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

FORM 10-Q

(Mark One)

☑ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended **March 31, 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 May 5, 2022, there were 23,717,281 shares of common stock outstanding.

CLEARPOINT NEURO, INC.

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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;
- future revenue from sales of ClearPoint system products and services; 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)

	March 31, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 49,658	$ 54,109
Accounts receivable, net	2,243	2,337
Inventory, net	5,732	4,938
Prepaid expenses and other current assets	380	508
Total current assets	58,013	61,892
Property and equipment, net	709	539
Operating lease rights of use	2,116	2,241
Software license inventory	484	519
Licensing rights	352	265
Other assets	94	125
Total assets	$ 61,768	$ 65,581
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 965	$ 427
Accrued compensation	1,344	2,604
Other accrued liabilities	602	537
Operating lease liabilities, current portion	521	507
Deferred product and service revenue, current portion	541	678
Total current liabilities	3,973	4,753
Operating lease liabilities, net of current portion	1,806	1,939
Deferred product and service revenue, net of current portion	408	264
2020 senior secured convertible notes payable, net	9,851	9,838
Total liabilities	16,038	16,794
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized; none issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Common stock, $0.01 par value; 200,000,000 shares authorized; 23,708,118 shares issued and outstanding at March 31, 2022; and 23,665,991 issued and outstanding at December 31, 2021	237	237
Additional paid-in capital	183,384	182,482
Accumulated deficit	(137,891)	(133,932)
Total stockholders' equity	45,730	48,787
Total liabilities and stockholders' equity	$ 61,768	$ 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 March 31,	
	2022	**2021**
Revenue:		
Product revenue	$ 3,163	$ 3,162
Service and other revenue	1,868	868
Total revenue	5,031	4,030
Cost of revenue	1,785	1,416
Gross profit	3,246	2,614
Research and development costs	2,533	1,563
Sales and marketing expenses	1,845	1,575
General and administrative expenses	2,732	1,657
Operating loss	(3,864)	(2,181)
Other expense:		
Other income (expense), net	11	(25)
Interest expense, net	(106)	(332)
Net loss	$ (3,959)	$ (2,538)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.17)	$ (0.13)
Weighted average shares used in computing net loss per share:		
Basic and diluted	23,682,442	18,852,828

See accompanying notes to Condensed Consolidated Financial Statements.

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

For The Three Months Ended March 31, 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

For The Three Months Ended March 31, 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

See accompanying notes to Condensed Consolidated Financial Statements.

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

	For The Three Months Ended March 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (3,959)	$ (2,538)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for doubtful accounts	(61)	3
Depreciation and amortization	86	15
Share-based compensation	899	320
Payment-in-kind interest	—	94
Amortization of debt issuance costs and original issue discounts	13	35
Amortization of lease rights of use, net of accretion in lease liabilities	133	133
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	155	(126)
Inventory, net	(880)	47
Prepaid expenses and other current assets	128	(10)
Other assets	30	3
Accounts payable and accrued expenses	(692)	(54)
Lease liabilities	(128)	(94)
Deferred revenue	7	41
Net cash flows from operating activities	(4,269)	(2,131)
Cash flows from investing activities:		
Purchases of property and equipment	(69)	(40)
Acquisition of licensing rights	(116)	—
Net cash flows from investing activities	(185)	(40)
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	3	145
Net cash flows from financing activities	3	46,930
Net change in cash and cash equivalents	(4,451)	44,759
Cash and cash equivalents, beginning of period	54,109	20,099
Cash and cash equivalents, end of period	$ 49,658	$ 64,858
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ —	$ —
Interest	$ 100	$ 214

NON-CASH INVESTING AND FINANCING TRANSACTIONS:

- The Company had $0.1 million in capital expenditures accrued but not yet paid at March 31, 2022.

- During the three months ended March 31, 2022 and 2021, the Company recorded net transfers of ClearPoint reusable components having an aggregate net book value of $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 companies.

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, can 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 approximately 45 pharmaceutical companies having a focus on biologics and drug delivery.

COVID-19

The extraordinary measures taken beginning in 2020 by federal, state and local governmental authorities in response to the novel strain of the coronavirus ("COVID-19") pandemic, including "stay-at-home" directives and mandates that substantially restricted daily activities and curtailed or ceased normal business operations, led to reduced economic activity, including the postponement or cancellation of elective surgical procedures, which historically have represented approximately 80% of the number of surgical procedures using the Company's ClearPoint system. Although economic activity is returning to normalized levels, new variants of COVID-19, such as Delta and Omicron, continue to spread in the United States and across the globe. The ultimate impact of the COVID-19 pandemic cannot be predicted at this time, and could depend on numerous factors, including vaccination rates among the population, the effectiveness of vaccines against different variants and the response by governmental bodies and regulators. Management is unable to determine the timing, adoption or viability of periodic resumption, if any, of elective procedures; and the resulting length of time that the COVID-19 pandemic will adversely affect the Company's product revenues.

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. Accordingly, reinstatement of directives and mandates requiring businesses to again curtail or cease normal operations, including the postponement or cancellation of elective surgeries, remains a possibility. Additionally, global economic and supply chain disruptions, labor shortages which may affect the Company's ability to retain and attract new talent, and inflationary conditions caused by the COVID-19 pandemic 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 directly or indirectly relating to 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 March 31, 2022 of $137.9 million. In addition, the Company's use of cash from operations amounted to $4.3 million for the three months ended March 31, 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 Note, 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 5 for additional information with respect to the 2020 Secured Notes.

As discussed in Note 7, on February 23, 2021, the Company completed a public offering of2,127,660 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 at March 31, 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 months ended March 31, 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 (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.

- *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 having been preceded by an evaluation period is recognized at the point in time that the equipment has been delivered to the customer.

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 revenue 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 at the point in time that the related services are performed.

The Company operates in one industry segment, and the vast majority 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 7, and the potential conversion of the First Closing Note, as described in Note 5, 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 holds substantially all its cash and cash equivalents on deposit with financial institutions in the U.S. insured by the Federal Deposit Insurance Corporation. At March 31, 2022, the Company had approximately $44.0 million in bank balances that were in excess of the insured limits.

At March 31, 2022, there were two customers (one of which is a related party as discussed below) whose accounts receivable balances represented 13% 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 5), 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 19% and 17% of total sales in the three-month periods ended March 31, 2022 and 2021, respectively.

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 March 31, 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 5) 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.

3. Revenue Recognition

Revenue by Service Line

	Three Months Ended March 31,	
(in thousands)	**2022**	**2021**
Functional neurosurgery navigation and therapy		
Disposable products	$ 1,863	$ 1,917
Services	375	—
Subtotal – Functional neurosurgery navigation and therapy	2,238	1,917
Biologics and drug delivery		
Disposable products	850	914
Services	1,304	746
Subtotal – Biologics and drug delivery revenue	2,154	1,660
Capital equipment and software		
Systems and software products	450	331
Services	189	122
Subtotal – Capital equipment and software revenue	639	453
Total revenue	$ 5,031	$ 4,030

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 upon delivery of such products or 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 such fees is classified as deferred revenue.

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

The Company offers an upgraded version of its software at no additional charge to customers purchasing a three-year systems service agreement. The transaction prices of the software and the service agreement are determined through an allocation of the service agreement price based on the standalone prices of the software and the service agreements customarily charged by the Company. The transaction price of the software is recognized as revenue upon its installation and comprised less than $0.1 million of unbilled accounts receivable at March 31, 2022 and 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 $0.9 million at March 31, 2022. The Company expects to recognize approximately54% of this revenue over the next twelve months and the remainder thereafter.

4. Inventory

Inventory consists of the following as of March 31, 2022 and 2021:

(in thousands)	March 31, 2022	December 31, 2021
Raw materials and work in process	$ 3,620	$ 2,718
Software licenses	210	210
Finished goods	1,902	2,010
Inventory, net, included in current assets	5,732	4,938
Software licenses – non-current	484	519
Total	$ 6,216	$ 5,457

5. 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 March 31, 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 of5% 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 March 31, 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. Pursuant to the terms of the SPA and a Board Observer Agreement entered into by the other 2020 Convertible Noteholder and the Company, the other 2020 Convertible Noteholder appointed a representative to attend and observe meetings of the Company's Board of Directors. On February 25, 2021, such 2020 Convertible Noteholder terminated the Board Observer Agreement, thus precluding its representative from attending future meetings of the Company's Board of Directors.

Scheduled Notes Payable Maturities

Scheduled principal payments as of March 31, 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	(149)
Total	9,851

6. 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 March 31, 2022 and 2021.

7. 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 selling, general and administrative expense in the condensed consolidated statements of operations:

Three Months Ended March 31, *(in thousands)*	
2022	**2021**
$899	$320

As of March 31, 2022, there was $0.9 million and $2.7 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 1.8 years and 2.1 years, respectively.

Stock Option Activity

Stock option activity under all of the Company's Plans during the three months ended March 31, 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	—	—		
Exercised	(1,000)	$ 2.60		
Forfeited or expired	(24,933)	$ 37.68		
Outstanding at March 31, 2022	1,324,540	$ 9.59	6.25	$ 7,499

(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 award ("RSA") activity for the three months ended March 31, 2022 is summarized below:

	Restricted Stock Award	Weighted - Average Grant Date Fair Value
Outstanding at December 31, 2021	380,105	$ 10.41
Granted	39,916	$ 8.63
Vested	(10,089)	$ 9.77
Forfeited or expired	(10,000)	$ 20.45
Outstanding at March 31, 2022	399,932	$ 9.79

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 are available for issuance pursuant to the terms of the ESPP. During the year ended December 31, 2021, 22,918 shares were purchased at an average per share price of $9.78. As of March 31, 2022, 377,082 shares of common stock were available for issuance under the Purchase Plan.

Warrants

Warrants to purchase shares of the Company's common stock were issued in connection with financing transactions in 2015 and 2017, and are for a term of generally five years. 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 March 31, 2022 will terminate in 2022 and 2023.

Common stock warrant activity for the three months ended March 31, 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	(14,728)	$ 2.20	
Outstanding at March 31, 2022	654,179	$ 2.98	$ 5,071

(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 companies.

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 companies in the biologics and drug delivery space to develop delivery methodologies for neurological drugs. Currently, approximately 45 of whom 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 months ended March 31, 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 March 31, 2022, we had accumulated losses of $137.9 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 federal, state and local governmental authorities in response to the novel strain of the coronavirus ("COVID-19") pandemic, including "stay-at-home" directives and mandates that substantially restricted daily activities and curtailed or ceased normal business operations, led to reduced economic activity, including the postponement or cancellation of elective surgical procedures, which historically have represented approximately 80% of the number of surgical procedures using our ClearPoint system. Although economic activity is returning to normalized levels, new variants of COVID-19, such as Delta and Omicron, continue to spread in the United States and across the globe. The ultimate impact of the COVID-19 pandemic cannot be predicted at this time, and could depend on numerous factors, including vaccination rates among the population, the effectiveness of vaccines against different variants and the response by governmental bodies and regulators. We are unable to determine the timing, adoption or viability of periodic resumption, if any, of elective procedures; and the resulting length of time that the COVID-19 pandemic will adversely affect our product revenues.

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. Accordingly, reinstatement of directives and mandates requiring

businesses to again curtail or cease normal operations, including the postponement or cancellation of elective surgeries, remains a possibility. Additionally, global economic and supply chain disruptions, labor shortages, which may affect our ability to retain and attract new talent, and inflationary conditions caused by the COVID-19 pandemic 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 directly or indirectly relating to 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 March 31, 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 customers, or "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 these Partners in support of their clinical trials is indicative of growth, the number of such relationships is also of importance as we recognize the possibility that some Partners' research will reach commercial success, and others may not. To the extent our Partners achieve commercial success, our expectation is that we will share in such success through our Partners' use of our products and services in their delivery of therapies. At March 31, 2022, we had commercial relationships with approximately 45 Partners, as compared with approximately 25 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 $3.2 million for the three months ended March 31, 2022, and was almost entirely related to our ClearPoint system. Our service revenue was approximately $1.9 million for the three months ended March 31, 2022, of which 70% 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 March 31, 2022, we have incurred approximately $73 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 related share-based compensation; marketing costs; professional fees, including fees for outside attorneys and accountants; occupancy costs; insurance; and other general and administrative expenses, which include, but are not limited to, corporate licenses, director fees, hiring costs, taxes, postage, office supplies, information technology and meeting costs. Our sales and marketing expenses are expected to increase due to costs associated with the commercialization of our ClearPoint system and the increased headcount necessary to support growth in operations.

Critical Accounting Policies

There have been no significant changes in our critical accounting policies during the three months ended March 31, 2022 as compared to the critical accounting policies described in our 2021 Form 10-K.

Results of Operations

Three Months Ended March 31, 2022 Compared to the Three Months Ended March 31, 2021

(Dollars in thousands)	Three Months Ended March 31, 2022	2021	Percentage Change
Product revenue	$ 3,163	$ 3,162	— %
Service and other revenue	1,868	868	115 %
Total revenue	5,031	4,030	25 %
Cost of revenue	1,785	1,416	26 %
Gross profit	3,246	2,614	24 %
Research and development costs	2,533	1,563	62 %
Sales and marketing expenses	1,845	1,575	17 %
General and administrative expenses	2,732	1,657	65 %
Other expense:			
Other income (expense), net	11	(25)	NM%
Interest expense, net	(106)	(332)	(68) %
Net loss	$ (3,959)	$ (2,538)	56 %

NM – The percentage change is not meaningful.

Revenue. Total revenue was $5.0 million for the three months ended March 31, 2022, and $4.0 million for the three months ended March 31, 2021, which represents an increase of $1.0 million, or 25%.

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 March 31, 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 March 31, 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 March 31, 2021 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 30% to $2.2 million for the three months ended March 31, 2022, from $1.7 million for the same period in 2021. This increase is attributable to a $0.6 million increase in service revenue related to new and continued partnerships with pharmaceutical companies and research organizations during the three months ended March 31, 2022 compared to the same period in 2021. This is partially offset by a $0.1 million decrease in product revenue. There were no increases in biologics and drug delivery product prices during the period between the three months ended March 31, 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 41% to $0.6 million for the three months ended March 31, 2022, from $0.5 million for the same period in 2021. 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 March 31, 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 $1.8 million, resulting in gross profit of $3.2 million and gross margin of 65%, for the three months ended March 31, 2022, and was $1.4 million, resulting in gross profit of $2.6 million and representing a gross margin of 65%, for the three months ended March 31, 2021. Gross margin was consistent for the three months ended March 31, 2022 due to an increased contribution of service revenue, which carries a higher gross

margin relative to our product lines as compared to the same period in 2021, which was fully offset by an increase in the excess and obsolete inventory reserve.

Research and Development Costs. Research and development costs were $2.5 million for the three months ended March 31, 2022, compared to $1.6 million for the same period in 2021, an increase of $1.0 million, or 62%. The increase was due primarily to increases in personnel costs of $0.3 million due to growth in headcount, and product development of $0.7 million, both resulting from our efforts to expand the applications of our technological platforms.

Sales and Marketing Expenses. Sales and marketing expenses were $1.8 million for the three months ended March 31, 2022, compared to $1.6 million for the same period in 2021, an increase of $0.3 million, or 17%. This increase was due primarily to increases in personnel costs resulting from increases in headcount of $0.2 million and marketing activities of $0.1 million.

General and Administrative Expenses. General and administrative expenses were $2.7 million for the three months ended March 31, 2022, compared to $1.7 million for the same period in 2021, an increase of $1 million, or 65%. This increase was due primarily to increased share-based compensation of $0.6 million and personnel costs of $0.3 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 March 31, 2022 was $0.1 million, compared to $0.3 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 5 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 March 31, 2022 of $137.9 million. In addition, our use of cash from operations amounted to $4.3 million for the three months ended March 31, 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 5 for additional information with respect to the 2020 Secured Notes.

As discussed in Note 7, 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 at March 31, 2022, are sufficient to support our operations and meet our obligations for at least the next twelve months.

Cash Flows

Cash activity for the three months ended March 31, 2022 and 2021 is summarized as follows:

	Three months ended March 31,	
(in thousands)	**2022**	**2021**
Cash used in operating activities	$ (4,269)	$ (2,131)
Cash used in investing activities	(185)	(40)
Cash provided by financing activities	3	46,930
Net change in cash and cash equivalents	$ (4,451)	$ 44,759

Net Cash Flows from Operating Activities. Net cash flows used in operating activities for the three months ended March 31, 2022 were $4.3 million, an increase of $2.1 million from the three months ended March 31, 2021. This increase consisted of a higher net loss of $1.4 million and increased net changes of operating assets and liabilities of $1.2 million, partially offset by a change in non-cash items of $0.5 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 shared-based compensation.

Net Cash Flows from Investing Activities. Net cash flows used in investing activities for the three months ended March 31, 2022 were $0.2 million and consisted of equipment acquisitions and licensing rights.

Net cash flows used in investing activities for the three months ended March 31, 2021, were $0.04 million and consisted of an acquisition of medical device license rights.

Net Cash Flows from Financing Activities. Net cash flows from financing activities for the three months ended March 31, 2022, consisted of proceeds from the exercise of common stock options.

Net cash flows from financing activities for the three months ended March 31, 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 $0.1 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 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 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 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 March 31, 2022, we had $10 million of principal outstanding under a First Closing Note, which is subject to interest rate fluctuations. A one-percent increase in one-month LIBOR would result in no net increase in interest expense on an annualized basis due to the fact that the First Closing Note is subject to a LIBOR floor of 2.00% and one-month LIBOR was below the floor as of March 31, 2022. Information with respect to the First Closing Notes may be found in Note 5 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 March 31, 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 March 31, 2022.

Changes in Internal Control Over Financial Reporting

During the quarter ended March 31, 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 and other future social and geopolitical 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, the United States, the European Union, the United Kingdom, and other G7 countries, among other countries, have imposed substantial financial and economic sanctions on certain industry sectors and parties in Russia. Broad restrictions on exports to Russia have also been imposed. These measures include: (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 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.

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
10.1	Confidential Resignation Agreement, dated as of February 14, 2022, by and between the Company and Peter G. Piferi (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on February 14, 2022).
10.2	Independent Consultant Agreement, dated as of dated as of February 14, 2022, by and between the Company and Peter G. Piferi (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on February 14, 2022).
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: May 11, 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)

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 March 31, 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: May 11, 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 March 31, 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: May 11, 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 March 31, 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: May 11, 2022

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

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