its inventory for excess and obsolete items and provides a reserve upon identification of potentially excess or obsolete items.

Revenue Recognition

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

Lines of Business; Timing of Revenue Recognition

Product Revenue:

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

the customer. For certain customers, legal title and risks and rewards of ownership transfer upon delivery to the customer as stated in their respective contracts, in which case revenue is recognized upon delivery.

•*Capital equipment and software sales:*

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

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

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

Service Revenue:

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

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

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

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

•*Capital equipment-related services:*

•*Equipment service:* Revenue from servicing 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 as well as 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 upon delivery to the customer and installation.

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

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

See Note 3 for additional information regarding revenue recognition.

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 Company's outstanding common stock options and unvested restricted stock units, as described in Note 8, would be anti-dilutive, due to the reporting of a net loss for each of the periods in the accompanying condensed consolidated statements of operations.

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 may at times invest its excess cash in interest bearing accounts and U.S. government debt securities. It classifies all highly liquid investments with original stated maturities of three months or less from the date of purchase as cash equivalents and all highly liquid investments with stated maturities of greater than three months but less than twelve months as short-term investments.

The Company holds the remainder of its cash and cash equivalents on deposit with financial institutions in the U.S. insured by the Federal Deposit Insurance Corporation. At September 30, 2025, the Company had approximately $0.2 million in bank balances that were in excess of the insured limits.

At September 30, 2025, there were no customers whose accounts receivable balances represented greater than 10% of accounts receivable at that date. At December 31, 2024, there were two customers whose aggregate accounts receivable balances represented 24% of accounts receivable at that date.

One pharmaceutical customer, a related party who is a stockholder, a former noteholder, and whose chief executive officer is a designated director on the Company's Board of Directors, for whom the Company provides hardware, software, clinical services and market development services in support of the customer's clinical trials, and from whom the Company earns a quarterly fee, accounted for 8% of total sales for each of the three and nine months ended September 30, 2025, and 9% of total sales for each of the three and nine months ended September 30, 2024. There was one additional customer who comprised 13% of the total sales in the three month period ended September 30, 2024.

Prior to granting credit to a customer, the Company generally performs credit evaluations of the customers' financial condition. In general, the Company does not require collateral from customers in connection 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 September 30, 2025 and December 31, 2024 was $1.3 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; dependence on third-party collaboration, license and joint development partners; changes in general economic conditions and interest rates; protection of proprietary technology; compliance with changing government regulations; uncertainty of widespread market acceptance of products; access to credit for capital purchases by customers; and product liability claims. Certain components used in manufacturing have relatively few alternative sources of supply and establishing additional or replacement suppliers for such components cannot be accomplished quickly. The inability of any of these suppliers to fulfill the Company's supply requirements may negatively impact future operating results.

Recent Accounting Standards Adopted

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures." The amendments improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. In addition, the amendments enhance interim disclosure requirements, clarify circumstances in which an entity can disclose multiple segment measures of profit or loss, provide new segment disclosure requirements for entities with a single reportable segment, and contain other disclosure requirements. The Company adopted the ASU on its annual reporting for the year ended December 31, 2024. See Note 9 in the accompanying notes to the condensed consolidated financial statements for further detail.

Recent Accounting Standards Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, "Improvements to Income Tax Disclosures," which requires that an entity, on an annual basis, disclose additional income tax information, primarily related to the rate reconciliation and

income taxes paid. The provisions of the ASU are intended to enhance the transparency and decision usefulness of income tax disclosures. The guidance will be applied on a prospective basis with the option to apply the standard retrospectively and is effective for calendar year-end public business entities in the 2025 annual period and in 2026 for interim periods with early adoption permitted. Except for the required expanded disclosures, the Company does not expect the adoption of this ASU to have a material effect on the consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, "Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses," which requires disclosure about the types of costs and expenses included in certain expense captions presented on the income statement. The new disclosure requirements are effective for the Company's annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. Except for the required expanded disclosures, the Company does not expect the adoption of this ASU to have a material effect on the consolidated financial statements.

Reclassification

The accompanying consolidated statement of operations for the three and nine months ended September 30, 2025 contains income tax expense formerly classified as general and administrative expense as a separate line on the consolidated statement of operations. The accompanying condensed consolidated statement of operations for the three and nine months ended September 30, 2024 has been adjusted to conform to the 2025 presentation.

3. Revenue Recognition

Revenue by Service Line

(in thousands)	Three Months Ended September 30, 2025	2024
Biologics and drug delivery		
Disposable products	$ 1,292	$ 2,062
Services and license fees	3,110	2,369
Subtotal – Biologics and drug delivery revenue	4,402	4,431
Neurosurgery navigation and therapy		
Disposable products	3,422	2,860
Subtotal – Neurosurgery navigation and therapy revenue	3,422	2,860
Capital equipment and software		
Systems and software products	647	552
Services	390	279
Subtotal – Capital equipment and software revenue	1,037	831
Total revenue	$ 8,861	$ 8,122

(in thousands)	Nine Months Ended September 30, 2025	2024
Biologics and drug delivery		
Disposable products	$ 4,943	$ 4,286
Services and license fees	8,889	8,779
Subtotal – Biologics and drug delivery revenue	13,832	13,065
Neurosurgery navigation and therapy		
Disposable products	10,131	7,373
Subtotal – Neurosurgery navigation and therapy revenue	10,131	7,373
Capital equipment and software		
Systems and software products	1,575	2,394
Services	1,023	787
Subtotal – Capital equipment and software revenue	2,598	3,181
Total revenue	$ 26,561	$ 23,619

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, 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 condensed consolidated balance sheets.

(in thousands)	September 30, 2025	December 31, 2024
Accounts receivable, net	$ 4,000	$ 4,713
Other contract assets		
Unbilled receivables	$ 1,256	$ 642

•*Contract liabilities* – Contract liabilities consist of amounts that have been invoiced and for which the Company has the right to bill, but that have not been recognized as revenue as the related goods or services have not been transferred. The Company's contract liabilities are generally comprised of the following: (1) capital equipment and software-related service fees that are typically billed and collected at the inception of the service agreements, which have terms ranging from one to three years; (2) annual fees for agreements with customers that bundle the capital equipment and software-related service fees with software and hardware upgrades that are made commercially available over the term of the contract; and (3) up-front payments from customers made in connection with consulting services. The unearned portion of all such fees is classified as contract liabilities.

(in thousands)	September 30, 2025	December 31, 2024
Contract liabilities	$ 2,488	$ 2,557

During the three and nine months ended September 30, 2025, the Company recognized approximately $0.2 million and $1.2 million of revenue, respectively, which was previously included in contract liabilities in the accompanying condensed consolidated balance sheet at December 31, 2024. During the three and nine months ended September 30, 2024, the Company recognized approximately $0.2 million and $2.2 million of revenue, respectively, which was previously included in contract liabilities in the accompanying condensed consolidated balance sheet at December 31, 2023.

Transaction price allocated to remaining performance obligations represents contracted revenue that has not yet been recognized, which includes contract liabilities 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 $2.3 million at September 30, 2025. The Company expects to recognize 66% of this revenue over the next twelve months and the remainder thereafter.

4. Fair Value Measurement

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

The fair value of cash and cash equivalents of $38.2 million and $20.1 million as of September 30, 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, and the carrying value is a reasonable estimate of fair value.

5. Inventory

Inventory consists of the following as of September 30, 2025 and December 31, 2024:

(in thousands)	September 30, 2025	December 31, 2024
Raw materials and work in process	$ 6,123	$ 5,503
Finished goods	3,474	3,619
Reserve for excess and obsolete inventory	(3,014)	(2,259)
	$ 6,583	$ 6,863

6. Note Payable

On May 12, 2025, the Company entered into the 2025 NPA with CALW SA LLC, an affiliate of Oberland Capital Management LLC, as Purchaser Agent, and the 2025 Investor.

Under the 2025 NPA, the Company may sell to the 2025 Investor, and the 2025 Investor may buy from the Company, tranches of notes (collectively, the “Notes”) in an aggregate principal amount of up to $105.0 million as follows: (a) an initial sale of $30.0 million principal amount of Notes (the “First Purchase Note”), which was funded upon contract signing; (b) at the option of the Company, a second sale (the “Second Sale”) of $25.0 million 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, a third sale (the “Third Sale”) of up to $50.0 million principal amount of Notes, at any time prior to December 31, 2026. The obligations of the 2025 Investor to purchase the Notes are subject to certain customary conditions precedent.

The purchase price of the Notes is, in each case, 98% of the principal amount thereof. The net proceeds in connection with the issuance 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 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 will mature on the sixth anniversary of the applicable Purchase Date (as defined in the 2025 NPA) 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, with the percentage increasing pro rata in the event of a Second Sale or Third Sale of Notes. 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 (as defined in the 2025 NPA). 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.

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 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 Investor's call option contingent on a change in control or event of default. The fair value of the identified derivative was determined to be nominal as the probability of change in control or event of default was negligible at inception and September 30, 2025. For each subsequent reporting period, the Company will evaluate the probability of the call option and record the applicable fair value as of the end of each reporting period.

Scheduled principal payment as of September 30, 2025 with respect to the First Purchase Note is summarized as follows:

Years ending December 31,	*(in thousands)*
2031	$ 30,490
Total scheduled principal payments	30,490
Less: unamortized discounts and financing costs	(1,287)
Total carrying amount	$ 29,203

7. Commitments and Contingencies

Operating Leases

The Company subleases office space in Solana Beach, California, which 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 leases space in Carlsbad, California, that serves as 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 then 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 was made available upon lease signing. The next two phases are expected to be made available by December 19, 2025 and July 1, 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.

The aforementioned leases are classified as operating leases in conformity with GAAP. The aggregate lease costs were $0.4 million and $0.2 million for the three months ended September 30, 2025 and 2024, respectively, and $0.8 million and $0.7 million for the nine months ended September 30, 2025 and 2024, respectively.

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.

8. Stockholders' Equity

2025 Stock Purchase Agreement ("2025 SPA")

On May 12, 2025, the Company entered into 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 Company's common stock, par value $0.01 per share 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 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 sold pursuant to the exercise of the underwriters' option to purchase additional shares at the public offering price.

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

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

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

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

Equity Compensation Plans

The Sixth Amended and Restated 2013 Incentive Compensation 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 options, restricted stock, restricted stock units and other awards to selected employees, directors and consultants of the Company. The equity incentive plans are more fully described in Note 9 to the consolidated financial statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2024 and the 2025 Proxy.

Share-Based Compensation Expense

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

(in thousands)	***Three Months Ended September 30,*** **2025**	**2024**
Cost of revenue	$ 31	$ 31
Research and development	501	461
Sales and marketing	550	537
General and administrative	940	875
Share-based compensation expense	$ 2,022	$ 1,904

(in thousands)	***Nine Months Ended September 30,*** **2025**	**2024**
Cost of revenue	$ 100	$ 82
Research and development	1,558	1,204
Sales and marketing	1,674	1,482
General and administrative	2,867	2,436
Share-based compensation expense	$ 6,199	$ 5,204

Share-based compensation expense by type of share-based award is summarized below:

(in thousands)	***Three Months Ended September 30,*** **2025**	**2024**
Stock options	$ 40	$ 151
RSAs and RSUs	1,923	1,719
ESPP	59	34
	$ 2,022	$ 1,904

(in thousands)	***Nine Months Ended September 30,*** **2025**	**2024**
Stock options	$ 233	$ 554
RSAs and RSUs	5,765	4,495
ESPP	201	155
	$ 6,199	$ 5,204

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

	September 30, 2025 **Unrecognized Expense**	**Remaining Weighted-Average Recognition Period (in years)**
Stock options	$ 67	0.43
RSAs and RSUs	$ 10,337	1.87

Stock Option Activity

Stock option activity during the nine months ended September 30, 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	(18,906)	$ 6.64		
Forfeited or expired	(36,311)	$ 32.15		
Outstanding at September 30, 2025	1,321,179	$ 5.78	4.06	$ 21,166
Exercisable at September 30, 2025	1,278,712	$ 5.70	3.95	$ 20,584
Vested and expected to vest at September 30, 2025	1,321,179	$ 5.78	4.06	$ 21,166

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

Restricted Stock Award Activity

Restricted stock award ("RSA") activity for the nine months ended September 30, 2025 is summarized below:

	Restricted Stock Awards	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2024	154,210	$ 11.12
Vested	(136,116)	$ 11.28
Forfeited or expired	(1,753)	$ 11.41
Outstanding at September 30, 2025	16,341	$ 9.77

Restricted Stock Unit Activity

Restricted stock unit ("RSU") activity for the nine months ended September 30, 2025 is summarized below:

	Restricted Stock Units	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2024	1,657,760	$ 6.76
Granted	638,482	$ 13.33
Vested	(617,218)	$ 7.07
Forfeited or expired	(25,017)	$ 8.01
Outstanding at September 30, 2025	1,654,007	$ 9.16

ESPP

In June 2021, the Company's stockholders adopted and approved the ClearPoint Neuro, Inc. Employee Stock Purchase Plan (the "ESPP"), which allows eligible employees to acquire shares of the Company's common stock through payroll deductions at a discount to market price. In May 2025, the ESPP was amended to increase the number of common shares

reserved for issuance from 400,000 to 700,000 shares. During the first offering period of 2025, 30,610 shares were purchased at an average offering price of $10.15.

9. Segment Disclosures

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

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

10. Subsequent Event

On November 6, 2025, the Company entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") with IRRAS Holdings, Inc. ("IRRAS"), a medical technology company selling products used in neurocritical care, with an emphasis on treatments for intracerebral hemorrhage, chronic subdural hematoma, and other conditions requiring intracranial fluid management. Pursuant to the terms of the Merger Agreement, the Ignite Merger Sub, Inc., a Delaware corporation and a direct wholly-owned subsidiary of the Company ("First Merger Sub"), will be merged with and into IRRAS (the "First Merger"), with IRRAS surviving the First Merger, and, immediately following the First Merger, IRRAS will merge with and into ClearPoint Holdings, LLC, a Delaware limited liability company and a direct wholly-owned subsidiary of the Company ("Second Merger Sub"), (the "Second Merger" and together with the First Merger, the "Merger"), with the Second Merger Sub surviving the Second Merger. If the Merger is completed, the Company will deliver closing consideration of $5.0 million in cash, payable at closing and 1,325,000 shares of the Company's common stock, issued at closing. As additional consideration for IRRAS' stockholders, the Merger Agreement provides for the Company to pay earnout consideration during three one-year earnout periods equal to 25% of net sales of certain IRRAS products above certain thresholds. The transaction is expected to close in the fourth quarter of 2025, subject to customary closing conditions.

On November 5, 2025, the Company entered into an agreement to access an additional $20.0 million in funding under the existing 2025 NPA, conditioned upon the closing of the Company's transaction to acquire IRRAS, and other customary closing conditions. The Company expects to use the additional funding to support integration activities, enhance working capital, and fund new growth initiatives for the combined business operations.

ITEM 2. 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 unaudited Condensed Consolidated Financial Statements and the related notes thereto appearing in Part I, Item 1 of this Quarterly 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 section titled "Risk Factors" appearing in our 2024 Form 10-K and in Part II, Item 1.A of this Quarterly Report for a discussion of important risk 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. In addition, historical results and trends that might appear in this Quarterly Report should not be interpreted as being indicative of future operations.

Overview

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

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

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

Substantially all our revenue for the three and nine months ended September 30, 2025 and 2024 relates to: (i) sales of our ClearPoint system products and related services; and (ii) consulting services from our customers in the biologics and drug delivery space. We have financed our operations and internal growth primarily through the sale of equity securities and the issuance of notes payable. We have incurred significant losses since our inception in 1998 as we have devoted substantial efforts to research and development. As of September 30, 2025, we had accumulated losses of $209.1 million. We may continue to incur operating losses as we expand our ClearPoint system platform, consulting services to our pharmaceutical and other medical technology customers, and our business generally.

Factors Which May Influence Future Results of Operations

The following is a description of factors that 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, funding through capital markets and other funding sources may not be available in the future 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.

Revenue

In 2010, we received 510(k) clearance from the United States Food and Drug Administration ("FDA") to market our ClearPoint system in the U.S. for general neurosurgical procedures; in February 2011 and May 2018, we also obtained CE marking for our ClearPoint system and SmartFlow cannula, respectively; and in June 2020, we obtained CE marking for version 2.0 of our ClearPoint software and our Inflexion head fixation frame. In January 2021, we received 510(k) clearance for the SmartFrame Array Neuro Navigation System. In September 2022, the ClearPoint Prism Neuro Laser Therapy System, for which we have exclusive global rights to commercialize, received 510(k) clearance through our Swedish partner, CLS. The Prism laser represents the first therapy product we have commercialized. In January 2024, we received 510(k) clearance from the FDA for the SmartFrame OR Stereotactic System.

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

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

Generating recurring revenue from the sale of products is an important part of our business model for our ClearPoint system. Our product revenue was $5.4 million and $16.6 million for the three and nine months ended September 30, 2025, respectively, and was almost entirely related to our ClearPoint system. Our service revenue was $3.5 million and $9.9 million for the three and nine months ended September 30, 2025, respectively, of which 89% and 90%, respectively, is related to the biologics and drug delivery service line.

Our revenue recognition policies are more fully described in Note 2 to the Condensed Consolidated Financial Statements included above in Part I, Item 1 in this Quarterly Report.

Our revenue from sales of products and services to our biologics and drug delivery customers comes from 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 (our "Partners"). This is a novel area in which commercialization must be preceded by FDA-mandated clinical trials, which are expensive and time consuming to conduct, and for which the commercial success is uncertain, pending, in part, 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 September 30, 2025, we had more than 60 Partners, as compared to more than 50 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 functional neurosurgery navigation products, biologics and drug delivery products, non-neurosurgery therapy products, and ClearPoint capital equipment and software that we have sold, and for which we have recognized the revenue in accordance with our revenue recognition policy, as well as labor hours and materials for the cost of providing preclinical, consulting, and service revenue. Cost of revenue also includes the allocation of manufacturing overhead costs and depreciation of loaned systems installed under our ClearPoint placement program, as well as provisions for obsolete, impaired, or excess inventory.

Research and Development Costs

Our research and development costs consist primarily of costs associated with the conceptualization, design, testing, and prototyping of our ClearPoint system products 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 intended for delivery of therapeutics into the central nervous system; (ii) expand products into the operating room and therapeutics space; and (iii) expand the application of our technological platforms internationally.

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

Sales and Marketing, and General and Administrative Expenses

Our sales and marketing, and general and administrative expenses consist primarily of salaries, incentive-based compensation, travel and benefits, including 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. Our sales and marketing expenses are expected to continue to increase due to costs associated with the continued commercialization of our products and services and the increased headcount necessary to support growth in operations.

Critical Accounting Policies and Estimates

There have been no significant changes in our critical accounting policies and estimates during the nine months ended September 30, 2025, as compared to the critical accounting policies and estimates described in our 2024 Form 10-K.

Results of Operations

Three Months Ended September 30, 2025, Compared to the Three Months Ended September 30, 2024

(Dollars in thousands)	Three Months Ended September 30, 2025	2024	Percentage Change
Product revenue	$ 5,361	$ 5,474	(2)%
Service and other revenue	3,500	2,648	32%
Total revenue	8,861	8,122	9%
Cost of revenue	3,261	3,275	(0)%
Gross profit	5,600	4,847	16%
Research and development costs	3,452	3,315	4%
Sales and marketing expenses	3,838	3,549	8%
General and administrative expenses	3,586	3,141	14%
Other income (expense):			
Other expense, net	(64)	(11)	NM
Interest (expense) income, net	(543)	209	(360)%
Income tax expense	(8)	(14)	NM
Net loss	$ (5,891)	$ (4,974)	18%

NM – The percentage change is not meaningful.

Revenue. Total revenue was $8.9 million for the three months ended September 30, 2025, and $8.1 million for the three months ended September 30, 2024, which represents an increase of $0.7 million, or 9%.

(Dollars in thousands)	Three Months Ended September 30, 2025	2024	Percentage Change
Biologics and drug delivery			
Disposable products	$ 1,292	$ 2,062	(37)%
Services and license fees	3,110	2,369	31%
Subtotal – Biologics and drug delivery revenue	4,402	4,431	(1)%
Neurosurgery navigation and therapy			
Disposable products	3,422	2,860	20%
Subtotal – Neurosurgery navigation and therapy revenue	3,422	2,860	20%
Capital equipment and software			
Systems and software products	647	552	17%
Services	390	279	40%
Subtotal – Capital equipment and software revenue	1,037	831	25%
Total revenue	$ 8,861	$ 8,122	9%

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored preclinical and clinical trials, stayed relatively consistent at $4.4 million for each of the three months ended September 30, 2025 and 2024. Service and other revenue increased $0.7 million due to new studies performed for our partners in the three months ended September 30, 2025, offset by a decrease in product revenue due to timing of the pharmaceutical partners' clinical and preclinical trials.

Neurosurgery navigation and therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 20% to $3.4 million for the three months ended September 30, 2025, from $2.9 million for the same period in 2024. The increase is driven by higher sales of Prism Laser Therapy, and the introduction

of our 3.0 operating room navigation software, which has positively impacted procedural volumes in the operating room during the three months ended September 30, 2025, compared to the same period in 2024.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software and related services, increased 25% to $1.0 million for the three months ended September 30, 2025, from $0.8 million for the same period in 2024 due to an increase in the sale of hardware and rental revenue.

Cost of Revenue and Gross Profit. Cost of revenue was $3.3 million, resulting in gross profit of $5.6 million for the three months ended September 30, 2025, and was $3.3 million, resulting in gross profit of $4.8 million for the three months ended September 30, 2024. Gross margin was 63% for the three months ended September 30, 2025, as compared to 60% in the same period in 2024. The increase in gross margin is primarily due to higher margins on biologics and drug delivery service revenue and mix of product sold for the three months ended September 30, 2025, as compared to the same period in 2024.

Research and Development Costs. Research and development costs were $3.5 million for the three months ended September 30, 2025, compared to $3.3 million for the same period in 2024, an increase of $0.1 million, or 4%. The increase was due primarily to higher product and software development costs.

Sales and Marketing Expenses. Sales and marketing expenses were $3.8 million for the three months ended September 30, 2025, compared to $3.5 million for the same period in 2024, an increase of $0.3 million, or 8%. This increase was due primarily to additional personnel costs, including share-based compensation, resulting from increases in headcount.

General and Administrative Expenses. General and administrative expenses were $3.6 million for the three months ended September 30, 2025, compared to $3.1 million for the same period in 2024, an increase of $0.4 million, or 14%. This increase was due primarily to higher personnel costs, including share-based compensation, of $0.2 million, as well as higher professional fees and information technology costs, each in the amount of $0.1 million.

Interest Income (Expense), net. Net interest expense was $0.5 million for the three months ended September 30, 2025, compared to net interest income of $0.2 million for the three months ended September 30, 2024. Interest expense increased from $0.2 million in the three months ended September 30, 2024 to $0.9 million in the three months ended September 30, 2025 as a result of the note payable entered into in May 2025. This was partially offset by interest income of $0.4 million in the three months ended September 30, 2025, which increased slightly from $0.3 million in the three months ended September 30, 2024, due to higher investment in U.S. Government debt securities. See Note 6 to the Condensed Consolidated Financial Statements included in Part 1, Item 1 in this Quarterly Report for additional information with respect to the note payable.

Nine Months Ended September 30, 2025, Compared to the Nine Months Ended September 30, 2024

(Dollars in thousands)	Nine Months Ended September 30, 2025	2024	Percentage Change
Product revenue	$ 16,649	$ 14,053	18 %
Service and other revenue	9,912	9,566	4 %
Total revenue	26,561	23,619	12 %
Cost of revenue	10,273	9,259	11 %
Gross profit	16,288	14,360	13 %
Research and development costs	10,660	9,060	18 %
Sales and marketing expenses	11,691	10,673	10 %
General and administrative expenses	11,056	8,725	27 %
Other income (expense):			
Other expense, net	(112)	(32)	NM
Interest (expense) income, net	(472)	646	(173)%
Income tax expense	(51)	(44)	NM
Net loss	$ (17,754)	$ (13,528)	31 %

NM – The percentage change is not meaningful.

Revenue. Total revenue was $26.6 million for the nine months ended September 30, 2025, and $23.6 million for the nine months ended September 30, 2024, which represents an increase of $2.9 million, or 12%.

(Dollars in thousands)	Nine Months Ended September 30, 2025	2024	Percentage Change
Biologics and drug delivery			
Disposable products	$ 4,943	$ 4,286	15 %
Services and license fees	8,889	8,779	1 %
Subtotal – Biologics and drug delivery revenue	13,832	13,065	6 %
Neurosurgery navigation and therapy			
Disposable products	10,131	7,373	37 %
Subtotal – Neurosurgery navigation and therapy revenue	10,131	7,373	37 %
Capital equipment and software			
Systems and software products	1,575	2,394	(34)%
Services	1,023	787	30 %
Subtotal – Capital equipment and software revenue	2,598	3,181	(18)%
Total revenue	$ 26,561	$ 23,619	12 %

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored preclinical and clinical trials, increased 6% to $13.8 million for the nine months ended September 30, 2025, from $13.1 million for the same period in 2024. This increase is primarily attributable to $0.7 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 37% to $10.1 million for the nine months ended September 30, 2025, from $7.4 million for the same period in 2024. The increase is driven by an increased customer base, and higher sales for new offerings of SmartFrame OR, Prism Laser Therapy, and introduction of our 3.0 operating room software, during the nine months ended September 30, 2025, compared to the same period in 2024.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software and related services, decreased 18% to $2.6 million for the nine months ended September 30, 2025, from $3.2 million for the same period in 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 $10.3 million, resulting in gross profit of $16.3 million for the nine months ended September 30, 2025, as compared to $9.3 million, resulting in gross profit of $14.4 million for the nine months ended September 30, 2024. Gross margin was 61% for the nine months ended September 30, 2025, and broadly in line with gross margin of 61% in the same period in 2024.

Research and Development Costs. Research and development costs were $10.7 million for the nine months ended September 30, 2025, compared to $9.1 million for the same period in 2024, an increase of $1.6 million, or 18%. The increase was due primarily to higher product and software development costs.

Sales and Marketing Expenses. Sales and marketing expenses were $11.7 million for the nine months ended September 30, 2025, compared to $10.7 million for the same period in 2024, an increase of $1.0 million, or 10%. This increase was due primarily to additional personnel costs, including share-based compensation, resulting from increases in headcount, of $1.1 million, partially offset by lower travel costs of $0.1 million.

General and Administrative Expenses. General and administrative expenses were $11.1 million for the nine months ended September 30, 2025, compared to $8.7 million for the same period in 2024, an increase of $2.3 million, or 27%. This increase was due primarily to higher personnel costs, including share-based compensation, of $0.8 million, higher bad debt expense of $0.7 million, higher professional service fees of $0.4 million, and higher IT costs of $0.3 million.

Interest Income (Expense), net. Net interest expense was $0.5 million for the nine months ended September 30, 2025, compared to net interest income of $0.6 million for the nine months ended September 30, 2024. Interest expense increased from $0.5 million in the nine months ended September 30, 2024 to $1.3 million in the nine months ended September 30, 2025 due to the note payable entered into in May 2025. This was partially offset by interest income of $0.8 million in the nine months ended September 30, 2025, which decreased from $1.2 million in the nine months ended September 30, 2024. The decrease in interest income is mainly as a result of decreased investment in U.S. Government securities due to lower cash balances in the first half of 2025. See Note 6 to the Condensed Consolidated Financial Statements included in Part 1, Item 1 in this Quarterly Report for additional information with respect to the note payable.

Liquidity and Capital Resources

We have incurred net losses since our inception, which has resulted in a cumulative deficit at September 30, 2025 of $209.1 million. In addition, our use of cash from operations amounted to $11.8 million for the nine months ended September 30, 2025, and $9.0 million for the year ended December 31, 2024. Since inception, we have financed our operations principally from the sale of equity securities and the issuance of notes payable.

In May 2025, the Company entered into 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 Company's common stock, par value $0.01 per share 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.

Contemporaneously with the 2025 SPA, the Company entered into the 2025 NPA under which the Company may sell to the 2025 Investor, and the 2025 Investor may buy from the Company, tranches of notes in an aggregate principal amount of up to $105.0 million. The net proceeds in connection with the issuance 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.

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

Additional information with respect to the stock offerings and the 2025 NPA is in Notes 8 and 6, respectively, to the condensed consolidated financial statements included in Part 1, Item 1 in this Quarterly Report.

As a result of these transactions and our business operations, our cash and cash equivalents totaled $38.2 million at September 30, 2025. In management's opinion, based on our current forecasts for revenue, expense and cash flows, our existing cash and cash equivalent balances at September 30, 2025, are sufficient to support our operations and meet our obligations for at least the next twelve months.

Cash Flows

Cash activity for the nine months ended September 30, 2025 and 2024 is summarized as follows:

	Nine Months Ended September 30,	
(in thousands)	**2025**	**2024**
Cash used in operating activities	$ (11,845)	$ (7,707)
Cash used in investing activities	(473)	(12)
Cash provided by financing activities	30,615	6,152
Net change in cash and cash equivalents	$ 18,297	$ (1,567)

Net Cash Flows from Operating Activities. Net cash flows used in operating activities for the nine months ended September 30, 2025 were $11.8 million, an increase of $4.1 million from the nine months ended September 30, 2024. This increase was primarily due to a higher net loss of $4.2 million and increased working capital requirements, mainly due to higher payments made as a result of bonus payouts. This was partially offset by an increase in non-cash expenses, including share-based compensation and the allowance for credit losses.

Net Cash Flows from Investing Activities. Net cash flows used in investing activities for the nine months ended September 30, 2025 were $0.5 million and related to equipment acquisitions.

Net cash flows used in investing activities for the nine months ended September 30, 2024 were nominal and related to equipment acquisitions.

Net Cash Flows from Financing Activities. Net cash flows provided by financing activities for the nine months ended September 30, 2025 consisted primarily of proceeds, net of financing costs and discount, of $28.7 million from the issuance of the note payable; proceeds, net of offering costs, of $3.3 million from the registered direct offering of common stock; partially offset by $1.7 million in payments for taxes related to shares withheld in connection with the vesting of restricted stock awards.

Net cash flows provided by financing activities for the nine months ended September 30, 2024 consisted of proceeds, net of offering costs, of $16.2 million received from the public offering of our common stock and $0.3 million in proceeds from the issuance of common stock under the employee stock purchase plan. This was partially offset by the repayment of the $10.0 million 2020 secured convertible note and payments of $0.3 million for taxes related to shares withheld in connection with the vesting of restricted stock awards.

Operating Capital and Capital Expenditure Requirements

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

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

- the ultimate duration and impact of macroeconomic trends, including inflationary pressures, changes in monetary policy, decreasing consumer confidence and spending, the introduction of or changes in tariffs or trade barriers, global or local recession, and geopolitical instability;
- the timing of broader market acceptance and adoption of our products;
- the scope, rate of progress and cost of our ongoing product development activities relating to our products;
- the ability of our Partners to achieve commercial success, including their use of our products and services in their preclinical studies, clinical trials and delivery of therapies;
- the cost and timing of expanding our sales, clinical support, marketing and distribution capabilities, and other corporate infrastructure;
- the cost and timing of establishing inventories at levels sufficient to support our sales;
- the effect of competing technological and market developments;
- the cost of pursuing additional applications of our technology platforms under current collaborative arrangements, and the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- the cost and timing of any clinical trials;
- the cost and timing of regulatory filings, clearances and approvals; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Interest Rate Risk

Our exposure to market risk is limited primarily to interest income and expense sensitivity, which is affected by changes in the general level of U.S. interest rates.

Our investments are in short-term bank deposits, short-term U.S. Government debt securities, and institutional money market funds. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. In the event we invest in short-term investments, due to the nature of our short-term investments and the Company's intent to hold such debt securities to maturity, we believe that we are not subject to any material market risk exposure.

At September 30, 2025, we had $30.5 million of principal outstanding under the First Purchase Note, which is subject to interest rate fluctuations. The outstanding principal balance bears interest at a rate 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%.

Given the rate is capped, the difference between the minimum rate and maximum rate is approximately $0.4 million in annual interest expense, based on the principal outstanding balance at September 30, 2025.

Foreign Currency Risk

To date, we have not recorded a significant amount of sales in currencies other than U.S. dollars, and have only limited business transactions in foreign currencies. We do not currently engage in hedging or similar transactions to reduce our foreign currency risks, which at present, are not material. We do not believe we have material exposure to risk from changes in foreign currency exchange rates at this time. We will continue to monitor and evaluate our internal processes relating to foreign currency exchange, including the potential use of hedging strategies.

ITEM 4. CONTROLS AND PROCEDURES.

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 (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 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 disclosure controls and procedures as of September 30, 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 September 30, 2025.

Changes in Internal Control Over Financial Reporting

During the quarter ended September 30, 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.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

We are involved from time-to-time with various legal matters arising in the ordinary course of business. These claims and legal proceedings are of a nature we believe are normal and incidental to a medical device company, and may include product liability, intellectual property, employment matters, and other general claims.

We make provisions for liabilities when it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Such provisions are assessed at least quarterly and adjusted to reflect the impact of any settlement negotiations, judicial and administrative rulings, advice of legal counsel, and other information and events pertaining to a particular case. We are currently not aware of any such legal proceedings or claim that we believe will have, individually or in the aggregate, a material adverse effect on our consolidated results of operations, cash flows, or financial condition. See Note 7 to the condensed consolidated financial statements included elsewhere in this Quarterly Report for further disclosure.

ITEM 1A. RISK FACTORS.

There have been no material changes to the risk factors disclosed under Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2024, other than the risks discussed below:

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 timelines for review, inspections, or regulatory correspondence. Any such changes or delays may postpone approvals or commercial launches of CGTs that rely on our products, which could delay adoption of our products, push out anticipated order volumes, and reduce the magnitude of our projected growth.

We currently have significant debt and may incur additional debt. Failure by us to fulfill our obligations under the 2025 NPA may cause repayment obligations to accelerate.

We entered into the 2025 NPA in May 2025 providing for our sale of up to $105 million in notes. The aggregate amount of our indebtedness under such notes as of September 30, 2025 was $30.5 million. For additional information on the 2025 NPA, see Note 6 in the accompanying notes to the condensed consolidated financial statements.

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 non-financial covenants, that limit our 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 our stockholders, repurchase stock and make investments, in each case subject to certain exceptions.

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, or if we breach a covenant, 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 would significantly impair our financial condition.

We may fail to realize the benefits expected from our acquisition of IRRAS and the combined company may not perform as we or the market expects, which could have an adverse effect on the price of our common stock.

On November 6, 2025, the Company entered into a Agreement and Plan of Merger and Reorganization (the "Merger Agreement") with IRRAS Holdings, Inc. ("IRRAS"), a medical technology company selling products used in neurocritical care, with an emphasis on treatments for intracerebral hemorrhage, chronic subdural hematoma, and other conditions requiring intracranial fluid management. Pursuant to the terms of the Merger Agreement, Ignite Merger Sub, Inc., a Delaware corporation and a direct wholly-owned subsidiary of the Company ("First Merger Sub"), will be merged with and into IRRAS (the "First Merger"), with IRRAS surviving the First Merger, and, immediately following the First Merger, IRRAS will merge with and into ClearPoint Holdings, LLC, a Delaware limited liability company and a direct wholly-owned subsidiary of the Company ("Second Merger Sub"), (the "Second Merger" and together with the First Merger, the "Merger"), with the Second Merger Sub surviving the Second Merger. If the Merger is completed, the Company will deliver closing consideration of: (i) $5.0 million in cash, payable at closing and; (ii) 1,325,000 shares of the Company's common stock, issued at closing. As additional consideration for IRRAS' stockholders, the Merger Agreement provides for the Company to pay earnout consideration during three one-year earnout periods equal to 25% of net sales of certain IRRAS products above certain thresholds. The transaction is expected to close in the fourth quarter of 2025, subject to customary closing conditions. The anticipated benefits we expect from this acquisition include, among other things, benefits relating to enhanced revenues, a strengthened market position for the combined company and operating efficiencies and these benefits are, necessarily, based on projections and assumptions about the combined businesses of our Company and IRRAS, which may not materialize as expected or which may prove to be inaccurate. The value of our common stock could be adversely affected if we are unable to realize the anticipated benefits from the Merger on a timely basis or at all. Achieving the benefits of the Merger will depend, in part, on our ability to close the transaction and integrate the business, operations and products of IRRAS successfully and efficiently with our business.

The combined company may not perform as we or the market expects. Risks associated with the combined company following the Merger include:

- integrating businesses is a difficult, expensive, and time-consuming process, and the failure to successfully integrate our businesses with the business of IRRAS timely would adversely affect our financial condition and results of operation;
- there may be inconsistencies in standards, controls, procedures and policies that will need to be reconciled;
- it is possible that our key employees or key employees of IRRAS might decide not to remain with us, and the loss of such personnel could have a material adverse effect on the financial condition, results of operations, and growth prospects of the combined company;
- the success of the combined company will also depend upon relationships with third parties and IRRAS's or our pre-existing customers, which relationships may be affected by customer preferences or public attitudes about the Merger. Any adverse changes in these relationships could adversely affect the combined company's business, financial condition, and results of operations;

- incurrence of significant costs in connection with consummating the Merger and integrating the operations of IRRAS into our business;
- our failure to identify or accurately assess the magnitude of certain liabilities we assumed in the Merger could result in unexpected litigation or regulatory exposure, unfavorable accounting charges, unexpected increases in taxes due, a loss of anticipated tax benefits or other known and unknown liabilities which could result in adverse effects on our business, operating results or financial condition.

The occurrence of any of these Merger-related events individually or in combination could materially and adversely affect our business, results of operations, financial condition and the market price of our common stock.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

None.

ITEM 5. OTHER INFORMATION.

Insider Trading Arrangements

During the quarter ended September 30, 2025, none of our officers or directors adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K.

ITEM 6. EXHIBITS.

The exhibits listed below are filed, furnished, or incorporated by reference as part of this Quarterly Report.

Exhibit Number	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation of MRI Interventions, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on 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 with the SEC on 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 with the SEC on 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 with the SEC on 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 with the SEC on 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 with the SEC on December 14, 2022).
10.1	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 with the SEC on November 6, 2025)
31.1*	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934
31.2*	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934
32+	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934 and Section 1350 of Chapter 60 of Title 18 of the United States Code
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover page formatted as Inline XBRL and contained in Exhibit 101

*Filed herewith.

+ This certification is being furnished solely to accompany this Quarterly 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 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.

Date: November 6, 2025

CLEARPOINT NEURO, INC.

By: /s/ Joseph M. Burnett
Joseph M. Burnett
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Danilo D'Alessandro
Danilo D'Alessandro
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

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

I, Joseph M. Burnett, certify that:

1.I have reviewed this quarterly report on Form 10-Q for the quarter ended September 30, 2025, of ClearPoint Neuro, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 6, 2025

/s/ Joseph M. Burnett

Joseph M. Burnett

Chief Executive Officer

Exhibit 31.2

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

I, Danilo D'Alessandro, certify that:

1.I have reviewed this quarterly report on Form 10-Q for the quarter ended September 30, 2025, of ClearPoint Neuro, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 6, 2025

/s/ Danilo D’Alessandro

Danilo D’Alessandro

Chief Financial Officer

Exhibit 32

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

Each of the undersigned, Joseph M. Burnett and Danilo D'Alessandro, certifies pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934 and Section 1350 of Chapter 63 of Title 18 of the United States Code, that (1) this quarterly report on Form 10-Q for the quarter ended September 30, 2025, of ClearPoint Neuro, Inc. (the "Company") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934, and (2) the information contained in this quarterly report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 6, 2025

/s/ Joseph M. Burnett

Joseph M. Burnett

Chief Executive Officer

/s/ Danilo D'Alessandro

Danilo D'Alessandro

Chief Financial Officer