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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 **March 31, 2025**

Or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: **001-34822**

**ClearPoint Neuro, Inc.**  
(Exact Name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation or Organization)

**58-2394628**  
(IRS Employer  
Identification Number)

**120 S. Sierra Ave., Suite 100**  
**Solana Beach, California**  
(Address of Principal Executive Offices)

**92075**  
(Zip Code)

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

**Securities registered pursuant to Section 12(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

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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 ☐

Non-accelerated filer ☒

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 May 7, 2025, there were 27,989,194 shares of common stock outstanding.

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CLEARPOINT NEURO, INC.

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#### Trademarks, Trade Names and Service Marks

*ClearPoint Neuro*<sup>®</sup>, *ClearPoint*<sup>®</sup>, *SmartFlow*<sup>®</sup>, *SmartFrame*<sup>®</sup>, *SmartGrid*<sup>®</sup>, *Inflexion*<sup>®</sup>, *SmartTwist*<sup>™</sup>, *SmartTip*<sup>™</sup>, *ClearPoint Maestro*<sup>®</sup>, *SmartFrame Array*<sup>®</sup>, *SmartFrame OR*<sup>™</sup>, *ClearPoint Neuro Orchestra*<sup>™</sup>, *ClearPoint Prism*<sup>®</sup>, *SmartFlow Flex*<sup>™</sup>, *ClearPointer*<sup>™</sup>, *When Your Path is Unclear, We Point The Way*<sup>®</sup>, and *ClearPoint Advanced Laboratories*<sup>™</sup> 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.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

In some cases, you can identify forward-looking statements by terms such as “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “will,” “would,” and similar expressions intended to identify forward-looking statements, although not all forward-looking statements contain these words. Although we believe that we have a reasonable basis for each forward-looking statement contained in this 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)

	March 31, 2025 (Unaudited)	December 31, 2024
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 12,387	\$ 20,104
Accounts receivable, net	3,651	4,713
Inventory, net	6,582	6,863
Prepaid expenses and other current assets	1,594	1,683
Total current assets	24,214	33,363
Property and equipment, net	2,183	2,005
Operating lease, right-of-use assets	2,960	3,086
Software license inventory	107	103
Licensing rights	458	484
Other assets	148	148
Total assets	<u>\$ 30,070</u>	<u>\$ 39,189</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,216	\$ 1,340
Accrued compensation	1,944	4,885
Other accrued liabilities	1,510	1,450
Operating lease liabilities, current portion	578	557
Contract liabilities, current portion	1,618	2,121
Total current liabilities	6,866	10,353
Operating lease liabilities, net of current portion	2,860	3,011
Contract liabilities, net of current portion	357	436
Total liabilities	10,083	13,800
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at March 31, 2025 and December 31, 2024	—	—
Common stock, \$0.01 par value; 90,000,000 shares authorized at March 31, 2025 and December 31, 2024; 27,980,184 and 27,617,415 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	280	276
Additional paid-in capital	217,103	216,483
Accumulated deficit	(197,396)	(191,370)
Total stockholders' equity	19,987	25,389
Total liabilities and stockholders' equity	<u>\$ 30,070</u>	<u>\$ 39,189</u>

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)**

	<b>For the Three Months Ended March 31,</b>	
	<b>2025</b>	<b>2024</b>
Revenue:		
Product revenue	\$ 5,291	\$ 3,635
Service and other revenue	3,194	4,004
Total revenue	8,485	7,639
Cost of revenue	3,353	3,114
Gross profit	5,132	4,525
Research and development costs	3,379	2,625
Sales and marketing expenses	3,834	3,290
General and administrative expenses	4,082	2,826
Operating loss	(6,163)	(4,216)
Other income (expense):		
Other income (expense), net	4	(26)
Interest income, net	151	111
Net loss before income taxes	(6,008)	(4,131)
Income tax expense	(18)	(15)
Net loss	<u>\$ (6,026)</u>	<u>\$ (4,146)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.22)	\$ (0.16)
Weighted average shares outstanding:		
Basic and diluted	<u>27,718,918</u>	<u>25,452,096</u>

See accompanying notes to Condensed Consolidated Financial Statements.

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

**For the Three Months Ended March 31, 2025**  
**Common Stock**

	Shares	Amount	Additional Paid-in Capital	Accumulated 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	<u>27,980,184</u>	<u>\$ 280</u>	<u>\$ 217,103</u>	<u>\$ (197,396)</u>	<u>\$ 19,987</u>

**For the Three Months Ended March 31, 2024**  
**Common Stock**

	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total
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	<u>27,416,345</u>	<u>\$ 274</u>	<u>\$ 210,912</u>	<u>\$ (176,602)</u>	<u>\$ 34,584</u>

See accompanying notes to Condensed Consolidated Financial Statements.



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

	<b>For the Three Months Ended March 31,</b>	
	<b>2025</b>	<b>2024</b>
Cash flows from operating activities:		
Net loss	\$ (6,026)	\$ (4,146)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for credit losses (recoveries)	217	(146)
Depreciation and amortization	103	243
Share-based compensation	1,908	1,504
Amortization of debt issuance costs and original issue discounts	—	15
Amortization of lease right of use assets, net of accretion in lease liabilities	231	231
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	846	846
Inventory, net	78	53
Prepaid expenses and other current assets	168	165
Other assets	—	(39)
Accounts payable and accrued expenses	(2,882)	(931)
Lease liabilities	(234)	(171)
Contract liabilities	(581)	(1,464)
Net cash flows from operating activities	(6,172)	(3,840)
Cash flows from investing activities:		
Purchases of property and equipment	(183)	—
Net cash flows from investing activities	(183)	—
Cash flows from financing activities:		
Proceeds from public offering of common stock, net of offering costs	—	16,183
Payment of At-The-Market offering costs	(78)	—
Proceeds from stock option exercises	21	21
Payments for taxes related to net share settlement of equity awards	(1,305)	(151)
Net cash flows from financing activities	(1,362)	16,053
Net change in cash and cash equivalents	(7,717)	12,213
Cash and cash equivalents, beginning of period	20,104	23,140
Cash and cash equivalents, end of period	<u>\$ 12,387</u>	<u>\$ 35,353</u>
<b>SUPPLEMENTAL CASH FLOW INFORMATION</b>		
<b>Cash paid for:</b>		
Income taxes	<u>\$ —</u>	<u>\$ —</u>
Interest	<u>\$ —</u>	<u>\$ 185</u>

**NON-CASH INVESTING AND FINANCING TRANSACTIONS:**

- During the three months ended March 31, 2025, the Company recorded net transfers of ClearPoint reusable components having an aggregate net book value of \$0.2 million between loaned systems, which are included in property and equipment in the accompanying condensed consolidated balance sheets, and inventory. The balance of such transfers during the three months ended March 31, 2024 was nominal.
- The Company had \$0.1 million in capital expenditures accrued but not yet paid at March 31, 2025.

See accompanying notes to Condensed Consolidated Financial Statements.

**CLEARPOINT NEURO, INC.**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

**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 March 31, 2025 of \$197.4 million. In addition, the Company’s use of cash from operations amounted to \$6.2 million for the three months ended March 31, 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 such sale of equity securities and/or issuance of notes payable will be at terms favorable to the Company or available at all in the future. 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 March 31, 2025 are sufficient to support the Company’s operations and meet its obligations for at least the next twelve months.

**CLEARPOINT NEURO, INC.**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

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. Through March 31, 2025, the Company had not issued any shares of common stock under the ATM Agreement. See Note 8 below for additional information with respect to these offerings.

In August 2024, the Company repaid in full the remaining \$10 million outstanding under the Securities Purchase Agreement (the “SPA”), entered into in 2020, pursuant to which it issued secured convertible notes to two investors raising gross proceeds of \$25 million, of which \$15 million had been previously converted to common stock. See Note 6 below for additional information with respect to these notes.

**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 months ended March 31, 2025, may not be indicative of the results to be expected for the entire year or any future periods.

*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. Software license inventory related to ClearPoint systems undergoing on-site customer evaluation is included in inventory in the accompanying condensed consolidated balance sheets. All other software license inventory is classified as a non-current asset. The Company periodically reviews its inventory for excess and obsolete items and provides a reserve upon identification of potentially excess or obsolete items.

**CLEARPOINT NEURO, INC.**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

*Intangible Assets*

The Company is a party to a license agreement that provides rights to the Company for the development and commercialization of products. Under the terms of the license agreement, the Company made payments to the licensor upon execution of the license agreement for access to the underlying technology, and future payments will be based upon achievement of regulatory and commercialization milestones as defined in the license agreement. In 2022, the Company made a payment to the licensor for the achievement of a regulatory milestone, which acts as a prepayment for future royalties.

In conformity with Accounting Standards Codification Section ("ASC") 350, "Intangibles – Goodwill and Other," the Company amortized the payments related to the license rights described above over an expected useful life of five years, which was fully amortized as of December 31, 2024. The royalty prepayment continues to be amortized as commercial sales occur. In addition, the Company periodically evaluates the recoverability of its investment in the license rights and records an impairment charge in the event such evaluation indicates that the Company's investment is not likely to be recovered.

*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

**CLEARPOINT NEURO, INC.**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

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.

**CLEARPOINT NEURO, INC.**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

•*Capital equipment-related services:*

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

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

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

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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 March 31, 2025, the Company had approximately \$1.4 million in bank balances that were in excess of the insured limits.

At March 31, 2025, there was one customer whose accounts receivable balance represented 12% 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 9% of total sales in each of the three-month periods ended March 31, 2025 and 2024. There was one additional customer who comprised 11% of the total sales in the three-month period ended March 31, 2025, and there were two additional customers, both of whom comprised 14% of the total sales in the three-month period ended March 31, 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 March 31, 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*

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.

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

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income tax disclosures. The guidance will be applied on a prospective basis with the option to apply the standard retrospectively and is effective for calendar year-end public business entities in the 2025 annual period and in 2026 for interim periods with early adoption permitted. The Company is currently evaluating the impact of this ASU on its consolidated financial statements.

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

*Reclassification*

The accompanying consolidated statement of operations for the three months ended March 31, 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 months ended March 31, 2024 has been conformed to the 2025 presentation.

**3. Revenue Recognition**

*Revenue by Service Line*

<i>(in thousands)</i>	<b>Three Months Ended March 31,</b>	
	<b>2025</b>	<b>2024</b>
Biologics and drug delivery		
Disposable products	\$ 1,780	\$ 553
Services and license fees	2,911	3,754
Subtotal – Biologics and drug delivery revenue	4,691	4,307
Neurosurgery navigation and therapy		
Disposable products	3,277	1,927
Services	—	—
Subtotal – Neurosurgery navigation and therapy revenue	3,277	1,927
Capital equipment and software		
Systems and software products	234	1,155
Services	283	250
Subtotal – Capital equipment and software revenue	517	1,405
Total revenue	<u>\$ 8,485</u>	<u>\$ 7,639</u>

*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. Additionally, at March 31, 2025, the Company had \$0.1 million in deferred contract costs, classified as other current assets, related to up-front costs for direct materials incurred to fulfill a customer contract.



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<i>(in thousands)</i>	<b>March 31, 2025</b>	<b>December 31, 2024</b>
Accounts receivable, net	\$ 3,651	\$ 4,713
Other contract assets		
Unbilled receivables	\$ 804	\$ 642
Deferred contract costs	\$ 108	\$ —

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

<i>(in thousands)</i>	<b>March 31, 2025</b>	<b>December 31, 2024</b>
Deferred revenues	\$ 1,975	\$ 2,557

During the three months ended March 31, 2025, the Company recognized approximately \$0.8 million of revenue, which was previously included in deferred revenue in the accompanying condensed consolidated balance sheet at December 31, 2024. During the three months ended March 31, 2024, the Company recognized approximately \$1.5 million of revenue, which was previously included in deferred revenue 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 deferred revenue that will be recognized as revenue in future periods. The majority of the remaining performance obligations relate to capital equipment and software-related service agreements and the upfront payments discussed under the heading "Contract Balances" above, which amounted to approximately \$1.7 million at March 31, 2025. The Company expects to recognize 79% 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 \$12.4 million and \$20.1 million as of March 31, 2025, and December 31, 2024, respectively, is derived using Level 1 inputs. The cash equivalents are comprised of short-term bank deposits, money market funds, and U.S. Government debt securities with original maturities of three months or less, and the carrying value is a reasonable estimate of fair value.

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**5. Inventory**

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

<i>(in thousands)</i>	<b>March 31, 2025</b>	<b>December 31, 2024</b>
Raw materials and work in process	\$ 5,653	\$ 5,503
Software licenses	265	265
Finished goods	664	1,095
Inventory included in current assets	6,582	6,863
Software licenses – non-current	107	103
	<u>\$ 6,689</u>	<u>\$ 6,966</u>

Inventory balances are presented net of an excess and obsolete reserve totaling \$2.5 million and \$2.3 million at March 31, 2025 and December 31, 2024, respectively.

**6. Note Payable**

In January 2020, the Company completed a financing transaction with two investors (the “2020 Convertible Noteholders”), whereby the Company issued an aggregate principal amount of \$17.5 million of secured convertible notes (the “First Closing Notes”) pursuant to the SPA, which, unless earlier converted or redeemed, were to mature on January 29, 2025, and bore interest at a rate equal to the sum of (i) the greater of (a) the three (3)-month Secured Overnight Financing Rate (“SOFR”) and (b) two percent (2%), plus (ii) a margin of 2% on the outstanding balance of the First Closing Notes, payable quarterly on the first business day of each calendar quarter. The First Closing Notes were convertible at a price of \$6.00 per share, subject to certain adjustments set forth in the SPA and the note agreement, and could not be prepaid without the consent of the noteholder. In May 2021, one of the 2020 Convertible Noteholders (the “Converting Noteholder”) converted the entire \$7.5 million principal amount of such Converting Noteholder’s First Closing Note, and related accrued interest of approximately \$0.04 million, into 1,256,143 shares of the Company’s common stock.

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

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

**7. Commitments and Contingencies**

*Operating Leases*

The Company subleases office space in Solana Beach, California, that serves as its corporate headquarters and houses certain management and personnel. The sublease term commenced on December 15, 2020, is set to expire on December 31, 2026, and is renewable for an additional five-year period, at the Company’s option, provided that the Company’s

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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.

The aforementioned leases are classified as operating leases in conformity with GAAP. The aggregate lease costs were \$0.2 million for each of the three months ended March 31, 2025 and 2024.

*Legal Contingencies*

The Company was named as a defendant to a lawsuit filed by a patient who suffered an adverse outcome in connection with a surgical procedure in which the Company's ClearPoint Navigation System was used, seeking damages in an unspecified amount with respect to the Company. The plaintiff also named as defendants the health care provider performing the surgical procedure and another medical device manufacturer whose product was also used in the procedure. A global demand of all defendants in this case has been made by the plaintiff in the amount of \$13.6 million. Trial is currently set for September 2025. Based on the Company's investigation to date, the Company believes that the claims against the Company in this lawsuit are without merit and intends to defend the lawsuit vigorously. The Company has tendered the claim to its Medical Technology Solutions policy insurer and expects coverage for this matter. The Company is unable to estimate the probable loss or range of loss that could potentially result from this lawsuit and will continue to evaluate information as it becomes known and will record an estimate for losses at the time when it is both probable that a loss has been incurred and the amount of the loss is reasonably estimable. Legal fees incurred by the Company are expensed in the period incurred.

**8. Stockholders' Equity**

*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

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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. Through March 31, 2025, the Company did not issue any shares of common stock under the ATM Agreement.

*Equity Compensation Plans*

The Fifth Amended and Restated 2013 Incentive Compensation Plan became effective in May 2024. 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.

*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:

	<i>Three Months Ended March 31,</i>			
	(in thousands)			
	<b>2025</b>		<b>2024</b>	
Cost of revenue	\$	32	\$	22
Research and development		484		337
Sales and marketing		491		421
General and administrative		901		724
Share-based compensation expense	\$	<u>1,908</u>	\$	<u>1,504</u>

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

	<i>Three Months Ended March 31,</i>			
	(in thousands)			
	<b>2025</b>		<b>2024</b>	
Stock options	\$	110	\$	208
RSAs and RSUs		1,727		1,236
ESPP		71		60
	\$	<u>1,908</u>	\$	<u>1,504</u>

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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):

		<i>March 31, 2025</i>
	<b>Unrecognized Expense</b>	<b>Remaining Weighted- Average Recognition Period (in years)</b>
Stock options	\$ 190	0.76
RSAs and RSUs	\$ 13,309	2.28

*Stock Option Activity*

Stock option activity under the Company's current and previous plans during the three months ended March 31, 2025 is summarized below:

	<b>Stock Options</b>	<b>Weighted- average Exercise price per share</b>	<b>Weighted- average Remaining Contractual Life (in years)</b>	<b>Intrinsic Value (in thousands)<sup>(1)</sup></b>
Outstanding at December 31, 2024	1,376,396	\$ 6.48		
Exercised	(11,906)	\$ 7.92		
Forfeited or expired	(11,875)	\$ 42.02		
Outstanding at March 31, 2025	<u>1,352,615</u>	<u>\$ 6.16</u>	<u>4.50</u>	<u>\$ 8,897</u>
Exercisable at March 31, 2025	<u>1,271,096</u>	<u>\$ 5.93</u>	<u>4.30</u>	<u>\$ 8,717</u>
Vested and expected to vest at March 31, 2025	<u>1,352,615</u>	<u>\$ 6.16</u>	<u>4.50</u>	<u>\$ 8,897</u>

- (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 three months ended March 31, 2025 is summarized below:

	<b>Restricted Stock Awards</b>	<b>Weighted- Average Grant Date Fair Value</b>
Outstanding at December 31, 2024	154,210	\$ 11.12
Vested	(12,996)	\$ 8.18
Forfeited or expired	(1,753)	\$ 11.41
Outstanding at March 31, 2025	<u>139,461</u>	<u>\$ 11.39</u>

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*Restricted Stock Unit Activity*

Restricted stock unit ("RSU") activity for the three months ended March 31, 2025 is summarized below:

	<b>Restricted Stock Units</b>	<b>Weighted- Average Grant Date Fair Value</b>
Outstanding at December 31, 2024	1,657,760	\$ 6.76
Granted	541,771	\$ 13.55
Vested	(455,585)	\$ 7.20
Forfeited or expired	(14,579)	\$ 6.86
Outstanding at March 31, 2025	1,729,367	\$ 8.77

*ESPP*

On June 3, 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. A total of 400,000 shares of the Company's common stock were made available for issuance pursuant to the terms of the ESPP. Each offering period is for six months, and the first offering period commenced on July 1, 2021. On March 31, 2025, 138,998 shares of common stock were available for issuance under the ESPP.

**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 May 12, 2025, the Company entered into a stock purchase agreement (the "SPA") with certain investors (the "Investors") 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 "Shares"). In addition, pursuant to the SPA, the Company granted the Investors, from the closing date and until December 31, 2026, a right to participate in any equity offerings consummated by the Company in an amount up to \$1.5 million, subject to certain limitations and exclusions set out in the SPA. The aggregate gross proceeds to the Company from the offering are expected to be approximately \$3.5 million before deducting estimated offering expenses payable by the Company.

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The closing of the offering is expected to occur on or about May 12, 2025, subject to customary closing conditions. The Company intends to use the proceeds from the offering for general corporate purposes, which may include capital expenditures, working capital and general and administrative expenses.

Contemporaneously with the SPA, the Company entered into a note purchase agreement (the “NPA”) with CALW SA LLC, an affiliate of Oberland Capital Management LLC, as Purchaser Agent, and certain funds managed by Oberland Capital Management LLC, as purchasers (the “Oberland Funds” and, together with other purchasers party thereto from time to time, the “Purchasers”), pursuant to which the Company may sell to the Purchasers, and the Purchasers may buy from the Company, notes (each a “Note” and collectively, the “Notes”) in an aggregate principal amount not to exceed \$105.0 million, consisting of the following three tranches of Notes:

- an initial sale of \$30.0 million principal amount of Notes;
- 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, subject to certain customary conditions precedent; and
- at the option of the Company and the Purchasers, a third sale (the “Third Sale”) of up to \$50.0 million principal amount of Notes, at any time prior to December 31, 2026, subject to certain customary conditions precedent.

The purchase price of the Notes is, in each case, 98% of the principal amount thereof. 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 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 until the sixth anniversary of the Closing Date or the date on which all amounts owing to the Purchasers under the NPA have been paid in full (the “Maturity Date”). For the first six (6) quarters (the “Initial PIK Period”) 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 Initial PIK Period may be extended by two (2) quarters at the Company’s option. Upon the occurrence and during the continuance of an Event of Default (as defined in the NPA) under the 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, the Purchasers will receive 0.375% (the “Revenue Participation Percentage”) of Net Revenue (as defined in the NPA) for any fiscal quarter (of up to \$50,000,000 of Net Revenue for each fiscal year), payable quarterly, with the Revenue Participation 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 Purchasers under the NPA, will be due on the 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 NPA). The Purchasers may demand redemption of the Notes prior to the Maturity Date in the event of a Change of Control (as defined in the NPA) of the Company or an Event of Default (as defined in the NPA), subject to payment of the Repayment Amount. 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

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redemption date, and assuming, in each case, that all PIK interest was added to the original principal amount of a Note on the date of issuance of such Note.

The NPA contains no financial covenants. The Company's obligations under the 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 NPA are secured by a security interest on substantially all of the Company's assets, including its intellectual property.



## 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 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 drug and delivery space. Our services include protocol consultation and solutions for preclinical study design and execution for 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 months ended March 31, 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 March 31, 2025, we had accumulated losses of \$197.4 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, our ability to access capital markets and other funding sources in the future may not be available on commercially reasonable terms, if at all. The rapid development and fluidity of these situations precludes any prediction as to the ultimate impact they will have on our business, financial condition, results of operation and cash flows, which will depend largely on future developments.

### *Revenue*

In 2010, we received 510(k) clearance from the FDA to market our ClearPoint system in the U.S. for general neurosurgical procedures; in February 2011 and May 2018, we also obtained CE marking for our ClearPoint system and SmartFlow cannula, respectively; and in June 2020, we obtained CE marking for version 2.0 of our ClearPoint software and our Inflexion head fixation frame. In January 2021, we received 510(k) clearance for the SmartFrame Array Neuro Navigation System. In September 2022, the ClearPoint Prism Neuro Laser Therapy System, for which we have exclusive global 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 \$5.3 million for the three months ended March 31, 2025, and was almost entirely related to our ClearPoint system. Our service revenue was \$3.2 million for the three months ended March 31, 2025, of which 91% 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.

Underlying the revenue from sales of products and services to our biologics and drug delivery customers is the number of direct customers and end users of our products and/or services ("Partners"). Our Partners consist of pharmaceutical and biotech companies, academic institutions, or customer-sponsored contract research organizations that are developing methods to deliver a wide variety of molecules, genes or proteins to targeted brain tissue or structures that would need to

bypass the blood-brain barrier for the treatment of a variety of disorders. This is a novel area in which commercialization must be preceded by FDA-mandated clinical trials, which are expensive and time consuming to conduct, and for which 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 March 31, 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 pre-clinical, 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 three months ended March 31, 2025, as compared to the critical accounting policies and estimates described in our 2024 Form 10-K.

## Results of Operations

Three Months Ended March 31, 2025, Compared to the Three Months Ended March 31, 2024

(Dollars in thousands)	Three Months Ended March 31,		Percentage Change
	2025	2024	
Product revenue	\$ 5,291	\$ 3,635	46 %
Service and other revenue	3,194	4,004	(20) %
Total revenue	8,485	7,639	11 %
Cost of revenue	3,353	3,114	8 %
Gross profit	5,132	4,525	13 %
Research and development costs	3,379	2,625	29 %
Sales and marketing expenses	3,834	3,290	17 %
General and administrative expenses	4,082	2,826	44 %
Other income (expense):			
Other income (expense), net	4	(26)	NM
Interest income, net	151	111	36 %
Income tax expense	(18)	(15)	NM
Net loss	<u>\$ (6,026)</u>	<u>\$ (4,146)</u>	45 %

NM – The percentage change is not meaningful.

*Revenue.* Total revenue was \$8.5 million for the three months ended March 31, 2025, and \$7.6 million for the three months ended March 31, 2024, which represents an increase of \$0.8 million, or 11%.

(Dollars in thousands)	Three Months Ended March 31,		Percentage Change
	2025	2024	
Biologics and drug delivery			
Disposable products	\$ 1,780	\$ 553	222 %
Services and license fees	2,911	3,754	(22) %
Subtotal – Biologics and drug delivery revenue	4,691	4,307	9 %
Neurosurgery navigation and therapy			
Disposable products	3,277	1,927	70 %
Services	—	—	—
Subtotal – Neurosurgery navigation and therapy revenue	3,277	1,927	70 %
Capital equipment and software			
Systems and software products	234	1,155	(80) %
Services	283	250	13 %
Subtotal – Capital equipment and software revenue	517	1,405	(63) %
Total revenue	<u>\$ 8,485</u>	<u>\$ 7,639</u>	11 %

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored preclinical and clinical trials, increased 9% to \$4.7 million for the three months ended March 31, 2025, from \$4.3 million for the same period in 2024. This increase is attributable to \$1.2 million of higher product revenue resulting from greater demand for disposables as multiple partners progress in their trials, partially offset by a \$0.8 million decrease in service revenue and other revenue due to less work performed in preclinical trials and consulting during the three months ended March 31, 2025, compared to the same period in 2024.

Neurosurgery navigation and therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 70% to \$3.3 million for the three months ended March 31, 2025, from \$1.9

million for the same period in 2024. The increase is driven by higher sales for new product offerings of SmartFrame OR and Prism Laser Therapy as well as an increased customer base, during the three months ended March 31, 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 63% to \$0.5 million for the three months ended March 31, 2025, from \$1.4 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 \$3.4 million, resulting in gross profit of \$5.1 million for the three months ended March 31, 2025, and was \$3.1 million, resulting in gross profit of \$4.5 million for the three months ended March 31, 2024. Gross margin was 60% for the three months ended March 31, 2025, as compared to 59% in the same period in 2024. The increase in gross margin is due to lower excess and obsolete inventory for the three months ended March 31, 2025, as compared to the same period in 2024.

*Research and Development Costs.* Research and development costs were \$3.4 million for the three months ended March 31, 2025, compared to \$2.6 million for the same period in 2024, an increase of \$0.8 million, or 29%. The increase was due primarily to higher product development costs of \$0.4 million, higher personnel costs, including share-based compensation of \$0.2 million, and higher regulatory fees of \$0.1 million.

*Sales and Marketing Expenses.* Sales and marketing expenses were \$3.8 million for the three months ended March 31, 2025, compared to \$3.3 million for the same period in 2024, an increase of \$0.5 million, or 17%. 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 \$4.1 million for the three months ended March 31, 2025, compared to \$2.8 million for the same period in 2024, an increase of \$1.3 million, or 44%. This increase was due primarily to higher bad debt expense, higher personnel costs, including share-based compensation, and higher professional service fees, each in the amount of \$0.4 million.

*Interest Income, net.* Net interest income was \$0.2 million and \$0.1 million for the three months ended March 31, 2025 and 2024, respectively. The increase in net interest income is a result of having no interest expense in the three months ended March 31, 2025 due to the full repayment of the First Closing note in August 2024, partially offset by lower interest income as a result of decreased investment in U.S. Government 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 First Closing Note.

#### **Liquidity and Capital Resources**

We have incurred net losses since our inception, which has resulted in a cumulative deficit at March 31, 2025 of \$197.4 million. In addition, our use of cash from operations amounted to \$6.2 million for the three months ended March 31, 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 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. Through March 31, 2025, we did not issue any shares of common stock under the ATM Agreement.

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

Additional information with respect to the public offerings and 2020 secured convertible notes is in 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 \$12.4 million at March 31, 2025. In management's opinion, based on our current forecasts for revenue, expense and cash flows, our existing cash and cash equivalent balances at March 31, 2025, are sufficient to support our operations and meet our obligations for at least the next twelve months.

## Cash Flows

Cash activity for the three months ended March 31, 2025 and 2024 is summarized as follows:

(in thousands)	Three Months Ended March 31,	
	2025	2024
Cash used in operating activities	\$ (6,172 )	\$ (3,840 )
Cash used in investing activities	(183 )	—
Cash (used in) provided by financing activities	(1,362 )	16,053
Net change in cash and cash equivalents	<u>\$ (7,717 )</u>	<u>\$ 12,213</u>

*Net Cash Flows from Operating Activities.* Net cash flows used in operating activities for the three months ended March 31, 2025, were \$6.2 million, an increase of \$2.3 million from the three months ended March 31, 2024. This increase was primarily due to a higher net loss of \$1.9 million and higher payments made against accrued liabilities, mainly as a result of bonus payouts, partially offset by higher share-based compensation expense and deferred revenue.

*Net Cash Flows from Investing Activities.* Net cash flows used in investing activities for the three months ended March 31, 2025 were \$0.2 million and related to equipment acquisitions.

The Company did not have any net cash flows from investing activities for the three months ended March 31, 2024.

*Net Cash Flows from Financing Activities.* Net cash flows used in financing activities for the three months ended March 31, 2025, consisted primarily of payments for taxes related to shares withheld in connection with the vesting of restricted stock awards of \$1.3 million.

Net cash flows provided by financing activities for the three months ended March 31, 2024, consisted of proceeds, net offering costs, of \$16.2 million received from the public offering of our common stock, partially offset by payments for taxes related to shares withheld in connection with the vesting of restricted stock awards of \$0.2 million.

## Operating Capital and Capital Expenditure Requirements

To date, we have not achieved profitability. We could continue to incur net losses as we continue our efforts to expand the commercialization of our 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.

#### **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 March 31, 2025 to ensure that the information required to be disclosed by us in the reports that we file or

submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer as appropriate, to allow timely decisions regarding required disclosure. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2025.

#### **Changes in Internal Control Over Financial Reporting**

During the quarter ended March 31, 2025, there were no changes in our internal control over financial reporting that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

## **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 in our 2024 Form 10-K.

### **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.**

Not applicable. Without limiting the generality of the foregoing, during the quarter ended March 31, 2025, no director or Section 16 officer adopted or terminated any Rule 10b5-1 trading arrangements, as defined in Item 408(a) of Regulation S-K.



## ITEM 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	<a href="#"><u>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).</u></a>
3.2	<a href="#"><u>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).</u></a>
3.3	<a href="#"><u>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).</u></a>
3.4	<a href="#"><u>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).</u></a>
3.5	<a href="#"><u>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).</u></a>
3.6	<a href="#"><u>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).</u></a>
31.1*	<a href="#"><u>Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934</u></a>
31.2*	<a href="#"><u>Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934</u></a>
32+	<a href="#"><u>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</u></a>
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: May 13, 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)*



**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 March 31, 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.

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Date: May 13, 2025

/s/ Joseph M. Burnett

Joseph M. Burnett

Chief Executive Officer



**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 March 31, 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.

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Date: May 13, 2025

/s/ Danilo D'Alessandro

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Danilo D'Alessandro  
Chief Financial Officer

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**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 March 31, 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: May 13, 2025

/s/ Joseph M. Burnett

Joseph M. Burnett  
Chief Executive Officer

/s/ Danilo D'Alessandro

Danilo D'Alessandro  
Chief Financial Officer

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