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

FORM 10-Q

(Mark One)

☑ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended **June 30, 2022**

Or

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

Commission file number: **001-34822**

ClearPoint Neuro, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

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

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

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

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

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

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

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

As of August 4, 2022, there were 24,488,255 shares of common stock outstanding.

CLEARPOINT NEURO, INC.

TABLE OF CONTENTS

Trademarks, Trade Names and Service Marks

ClearPoint Neuro®, *ClearPoint*®, *ClearTrace*®, *SmartFlow*®, *SmartFrame*®, *SmartGrid*®, *Inflexion*™, *SmartTwist*™, *SmartTip*™, *ClearPoint Pursuit*®, *ClearPoint Maestro*™, *ClearPoint Revolution*™, *SmartFrame Array*™, *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 United States federal securities laws. The forward-looking statements are contained principally in the section of this Quarterly Report entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations." 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. Forward-looking statements include, but are not limited to, statements about:

- the effects of the COVID-19 pandemic and measures taken or that may be taken by federal, state and local governmental authorities to combat the spread of the disease;
- domestic and global geopolitical conditions and the impact of global and domestic economic conditions, including inflationary pressures and changes in the cost or availability of materials, supply chain shortages and disruptions, and the availability of labor, particularly in light of current labor market conditions;
- future revenue from sales of ClearPoint system products and services;
- the ability of our biologics and drug delivery customers, or partners, to achieve commercial success, including their use of our products and services in their delivery of therapies; and
- our ability to market, commercialize and achieve broader market acceptance for our ClearPoint system products.

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.

You should refer to the section titled "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, which we filed with the United States Securities and Exchange Commission ("SEC") on March 9, 2022 (the "2021 Form 10-K") and in this Quarterly Report, for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by the forward-looking statements contained in this Quarterly Report. As a result of these 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, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,524	$ 54,109
Short-term investments	21,613	—
Accounts receivable, net	3,348	2,337
Inventory, net	6,639	4,938
Prepaid expenses and other current assets	1,517	508
Total current assets	56,641	61,892
Property and equipment, net	689	539
Operating lease rights of use	1,992	2,241
Software license inventory	504	519
Licensing rights	320	265
Other assets	94	125
Total assets	$ 60,240	$ 65,581
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,592	$ 427
Accrued compensation	1,814	2,604
Other accrued liabilities	870	537
Operating lease liabilities, current portion	532	507
Deferred product and service revenue, current portion	675	678
Total current liabilities	5,483	4,753
Operating lease liabilities, net of current portion	1,671	1,939
Deferred product and service revenue, net of current portion	401	264
2020 senior secured convertible notes payable, net	9,865	9,838
Total liabilities	17,420	16,794
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized; none issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Common stock, $0.01 par value; 200,000,000 shares authorized; 24,480,600 shares issued and outstanding at June 30, 2022; and 23,665,991 issued and outstanding at December 31, 2021	245	237
Additional paid-in capital	184,769	182,482
Accumulated deficit	(142,194)	(133,932)
Total stockholders' equity	42,820	48,787
Total liabilities and stockholders' equity	$ 60,240	$ 65,581

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,	
	2022	**2021**
Revenue:		
Product revenue	$ 3,457	$ 2,363
Service and other revenue	1,743	1,050
Total revenue	5,200	3,413
Cost of revenue	1,943	1,139
Gross profit	3,257	2,274
Research and development costs	2,284	2,109
Sales and marketing expenses	2,187	1,590
General and administrative expenses	2,990	1,982
Operating loss	(4,204)	(3,407)
Other expense:		
Other expense, net	(8)	(96)
Interest expense, net	(91)	(240)
Net loss	$ (4,303)	$ (3,743)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.18)	$ (0.17)
Weighted average shares used in computing net loss per share:		
Basic and diluted	23,985,577	21,523,393

	For The Six Months Ended June 30,	
	2022	**2021**
Revenue:		
Product revenue	$ 6,620	$ 5,525
Service and other revenue	3,611	1,918
Total revenue	10,231	7,443
Cost of revenue	3,728	2,555
Gross profit	6,503	4,888
Research and development costs	4,817	3,673
Sales and marketing expenses	4,032	3,165
General and administrative expenses	5,722	3,638
Operating loss	(8,068)	(5,588)
Other expense:		
Other income (expense), net	3	(122)
Interest expense, net	(197)	(571)
Net loss	$ (8,262)	$ (6,281)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.35)	$ (0.31)
Weighted average shares used in computing net loss per share:		
Basic and diluted	23,834,847	20,195,488

See accompanying notes to Condensed Consolidated Financial Statements.

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

For The 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

For The Six Months Ended June 30, 2021

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balances, January 1, 2021	17,047,584	$ 170	$ 121,729	$ (119,522)	$ 2,377
Adoption of ASU 2020-06	—	—	(3,107)	—	(3,107)
Issuances of common stock:					
Public offering of common stock	2,127,660	21	46,764	—	46,785
Share-based compensation	20,709	1	319	—	320
Warrant and option exercises (cash and cashless)	1,482,327	15	130	—	145
Net loss for the period	—	—	—	(2,538)	(2,538)
Balances, March 31, 2021	20,678,280	$ 207	$ 165,835	$ (122,060)	$ 43,982
Conversion of 2020 senior secured convertible note	1,256,143	13	7,118	—	7,131
Issuances of common stock:					
Share-based compensation	26,435	—	247	—	247
Warrant and option exercises (cash and cashless)	361,486	3	346	—	349
Net loss for the period	—	—	—	(3,743)	(3,743)
Balances, June 30, 2021	22,322,344	$ 223	$ 173,546	$ (125,803)	$ 47,966

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,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (8,262)	$ (6,281)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for doubtful accounts	(10)	92
Depreciation and amortization	187	62
Share-based compensation	1,779	567
Payment-in-kind interest	—	189
Amortization of debt issuance costs and original issue discounts	27	54
Amortization of lease rights of use, net of accretion in lease liabilities	267	267
Accretion of discounts on short-term investments	(23)	—
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(1,001)	(617)
Inventory, net	(1,786)	(304)
Prepaid expenses and other current assets	(1,010)	(760)
Other assets	30	(93)
Accounts payable and accrued expenses	679	1,312
Lease liabilities	(261)	(195)
Deferred revenue	134	(142)
Net cash flows from operating activities	(9,250)	(5,849)
Cash flows from investing activities:		
Purchases of property and equipment	(145)	(5)
Acquisition of licensing rights	(116)	—
Purchase of short-term investments	(21,590)	—
Net cash flows from investing activities	(21,851)	(5)
Cash flows from financing activities:		
Proceeds from public offering of common stock, net of offering costs	—	46,785
Proceeds from stock option and warrant exercises	256	494
Proceeds from issuance of common stock under employee stock purchase plan	260	—
Net cash flows from financing activities	516	47,279
Net change in cash and cash equivalents	(30,585)	41,425
Cash and cash equivalents, beginning of period	54,109	20,099
Cash and cash equivalents, end of period	$ 23,524	$ 61,524
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ —	$ —
Interest	$ 207	$ 353

NON-CASH INVESTING AND FINANCING TRANSACTIONS:

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

- During the six months ended June 30, 2022 and 2021, 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 2, on January 1, 2021, the Company adopted the provisions of Topic 470-20 within the Accounting Standards Codification, which resulted in the elimination of a previously recorded discount in connection with the issuance of the 2020 Secured Notes and a corresponding reduction of additional paid-in capital, each in the amount of $3.1 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 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 approval for its ClearPoint system. In 2011 and 2018, the Company received 510(k) clearance and CE marking approval, respectively, for its SmartFlow cannula which is being used, or is under evaluation, by more than 45 pharmaceutical and biotech companies, academic institutions, or contract research organizations having a focus on biologics and drug delivery.

COVID-19

The extraordinary measures taken beginning in 2020 by governmental authorities in response to the novel strain of the coronavirus ("COVID-19") pandemic led to reduced economic activity, including the postponement or cancellation of elective surgical procedures. Although economic activity is returning to normalized levels, new variants of COVID-19 continue to spread in the United States and across the globe.

Furthermore, recessionary conditions on the global economy caused by the COVID-19 pandemic could have a material adverse effect on the Company's business. Although most segments of the United States economy have reopened, future surges of COVID-19 due to new variants could occur in the future, and directives, such as the postponement or cancellation of elective surgeries, which historically have represented approximately 80% of the number of surgical procedures using the Company's ClearPoint system, could be reinstated. Additionally, global economic and supply chain disruptions, labor shortages and inflationary conditions caused by the COVID-19 pandemic and geopolitical instability could have a material adverse effect on the Company's business. The rapid development and fluidity of the situation precludes any prediction as to the ultimate impact COVID-19 will have on the Company's business, financial condition, results of operation and cash flows, which will depend largely on future developments, including vaccination rates, the effectiveness of vaccines, the response by governmental authorities and regulators and the duration and scope of the COVID-19 outbreak in the United States.

Liquidity

The Company has incurred net losses since its inception, which has resulted in a cumulative deficit at June 30, 2022 of $142.2 million. In addition, the Company's use of cash from operations amounted to $9.3 million for the six months ended June 30, 2022 and $12.7 million for the year ended December 31, 2021. Since its inception, the Company has financed its operations principally from the sale of equity securities and the issuance of notes payable.

In January 2020, the Company entered into a Securities Purchase Agreement (the "SPA") with two investors (each, a "2020 Convertible Noteholder," and together, the "2020 Convertible Noteholders") under which the Company issued an aggregate principal amount of $17.5 million of floating rate secured convertible notes with afive-year term (the

"First Closing Notes"), resulting in proceeds, net of financing costs and a commitment fee paid to one of the 2020 Convertible Noteholders, of approximately $16.8 million.

The SPA also gave the Company the right, but not the obligation, to request one of the 2020 Convertible Noteholders to purchase an additional $5.0 million in principal amount of a note (the "Second Closing Note", and, together with the First Closing Notes, the "2020 Secured Notes"). On December 29, 2020, under the terms of an amendment to the SPA (the "Amendment") which, among other provisions, increased the principal amount of the Second Closing Note, the Company issued the Second Closing Note in the principal amount of $7.5 million to one of the 2020 Convertible Noteholders.

See Note 6 for additional information with respect to the 2020 Secured Notes.

As discussed in Note 8, on February 23, 2021, the Company completed a public offering of 2,127,660 shares of its common stock. Net proceeds from the offering were approximately $46.8 million after deducting the underwriting discounts and commissions and other estimated offering expenses payable by the Company.

Based on the foregoing, in management's opinion, cash and cash equivalent balances and short-term investments at June 30, 2022 are sufficient to support the Company's operations and meet its obligations for at least the next twelve months.

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, 2021 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 generally accepted accounting principles in the U.S. ("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 2021 Form 10-K. The accompanying condensed consolidated balance sheet as of December 31, 2021 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, 2022 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 (first-in, first-out method) or net realizable value. Items in inventory relate predominantly to the Company's ClearPoint system. 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 obsolete items and provides a reserve upon identification of potentially obsolete items.

Intangible Assets

The Company is a party to certain license agreements that provide rights to the Company for the development and commercialization of products. Under the terms of those license agreements, the Company made payments to the licensors upon execution of the license agreements for access to the underlying technologies and will make future payments based on the achievement of regulatory and commercialization milestones as defined in the license agreements.

In conformity with Accounting Standards Codification Section 350, "Intangibles – Goodwill and Other," the Company amortizes its investment in the license rights described above over an expected useful life of five years. 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; and (4) consultation revenue and clinical case support revenue in connection with customer-sponsored clinical trials. The Company recognizes revenue when control of the Company's products and services is transferred to its customers in an amount that reflects the consideration the Company expects to receive from its customers in exchange for those 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 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 are 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 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 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 Company's 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:*

  - *Consultation Services:* The Company recognizes consultation revenue at the point in time such services are performed.

  - *Clinical Service Access Fees:* For contracts in which the Company receives a periodic fixed fee, irrespective of the number of cases attended by Company personnel or hours of services provided to the customer 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.

- *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. In line with equipment service, a time-elapsed output method is used as the Company is providing a stand-ready service.

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

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 entire amount of the Company's outstanding common stock options and warrants, as described in Note 8, and the potential conversion of the 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. Treasury Bills. It classifies all highly liquid investments with original stated maturities of three months or less from 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. Treasury Bills as held-to-maturity in accordance with ASC 320, "Investments - Debt and Equity Securities." Held-to-maturity securities are those securities which 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 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, 2022, the Company had approximately $12.4 million in bank balances that were in excess of the insured limits.

At June 30, 2022, there were two customers whose accounts receivable balances represented18% and 11% of accounts receivable at that date. At December 31, 2021, one customer accounted for 15% of accounts receivable at that date.

One pharmaceutical customer, a related party who is a stockholder, a noteholder, and who has 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 14% and 21% of total sales in the three-month periods ended June 30, 2022 and 2021, respectively, and16% and 19% of total sales in the six-month periods ended June 30, 2022 and 2021, respectively. There was an additional customer who comprised 11% of total sales in the three-month period ended June 30, 2022.

Prior to granting credit, the Company performs credit evaluations of its customers' financial condition, and generally does not require collateral from its customers. The Company will provide an allowance for doubtful accounts when collections become doubtful. The allowance for doubtful accounts at June 30, 2022 and December 31, 2021 was $0.2 million and $0.3 million, respectively.

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

Effective January 1, 2021, the Company adopted, on a modified retrospective method of transition, the provisions of Accounting Standards Update No. 2020-06, "Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40) – Accounting for Convertible Instruments and Contracts in an Entity's Own Equity" (the "ASU"). The ASU is effective for public companies, other

than smaller reporting companies as defined by the SEC, for fiscal years beginning after December 15, 2021, and for smaller reporting companies, which is the Company's current classification, for fiscal years beginning after December 31, 2023. However, the ASU permits early adoption no earlier than for fiscal years beginning after December 31, 2020, and the Company elected such early adoption. The ASU amends prior authoritative literature to reduce the number of accounting models for, among others, convertible debt instruments for which the embedded conversion features of such instruments had previously been required to be separated from the host contract. The Company determined that the conversion feature embedded in the Second Closing Note (see Note 6) was within the scope of the ASU. Accordingly, the discount originally recorded in connection with the issuance of the Second Closing Note and a corresponding amount recorded in additional paid-in capital, each in the amount of approximately $3.1 million at the date of issuance of the Second Closing Note, were reversed as of the date of adoption of the ASU.

Reclassifications

The accompanying consolidated statement of operations for the three and six months ended June 30, 2022 contains certain items formerly classified as sales and marketing expenses and research and development expenses that have been reclassified to cost of revenue. The accompanying condensed consolidated statements of operations for the three and six months ended June 30, 2021 have been conformed to the 2022 presentation.

3. Revenue Recognition

Revenue by Service Line

	Three Months Ended June 30,	
(in thousands)	**2022**	**2021**
Functional neurosurgery navigation and therapy		
Disposable products	$ 1,798	$ 1,861
Services	375	—
Subtotal – Functional neurosurgery navigation and therapy	2,173	1,861
Biologics and drug delivery		
Disposable products	1,225	450
Services	1,183	940
Subtotal – Biologics and drug delivery revenue	2,408	1,390
Capital equipment and software		
Systems and software products	434	52
Services	185	110
Subtotal – Capital equipment and software revenue	619	162
Total revenue	$ 5,200	$ 3,413

(in thousands)	Six Months Ended June 30, 2022	2021
Functional neurosurgery navigation and therapy		
Disposable products	$ 3,661	$ 3,779
Services	750	—
Subtotal – Functional neurosurgery navigation and therapy	4,411	3,779
Biologics and drug delivery		
Disposable products	2,075	1,364
Services	2,487	1,685
Subtotal – Biologics and drug delivery revenue	4,562	3,049
Capital equipment and software		
Systems and software products	884	382
Services	374	233
Subtotal – Capital equipment and software revenue	1,258	615
Total revenue	$ 10,231	$ 7,443

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.

- *Contract liabilities* – The Company generally bills and collects capital equipment and software-related service fees at the inception of the service agreements, which have terms ranging from one to three years. The Company may also enter into 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. The unearned portion of all such fees is classified as deferred revenue.

During the three and six months ended June 30, 2022, the Company recognized capital equipment and software-related service revenue of approximately $0.1 million and $0.3 million, respectively, which was previously included in deferred revenue in the accompanying condensed consolidated balance sheet at December 31, 2021.

Revenue with respect to remaining performance obligations related to capital equipment and software-related service agreements and the upfront payments discussed under the heading "Contract Balances" above amounted to approximately $0.8 million at June 30, 2022. The Company expects to recognize approximately 53% 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 $23.5 million and $54.1 million as of June 30, 2022 and December 31, 2021, respectively, is derived using Level 1 inputs. The cash equivalents are comprised of short-term bank deposits,

money market funds, and U.S. Treasury bills with original maturities of three months or less, and the carrying value is a reasonable estimate of fair value.

At June 30, 2022, the Company had $21.6 million of short-term investments, consisting of six and twelve month U.S. Treasury Bills, which are classified as held to maturity and carried at amortized cost, adjusted for the accretion of discounts using the interest method. The carrying value of the debt securities approximates fair value based on Level 1 inputs. The Company has the intent and ability to hold these investments to maturity in order to collect interest payments over the life of the investments.

5. Inventory

Inventory consists of the following as of June 30, 2022 and 2021:

(in thousands)	June 30, 2022	December 31, 2021
Raw materials and work in process	$ 4,753	$ 2,718
Software licenses	210	210
Finished goods	1,676	2,010
Inventory, net, included in current assets	6,639	4,938
Software licenses – non-current	504	519
Total	$ 7,143	$ 5,457

6. Notes Payable

As a result of the transactions described below, an aggregate principal amount of $10 million of the 2020 Secured Convertible Notes was outstanding at June 30, 2022. At the option of the holder, who is a customer and has a representative on the Company's Board of Directors, at any time prior to maturity, 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 (the “2020 Financing Transaction”) with two investors (the "2020 Convertible Noteholders"), whereby the Company issued an aggregate principal amount of $17.5 million of First Closing Notes pursuant to the SPA, which, unless earlier converted or redeemed, mature on the fifth anniversary of the Closing Date 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 may not be pre-paid without the consent of the noteholder, provided that the Company must offer to pre-pay such other noteholder on the same terms and conditions.

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 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 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. 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 amounts of the First Closing Notes in the accompanying June 30, 2022 and December 31, 2021 condensed consolidated balance sheets are presented net of financing costs, comprised of commissions and legal expenses, having an unamortized balance of $0.1 million and $0.2 million at those respective dates. Prior to the conversion of the First Closing Note, the aggregate carrying amount was presented net of a discount, comprised of a commitment fee paid to the Converting Noteholder, amounting to $0.2 million. Upon conversion of the related note, the discount was reversed, with a corresponding amount being recorded as a reduction of additional paid-in capital. The unamortized balances of the financing costs and the discount, during the period prior to the conversion of the related First Closing Note, were charged to interest expense over the respective terms of the First Closing Notes under the effective interest method.

Upon issuance of the Second Closing Note, the carrying amount was presented net of a discount, amounting to approximately $3.1 million, which represented the value of the deemed beneficial conversion feature embedded in the Second Closing Note. A conversion feature is deemed to be beneficial when the conversion price, discussed above, is lower than the closing price per share of the Company's common stock, which was $14.34 on the date of issuance of the Second Closing Note. As discussed in Note 2, effective January 1, 2021, the Company adopted the provisions of ASU 2020-06 which no longer required such beneficial conversion features to be separately accounted for, and as a result, the accompanying December 31, 2021 condensed consolidated balance sheet reflects the elimination of both the discount and a corresponding increase to additional paid-in capital.

Under the terms of the SPA, as amended, the Company had the right, but not the obligation, to request a 2020 Convertible Noteholder to purchase the Third Closing Note, and the 2020 Convertible Noteholder had the right, but not the obligation, to purchase such note. As of January 11, 2022, the Company's right expired.

The 2020 Secured Notes are secured by all the assets of the Company.

An executive officer of one of the 2020 Convertible Noteholders is a member of the Company's Board of Directors.

Scheduled Notes Payable Maturities

Scheduled principal payments as of June 30, 2022 with respect to notes payable are summarized as follows:

Year ending December 31,	*(in thousands)*
2025	$ 10,000
Total scheduled principal payments	10,000
Less: Unamortized financing costs	(135)
Total	$ 9,865

7. Leases

The Company leases space in Irvine, California that houses office space and a manufacturing facility under a non-cancellable lease. The lease term commenced on October 1, 2018 and expires in September 2023. The Company has the option to renew the lease for two additional periods of five years each. The Company also leases office space in Solana Beach, California that serves as its corporate headquarters and houses certain management and research and

development personnel. The lease 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 lease for the office space that encompasses the Company's office space for at least five years. Both leases are classified as operating leases in conformity with GAAP.

The aggregate lease costs, included in general and administrative expense, were $0.1 million for each of the three months ended June 30, 2022 and 2021, and was $0.3 million for the six months ended June 30, 2022 and 2021.

8. Stockholders' Equity

2021 Public Offering

On February 23, 2021, the Company completed a public offering of 2,127,660 shares of its common stock, composed of 1,850,140 shares of common stock initially offered at a public offering price of $23.50 per share and an additional 277,520 shares of common stock sold pursuant to the exercise of the underwriters' option to purchase additional shares at the price of $22.09 per share.

Net proceeds from the offering totaled approximately $46.8 million after deducting underwriting discounts and commissions, and other offering expenses paid by the Company.

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

Share-Based Compensation Expense

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

Three Months Ended June 30, *(in thousands)*		Six Months Ended June 30, *(in thousands)*	
2022	**2021**	**2022**	**2021**
$880	$247	$1,779	$567

As of June 30, 2022, there was $1.8 million and $6.6 million of total unrecognized compensation expense related to stock options and restricted stock, respectively, which is expected to be recognized over a weighted-average period of 2.2 years and 2.4 years, respectively.

Stock Option Activity

Stock option activity under all of the Company's plans during the six months ended June 30, 2022 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, 2021	1,350,473	$ 10.10		
Granted	147,723	$ 10.91		
Exercised	(1,000)	$ 2.60		
Forfeited or expired	(75,723)	$ 40.07		
Outstanding at June 30, 2022	1,421,473	$ 8.59	6.6	$ 10,479

(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 Activity

Restricted stock activity, which includes restricted stock awards ("RSA") and restricted stock unit awards ("RSU"), for the six months ended June 30, 2022 is summarized below:

	Restricted Stock	Weighted - Average Grant Date Fair Value
Outstanding at December 31, 2021	380,105	$ 10.41
Granted	447,175	$ 10.90
Vested	(32,107)	$ 10.01
Forfeited	(22,991)	$ 14.41
Outstanding at June 30, 2022	772,182	$ 10.25

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. The first offering period commenced on July 1, 2021. During the six months ended June 30, 2022, 26,354 shares were purchased at an average per share price of $9.86.

Warrants

Warrants to purchase shares of the Company's common stock were issued in connection with financing transactions in 2015 and 2017. These warrants contain 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 warrants outstanding at June 30, 2022 will terminate in 2023.

Common stock warrant activity for the six months ended June 30, 2022 is as follows:

	Warrant Shares	Weighted-average Exercise price per share	Intrinsic Value[(1)] *(in thousands)*
Outstanding at December 31, 2021	668,907	$ 2.97	
Exercised	(462,353)	$ 2.20	
Terminated	(170,000)	$ 2.20	
Outstanding at June 30, 2022	36,554	$ 16.23	$ —

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

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 2021 Form 10-K and in Part II, Item 1.A of this Quarterly Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements described in the following discussion and analysis. 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. In 2021, our efforts expanded beyond the MRI suite to encompass development and commercialization of new neurosurgical device products for the operating room, as well as 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 collaborating with pharmaceutical and biotech companies, academic institutions, and contract research organizations to develop delivery methodologies for neurological drugs. Currently, there are more than 45 such entities who are either evaluating or using our SmartFlow cannula and, in certain cases, in conjunction with our full ClearPoint Neuro Navigation platform.

In 2010, we received regulatory clearance from the FDA to market our ClearPoint system in the U.S. for general neurosurgery procedures. In 2011, we also obtained CE marking approval for our ClearPoint system, which enables us to sell our ClearPoint system in the European Union. Substantially all our product revenue for the three and six months ended June 30, 2022 and 2021 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, 2022, we had accumulated losses of $142.2 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.

COVID-19

The extraordinary measures taken beginning in 2020 by governmental authorities in response to the novel strain of the coronavirus ("COVID-19") pandemic led to reduced economic activity, including the postponement or cancellation of elective surgical procedures. Although economic activity is returning to normalized levels, new variants of COVID-19 continue to spread in the United States and across the globe.

Furthermore, the recessionary conditions on the global economy caused by the COVID-19 pandemic could have a material adverse effect on our business. Although most segments of the United States economy have reopened, future surges of COVID-19 due to new variants could occur in the future, and directives, such as the postponement or cancellation of elective surgeries, which historically have represented approximately 80% of the number of surgical procedures using our ClearPoint system, could be reinstated. Additionally, global economic and supply chain disruptions, labor shortages and inflationary conditions caused by the COVID-19 pandemic and geopolitical instability could have a material adverse effect on our business. The rapid development and fluidity of the situation precludes any prediction as to the ultimate impact COVID-19 will have on our business, financial condition, results of operation and cash flows, which will depend largely on

future developments, including vaccination rates, the effectiveness of vaccines, the response by governmental authorities and regulators, and the duration and scope of the COVID-19 outbreak in the United States.

Key Performance Indicators

The key performance indicators we utilize to monitor our progress against our strategic plan are:

- Functional neurosurgery navigation
    - Number of "Active Surgery Centers" – For purposes of analyzing this performance indicator, an Active Surgery Center is a hospital or customer-sponsored contract research organization that has purchased products from us or has performed procedures utilizing our ClearPoint system within a rolling 24-month period, and includes hospital sites having purchased the ClearPoint system, as well as sites in which the ClearPoint system is being used on an evaluation basis. The justification for including "evaluation sites" is that our disposable neurosurgery product is sold to such hospitals for their use in cases. In addition to signifying growth, the number of Active Surgery Centers, when analyzed in conjunction with case volume data, further informs targeted sales and marketing activities and confirms where these activities have led to increased penetration of our product lines. As of June 30, 2022, the ClearPoint system was used in approximately 60 Active Surgery Centers, which is comparable to the number of such centers of the same date in 2021.
- Biologics and drug delivery
    - Number of "Partners" – 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, 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, 2022, we had more than 45 Partners, as compared with approximately 35 Partners as of the same date in 2021.

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 marketing approval for our ClearPoint system and SmartFlow cannula, respectively; and in June 2020 we obtained CE marking approval 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. 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 $3.5 million and $6.6 million for the three and six months ended June 30, 2022, respectively, and was almost entirely related to our ClearPoint system. Our service revenue was approximately $1.7 million and $3.6 million for the three and six months ended June 30, 2022, respectively, of which 68% and 69%, respectively, 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.

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 which we have sold, and for which we have recognized the revenue in accordance with our revenue recognition policy, as well as labor hours for the cost of providing 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, 2022, we have incurred approximately $75 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 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, 2022 as compared to the critical accounting policies and estimates described in our 2021 Form 10-K.

Results of Operations

Three Months Ended June 30, 2022 Compared to the Three Months Ended June 30, 2021

	Three Months Ended June 30,		
(Dollars in thousands)	2022	2021	Percentage Change
Product revenue	$ 3,457	$ 2,363	46 %
Service and other revenue	1,743	1,050	66 %
Total revenue	5,200	3,413	52 %
Cost of revenue	1,943	1,139	71 %
Gross profit	3,257	2,274	43 %
Research and development costs	2,284	2,109	8 %
Sales and marketing expenses	2,187	1,590	38 %
General and administrative expenses	2,990	1,982	51 %
Other expense:			
Other expense, net	(8)	(96)	NM%
Interest expense, net	(91)	(240)	(62) %
Net loss	$ (4,303)	$ (3,743)	15 %

NM – The percentage change is not meaningful.

Revenue. Total revenue was $5.2 million for the three months ended June 30, 2022, and $3.4 million for the three months ended June 30, 2021, which represents an increase of $1.8 million, or 52%.

Functional neurosurgery navigation and therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 17% to $2.2 million for the three months ended June 30, 2022, from $1.9 million for the same period in 2021. This increase reflects $0.4 million of service revenue related to development services during the three months ended June 30, 2022 compared to no service revenue for the same period in 2021, partially offset by a $0.1 million decrease in product revenue. There were no increases in functional neurosurgery product prices during the period between the three months ended June 30, 2022 and the same period in 2021 that would be reasonably expected to affect a typical customer order.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored clinical trials utilizing our products, increased 73% to $2.4 million for the three months ended June 30, 2022, from $1.4 million for the same period in 2021. This increase is attributable to a $0.8 million increase in product revenue and $0.2 million increase in service revenue related to new and continued partnerships with pharmaceutical and biotech companies, academic institutions, and contract research organizations during the three months ended June 30, 2022 compared to the same period in 2021. There were no increases in biologics and drug delivery product prices during the period between the three months ended June 30, 2021 and the same period in 2021 that would be reasonably expected to affect a typical customer order.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, increased 282% to $0.6 million for the three months ended June 30, 2022, from $0.2 million for the same period in 2021 due primarily to an increase in the sale of ClearPoint systems. Revenue from this product line historically has varied from quarter to quarter, and overall, we believe that hospitals' capital equipment acquisition activities remain at a low level, relative to the acquisition activity prior to the onset of the COVID-19 pandemic. There were no increases in capital equipment product prices during the period between the three months ended June 30, 2022 and the same period in 2021 that would be reasonably expected to affect a typical customer order.

Cost of Revenue and Gross Profit. Cost of revenue was $1.9 million, resulting in gross profit of $3.3 million and gross margin of 63%, for the three months ended June 30, 2022, and was $1.1 million, resulting in gross profit of $2.3 million and representing a gross margin of 67%, for the three months ended June 30, 2021. The decrease in gross margin was due primarily to an increase in overhead expenses, excess and obsolete reserves and a decreased contribution, during the three months ended June 30, 2022 as compared to the same period in 2021, from functional neurosurgery disposable product

sales, which carry a higher gross margin relative to other product lines, as well as an increased contribution of sales of capital equipment, which carry a relatively lower gross margin. This was partially offset by slightly higher contribution of service revenue, which carries a higher gross margin relative to other product lines.

Research and Development Costs. Research and development costs were $2.3 million for the three months ended June 30, 2022, compared to $2.1 million for the same period in 2021, an increase of $0.2 million, or 8%. The increase was due primarily to increases in product development of $0.1 million resulting from our efforts to expand the applications of our technological platforms.

Sales and Marketing Expenses. Sales and marketing expenses were $2.2 million for the three months ended June 30, 2022, compared to $1.6 million for the same period in 2021, an increase of $0.6 million, or 38%. This increase was due primarily to additional personnel costs resulting from increases in headcount of $0.3 million, as well as increases in travel costs of $0.1 million and marketing activities of $0.1 million.

General and Administrative Expenses. General and administrative expenses were $3.0 million for the three months ended June 30, 2022, compared to $2.0 million for the same period in 2021, an increase of $1.0 million, or 51%. This increase was due primarily to increased share-based compensation of $0.5 million and personnel costs of $0.4 million, both attributed to increases in headcount, and $0.1 million as a result of increased insurance costs.

Interest Expense. Net interest expense for the three months ended June 30, 2022 was $0.1 million, compared to $0.2 million for the same period in 2021, due to the conversion of a portion of the 2020 Secured Convertible Notes in May and November 2021. Additional information with respect to the Secured Notes is in Note 6 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report.

Six Months Ended June 30, 2022 Compared to the Six Months Ended June 30, 2021

	Six Months Ended June 30,		
(Dollars in thousands)	**2022**	**2021**	**Percentage Change**
Product revenue	$ 6,620	$ 5,525	20 %
Service and other revenue	3,611	1,918	88 %
Total revenue	10,231	7,443	37 %
Cost of revenue	3,728	2,555	46 %
Gross profit	6,503	4,888	33 %
Research and development costs	4,817	3,673	31 %
Sales and marketing expenses	4,032	3,165	27 %
General and administrative expenses	5,722	3,638	57 %
Other expense:			
Other income (expense), net	3	(122)	NM%
Interest expense, net	(197)	(571)	(66) %
Net loss	$ (8,262)	$ (6,281)	32 %

NM – The percentage change is not meaningful.

Revenue. Total revenue was $10.2 million for the six months ended June 30, 2022, and $7.4 million for the six months ended June 30, 2021, which represents an increase of $2.8 million, or 37%.

Functional neurosurgery navigation and therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 17% to $4.4 million for the six months ended June 30, 2022, from $3.8 million for the same period in 2021. This increase reflects $0.8 million of service revenue related to development services during the six months ended June 30, 2022 compared to no service revenue for the same period in 2021, partially offset by a $0.1 million decrease in product revenue. There were no increases in functional neurosurgery product prices during the period between the six months ended June 30, 2022 and the same period in 2021 that would be reasonably expected to affect a typical customer order.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored clinical trials utilizing our products, increased 50% to $4.6 million for the six months ended June 30, 2022, from $3.0 million for the same period in 2021. This increase is attributable to a $0.8 million increase in service revenue as well as a $0.7 million increase in product revenue related to new and continued partnerships with pharmaceutical and biotech companies, academic institutions, and contract research organizations during the six months ended June 30, 2022 compared to the same period in 2021. There were no increases in biologics and drug delivery product prices during the period between the six months ended June 30, 2021 and the same period in 2021 that would be reasonably expected to affect a typical customer order.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, increased 105% to $1.3 million for the six months ended June 30, 2022, from $0.6 million for the same period in 2021 due primarily to an increase in the sale of ClearPoint systems. Revenue from this product line historically has varied from quarter to quarter, and overall, we believe that hospitals' capital equipment acquisition activities remain at a low level, relative to the acquisition activity prior to the onset of the COVID-19 pandemic. There were no increases in capital equipment product prices during the period between the six months ended June 30, 2022 and the same period in 2021 that would be reasonably expected to affect a typical customer order.

Cost of Revenue and Gross Profit. Cost of revenue was $3.7 million, resulting in gross profit of $6.5 million and gross margin of 64%, for the six months ended June 30, 2022, and was $2.6 million, resulting in gross profit of $4.9 million and representing a gross margin of 66%, for the six months ended June 30, 2021. The decrease in gross margin was due primarily to a decreased contribution, during the six months ended June 30, 2022 as compared to the same period in 2021, from functional neurosurgery disposable product sales, which carry a higher gross margin relative to other product lines, as well as an increased contribution of sales of capital equipment, which carry a relatively lower gross margin, as well as an increase in the excess and obsolete inventory reserve and higher overhead expenses. This was partially offset by higher contribution of service revenue, which carries a higher gross margin relative to other product lines.

Research and Development Costs. Research and development costs were $4.8 million for the six months ended June 30, 2022, compared to $3.7 million for the same period in 2021, an increase of $1.1 million, or 31%. The increase was due primarily to increases in personnel costs of $0.3 million due to growth in headcount, and product and software development of $0.8 million, both resulting from our efforts to expand the applications of our technological platforms.

Sales and Marketing Expenses. Sales and marketing expenses were $4.0 million for the six months ended June 30, 2022, compared to $3.2 million for the same period in 2021, an increase of $0.9 million, or 27%. This increase was due primarily to additional personnel costs resulting from increases in headcount of $0.3 million, increased marketing activities of $0.2 million, and travel related costs of $0.2 million.

General and Administrative Expenses. General and administrative expenses were $5.7 million for the six months ended June 30, 2022, compared to $3.6 million for the same period in 2021, an increase of $2.1 million, or 57%. This increase was due primarily to increased share-based compensation of $1.1 million and personnel costs of $0.6 million, both attributed to increases in headcount, and $0.2 million as a result of increased insurance costs.

Interest Expense. Net interest expense for the six months ended June 30, 2022 was $0.2 million, compared to $0.6 million for the same period in 2021, due to the conversion of a portion of the 2020 Secured Convertible Notes in May and November 2021. Additional information with respect to the Secured Notes is in Note 6 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report.

Liquidity and Capital Resources

We have incurred net losses since our inception, which has resulted in a cumulative deficit at June 30, 2022 of $142.2 million. In addition, our use of cash from operations amounted to $9.3 million for the six months ended June 30, 2022 and $12.7 million for the year ended December 31, 2021. Since inception, we have financed our operations principally from the sale of equity securities and the issuance of notes payable.

In January 2020, we entered into the SPA with the 2020 Convertible Noteholders under which we issued the First Closing Notes having an aggregate principal amount of $17.5 million, resulting in proceeds, net of financing costs and a commitment fee paid to one of the 2020 Convertible Noteholders, of approximately $16.8 million.

The SPA also gave us the right, but not the obligation, to request one of the 2020 Convertible Noteholders to purchase an additional $5.0 million in principal amount of the Second Closing Note. On December 29, 2020, under the terms of the Amendment to the SPA which, among other provisions, increased the principal amount of the Second Closing Note, we issued the Second Closing Note to one of the 2020 Convertible Noteholders in the principal amount of $7.5 million.

See Note 6 for additional information with respect to the 2020 Secured Notes.

As discussed in Note 8, on February 23, 2021, we completed a public offering of 2,127,660 shares of our common stock. Net proceeds from the offering were approximately $46.8 million after deducting the underwriting discounts and commissions and other estimated offering expenses payable by us.

Based on the foregoing, in management's opinion, cash and cash equivalent balances and short-term investments at June 30, 2022, 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, 2022 and 2021 is summarized as follows:

	Six months ended June 30,	
(in thousands)	**2022**	**2021**
Cash used in operating activities	$ (9,250)	$ (5,849)
Cash used in investing activities	(21,851)	(5)
Cash provided by financing activities	516	47,279
Net change in cash and cash equivalents	$ (30,585)	$ 41,425

Net Cash Flows from Operating Activities. Net cash flows used in operating activities for the six months ended June 30, 2022 were $9.3 million, an increase of $3.4 million from the six months ended June 30, 2021. This increase consisted of a higher net loss of $2.0 million and increased net changes of operating assets and liabilities of $2.4 million, partially offset by a change in non-cash items of $1.0 million. The change in operating assets and liabilities is primarily due to the use of cash for increases in inventory and the change in the non-cash items results from increases in share-based compensation.

Net Cash Flows from Investing Activities. 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 of $21.6 million as well as equipment acquisitions and licensing rights.

Net cash flows used in investing activities for the six months ended June 30, 2021, were less than $0.01 million and consisted of equipment acquisitions.

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

Net cash flows from financing activities for the six months ended June 30, 2021 consisted of the proceeds, net offering costs, of $46.8 million received from the public offering of our common stock, and proceeds from the exercise of common stock options and warrants aggregating $0.5 million.

Operating Capital and Capital Expenditure Requirements

To date, we have not achieved profitability. We could continue to incur net losses as we continue our efforts to expand the commercialization of our 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 the COVID-19 pandemic;
- the timing of broader market acceptance and adoption of our ClearPoint system products;
- the scope, rate of progress and cost of our ongoing product development activities relating to our ClearPoint system;
- the ability of our Partners to achieve commercial success, including their use of our products and services in their 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, three to twelve month U.S. Treasury Bills, 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. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure.

At June 30, 2022, we had $10 million of principal outstanding under a First Closing Note, which is subject to interest rate fluctuations. The note bears 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. At June 30, 2022, the three-month LIBOR was greater than the 2% floor as a result of rising interest rates. If the LIBOR continues to increase, a one-percent to two-percent increase would result in additional annual interest expense of $0.1 million to $0.2 million above the floor, respectively. Information with respect to the First Closing Notes may be found in Note 6 to the condensed consolidated financial statements included elsewhere 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 believe we have no 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, 2022 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, 2022.

Changes in Internal Control Over Financial Reporting

During the quarter ended June 30, 2022, 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.

None.

ITEM 1A. RISK FACTORS.

There have been no material changes to the risk factors disclosed in our 2021 Form 10-K, except as set forth below.

Our business, financial condition, and results of operations may be adversely affected by the current military conflict between Russia and Ukraine, other future social and geopolitical instability and resulting domestic and foreign economic instability.

We are exposed to the risk of changes in social, geopolitical, legal, and economic conditions. The global economy has been, and may continue to be, negatively impacted by Russia's invasion of Ukraine in 2022. As a result of Russia's invasion of Ukraine, various countries have imposed measures including: (i) comprehensive financial sanctions against major Russian banks; (ii) additional designations of Russian individuals with significant business interests and government connections; (iii) designations of individuals and entities involved in Russian military activities; and (iv) enhanced export controls and trade sanctions limiting Russia's ability to import various goods. The negative impacts arising from the conflict and these sanctions and export restrictions, including those imposed by Russia, may include reduced consumer demand, supply chain disruptions, increased cybersecurity risks, and increased costs for transportation, energy, and raw materials. Although none of our operations are in Russia or Ukraine, further escalation of geopolitical tensions could have a broader impact that expands into other markets where we do business, which may adversely affect our business, financial condition and results of operations.

Further, 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 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, could adversely affect our business, financial condition and 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.

None.

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 26, 2022).
3.6	Certificate of Correction of Certificate of Amendment of 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 June 6, 2022).
3.7	Amended and Restated Bylaws of MRI Interventions, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 11, 2012).
3.8	Second Amended and Restated Bylaws of ClearPoint Neuro, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the SEC on February 12, 2020).
3.9	Third Amended and Restated Bylaws of ClearPoint Neuro, Inc. (incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on December 17, 2021).
10.1	ClearPoint Neuro, Inc. Non-Employee Director Compensation Plan, as amended and restated by the Board of Directors on May 21, 2022 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on May 23, 2022).
10.2	Fourth Amended and Restated 2013 Incentive Compensation Plan (incorporated by reference to Appendix A to ClearPoint Neuro, Inc.'s Definitive Proxy Statement on Schedule 14A, filed with the SEC on April 14, 2022).
10.3*	ClearPoint Neuro, Inc. Fourth Amended and Restated 2013 Incentive Compensation Plan Form of Restricted Stock Unit Award Agreement
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 9, 2022

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)

RESTRICTED STOCK UNIT AWARD AGREEMENT
UNDER THE CLEARPOINT NEURO, INC.
FOURTH AMENDED AND RESTATED
2013 INCENTIVE COMPENSATION PLAN

Name of Grantee: _____

No. of Restricted Stock Units: _____

Grant Date: _____

Pursuant to the ClearPoint Neuro, Inc. Fourth Amended and Restated 2013 Incentive Compensation Plan as amended through the date hereof (the "Plan"), ClearPoint Neuro, Inc. (the "Company") hereby grants under this Agreement (the " Agreement") to the Grantee named above the number of Restricted Stock Units specified above (an "Award"), subject to the restrictions and conditions set forth in this Agreement and in the Plan. Each Restricted Stock Unit shall relate to one Share, par value $0.01 per share, of the Company. Capitalized terms in this Agreement shall have the meanings specified in the Plan, unless a different meaning is specified herein.

1. Restrictions on Transfer of Award. This Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of by the Grantee, and any Shares issuable with respect to the Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of until (i) the Restricted Stock Units have vested as provided in Paragraph 2 of this Agreement and (ii) Shares have been issued to the Grantee in accordance with the terms of the Plan and this Agreement.

2. Vesting of Restricted Stock Units. The restrictions and conditions in Section 1 of this Agreement shall lapse on the Vesting Date or Dates specified in the following schedule so long as the Grantee remains in the Employment of the Company or an Affiliate on such dates. If a series of Vesting Dates is specified, then the restrictions and conditions in Section 2 shall lapse only with respect to the number of Restricted Stock Units specified as vested on such date.

Incremental Number of Restricted Stock Units Vested	Vesting Date
_____ (___%)	_____
_____ (___%)	_____
_____ (___%)	_____
_____ (___%)	_____

The Committee may at any time accelerate the vesting schedule specified in this Paragraph 2.

3. Termination of Service. If the Grantee's Employment with the Company and its Affiliates is voluntarily or involuntarily terminated for any reason (including death or disability) prior to the satisfaction of the vesting conditions set forth in Paragraph 2 above, any Restricted Stock Units that have not vested as of such date shall automatically and without notice terminate and be forfeited, and neither the Grantee nor any of his or her successors, heirs, assigns, or personal representatives will thereafter have any further rights or interests in such unvested Restricted Stock Units.

4. Issuance of Shares of Stock. As soon as practicable following each Vesting Date (but in no event later than two and one-half months after the end of the year in which the Vesting Date occurs), the Company shall issue to the Grantee the number of Shares equal to the aggregate number of Restricted Stock Units that have vested pursuant to Paragraph 2 of this Agreement on such date and the Grantee shall thereafter have all the rights of a stockholder of the Company with respect to such Shares.

5. Tax Withholding . The Grantee shall, not later than the date as of which the receipt of this Agreement becomes a taxable event for Federal income tax purposes, pay to the Company or make arrangements satisfactory to the Committee for payment of any Federal, state, and local taxes required by law to be withheld on account of such taxable event. The Company shall have the authority to cause the required tax withholding obligation to be satisfied, in whole or in part, by (i) withholding from Shares to be issued to the Grantee a number of Shares with an aggregate Fair Market Value that would satisfy the withholding amount due; or (ii) causing its transfer agent to sell from the number of Shares to be issued to the Grantee, the number of Shares necessary to satisfy the Federal, state, provincial and local taxes required by law to be withheld from the Grantee on account of such transfer.

6. Incorporation of Plan. Notwithstanding anything herein to the contrary, the Restricted Stock Units shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Committee set forth in Section 4 of the Plan.

7. Section 409A of the Code. This Agreement shall be interpreted in such a manner that all provisions relating to the settlement of the Award are exempt from the requirements of Section 409A of the Code as "short-term deferrals" as described in Section 409A of the Code.

8. No Obligation to Continue Employment. Neither the Company nor any of its Affiliates is obligated by or as a result of the Plan or this Agreement to continue the Grantee in employment and neither the Plan nor this Agreement shall interfere in any way with the right of the Company or any such Affiliate to terminate the employment of the Grantee at any time.

9. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Grantee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

10. Amendment. Pursuant to Section 15 of the Plan, the Committee may at any time amend, alter or discontinue the Plan, but no such action may be taken that adversely affects the Grantee's rights under this Agreement without the Grantee's consent.

11. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Award and supersedes all prior agreements and discussions between the parties concerning such subject matter.

12. No Fractional Shares. No fractional shares of the Company's common stock shall be issued or delivered pursuant to this Agreement, and the Committee shall determine whether cash, other securities or other property shall be paid or transferred in lieu of any such fractional shares or whether such fractional shares or any rights thereto shall be canceled, terminated or otherwise eliminated.

13. Inconsistencies. In the event of an inconsistency between the terms of this Agreement and the Grantee's employment agreement with the Company, if any, the terms of such employment agreement shall govern.

14. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its Affiliates, and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security, social insurance or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the "Relevant Information"). By entering into this Agreement, the Grantee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Grantee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Grantee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

15. Electronic Consent. The Company may choose to deliver certain statutory materials relating to the Plan in electronic form. By accepting this Award, the Grantee agrees that the Company may deliver these materials in an electronic format. If at any time the Grantee would prefer to receive paper copies of these documents, as the Grantee is entitled to, the Company will provide paper copies upon written request by the Grantee to the Secretary of the Company.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Company has executed this Agreement on and as of the day and year first above written.

CLEARPOINT NEURO, INC.

By: _____

Name: _____

Title: _____

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Grantee (including through an online acceptance process) is acceptable.

_____

Grantee's Signature

_____

Grantee's Name

Grantee's Address:

_____

_____

_____

33066102.2

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, 2022, 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 9, 2022

/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, 2022, 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 9, 2022

/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, 2022, 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 9, 2022

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

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