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, 2021

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)

(949) 900-6833
(Registrant's Telephone Number, Including Area Code)

5 Musick
Irvine, California 92618
(Former name, former address and former fiscal year, if change since last report)

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

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

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

As of May 7, 2021, there were 20,761,486 shares of common stock outstanding.

CLEARPOINT NEURO, INC.

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Trademarks, Trade Names and Service Marks

ClearPoint Neuro®, *ClearPoint*®, *ClearTrace*®, *SmartFlow*®, *Inflexion*™ and *MRI Interventions*® are 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, 2020, which we filed with the United States Securities and Exchange Commission ("SEC") on March 22, 2021 (the "2020 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, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 64,858	$ 20,099
Accounts receivable, net	2,004	1,881
Inventory, net	3,266	3,238
Prepaid expenses and other current assets	254	244
Total current assets	70,382	25,462
Property and equipment, net	292	319
Operating lease rights of use	2,613	2,736
Software license inventory	589	589
Licensing rights	331	353

Other assets	56	59
Total assets	$ 74,263	$ 29,518
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 727	$ 300
Accrued compensation	990	1,595
Other accrued liabilities	473	349
Operating lease liabilities, current portion	430	394
Deferred product and service revenue	501	562
Total current liabilities	3,121	3,200
Operating lease liabilities, net of current portion	2,327	2,446
Deferred product and service revenue, net of current portion	318	215
2020 senior secured convertible notes payable, net	24,515	21,280
Total liabilities	30,281	27,141
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized; none issued and outstanding at March 31, 2021 and December 31, 2020	—	—
Common stock, $0.01 par value; 200,000,000 shares authorized; 20,678,280 shares issued and outstanding at March 31, 2021; and 17,047,584 issued and outstanding at December 31, 2020	207	170
Additional paid-in capital	165,835	121,729
Accumulated deficit	(122,060)	(119,522)
Total stockholders' equity	43,982	2,377
Total liabilities and stockholders' equity	$ 74,263	$ 29,518

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,	
	2021	**2020**
Revenue:		
Product revenue	$ 3,162	$ 2,179
Service and other revenue	868	937
Total revenue	4,030	3,116
Cost of revenue	1,416	932
Research and development costs	1,563	818
Sales and marketing expenses	1,575	1,299
General and administrative expenses	1,657	1,276
Operating loss	(2,181)	(1,209)
Other expense:		
Other expense, net	(25)	(4)
Interest expense, net	(332)	(842)
Net loss	$ (2,538)	$ (2,055)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.13)	$ (0.13)
Weighted average shares outstanding:		
Basic and diluted	18,852,828	15,438,276

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, 2021

	Common Stock		Additional Paid-in	Accumulated	
	Shares	**Amount**	**Capital**	**Deficit**	**Total**
Balances, January 1, 2021	17,047,584	$ 170	$ 121,729	$ (119,522)	$ 2,377
Adoption of ASU 2020-06 (Note 2)	—	—	(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

For The Three Months Ended March 31, 2020

	Common Stock		Additional Paid-in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balances, January 1, 2020	15,235,308	$ 152	$ 117,174	$ (112,740)	$ 4,586
Issuances of common stock:					
Share-based compensation	9,696	—	228	—	228
Warrant exercises (cashless)	262,145	3	(3)	—	—
Net loss for the period	—	—	—	(2,055)	(2,055)
Balances, March 31, 2020	15,507,149	$ 155	$ 117,399	$ (114,795)	$ 2,759

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,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (2,538)	$ (2,055)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	15	58
Share-based compensation	320	228
Payment-in-kind interest	94	—
Amortization of debt issuance costs and original issue discounts	35	787
Amortization of lease rights of use, net of accretion in lease liabilities	133	25
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(123)	105
Inventory, net	47	(365)
Prepaid expenses and other current assets	(10)	169
Other assets	3	70
Accounts payable and accrued expenses	(54)	(161)
Accrued interest	—	(960)
Lease liabilities	(94)	(23)
Deferred revenue	41	(209)
Net cash flows from operating activities	(2,131)	(2,331)
Cash flows from investing activities:		
Purchases of property and equipment	(40)	—
Acquisition of licensing rights	—	(441)
Net cash flows from investing activities	(40)	(441)
Cash flows from financing activities:		
Proceeds from issuance of 2020 senior secured convertible notes, net of financing costs and discount	—	16,890
Proceeds from public offering of common stock, net of offering costs	46,785	—
Proceeds from stock option and warrant exercises	145	—
Repayment of notes payable	—	(2,838)
Net cash flows from financing activities	46,930	14,052
Net change in cash and cash equivalents	44,759	11,280
Cash and cash equivalents, beginning of period	20,099	5,696
Cash and cash equivalents, end of period	$ 64,858	$ 16,976
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ —	$ —
Interest	$ 214	$ 1,043

NON-CASH TRANSACTIONS:

- During the three months ended March 31, 2021 and 2020, the Company recorded net transfers of ClearPoint reusable components having an aggregate net book value of $0.06 million and $0.03 million, respectively, from loaned systems, which are included in property and equipment in the accompanying condensed consolidated balance sheets, to inventory.
- In connection with its issuance of the 2020 Secured Notes (see Note 1), the Company incurred financing costs of $0.1 million that were included in accounts payable at March 31, 2020.
- 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.

ClearPoint Neuro, Inc.

Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Description of the Business and Financial Condition

ClearPoint Neuro, Inc. (the "Company") is a medical device company focused on the development and commercialization of technology that enables physicians to see inside the brain using direct, intra-procedural magnetic resonance imaging ("MRI") guidance while performing minimally invasive surgical procedures.

The Company's ClearPoint® system, an integrated system comprised of capital equipment and disposable products, is designed to allow minimally invasive procedures in the brain to be performed in an MRI suite. 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 neurological interventional procedures.

COVID-19

On March 11, 2020, the World Health Organization characterized the spread of a novel strain of coronavirus ("COVID-19") as a global pandemic, and on March 13, 2020, the President of the United States proclaimed that the COVID-19 outbreak in the United States constituted a national emergency. Continued widespread infection in the United States is a possibility. Extraordinary actions have been taken by federal, state and local governmental authorities to combat the spread of COVID-19, including issuance of "stay-at-home" directives and similar mandates for many individuals to substantially restrict daily activities and for many businesses to curtail or cease normal operations. These measures, while intended to protect human life, have 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.

Furthermore, the recessionary conditions on the global economy caused by the COVID-19 pandemic could have a material adverse effect on the Company's business, as hospitals postpone or reduce capital purchases and overall spending. Although most segments of the United States economy have reopened, the effects of the COVID-19 pandemic remain intense in many areas of the country, and many public health experts continue to warn of the potential for future surges of COVID-19. 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. The continuing uncertainty as to whether the federal government will address the resulting fiscal condition in both the near term and long term with measures such as additional fiscal stimulus, as well as other geopolitical issues relating to the global economic slowdown, has increased domestic and global instability. The rapid development and fluidity of the situation preclude 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, 2021 of $122 million. In addition, the Company's use of cash from operations amounted to $2.1 million for the three months ended March 31, 2021 and $7.8 million for the year ended December 31, 2020. Since its inception, the Company has financed its operations principally from the sale of equity securities, the issuance of notes payable, product and service contracts and license arrangements.

In January 2020, the Company entered into a Securities Purchase Agreement (the "SPA") with two investors (the "2020 Convertible Noteholders") under which the Company issued an aggregate principal amount of $17.5 million of floating rate secured convertible notes (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. From the net proceeds received from the issuance of the First Closing Notes, which have a five-year term, the Company repaid and retired the 2010 Junior Secured Notes Payable (the "2010 Secured Notes") that otherwise would have matured in October and November 2020.

ClearPoint Neuro, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

The SPA also gave the Company the right, but not the obligation, to request one of the 2020 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 which, among other provisions, increased the principal amount of the Second Closing Note, the Company issued the Second Closing Note to the 2020 Convertible Noteholder in the principal amount of $7.5 million.

In April 2020, the Company received $0.9 million in proceeds through a loan funded under the Payroll Protection Program as part of the CARES Act (the "PPP Loan"). In November 2020, the Company was notified by the U.S. Small Business Administration that the loan had been forgiven under the provision of the CARES Act.

See Note 5 for additional information with respect to the 2020 Secured Notes and the PPP Loan.

As discussed in Note 7, 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 at March 31, 2021, 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, 2020 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 2020 Form 10-K. The accompanying condensed consolidated balance sheet as of December 31, 2020 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, 2021 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 potential 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 in the functional neurosurgery field. 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 of being 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) 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 recognized at the point in time of delivery to the customer, which is the point at which legal title, and risks and rewards of ownership, along with physical possession, transfer to the customer.

- *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 of generally 90 days. 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.

- *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-Outsourced technical clinical support of cases performed pursuant to customer-sponsored clinical trials:*

- *Service Access Fees:* For contracts in which the Company receives a periodic fixed fee, irrespective of the number of cases attended by Company personnel 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.

- *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.

- *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 substantially all its sales are to U.S.-based customers.

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

The Company provides a one-year warranty on its functional neurosurgery navigation products, biologics and drug delivery products, and capital equipment and software products that are not otherwise covered by a third-party manufacturer's warranty. The Company's contracts with customers do not provide for a right of return other than for product defects.

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 2020 Secured Notes and the Second Closing Note, as described in Note 5, would be anti-dilutive.

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, 2021, the Company had approximately $60 million in bank balances that were in excess of the insured limits.

One customer accounted for 14% of accounts receivable at March 31, 2021, and one customer accounted for 11% of accounts receivable at December 31, 2020.

One customer, a related party as discussed in Note 3, accounted for 17% and 28% of total sales in the three-month periods ended March 31, 2021 and 2020, 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 each of March 31, 2021 and December 31, 2020 was $0.06 million.

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; 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.

Reclassifications

The accompanying consolidated statement of operations for the three months ended March 31, 2021 contains: (a) certain items formerly classified as service revenue that that have been reclassified to product revenue; (b) certain items formerly classified as general and administrative expenses, research and development expenses, and sales and marketing expenses that have been reclassified to cost of revenue; and (c) an item formerly classified as interest expense that has been reclassified as other expense. The accompanying condensed consolidated statement of operations for the three months ended March 31, 2020 has been conformed to the 2021 presentation.

ClearPoint Neuro, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

3. Revenue Recognition

Revenue by Service Line

(in thousands)	Three Months Ended March 31, 2021	2020
Functional neurosurgery navigation and therapy		
Disposable products	$ 1,917	$ 1,742
Biologics and drug delivery		
Disposable products	914	173
Services	746	856
Subtotal – biologics and drug delivery revenue	1,660	1,029
Capital equipment and software		
Systems and software products	331	264
Services	122	81
Subtotal – capital equipment and software revenue	453	345
Total revenue	$ 4,030	$ 3,116

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 unearned portion of such service fees is classified as deferred revenue.

  During the three months ended March 31, 2021, 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, 2020.

In 2019, the Company entered into a Development Services Agreement with a customer under which the Company was entitled to bill the customer for an upfront payment of $0.13 million, of which approximately $0.06 million is included in deferred revenue in each of the accompanying March 31, 2021 and December 31, 2020 condensed consolidated balance sheets.

Commencing in 2019, the Company was a party to a Letter of Intent and a related Statement of Work (together with the Letter of Intent, the "Project Documents") with a customer who is a stockholder and a noteholder (see Note 5), and an officer of whom is a member of the Company's Board of Directors, to commence a product development project. Under the terms of the Project Documents, the Company was entitled to bill the customer for: (a) an upfront, nonrefundable payment of $0.5 million which was received in 2019; and (b) quarterly service fees of $0.5 million. In February 2020, the Company entered into a Supply Agreement and a Statement of Work (the "European SOW") with a European affiliate of the customer. Under the terms of the European SOW, the Company was entitled to bill the customer on a quarterly basis, commencing in the first quarter of 2020, for service fees of $0.25 million. During 2020, the clinical trials contemplated by the Project Documents and the European SOW were delayed as a result of the COVID-19 pandemic. As a result, the Company agreed to reduce such quarterly service fees by an aggregate of $0.25 million through September 30, 2020. In November 2020, the Company entered into an addendum to the Project Documents and the European SOW that, among other provisions, set the customer's aggregate at $0.7 million per quarter, effective October 1, 2020. The Company recognized as revenue the upfront payment described in this paragraph ratably over the initial two years of the term of the Project Documents, corresponding to the estimated period in which the related performance obligations were expected to be satisfied, and recognizes as revenue the quarterly service fees described in this paragraph as stand-by services beginning in the quarter such services commenced. Based on the foregoing: (a) the Company recognized revenue of approximately $0.7 million for each of the three months ended March 31, 2021 and 2020; (b) there was no accounts receivable balance from the customer at March 31, 2021; accounts receivable from the customer at December 31, 2020 amounted to approximately $0.1 million; and (c) approximately $0.07 million and $0.1 million of the aggregate amount of all the payments described in this paragraph were included in deferred revenue in the accompanying condensed consolidated balance sheets at March 31, 2021 and December 31, 2020, respectively.

ClearPoint Neuro, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

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 approximately $0.1 million of unbilled accounts receivable at each of March 31, 2021 and December 31, 2020.

Remaining Performance Obligations

The Company's contracts with customers, other than capital equipment and software-related service agreements discussed below, are predominantly of terms less than one year. Accordingly, the transaction prices of remaining performance obligations related to such contracts at March 31, 2021 are not material.

Revenue with respect to remaining performance obligations related to capital equipment and software-related service agreements with original terms in excess of one year and the upfront payments discussed under the heading "Contract Balances" above amounted to approximately $0.6 million at March 31, 2021. The Company expects to recognize this revenue within the next three years.

4. Inventory

Inventory consists of the following as of:

(in thousands)	March 31, 2021	December 31, 2020
Raw materials and work in process	$ 1,630	$ 1,485
Software licenses	175	193
Finished goods	1,461	1,560
Inventory, net, included in current assets	3,266	3,238
Software licenses – non-current	589	589
Total	$ 3,855	$ 3,827

5. Notes Payable

On January 29, 2020 (the "Closing Date"), the Company completed a financing transaction (the "2020 Financing Transaction") with the 2020 Convertible Noteholders, whereby the Company issued an aggregate principal amount of $17,500,000 of the First Closing Notes pursuant to the SPA dated January 11, 2020. Unless earlier converted or redeemed, the First Closing Notes will 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.

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

The aggregate carrying amount of the First Closing Notes in the accompanying March 31, 2021 and December 31, 2020 condensed consolidated balance sheets is presented net of: (a) financing costs, comprised of commissions and legal expenses, having an unamortized balance of $0.3 million and $0.4 million at those respective dates; and (b) a discount, comprised of a commitment fee paid to one of the 2020 Convertible Noteholders, having an unamortized balance amounting to $0.2 million at each of those respective dates. The unamortized balance of the financing costs and the discount are charged to interest expense over the term of the First Closing Notes under the effective interest method.

The carrying amount of the Second Closing Note in the accompanying December 31, 2020 consolidated balance sheet is presented net of a discount, amounting to approximately $3.1 million at December 31, 2020, and representing the value of the deemed beneficial conversion feature embedded in the Second Closing Note. A beneficial 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. Under GAAP in existence at the date of issuance of the Second Closing Note, the resulting discount was calculated as the product of (i) the number of shares into which the Second Closing Note could be converted, multiplied by (ii) the difference between the closing price per share and the conversion price. Upon recordation of the discount, a corresponding amount was added to additional paid-in capital. As discussed in Note 2, effective January 1, 2021, the Company adopted the provisions of the ASU that no longer required such beneficial conversion features to be separately accounted for as previously described in this paragraph. As a result, the accompanying March 31, 2021 condensed consolidated balance sheet reflects the elimination of both the discount and the corresponding increase to additional paid-in capital previously described in this paragraph.

Under the terms of the SPA, as amended, the Company retains the right, but not the obligation, to request the 2020 Convertible Noteholder to purchase the Third Closing Note, and the 2020 Convertible Noteholder has the right, but not the obligation, to purchase such note. As of March 31, 2021, the Company had not made such a request.

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, and, 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.

On January 27, 2020, as a condition to completion of the 2020 Financing Transaction, the Company entered into the Fourth Omnibus Amendment to notes the 2010 Secured Notes, whereby the 2010 Secured Notes were subordinated to the Company's obligations under the terms of the 2020 Secured Notes and the Additional Convertible Notes, as applicable. During the three months ended March 31, 2020, the Company repaid in full the aggregate outstanding principal amount of the 2010 Secured Notes, amounting to approximately $2.8 million, which, along with the Company's payment of accrued interest amounting to approximately $0.9 million, resulted in the full retirement of the 2010 Secured Notes.

Scheduled Notes Payable Maturities

Scheduled principal payments as of March 31, 2021 with respect to notes payable are summarized as follows:

Years ending December 31,	*(in thousands)*
2025	$ 25,097
Total scheduled principal payments	25,097
Less: Unamortized financing costs and discount	(582)
Total	$ 24,515

6. Leases

The Company leases office space in Irvine, California that houses office space and manufacturing facility under a non-cancellable operating 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 houses certain management, and research and development personnel, and now serves as its corporate headquarters. 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 office leases are classified as operating leases in conformity with GAAP.

The lease cost, included in general and administrative expense, was $0.1 million and $0.03 million for the three months ended March 31, 2021 and 2020, respectively.

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.

Issuance of Common Stock in Lieu of Cash Payments

Under the terms of the Amended and Restated Non-Employee Director Compensation Plan, each compensated non-employee member of the Company's Board of Directors may elect to receive all or part of his or her director fees in shares of the Company's common stock. Director fees, whether paid in cash or in shares of common stock, are payable quarterly on the last day of each fiscal quarter. The number of shares of common stock issued to directors is determined by dividing the product of: (i)(a) the fees otherwise payable to each director in cash, times (b) the percentage of fees the director elected to receive in shares of common stock, by (ii) the volume weighted average price per share of common stock over the last five trading days of the quarter. During the three months ended March 31, 2021 and 2020, 2,009 shares and 9,731 shares, respectively, were issued to directors as payment for director fees amounting to $0.04 million in each of the three-month periods ended March 31, 2021 and 2020.

Stock Incentive Plans

The Company has various share-based compensation plans and share-based compensatory contracts (collectively, the "Plans") under which it has granted share-based awards, such as stock grants, and incentive and non-qualified stock options, to employees, directors, consultants and advisors. Awards may be subject to a vesting schedule as set forth in individual award agreements. Certain of the Plans also have provided for cash-based performance bonus awards.

From October 2017 until June 2020, the Company granted share-based awards under the Company's Second Amended and Restated 2013 Incentive Compensation Plan (the "Second Amended Plan"). On June 2, 2020, the Company's stockholders approved the Company's Third Amended and Restated 2013 Incentive Compensation Plan (the "Third Amended Plan" and, together with the Second Amended Plan, the "2013 Plan"), under which 1.0 million shares of the Company's common stock were made available for future issuances under the 2013 Plan, resulting in a total of 2,956,250 shares of the Company's common stock being reserved for issuance under the 2013 Plan. Of this amount, stock grants of 681,192 shares have been awarded and option grants, net of options terminated, expired or forfeited, of 1,269,947 shares were outstanding as of March 31, 2021. Accordingly, 1,005,111 shares remained available for grants under the 2013 Plan as of that date.

Stock option activity under all of the Company's Plans during the three months ended March 31, 2021 is summarized below:

	Shares	Weighted-average Exercise price per share	Intrinsic Value[(1)] *(in thousands)*
Outstanding at January 1, 2021	1,806,092	$ 7.12	$ 20,760
Exercised	(416,900)	2.60	
Outstanding at March 31, 2021	1,389,192	$ 8.46	$ 21,516

(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.

As of March 31, 2021, there was unrecognized compensation expense of approximately $1.8 million related to outstanding stock options and shares of restricted stock, which is expected to be recognized over a weighted average period of 2.16 years.

Warrants

Warrants have generally been issued in connection with financing transactions and for terms of up to five years. Common stock warrant activity for the three months ended March 31, 2021 was as follows:

	Shares	Weighted-average Exercise price per share	Intrinsic Value[1] *(in thousands)*
Outstanding at January 1, 2021	3,082,987	$ 3.82	$ 37,379
Exercised	(1,150,647)	2.31	
Outstanding at March 31, 2021	1,932,340	$ 4.72	$ 31,778

(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.

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 2020 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 medical device company that develops and commercializes innovative platforms for performing minimally invasive surgical procedures in the brain under direct, intra-procedural MRI guidance. Our principal product platform is our ClearPoint system, which is in commercial use and is used to perform minimally invasive surgical procedures in the brain. The ClearPoint system utilizes intra-procedural MRI to guide the procedures and is designed to work in a hospital's existing MRI suite. We believe that this product platform delivers better patient outcomes, enhances revenue potential for both physicians and hospitals, and reduces costs to the healthcare system.

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, 2021 and 2020 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, the issuance of convertible and other secured notes, and license arrangements. We have incurred significant losses since our inception in 1998 as we have devoted substantial efforts to research and development. As of March 31, 2021, we had accumulated losses of approximately $122 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

On March 11, 2020, the World Health Organization characterized the spread of COVID-19 as a global pandemic, and on March 13, 2020, the President of the United States proclaimed that the COVID-19 outbreak in the United States constituted a national emergency. Continued widespread infection in the United States is a possibility. Extraordinary actions have been taken by federal, state and local governmental authorities to combat the spread of COVID-19, including issuance of "stay-at-home" directives and similar mandates for many individuals to substantially restrict daily activities and for many businesses to curtail or cease normal operations. These measures, while intended to protect human life, have 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.

Furthermore, the recessionary conditions on the global economy caused by the COVID-19 pandemic could have a material adverse effect on the Company's business, as hospitals postpone or reduce capital purchases and overall spending. Although most segments of the United States economy have reopened, the effects of the COVID-19 pandemic remain intense in many areas of the country, and many public health experts continue to warn of the potential for future surges of COVID-19. 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. The continuing uncertainty as to whether the federal government will address the resulting fiscal condition in both the near term and long term with measures such as additional fiscal stimulus, as well as other geopolitical issues relating to the global economic slowdown, has increased domestic and global instability. The rapid development and the fluidity of the situation preclude 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.

Key Performance Indicators

The key performance indicators we utilize on a tactical basis are integrated into our longer-term strategic plan within the following categories:

- Functional neurosurgery navigation
  - Case volume – Underlying the revenue from sales of our functional neurosurgery navigation products reflected in the accompanying Condensed Consolidated Financial Statements appearing elsewhere in this Quarterly Report are the procedures, or cases, performed in hospitals utilizing one or more of our products or our clinical services. Case volume data is not influenced by variations in pricing or quantities of product used on a per case basis, and thus provide a more reliable indicator of the growth of our functional neurosurgery navigation line of business. Management analyzes case volume by hospital and by type of procedure to gain information that informs targeted sales and marketing activities. During the three months ended March 31, 2021, the ClearPoint system was used in 214 cases, as compared to 187 cases during the same period in 2020, representing an increase of 14% for the comparative three-month periods. Consistent with the discussion in the section "Results of Operations –Revenue," we attribute this increase to the resumption of elective neurosurgical procedures to near pre-COVID-19 pandemic levels during the three months ended March 31, 2021, as compared to the cessation of such procedures during the same period in 2020.

- Number of "Active Surgery Centers" – For purposes of analyzing this performance indicator, an Active Surgery Center is a hospital 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, 2021, the ClearPoint system was used in more than 60 Active Surgery Centers, which is comparable to the number of such centers as of the same date in 2020. Consistent with the discussion in the section "Results of Operations – Revenue," we attribute the lack of growth in this performance indicator to the COVID-19 pandemic.

- 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 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, 2021, we had commercial relationships with more than 25 Partners, as compared with approximately 20 Partners as of the same date in 2020.

- Therapy products – We do not expect meaningful revenue from therapy products in 2021 insofar as we are targeting a limited market release of such products in 2022. As a result, our milestones in the therapy space are focused on refining the product and obtaining regulatory clearance. Should we be successful in achieving these milestones, we believe our initial performance indicators will focus on case volume and number of Active Surgery Centers, as are currently used in measuring our performance in functional neurosurgery navigation.

- Global scale and efficiency – We have been cautious in setting our goals for operations beyond the U.S. so as to conserve our resources and not establish a foreign presence in advance of being assured of a corresponding revenue stream. In late 2020 we took the first steps in leveraging the CE Marks we have for our ClearPoint system and SmartFlow cannula by establishing an initial presence in Europe for product sales and clinical advisory services. From this initial presence, we believe that future global key performance indicators will be similar to those described above for our U.S. business: case volume, number of Active Surgery Centers and number of biologics and drug delivery Partners.

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. 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. We anticipate that, over time, recurring revenue will constitute an increasing percentage of our total revenue as we leverage installations of our ClearPoint system to generate recurring sales of our functional neurosurgery navigation products. Our product revenue was approximately $3.2 million for the three months ended March 31, 2021 and were almost entirely related to our ClearPoint system.

In addition, we expect that, over time, service revenue will constitute an increasing portion of our total revenue based on: (a) leveraging current and future installations of ClearPoint systems, as discussed above, so as to result in an increase in functional neurosurgery service revenue; and (b) increasing biologics and drug delivery service revenue should our customers in this space be successful in expansion of their clinical trials, and should we be successful in continuing to establish relationships with new biologic and drug delivery partners. Our service revenue was approximately $0.9 million for the three months ended March 31, 2021.

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. 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. With the anticipated increases in the contribution to total revenue of sales of recurring products and services, as discussed above, we expect gross margin, as a percentage of total revenue, to increase over time.

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. Such costs include salaries, travel, and benefits for research and development personnel, including related share-based compensation; materials and laboratory supplies in research and development activities; 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 (ii) seek to expand the application of our technological platforms. From our inception through March 31, 2021, we have incurred approximately $63 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 attorneys and outside 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 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, 2021 as compared to the critical accounting policies described in our 2020 Form 10-K.

Results of Operations

Three Months Ended March 31, 2021 Compared to the Three Months Ended March 31, 2020

	Three Months Ended March 31,		
(Dollars in thousands)	**2021**	**2020**	**Percentage Change**
Product revenue	$ 3,162	$ 2,179	45%
Service and other revenue	868	937	(7)%
Total revenue	4,030	3,116	29%
Cost of revenue	1,416	932	52%
Research and development costs	1,563	818	91%
Sales and marketing expenses	1,575	1,299	21%
General and administrative expenses	1,657	1,276	30%
Other expense:			
Other expense, net	(25)	(4)	NM%
Interest expense, net	(332)	(842)	(61)%
Net loss	$ (2,538)	$ (2,055)	24%

NM – The percentage change is not meaningful.

Revenue. Total revenue was $4.0 million for the three months ended March 31, 2021, and $3.1 million for the three months ended March 31, 2020, which represents an increase of $0.9 million, or 29%.

Functional neurosurgery navigation revenue, which consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 10% to $1.9 million for the three months ended March 31, 2021, from $1.7 million for the same period in 2020. This increase reflects the resumption in the three months ended March 31, 2021, of elective surgical procedures, which were postponed or cancelled during the three months ended March 31, 2020, due to the effects of the COVID-19 pandemic. Although elective surgeries have resumed, we are unable to determine the extent to which such factors as the timing, adoption or viability of such resumption will impact our revenue due to the persistence of the COVID-19 pandemic and our inability to determine the length of time that the COVID-19 pandemic will adversely affect our 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 2020 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 61% to $1.7 million for the three months ended March 31, 2021, from $1.0 million for the same period in 2020. This increase was due to an increase, during the quarter ended March 31, 2021, relative to the same period in 2020, in biologic and drug delivery product revenue of $0.7 million, partially offset by a decrease in biologic and drug delivery service revenue. This increase notwithstanding, our biologic and drug delivery customers are reestablishing their estimated timelines for initiation or resumption of their clinical trials, however, these timelines have not been finalized, given the uncertainties of when hospitals will be able to resume such clinical trial cases. Accordingly, depending on the length of the COVID-19 pandemic, future biologics and drug delivery revenue could be adversely impacted. 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 2020 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 31% to $0.5 million for the three months ended March 31, 2021, from $0.3 million for the same period in 2020. While revenue from this product line historically has varied from quarter to quarter, we believe that the increase represents the partial resumption of hospitals' capital equipment acquisition activities subsequent to such activities having been curtailed due to the COVID-19 pandemic. There were no increases in capital equipment product prices during the period between the three months ended March 31, 2021 and the same period in 2020 that would be reasonably expected to affect a typical customer order.

Cost of Revenue. Cost of revenue was $1.4 million, representing a gross margin of 65%, for the three months ended March 31, 2021, and was $0.9 million, representing a gross margin of 70%, for the three months ended March 31, 2020. This decrease in gross margin was due primarily to: (a) higher production volume during the three months ended March 31, 2021, relative to the same period in 2020, resulting in a larger portion of overhead being allocated to cost of revenue; and (b) a shift in the mix of revenue by line of business stemming from service revenue, which bear higher gross margins in comparison to other product lines, representing a greater contribution to total sales for the three months ended March 31, 2020, relative to the same period in 2021, due to the adverse effects during the 2020 period of the COVID-19 pandemic on hospitals' purchases of products, as discussed above.

Research and Development Costs. Research and development costs were $1.6 million for the three months ended March 31, 2021, compared to $0.8 million for the same period in 2020, an increase of $0.8 million, or 91%. The increase was due primarily to increases in personnel costs of $0.5 million due to growth in headcount, and in new product development of $0.1 million, each increase resulting from our efforts to expand the applications of our technological platforms.

Sales and Marketing Expenses. Sales and marketing expenses were $1.6 million for the three months ended March 31, 2021, compared to $1.3 million for the same period in 2019, an increase of $0.3 million, or 21%. This increase was due primarily to increases in personnel costs of $0.4 million resulting from increases in headcount in our clinical specialist and marketing teams. These increases were partially offset by a decrease of $0.1 million due primarily to a change in timing of our annual national sales meeting.

General and Administrative Expenses. General and administrative expenses were $1.7 million for the three months ended March 31, 2021, compared to $1.3 million for the same period in 2020, an increase of $0.4 million, or 30%. This increase was due primarily to increases in insurance costs of $0.1 million, occupancy costs of $0.1 million, audit fees and consulting fees of $0.1 million, and incentive-based and share-based compensation of $0.05 million each.

Interest Expense. Net interest expense for the three months ended March 31, 2021 was $0.3 million, compared with $0.8 million for the same period in 2020. This decrease was primarily due to the charge to interest expense during the three months ended March 31, 2020 and amounting to approximately $0.8 million related to the unamortized balance of the 2010 Secured Notes that were repaid in full during the three months ended March 31, 2020. This decrease was partially offset by an increase in interest expense associated with the 2020 Secured Notes during the three months ended March 31, 2021, relative to the interest incurred during the three months ended March 31, 2020 associated with the 2010 Secured Notes. Additional information with respect to the 2010 Secured Notes and the 2020 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, 2021 of $122 million. In addition, our use of cash from operations amounted to $2.1 million for the three months ended March 31, 2021 and $7.8 million for the year ended December 31, 2020. Since inception, we have financed our operations principally from the sale of equity securities, the issuance of notes payable, product and service contracts and license arrangements.

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. From the net proceeds received from the issuance of the First Closing Notes, which have a five-year term, we repaid and retired the 2010 Secured Notes that otherwise would have matured in October and November 2020.

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

In April 2020, we received $0.9 million in proceeds under the terms of the PPP Loan. In November 2020, we were notified by the U.S. Small Business Administration that the loan had been forgiven under the provision of the CARES Act.

See Note 5 for additional information with respect to the 2020 Secured Notes and the PPP Loan.

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, 2021, 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, 2021 and 2020 is summarized as follows:

	Three Months Ended March 31,	
(in thousands)	**2021**	**2020**
Cash used in operating activities	$ (2,131)	$ (2,331)
Cash used in investing activities	(40)	(441)
Cash provided by financing activities	46,930	14,052
Net change in cash and cash equivalents	$ 44,759	$ 11,280

Net Cash Flows from Operating Activities. We used $2.1 million and $2.3 million of cash for operating activities during the three months ended March 31, 2021 and 2020, respectively.

During the three months ended March 31, 2021, uses of cash in operating activities primarily consisted of: (i) our $2.5 million net loss; (ii) increases in accounts receivable of $0.1 million, and prepaid expenses and other current assets of $0.01 million; and (iii) decreases in accounts payable and accrued expenses of $0.05 million, and lease liabilities of $0.1 million. These uses were partially offset by: (a) a decrease in inventory of $0.05 million; (b) an increase in deferred revenue of $0.04 million; and (c) net non-cash expenses included in our net loss aggregating $0.6 million and consisting primarily of depreciation and amortization, share-based compensation, payment-in-kind interest and amortization of debt issuance costs, original issue discounts on debt and lease rights-of-use, net of accretion in lease liabilities.

During the three months ended March 31, 2020, uses of cash in operating activities primarily consisted of: (i) our $2.1 million net loss; (ii) an increase in inventory of $0.4 million; and (iii) decreases in accounts payable and accrued expenses of $0.2 million, accrued interest of $1.0 million, lease liabilities of $0.02 million, and deferred revenue of $0.2 million. These uses were partially offset by: (a) decreases in accounts receivable of $0.1 million, prepaid expenses and other current assets of $0.2 million, and other assets of $0.07 million; and (b) net non-cash expenses included in our net loss aggregating $1.1 million and consisting primarily of depreciation and amortization, share-based compensation, and amortization of debt issuance costs, original issue discounts on debt and lease rights-of-use, net of accretion in lease liabilities.

Net Cash Flows from Investing Activities. Net cash flows used in investing activities for the three months ended March 31, 2021 were $0.04 million and consisted primarily of equipment acquisitions.

Net cash flows used in investing activities for the three months ended March 31, 2020 were $0.4 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, 2021 consisted of: (a) the proceeds, net offering costs, of $46.8 million received from the public offering of our common stock; and (b) proceeds from the exercise of common stock options and warrants aggregating $0.1 million.

Net cash flows from financing activities for the three months ended March 31, 2020 consisted of the proceeds, net financing costs and discount paid as of that date, of $16.9 million received from the issuance of the First Closing Note, partially offset by the repayment of the 2010 Secured Notes amounting to $2.8 million, both as described in Note 5 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report.

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.

Off-Balance Sheet Arrangements

We are not a party to any off-balance sheet arrangements that have, or are reasonably likely to have, a material current or future effect on our financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources.

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, 2021, we had $17.5 million of principal outstanding under the 2020 Secured Notes. A one-percent increase in one-month LIBOR would result in a net increase in interest expense of $0.175 million on an annualized basis due to the fact that the Secured Notes are subject to a LIBOR floor of 2.00% and one-month LIBOR was below the floor as of March 31, 2021.

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, 2021 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, 2021.

Changes in Internal Control Over Financial Reporting

During the quarter ended March 31, 2021, 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 2020 Form 10-K.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

None.

ITEM 5. OTHER INFORMATION.

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
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

* 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, 2021

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, 2021, 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, 2021

/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, 2021, 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, 2021

/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, 2021, 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, 2021

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

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