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

FORM 10-Q

(Mark One)

þ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended **June 30, 2023**

Or

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from_____to _____

Commission file number: **001-34822**

ClearPoint Neuro, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**58-2394628**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification Number)
120 S. Sierra Ave., Suite 100 **Solana Beach, California**	**92075**
(Address of Principal Executive Offices)	(Zip Code)

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files.) þ Yes o 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 o	Accelerated filer ☐
Non-accelerated filer þ	Smaller reporting company þ
	Emerging growth company o

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. o

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

As of August 2, 2023, there were 24,636,678 shares of common stock outstanding.

CLEARPOINT NEURO, INC.

TABLE OF CONTENTS

		Page Number
PART I – FINANCIAL INFORMATION		1
Item 1.	Financial Statements (unaudited)	1
	Condensed Consolidated Balance Sheets as of June 30, 2023 and December 31, 2022	1
	Condensed Consolidated Statements of Operations for the three months ended June 30, 2023 and 2022	3
	Condensed Consolidated Statements of Operations for the six months ended June 30, 2023 and 2022	3
	Condensed Consolidated Statements of Stockholders' Equity for the three and six months ended June 30, 2023 and 2022	4
	Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2023 and 2022	5
	Notes to Condensed Consolidated Financial Statements	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	20
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	28
Item 4.	Controls and Procedures	28
PART II – OTHER INFORMATION		
Item 1.	Legal Proceedings	29
Item 1A.	Risk Factors	29
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	29
Item 3.	Defaults Upon Senior Securities	29
Item 4.	Mine Safety Disclosures	29
Item 5.	Other Information	29
Item 6.	Exhibits	30
SIGNATURES		31

Trademarks, Trade Names and Service Marks

ClearPoint Neuro®, *ClearPoint*®, *SmartFlow*®, *SmartFrame*®, *SmartGrid*®, *Inflexion*®, *SmartTwist*®, *SmartTip*®, *ClearPoint Maestro*®, *ClearPoint Revolution*™, *SmartFrame Array*®, *ClearPoint Orchestra*™, *ClearPoint Prism*™, *SmartFlow Flex*™, *ClearPointer*™, *When Your Path is Unclear, We Point The Way*®, and *MRI Interventions*® are all trademarks of ClearPoint Neuro, Inc. Any other trademarks, trade names or service marks referred to in this Quarterly Report on Form 10-Q (this "Quarterly Report") are the property of their respective owners.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report contains “forward-looking statements” as defined under 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, 2022, which we filed with the United States Securities and Exchange Commission (“SEC”) on March 1, 2023 (the “2022 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
(Dollars in thousands, except for per share data)

	June 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 26,464	$ 27,615
Short-term investments, at amortized cost	—	9,874
Accounts receivable, net	2,799	2,665
Inventory, net	9,204	9,303
Prepaid expenses and other current assets	2,244	1,723
Total current assets	40,711	51,180
Property and equipment, net	1,360	806
Operating lease, right-of-use assets	3,956	1,895
Software license inventory	407	450
Licensing rights	1,051	1,028
Other assets	156	131
Total assets	$ 47,641	$ 55,490
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,273	$ 272
Accrued compensation	2,339	2,824
Other accrued liabilities	1,373	2,065
Operating lease liabilities, current portion	493	561
Deferred product and service revenue, current portion	724	1,066
Total current liabilities	6,202	6,788
Operating lease liabilities, net of current portion	3,855	1,532
Deferred product and service revenue, net of current portion	253	390
2020 senior secured convertible note payable, net	9,921	9,893
Total liabilities	20,231	18,603
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized; none issued and outstanding at June 30, 2023 and December 31, 2022	—	—
Common stock, $0.01 par value; 90,000,000 shares authorized at June 30, 2023 and 200,000,000 shares authorized at December 31, 2022; 24,627,674 shares issued and outstanding at June 30, 2023; and 24,578,983 issued and outstanding at December 31, 2022	246	246
Additional paid-in capital	190,192	187,008
Accumulated deficit	(163,028)	(150,367)
Total stockholders' equity	27,410	36,887
Total liabilities and stockholders' equity	$ 47,641	$ 55,490

See accompanying notes to Condensed Consolidated Financial Statements.

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

	For The Three Months Ended June 30,	
	2023	**2022**
Revenue:		
Product revenue	$ 2,337	$ 3,457
Service and other revenue	3,613	1,743
Total revenue	5,950	5,200
Cost of revenue	2,824	1,945
Gross profit	3,126	3,255
Research and development costs	3,605	2,411
Sales and marketing expenses	3,474	2,387
General and administrative expenses	3,178	2,661
Operating loss	(7,131)	(4,204)
Other expense:		
Other expense, net	(2)	(8)
Interest income (expense), net	81	(91)
Net loss	$ (7,052)	$ (4,303)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.29)	$ (0.18)
Weighted average shares used in computing net loss per share:		
Basic and diluted	24,583,712	23,985,577

	For The Six Months Ended June 30,	
	2023	**2022**
Revenue:		
Product revenue	$ 4,967	$ 6,620
Service and other revenue	6,416	3,611
Total revenue	11,383	10,231
Cost of revenue	5,055	3,746
Gross profit	6,328	6,485
Research and development costs	6,628	5,312
Sales and marketing expenses	6,407	4,404
General and administrative expenses	6,136	4,837
Operating loss	(12,843)	(8,068)
Other expense:		
Other (expense) income, net	(13)	3
Interest income (expense), net	195	(197)
Net loss	$ (12,661)	$ (8,262)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.52)	$ (0.35)
Weighted average shares used in computing net loss per share:		
Basic and diluted	24,583,439	23,834,847

See accompanying notes to Condensed Consolidated Financial Statements.

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

For The Three and Six Months Ended June 30, 2023

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balances, January 1, 2023	24,578,983	$ 246	$ 187,008	$ (150,367)	$ 36,887
Issuances of common stock:					
Share-based compensation	3,782	—	1,307	—	1,307
Payments for taxes related to net share settlement of equity awards	(514)	—	(5)	—	(5)
Net loss for the period	—	—	—	(5,609)	(5,609)
Balances, March 31, 2023	24,582,251	$ 246	$ 188,310	$ (155,976)	$ 32,580
Issuances of common stock:					
Share-based compensation	5,484	—	1,645	—	1,645
Payments for taxes related to net share settlement of equity awards	(11,102)	—	(77)	—	(77)
Issuance of common stock under employee stock purchase plan	51,041	—	314	—	314
Net loss for the period	—	—	—	(7,052)	(7,052)
Balances, June 30, 2023	24,627,674	$ 246	$ 190,192	$ (163,028)	$ 27,410

For The Three and Six Months Ended June 30, 2022

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balances, January 1, 2022	23,665,991	$ 237	$ 182,482	$ (133,932)	$ 48,787
Issuances of common stock:					
Share-based compensation	29,916	—	899	—	899
Warrant and option exercises (cash and cashless)	12,211	—	3	—	3
Net loss for the period	—	—	—	(3,959)	(3,959)
Balances, March 31, 2022	23,708,118	$ 237	$ 183,384	$ (137,891)	$ 45,730
Issuances of common stock:					
Share-based compensation	379,122	4	876	—	880
Warrant exercises (cash and cashless)	367,006	4	249	—	253
Issuance of common stock under employee stock purchase plan	26,354	—	260	—	260
Net loss for the period	—	—	—	(4,303)	(4,303)
Balances, June 30, 2022	24,480,600	$ 245	$ 184,769	$ (142,194)	$ 42,820

See accompanying notes to Condensed Consolidated Financial Statements.

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

	For The Six Months Ended June 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (12,661)	$ (8,262)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for credit losses (recoveries)	454	(10)
Depreciation and amortization	285	187
Share-based compensation	2,952	1,779
Amortization of debt issuance costs and original issue discounts	28	27
Amortization of lease right-of-use, net of accretion in lease liabilities	325	267
Accretion of discounts on short-term investments	(126)	(23)
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(588)	(1,001)
Inventory, net	94	(1,786)
Prepaid expenses and other current assets	(438)	(1,010)
Other assets	(25)	30
Accounts payable and accrued expenses	(282)	679
Lease liabilities	(293)	(261)
Deferred revenue	(480)	134
Net cash flows from operating activities	(10,755)	(9,250)
Cash flows from investing activities:		
Purchases of property and equipment	(461)	(145)
Acquisition of licensing rights	(167)	(116)
Purchase of short-term investments	—	(21,590)
Proceeds from maturities of short-term investments	10,000	—
Net cash flows from investing activities	9,372	(21,851)
Cash flows from financing activities:		
Proceeds from stock option and warrant exercises	—	256
Payments for taxes related to net share settlement of equity awards	(82)	—
Proceeds from issuance of common stock under employee stock purchase plan	314	260
Net cash flows from financing activities	232	516
Net change in cash and cash equivalents	(1,151)	(30,585)
Cash and cash equivalents, beginning of period	27,615	54,109
Cash and cash equivalents, end of period	$ 26,464	$ 23,524
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ —	$ —
Interest	$ 369	$ 207

NON-CASH INVESTING AND FINANCING TRANSACTIONS:

- The Company had $0.2 million and $0.1 million in capital expenditures accrued but not yet paid at June 30, 2023 and 2022, respectively.

- During the six months ended June 30, 2023 and 2022, the Company recorded net transfers of ClearPoint reusable components having an aggregate net book value of less than $0.1 million, between loaned systems, which are included in property and equipment in the accompanying condensed consolidated balance sheets, and inventory.

- As discussed in Note 7, the Company entered into a lease for a manufacturing facility in Carlsbad, California, which commenced in June 2023. In connection with the new lease, the Company recorded a right-of-use asset in exchange for an operating lease liability in the amount of approximately $2.5 million.

See accompanying notes to Condensed Consolidated Financial Statements.

1. Description of the Business and Financial Condition

ClearPoint Neuro, Inc. (the "Company") is a commercial-stage medical device company focused on the development and commercialization of innovative platforms for performing minimally invasive surgical procedures in the brain. From the Company's inception in 1998, the Company has deployed significant resources to fund its efforts to develop the foundational capabilities for enabling MRI-guided interventions, building an intellectual property portfolio, and identifying and building out commercial applications for the technologies it develops. In 2021, the Company's efforts expanded beyond the MRI suite to encompass development and commercialization of new neurosurgical device products for the operating room setting, as well as consulting services for pharmaceutical and biotech companies, academic institutions, and contract research organizations.

The Company's initial product offering, the ClearPoint system, is an integrated system comprised of capital equipment and disposable products, designed to allow minimally invasive procedures in the brain to be performed in an MRI suite. The ClearPoint Array Neuro Navigation System and its principal disposable component, introduced in 2021, is designed to be deployed in an operating room setting while also being usable in an MRI suite. Both systems provide guidance for the placement and operation of instruments or devices during the planning and operation of neurosurgical procedures. The Company received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") in 2010 to market the ClearPoint system in the United States for general neurosurgical interventional procedures; in February 2011, the Company also obtained CE marking for its ClearPoint system. In 2011 and 2018, the Company received 510(k) clearance and CE marking, respectively, for its SmartFlow cannula which is being used, or is under evaluation, along with the Company's services, by more than 50 pharmaceutical and biotech companies, academic institutions, or contract research organizations having a focus on biologics and drug delivery. In 2021, the Company received 510(k) clearance for the Array Neuro Navigation System. In September 2022 the ClearPoint Prism Neuro Laser Therapy System, for which the Company has exclusive global commercialization rights, received 510(k) clearance through the Company's Swedish partner Clinical Laserthermia Systems ("CLS"). The ClearPoint Prism laser represents the first therapy product the Company has commercialized.

Macroeconomic Trends

The Company continues to monitor the impact of various macroeconomic trends, such as global economic and supply chain disruptions, geopolitical instability, labor shortages, instability of financial institutions and inflationary conditions. Changes in domestic and global economic conditions, supply chain disruptions, labor shortages, as well as other stimulus and spending programs, have led to higher inflation, which is likely to lead to increased costs and may cause further changes in fiscal and monetary policy. Impacts from inflationary pressures, such as increasing costs for research and development of the Company's products, administrative and other costs of doing business, the potential for instability of the financial institutions where we maintain our deposits or other assets, and the Company's access to capital markets and other sources of funding in the future could adversely affect our business, financial condition and results of operations. Additionally, these 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 payment, which could harm the Company's collection of accounts receivable and financial results. 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 June 30, 2023 of $163.0 million. In addition, the Company's use of cash from operations amounted to $10.8 million for the six months ended June 30, 2023, and $16.2 million for the year ended December 31, 2022. 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 June 30, 2023 are sufficient to support the Company's operations and meet its obligations for at least the next twelve months.

In 2020, pursuant to the terms of a Securities Purchase Agreement (the "SPA"), the Company issued secured convertible notes totwo investors which raised gross proceeds of $25 million, of which $15 million has been converted to common stock and $10 million remains outstanding (the "Outstanding First Closing Note"). See Note 6 below for additional information with respect to these notes. In February 2021, the Company completed a public offering of 2,127,660 shares of its common stock from which the net proceeds totaled approximately $46.8 million after deducting underwriting discounts and commissions, and other offering expenses paid by the Company.

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, 2022 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 2022 Form 10-K. The accompanying condensed consolidated balance sheet as of December 31, 2022 has been derived from the audited consolidated financial statements at that date but does not include all information and footnotes required by GAAP for a complete set of financial statements. The results of operations for the three and six months ended June 30, 2023, 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.

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

Revenue Recognition

The Company's revenue is comprised primarily of: (1) product revenue, resulting from the sale of functional neurosurgery, navigation, therapy, and biologics and drug delivery disposable products; (2) product revenue resulting from the sale of ClearPoint capital equipment and software; (3) revenue resulting from the service, installation, training, and shipping related to ClearPoint capital equipment and software; (4) consultation revenue and clinical case support revenue in connection with customer-sponsored pre-clinical and clinical trials; and (5) license revenue for the granting of licenses to develop and commercialize the Company's SmartFlow Cannula devices with our customers' proprietary biologics as a combination product. 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, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. When a contract calls for the satisfaction of multiple performance obligations for a single contract price, the Company typically allocates the contract price among the performance obligations based on the relative stand-alone prices for each such performance obligation customarily charged by the Company. The Company considers a performance obligation satisfied once it has transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. The Company recognizes revenue for satisfied performance obligations only when it determines there are no uncertainties regarding payment terms or transfer of control.

Lines of Business; Timing of Revenue Recognition

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

- *Capital equipment and software sales:*

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

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

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

- *Functional neurosurgery navigation and therapy services:* The Company recognizes revenue for such services at the point in time that the performance obligation has been satisfied.

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

    - *Consultation Services:* The Company recognizes consultation revenue over time as the services are delivered to the customer based on the extent of progress towards completion of the performance obligation.

    - *Clinical Service Access Fees:* For contracts in which the Company receives a periodic fixed fee, irrespective of the number of cases attended by the Company's personnel or hours incurred during such periods, revenue is recognized ratably over the period covered by such fees. A time-elapsed output method is used for such fees because the Company transfers control evenly by providing a stand-ready service.

    - *Clinical Service Procedure-Based Fees:* The Company recognizes revenue at the point in time a case is attended by Company personnel.

    - *License fees:* 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.

- *Capital equipment-related services:*

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

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

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

The Company operates in one industry segment, and the predominance of its sales are to U.S.-based customers.

Payment terms under contracts with customers generally are in a range of30-60 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, unvested restricted stock and restricted stock units, as described in Note 8, and the potential conversion of the Outstanding First Closing Note, as described in Note 6, would be anti-dilutive, due to the reporting of a net loss for each of the periods in the accompanying condensed consolidated statements of operations.

Concentration Risks and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company may at times invest its excess cash in interest bearing accounts and U.S. government debt securities. It classifies all highly liquid investments with original stated maturities of three months or less from the date of purchase as cash equivalents and all highly liquid investments with stated maturities of greater than three months but less than twelve months as short-term investments. The Company classifies the U.S. government debt securities as held-to-maturity in accordance with ASC 320, "Investments - Debt and Equity Securities." Held-to-maturity securities are those securities that the Company has the ability and intent to hold until maturity and are recorded at amortized cost on the accompanying condensed consolidated balance sheet, adjusted for the accretion of discounts using the effective interest method.

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 June 30, 2023, the Company had approximately $1.6 million in bank balances that were in excess of the insured limits.

At June 30, 2023, there were three customers whose accounts receivable balances represented 24%, 12%, and 11% of accounts receivable at that date. At December 31, 2022, one customer accounted for 19% of accounts receivable at that date.

One pharmaceutical customer, a related party who is a stockholder, a noteholder, and whose Chief Executive Officer is a representative on the Company's Board of Directors (see Note 6), 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 12% and 14% of total sales in the three-month periods ended June 30, 2023 and 2022, respectively, and 13% and 16% of total sales in the six-month periods ended June 30, 2023 and 2022, respectively. There were two additional customers who comprised 14% and 13% of the total sales in the three-month period ended June 30, 2023.

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 June 30, 2023, and December 31, 2022, was $0.6 million and $0.1 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.

Adoption of New Accounting Standard

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments - Credit Losses (Topic 326)," which replaces the previous incurred loss impairment methodology for most financial assets with the current expected credit loss, or CECL, methodology. The new guidance requires entities to use a forward-looking approach based on expected losses rather than incurred losses to estimate credit losses on certain types of financial instruments, including trade receivables. The Company adopted the new standard effective January 1, 2023, which did not have a material impact to the condensed consolidated financial statements.

Reclassifications

The accompanying condensed consolidated statement of operations for the three and six months ended June 30, 2023 classifies share-based compensation in the same income statement line items as the cash compensation paid to recipient employees, rather than in general and administrative expense, as had been the practice in previous years. The accompanying condensed consolidated statements of operations for the three and six months ended June 30, 2022 have been conformed to the 2023 presentation.

3. Revenue Recognition

Revenue by Service Line

	Three Months Ended June 30,	
(in thousands)	**2023**	**2022**
Functional neurosurgery navigation and therapy		
Disposable products	$ 1,818	$ 1,798
Services	383	375
Subtotal – Functional neurosurgery navigation and therapy	2,201	2,173
Biologics and drug delivery		
Disposable products	346	1,225
Services and license fees	3,022	1,183
Subtotal – Biologics and drug delivery revenue	3,368	2,408
Capital equipment and software		
Systems and software products	173	434
Services	208	185
Subtotal – Capital equipment and software revenue	381	619
Total revenue	$ 5,950	$ 5,200

(in thousands)	Six Months Ended June 30, 2023	2022
Functional neurosurgery navigation and therapy		
Disposable products	$ 3,676	$ 3,661
Services	886	750
Subtotal – Functional neurosurgery navigation and therapy	4,562	4,411
Biologics and drug delivery		
Disposable products	940	2,075
Services and license fees	5,104	2,487
Subtotal – Biologics and drug delivery revenue	6,044	4,562
Capital equipment and software		
Systems and software products	351	884
Services	426	374
Subtotal – Capital equipment and software revenue	777	1,258
Total revenue	$ 11,383	$ 10,231

Contract Balances

- *Contract assets* – Substantially all the Company's contracts with customers are based on customer-issued purchase orders for distinct products or services. Customers are billed generally upon shipment of such products or delivery of such services, and the related contract assets comprise the accounts receivable balances included in the accompanying condensed consolidated balance sheets. At December 31, 2022, the Company had $0.3 million in deferred contract costs, classified as other current assets, related to up-front costs for direct materials incurred to fulfill a customer contract. These costs were recognized as cost of revenue in the second quarter of 2023.

- *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. Additionally, at December 31, 2022, the Company had a $0.5 million refund liability resulting from an up-front customer payment which was potentially refundable if the parties did not enter into the ensuing agreement. In 2023, the uncertainties underlying this amount were resolved and the amount was recognized as revenue.

During the three and six months ended June 30, 2023, the Company recognized approximately $0.5 million and $0.8 million of revenue, respectively, which was previously included in deferred revenue in the accompanying condensed consolidated balance sheet at December 31, 2022.

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 $0.9 million at June 30, 2023. The Company expects to recognize approximately 73% 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 $26.5 million and $27.6 million as of June 30, 2023, and December 31, 2022, 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.

The Company had $9.9 million of short-term investments on December 31, 2022, consisting of twelve-month U.S. Government debt securities, which were classified as held to maturity and carried at amortized cost, adjusted for the accretion of discounts using the effective interest method. The carrying value of the debt securities approximates fair value based on Level 1 inputs. The Company held the investments to maturity, which occurred in the second quarter of 2023.

5. Inventory

Inventory consists of the following as of June 30, 2023 and December 31, 2022:

(in thousands)	June 30, 2023	December 31, 2022
Raw materials and work in process	$ 7,315	$ 6,513
Software licenses	210	210
Finished goods	1,679	2,580
Inventory, net, included in current assets	9,204	9,303
Software licenses – non-current	407	450
Total	$ 9,611	$ 9,753

6. Note Payable

As a result of a note financing in 2020, and further described in the following paragraphs, the Outstanding First Closing Note in an aggregate principal amount of $0 million was outstanding at June 30, 2023. At the option of the holder at any time prior to maturity on January 29, 2025, the principal amount may be convertible to the Company's common stock at a conversion price of $6.00, subject to adjustments as set forth in the SPA and the note agreement.

On January 29, 2020 (the "Closing Date"), the Company completed a financing transaction withtwo 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, mature on the fifth anniversary of the issuance and bear interest at a rate equal to the sum of (i) the greater of (a) the three (3)-month London Interbank Offered Rate ("LIBOR") and (b) two percent (2%), plus (ii) a margin of 2% on the outstanding balance of the First Closing Notes, payable quarterly on the first business day of each calendar quarter. The First Closing Notes may be converted at a price of $6.00 per share, subject to certain adjustments set forth in the SPA and the note agreement, and may not be pre-paid without the consent of the noteholder.

On July 31, 2023, the Company and the 2020 Convertible Noteholders entered into an amendment to the SPA and note agreement to replace LIBOR with an interest rate benchmark based on the Secured Overnight Financing Rate. Refer to Note 9 Subsequent Events.

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, amounting to approximately $0.04 million, into 1,256,143 shares of the Company's common stock.

At the Closing Date, the SPA gave the Company the right, but not the obligation, to request at any time on or prior to January 11, 2022, that one of the 2020 Convertible Noteholders purchase an additional $5.0 million in aggregate principal amount of Second Closing Note (as defined in the SPA) and an additional $10.0 million in aggregate principal amount of Third Closing Note (as defined in the SPA; together, with the Second Closing Note, the "Additional Convertible Notes"), provided that such 2020 Convertible Noteholder has the right, but not the obligation, to purchase such notes. The Additional Convertible Notes would also mature on the fifth anniversary of the Closing Date.

On December 29, 2020, the Company and the 2020 Convertible Noteholders entered into the amendment to the SPA (the "Amendment"), the terms of which, among other provisions, provided for: (a) an increase in the principal amount of the Second Closing Note to $7.5 million; (b) a revision of the interest rate to be borne by the Second Closing Note to consist of: (i) cash interest of 2% per annum, payable quarterly; and (ii) payment-in-kind interest of 5% per annum, accruable quarterly as an addition to the unpaid principal balance of the Second Closing Note; and (c) an increase in the conversion price of the Second Closing Notes to $10.14 per share, subject to certain adjustments set forth in the SPA and the note agreement. Upon execution of the Amendment, the Company issued the Second Closing Note to one of the 2020 Convertible Noteholders.

On November 3, 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.

The aggregate carrying amount of the Outstanding First Closing Note in the accompanying June 30, 2023 and December 31, 2022 condensed consolidated balance sheets is presented net of financing costs, comprised of commissions and legal expenses, having an unamortized balance of $0.1 million at each of those respective dates.

The Outstanding First Closing Note is secured by all the assets of the Company.

The holder of the Outstanding First Closing Note is a significant customer of the Company, whose chief executive officer is a member of the Company's Board of Directors. See Note 2, *Concentration Risks and Other Risks and Uncertainties*.

Scheduled Note Payable Maturity

Scheduled principal payment as of June 30, 2023 with respect to the remaining note payable is summarized as follows:

Year ending December 31,	*(in thousands)*
2025	$ 10,000
Total scheduled principal payment	10,000
Less: Unamortized financing costs	(79)
Total	$ 9,921

7. Leases

The Company subleases office space in Solana Beach, California, that serves as its corporate headquarters and houses certain management and research and development personnel. The sublease term commenced on December 15, 2020, is set to expire on December 31, 2026, and is renewable for an additional five-year period, at the Company's option, provided that the Company's landlord has entered into an extension of its prime lease for the office space that encompasses the Company's office space for at least five years.

In November 2022, the Company entered into a lease agreement to lease an approximately 19,462 square foot industrial building in Carlsbad, California to use as an office and manufacturing facility. Under the agreement, the lease term commenced on June 1, 2023 and ends on May 31, 2033. The base rent payable under the lease agreement is $36,977.80 per month, which is subject to annual increases of 3.5% during the lease term. The Company has two

options to extend the lease term for thirty-six or sixty months, at the fair market rental value. The total minimum lease payments related to this lease are $5.1 million.

The Company leases space in Irvine, California, that houses office space and a manufacturing facility under a lease that commenced on October 1, 2018 and expires in September 2024.

All the aforementioned leases are classified as operating leases in conformity with GAAP. The aggregate lease costs, included in general and administrative expense, were $0.2 million and $0.1 million for each of the three months ended June 30, 2023 and 2022, respectively, and $0.3 million for each of the six months ended June 30, 2023 and 2022.

8. Stockholders' Equity

The Fourth Amended and Restated 2013 Incentive Compensation Plan became effective in 2022. 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 our Annual Report on Form 10-K for the year ended December 31, 2022.

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:

	Three Months Ended June 30, (in thousands)	
	2023	**2022**
Cost of revenue	27	6
Research and development	370	124
Sales and marketing	484	189
General and administrative	764	561
Share-based compensation expense	$ 1,645	$ 880

	Six Months Ended June 30, (in thousands)	
	2023	**2022**
Cost of revenue	47	16
Research and development	652	485
Sales and marketing	847	339
General and administrative	1,406	939
Share-based compensation expense	$ 2,952	$ 1,779

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

	Three Months Ended June 30, (in thousands)	
	2023	**2022**
Stock options	266	253
RSAs and RSUs	1,312	571
ESPP	67	56
	$ 1,645	$ 880

	Six Months Ended June 30, *(in thousands)*	
	2023	**2022**
Stock options	514	571
RSAs and RSUs	2,304	1,096
ESPP	134	112
	$ 2,952	$ 1,779

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):

	June 30, 2023	
	Unrecognized Expense	**Remaining Weighted-Average Recognition Period (in years)**
Stock options	$ 1,441	2.00
RSAs and RSUs	$ 9,497	2.14

Stock Option Activity

Stock option activity under the Company's current and previous plans during the six months ended June 30, 2023 is summarized below:

	Stock Options	**Weighted-average Exercise price per share**	**Weighted-average Remaining Contractual Life (in years)**	**Intrinsic Value[1]** *(in thousands)*
Outstanding at December 31, 2022	1,398,286	$ 8.69		
Granted	111,107	$ 8.10		
Forfeited or expired	(3,437)	$ 39.67		
Outstanding at June 30, 2023	1,505,956	$ 8.58	5.93	$ 4,097
Exercisable at June 30, 2023	1,198,832	$ 8.18	5.21	$ 3,951
Vested and expected to vest at June 30, 2023	1,505,956	$ 8.58	5.93	$ 4,097

(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 six months ended June 30, 2023 is summarized below:

	Restricted Stock Awards	Weighted - Average Grant Date Fair Value
Outstanding at December 31, 2022	684,389	$ 11.10
Vested	(147,992)	$ 11.21
Forfeited	(1,064)	$ 9.40
Outstanding at June 30, 2023	535,333	$ 11.08

Restricted Stock Unit Activity

Restricted stock unit ("RSU") activity for the six months ended June 30, 2023 is summarized below:

	Restricted Stock Units	Weighted - Average Grant Date Fair Value
Outstanding at December 31, 2022	13,146	$ 11.41
Granted	758,437	$ 8.12
Vested	(7,474)	$ 9.41
Outstanding at June 30, 2023	764,109	$ 8.17

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. During the six months ended June 30, 2023, 51,041 shares were purchased at an average per share price of $6.15.

Warrants

Warrants to purchase shares of the Company's common stock were issued in connection with financing transactions in 2015 and 2017. These warrants contained net exercise provisions giving the holder the option of acquiring a number of shares having a value equal to the difference between the exercise price and the current stock price, in lieu of paying the exercise price to acquire the full number of stated shares. All of the remaining outstanding warrants expired in the second quarter of 2023.

	Shares	Weighted - Average Exercise Price
Outstanding at December 31, 2022	36,554	$ 16.23
Expired	(36,554)	$ 16.23
Outstanding at June 30, 2023	—	—

9. Subsequent Event

On July 31, 2023, the Company and the 2020 Convertible Noteholders entered into an amendment to the SPA and notes, the terms of which, among other provisions, replaced LIBOR and the LIBOR-based mechanics with an interest rate benchmark based on the Secured Overnight Financing Rate ("SOFR") and related SOFR-based mechanics. The amendment is not expected to have a material impact on our condensed consolidated financial statements.

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 2022 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 foundational capabilities for enabling MRI-guided interventions, building an intellectual property portfolio, and identifying and building out commercial applications for the technologies developed by our company. Beginning in 2021, our efforts have expanded beyond the MRI suite to encompass development and commercialization of new neurosurgical device products for the operating room, as well as clinical and pre-clinical consulting services for pharmaceutical and biotech companies, academic institutions, and contract research organizations.

Since 2020, we have evolved to become a company comprised of two parts. The first foundational part is a medical device company providing medical devices for neurosurgery applications. The second part is focused on partnerships in the drug and delivery space. Currently, we have more than 50 partners who are pharmaceutical/biotech companies, academic institutions, and contract research organizations, who are evaluating or using our products and services in trials (or in a preclinical setting) to inject gene and cell therapies directly into the brain.

In 2022, we commenced the limited market commercialization of the ClearPoint Prism Neuro Laser Therapy System. The laser system was developed by CLS, and is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under 3.0T magnetic resonance imaging ("MRI") guidance. We have exclusive global rights to commercialize the CLS magnetic resonance ("MR") guided laser interstitial thermal therapy ("MRgLITT") system for neuro applications.

Substantially all our product revenue for the three and six months ended June 30, 2023 and 2022 relates to sales of our ClearPoint system products and related services. We have financed our operations and internal growth primarily through the sale of equity securities and the issuance of convertible and other secured notes. We have incurred significant losses since our inception in 1998 as we have devoted substantial efforts to research and development. As of June 30, 2023, we had accumulated losses of $163.0 million. We may continue to incur operating losses as we expand our ClearPoint system platform and our business generally.

Factors Which May Influence Future Results of Operations

The following is a description of factors 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 impact of various macroeconomic trends, such as global economic and supply chain disruptions, geopolitical instability, labor shortages, instability of financial institutions and inflationary conditions. Changes in domestic and global economic conditions, supply chain disruptions, labor shortages, as well as other stimulus and spending programs, have led to higher inflation, which is likely to lead to increased costs and may cause further changes in fiscal and monetary policy. Impacts from inflationary pressures, such an increasing costs for research and development of our products, administrative and other costs of doing business, the potential for instability of the financial institutions where we maintain our deposits or other assets, and our availability to access capital markets and other sources of funding in the future could adversely affect our business, financial condition and results of operations. Additionally, these trends could adversely affect our customers, which could impact their willingness to spend on our products and services, or their ability to make payment, which could harm the Company's collection of accounts receivable and financial results. 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 neurosurgery 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, which we have exclusive global right to commercialize, received 510(k) clearance through CLS. The Prism laser represents the first therapy product we have commercialized. 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 approximately $2.3 million and $5.0 million for the three and six months ended June 30, 2023, respectively, and was almost entirely related to our ClearPoint system. Our service revenue was approximately $3.6 million and $6.4 million for the three and six months ended June 30, 2023, respectively, of which 84% and 80%, respectively, is related to the biologics and drug delivery service line.

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

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 June 30, 2023, we had more than 50 Partners, as compared with approximately 45 Partners as of the same date in 2022.

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) continue to develop enhancements to our ClearPoint system and SmartFlow cannula; and (ii) seek to expand the application of our technological platforms. From our inception through June 30, 2023, we have incurred approximately $88 million in research and development expenses.

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

Sales and Marketing, and General and Administrative Expenses

Our sales and marketing, and general and administrative expenses consist primarily of salaries, incentive-based compensation, travel and benefits, including 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 ClearPoint system 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 six months ended June 30, 2023, as compared to the critical accounting policies and estimates described in our 2022 Form 10-K.

Results of Operations

Three Months Ended June 30, 2023, Compared to the Three Months Ended June 30, 2022

	Three Months Ended June 30,		
(Dollars in thousands)	**2023**	**2022**	**Percentage Change**
Product revenue	$ 2,337	$ 3,457	(32) %
Service and other revenue	3,613	1,743	107 %
Total revenue	5,950	5,200	14 %
Cost of revenue	2,824	1,945	45 %
Gross profit	3,126	3,255	(4) %
Research and development costs	3,605	2,411	50 %
Sales and marketing expenses	3,474	2,387	46 %
General and administrative expenses	3,178	2,661	19 %
Other expense:			
Other expense, net	(2)	(8)	NM%
Interest income (expense), net	81	(91)	190 %
Net loss	$ (7,052)	$ (4,303)	64 %

NM – The percentage change is not meaningful.

Revenue. Total revenue was $6.0 million for the three months ended June 30, 2023, and $5.2 million for the three months ended June 30, 2022, which represents an increase of $0.8 million, or 14%.

(Dollars in thousands)	Three Months Ended June 30, 2023	2022	Percentage Change
Functional neurosurgery navigation and therapy			
Disposable products	$ 1,818	$ 1,798	1 %
Services	383	375	2 %
Subtotal – Functional neurosurgery navigation and therapy	2,201	2,173	1 %
Biologics and drug delivery			
Disposable products	346	1,225	(72) %
Services and license fees	3,022	1,183	155 %
Subtotal – Biologics and drug delivery revenue	3,368	2,408	40 %
Capital equipment and software			
Systems and software products	173	434	(60) %
Services	208	185	13 %
Subtotal – Capital equipment and software revenue	381	619	(38) %
Total revenue	$ 5,950	$ 5,200	14 %

Functional neurosurgery navigation and therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, remained relatively consistent at $2.2 million for the three months ended June 30, 2023 and 2022.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored pre-clinical and clinical trials, increased 40% to $3.4 million for the three months ended June 30, 2023, from $2.4 million for the same period in 2022. This increase is attributable to a $1.8 million increase in service revenue related to new pre-clinical trials and consulting agreements entered into with our Partners during the three months ended June 30, 2023, compared to the same period in 2022, partially offset by a $0.9 million decrease in product revenue.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software and related services, decreased 38% to $0.4 million for the three months ended June 30, 2023, from $0.6 million for the same period in 2022 due primarily to a decrease in the placements of ClearPoint capital and software.

Cost of Revenue and Gross Profit. Cost of revenue was $2.8 million, resulting in gross profit of $3.1 million and gross margin of 53%, for the three months ended June 30, 2023, and was $1.9 million, resulting in gross profit of $3.3 million and representing a gross margin of 63%, for the three months ended June 30, 2022. The decrease in gross margin was primarily due to an increase in biologics and drug delivery pre-clinical services, which, to date, have had a lower margin than product sales as we launch new services and increase our presence in this space. Increased costs related to the transition to the new manufacturing facility also contributed to the decrease in gross margin.

Research and Development Costs. Research and development costs were $3.6 million for the three months ended June 30, 2023, compared to $2.4 million for the same period in 2022, an increase of $1.2 million, or 50%. The increase was due primarily to increases in personnel costs, including share-based compensation, of $0.8 million and increases in product development costs of $0.4 million.

Sales and Marketing Expenses. Sales and marketing expenses were $3.5 million for the three months ended June 30, 2023, compared to $2.4 million for the same period in 2022, an increase of $1.1 million, or 46%. This increase was due primarily to additional personnel costs, including share-based compensation, resulting from increases in headcount.

General and Administrative Expenses. General and administrative expenses were $3.2 million for the three months ended June 30, 2023, compared to $2.7 million for the same period in 2022, an increase of $0.5 million, or 19%. This increase was due primarily to increases in share-based compensation of $0.2 million, an increase in the allowance for credit losses of $0.2 million, and an increase of $0.1 million for professional fees.

Interest Income (Expense). Net interest income for the three months ended June 30, 2023 was $0.1 million, compared to $0.1 million net interest expense for the same period in 2022. The increase in interest income was due to higher interest rates and the Company's investment in U.S. Government debt securities, offset partially by the higher amount of interest

paid on the 2020 Secured Convertible Note during the three months ended June 30, 2023, relative to the same period in 2022. See Note 6 to the Condensed Consolidated Financial Statements included above in Part 1, Item 1 in this Quarterly Report for additional information with respect to the 2020 secured notes.

Six Months Ended June 30, 2023, Compared to the Six Months Ended June 30, 2022

	Six Months Ended June 30,		
(Dollars in thousands)	2023	2022	Percentage Change
Product revenue	$ 4,967	$ 6,620	(25) %
Service and other revenue	6,416	3,611	78 %
Total revenue	11,383	10,231	11 %
Cost of revenue	5,055	3,746	35 %
Gross profit	6,328	6,485	(2) %
Research and development costs	6,628	5,312	25 %
Sales and marketing expenses	6,407	4,404	45 %
General and administrative expenses	6,136	4,837	27 %
Other expense:			
Other (expense) income, net	(13)	3	NM%
Interest income (expense), net	195	(197)	199 %
Net loss	$ (12,661)	$ (8,262)	53 %

NM – The percentage change is not meaningful.

Revenue. Total revenue was $11.4 million for the six months ended June 30, 2023, and $10.2 million for the six months ended June 30, 2022, which represents an increase of $1.2 million, or 11%.

	Six Months Ended June 30,		
(Dollars in thousands)	2023	2022	Percentage Change
Functional neurosurgery navigation and therapy			
Disposable products	$ 3,676	$ 3,661	— %
Services	886	750	18 %
Subtotal – Functional neurosurgery navigation and therapy	4,562	4,411	3 %
Biologics and drug delivery			
Disposable products	940	2,075	(55) %
Services and license fees	5,104	2,487	105 %
Subtotal – Biologics and drug delivery revenue	6,044	4,562	32 %
Capital equipment and software			
Systems and software products	351	884	(60) %
Services	426	374	14 %
Subtotal – Capital equipment and software revenue	777	1,258	(38) %
Total revenue	$ 11,383	$ 10,231	11 %

Functional neurosurgery navigation and therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 3% to $4.6 million for the six months ended June 30, 2023, from $4.4 million for the same period in 2022. This increase reflects additional $0.1 million in service revenue related to new pre-clinical services for brain computer interface during the six months ended June 30, 2023, compared to the same period in 2022.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored pre-clinical and clinical trials, increased 32% to $6.0 million for the six months ended June 30, 2023, from $4.6

million for the same period in 2022. This increase is attributable to a $2.6 million increase in service revenue related to new pre-clinical trials entered into with our partners and the recognition of license fees during the six months ended June 30, 2023, compared to the same period in 2022, partially offset by a $1.1 million decrease in product revenue.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software and related services, decreased 38% to $0.8 million for the six months ended June 30, 2023, from $1.3 million for the same period in 2022 due primarily to a decrease in the placements of ClearPoint capital and software.

Cost of Revenue and Gross Profit. Cost of revenue was $5.1 million, resulting in gross profit of $6.3 million and gross margin of 56%, for the six months ended June 30, 2023, and was $3.7 million, resulting in gross profit of $6.5 million and representing a gross margin of 63%, for the six months ended June 30, 2022. The decrease in gross margin was primarily due to an increase in biologics and drug delivery pre-clinical services, which, to date, have had a lower margin than product sales as we launch new services and increase our presence in this space. Increased costs related to the transition to the new manufacturing facility also contributed to the decrease in gross margin.

Research and Development Costs. Research and development costs were $6.6 million for the six months ended June 30, 2023, compared to $5.3 million for the same period in 2022, an increase of $1.3 million, or 25%. The increase was due primarily to increases in personnel costs, including share-based compensation, of $1.1 million, and increases in product and software development costs of $0.2 million.

Sales and Marketing Expenses. Sales and marketing expenses were $6.4 million for the six months ended June 30, 2023, compared to $4.4 million for the same period in 2022, an increase of $2.0 million, or 45%. This increase was due primarily to additional personnel costs, including share-based compensation, resulting from increases in headcount of $1.9 million.

General and Administrative Expenses. General and administrative expenses were $6.1 million for the six months ended June 30, 2023, compared to $4.8 million for the same period in 2022, an increase of $1.3 million, or 27%. This increase was due primarily to increases in personnel costs, including share-based compensation of $0.6 million, an increase in the allowance for credit losses of $0.5 million, and increases in professional fees of $0.1 million.

Interest Income (Expense). Net interest income for the six months ended June 30, 2023 was $0.2 million, compared to $0.2 million net interest expense for the same period in 2022. The increase in interest income was due to higher interest rates and the Company's investment in U.S. Government debt securities, offset partially by the higher amount of interest paid on the 2020 Secured Convertible Note, during the six months ended June 30, 2023, relative to the same period in 2022. See Note 6 to the Condensed Consolidated Financial Statements included above in Part 1, Item 1 in this Quarterly Report for additional information with respect to the 2020 secured notes.

Liquidity and Capital Resources

We have incurred net losses since our inception, which has resulted in a cumulative deficit at June 30, 2023 of $163.0 million. In addition, our use of cash from operations amounted to $10.8 million for the six months ended June 30, 2023, and $16.2 million for the year ended December 31, 2022.

Since inception, we have financed our operations principally from the sale of equity securities and the issuance of notes payable. In 2020, we issued secured convertible notes to two investors which raised gross proceeds of $25 million, of which $15 million has been converted to common stock and $10 million remains outstanding.

See Note 6 to the Condensed Consolidated Financial Statements included above in Part 1, Item 1 in this Quarterly Report for additional information with respect to the 2020 secured notes.

In February 2021, we completed a public offering of 2,127,660 shares of our common stock from which the net proceeds totaled approximately $46.8 million after deducting underwriting discounts and commissions, and other offering expenses paid by us.

As a result of these transactions and our business operations, our cash and cash equivalents totaled $26.5 million at June 30, 2023. In management’s opinion, based on our current forecasts for revenue, expense and cash flows, our existing cash and cash equivalent balances at June 30, 2023, are sufficient to support our operations and meet our obligations for at least the next twelve months.

Cash Flows

Cash activity for the six months ended June 30, 2023 and 2022 is summarized as follows:

	Six months ended June 30,	
(in thousands)	**2023**	**2022**
Cash used in operating activities	(10,755)	$ (9,250)
Cash provided by (used in) investing activities	9,372	(21,851)
Cash provided by financing activities	232	516
Net change in cash and cash equivalents	$ (1,151)	$ (30,585)

Net Cash Flows from Operating Activities. Net cash flows used in operating activities for the six months ended June 30, 2023, were $10.8 million, an increase of $1.5 million from the six months ended June 30, 2022. This increase consisted of an increase in net loss of $4.4 million, partially offset by a net decrease in operating assets and liabilities of $1.2 million and a net increase in non-cash items of $1.7 million. The change in operating assets and liabilities is primarily due to lower inventory purchases after a ramping up of inventory stock in response to supply chain disruptions over the past year, partially offset by increased use of cash to pay down accounts payables and accrued expenses. The change in the non-cash items results primarily from increases in share-based compensation and allowance for credit losses.

Net Cash Flows from Investing Activities. Net cash flows provided by investing activities for the six months ended June 30, 2023, were $9.4 million and consisted of proceeds from the maturities of short-term investments, partially offset primarily by equipment acquisitions related to our new manufacturing site in Carlsbad, California.

Net cash flows used in investing activities for the six months ended June 30, 2022, were $21.9 million and consisted primarily of the purchase of short-term investments as well as equipment acquisitions and licensing rights.

Net Cash Flows from Financing Activities. Net cash flows provided by financing activities for the six months ended June 30, 2023, consisted of proceeds from the issuance of common stock under the employee stock purchase plan, partially offset by payments for taxes related to shares withheld in connection with the vesting of restricted stock awards.

Net cash flows from financing activities for the six months ended June 30, 2022, consisted of the proceeds from the exercise of common stock options and warrants and the sale of common stock under the employee stock purchase plan.

Operating Capital and Capital Expenditure Requirements

To date, we have not achieved profitability. We could continue to incur net losses as we continue our efforts to expand the commercialization of our ClearPoint system products and pursue additional applications for our technology platforms. Our cash balances are 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 continue to commercialize our ClearPoint system products and pursue additional applications for our technology platforms. Our future capital requirements will depend on many factors, including, but not limited to, the following:

- the ultimate duration and impact of macroeconomic trends, including inflationary pressures, supply chain disruptions, geopolitical instability, and instability of financial institutions;
- 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 pre-clinical 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 income we receive without significantly increasing risk. In the event we invest in short-term investments, due to the nature of our short-term investments and the Company's intent to hold such debt securities to maturity, we believe that we are not subject to any material market risk exposure.

At June 30, 2023, we had $10 million of principal outstanding under the Outstanding First Closing Note, which is subject to interest rate fluctuations. Prior to July 1, 2023, the Outstanding First Closing Note bore interest at a rate equal to the sum of (i) the greater of (a) the three (3)-month LIBOR and (b) two percent (2%), plus (ii) a margin of 2% on the outstanding balance of the Outstanding First Closing Note. At June 30, 2023, the three-month LIBOR was greater than the 2% floor as a result of rising interest rates, and the rate paid on the Outstanding First Closing Note was 7.5%. Effective July 1, 2023, the reference to LIBOR was replaced by an interest rate benchmark based on the SOFR. If interest rates continue to increase, a one-percent to two-percent increase would result in additional annual interest expense of $0.5 million to $0.6 million above the floor, respectively. Information with respect to the Outstanding First Closing Note may be found in Note 6 to the Condensed Consolidated Financial Statements included above in Part 1, Item 1 in this Quarterly Report.

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 June 30, 2023 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 June 30, 2023.

Changes in Internal Control Over Financial Reporting

During the quarter ended June 30, 2023, 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.

ITEM 1A. RISK FACTORS.

There have been no material changes to the risk factors disclosed in our 2022 Form 10-K, except as set forth below:

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

On March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the FDIC as receiver. On March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Similarly, on May 1, 2023, First Republic Bank was swept into receivership. A statement by the Department of the Treasury, the Federal Reserve and the FDIC stated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts. Although we do not have any funds deposited with SVB, Signature Bank, Silvergate Capital Corp., or First Republic Bank, we currently have our cash and cash equivalents held in deposit in accounts at certain FDIC-insured financial institutions, some of which include amounts in excess of the insurance coverage offered by the FDIC. In the future, we may maintain our cash assets at financial institutions in the United States in amounts that may be in excess of the FDIC insurance limit of $250,000. In the event of a failure of any of these financial institutions where we maintain our deposits or other assets, we may incur a loss to the extent such deposits or assets exceeds the FDIC insurance limitation, which could have a material adverse effect upon our liquidity, financial condition and our results of operations.

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 June 30, 2023, no director or Section 16 officeradopted or terminated any Rule 10b5-1 trading arrangements, as defined in Item 408(a) of Regulation.

ITEM 6. EXHIBITS.

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

Exhibit Number	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation of MRI Interventions, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 11, 2012).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of MRI Interventions, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 8, 2015).
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of MRI Interventions, Inc. (incorporated by reference to Exhibit 3.3 to the Company's Registration Statement on Form S-1, filed with the SEC on August 2, 2016).
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of ClearPoint Neuro, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on February 12, 2020).
3.5	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of ClearPoint Neuro, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on May 25, 2023).
3.6	Fourth Amended and Restated Bylaws of ClearPoint Neuro, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on December 14, 2022).
10.1	ClearPoint Neuro, Inc. Non-Employee Director Compensation Plan, as amended and restated by the Board of Directors on May 22, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on May 22, 2023).
31.1*	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934
31.2*	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934
32+	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934 and Section 1350 of Chapter 60 of Title 18 of the United States Code
101.INS*	XBRL Instance
101.SCH*	XBRL Taxonomy Extension Schema
101.CAL*	XBRL Taxonomy Extension Calculation
101.DEF*	XBRL Taxonomy Extension Definition
101.LAB*	XBRL Taxonomy Extension Labels
101.PRE*	XBRL Taxonomy Extension Presentation
104*	Cover Page Interactive Data File (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: August 8, 2023

CLEARPOINT NEURO, INC.

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

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

Exhibit 31.1

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

I, Joseph M. Burnett, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarter ended June 30, 2023, of ClearPoint Neuro, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 8, 2023

/s/ Joseph M. Burnett

Joseph M. Burnett

Chief Executive Officer

Exhibit 31.2

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

I, Danilo D'Alessandro, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarter ended June 30, 2023, of ClearPoint Neuro, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 8, 2023

/s/ Danilo D'Alessandro

Danilo D'Alessandro

Chief Financial Officer

Exhibit 32

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

Each of the undersigned, Joseph M. Burnett and Danilo D'Alessandro, certifies pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934 and Section 1350 of Chapter 63 of Title 18 of the United States Code, that (1) this quarterly report on Form 10-Q for the quarter ended June 30, 2023, 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: August 8, 2023

/s/ Joseph M. Burnett
Joseph M. Burnett
Chief Executive Officer

/s/ Danilo D'Alessandro
Danilo D'Alessandro
Chief Financial Officer