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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2020

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)
5 Musick **Irvine, California**	**92618**
(Address of Principal Executive Offices)	(Zip Code)

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

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

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

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

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

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

Large accelerated filer ☐
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 August 10, 2020, there were 15,731,352 shares of common stock outstanding.

CLEARPOINT NEURO, INC.

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Trademarks, Trade Names and Service Marks

ClearPoint®, *ClearTrace*® and *ClearPoint Neuro*® 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 COVID-19 pandemic and measures taken or that may be taken to combat the spread of the disease;
- future revenues from sales of ClearPoint system products and services;
- our ability to market, commercialize and achieve broader market acceptance for our ClearPoint system products; and
- estimates regarding the sufficiency of our cash resources and our ability to obtain additional financing, to the extent necessary or advisable.

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, 2019, which we filed with the SEC on March 27, 2020 (the "2019 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.
(formerly MRI Interventions, Inc.)
Condensed Consolidated Balance Sheets

	June 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,032,082	$ 5,695,722
Accounts receivable, net	1,163,663	1,089,917
Inventory, net	3,598,980	3,240,218
Prepaid expenses and other current assets	537,940	357,227
Total current assets	21,332,665	10,383,084
Property and equipment, net	342,584	447,162
Operating lease rights of use	321,155	374,218
Software license inventory	506,800	504,400
Licensing rights	517,207	135,000
Other assets	12,438	82,573
Total assets	$ 23,032,849	$ 11,926,437
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,491,377	$ 965,783
Accrued compensation	969,877	1,408,292
Other accrued liabilities	334,627	328,460
Operating lease liabilities, current portion	110,914	113,520
Deferred product and service revenue	620,126	1,016,892
Paycheck Protection Program loan payable, current portion	296,677	—
Total current liabilities	3,823,598	3,832,947
Accrued interest	—	959,659
Operating lease liabilities, net of current portion	227,714	276,669
Deferred product and service revenue, net of current portion	228,286	197,862
2020 senior secured convertible notes payable, net	16,814,099	—
2010 junior secured notes payable, net	—	2,072,583
Paycheck Protection Program loan payable, net of current portion	599,323	—
Total liabilities	21,693,020	7,339,720
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized; none issued and outstanding at June 30, 2020 and December 31, 2019	—	—
Common stock, $0.01 par value; 200,000,000 shares authorized; 15,512,687 shares issued and outstanding at June 30, 2020; and 15,235,308 issued and outstanding at December 31, 2019	155,127	152,353
Additional paid-in capital	117,640,195	117,173,984
Accumulated deficit	(116,455,493)	(112,739,620)
Total stockholders' equity	1,339,829	4,586,717
Total liabilities and stockholders' equity	$ 23,032,849	$ 11,926,437

See accompanying notes to Condensed Consolidated Financial Statements.

CLEARPOINT NEURO, INC.

(formerly MRI Interventions, Inc.)
Condensed Consolidated Statements of Operations
(Unaudited)

	For The Three Months Ended June 30,	
	2020	**2019**
Revenues:		
Product revenues	$ 1,593,070	$ 2,194,194
Service and other revenues	884,712	412,204
Total revenues	2,477,782	2,606,398
Cost of revenues	640,805	1,030,316
Research and development costs	822,301	697,803
Sales and marketing expenses	1,124,378	1,143,056
General and administrative expenses	1,365,084	1,028,291
Operating loss	(1,474,786)	(1,293,068)
Other income (expense):		
Other income, net	10,851	1,693
Interest expense, net	(197,113)	(259,020)
Net loss	$ (1,661,048)	$ (1,550,395)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.11)	$ (0.13)
Weighted average shares outstanding:		
Basic and diluted	15,504,169	12,302,667

See accompanying notes to Condensed Consolidated Financial Statements.

CLEARPOINT NEURO, INC.
(formerly MRI Interventions, Inc.)
Condensed Consolidated Statements of Operations
(Unaudited)

	For The Six Months Ended June 30,	
	2020	**2019**
Revenues:		
Product revenues	$ 3,696,455	$ 4,358,148
Service and other revenues	1,896,921	720,767
Total revenues	5,593,376	5,078,915
Cost of revenues	1,558,141	1,916,798
Research and development costs	1,651,829	1,282,343
Sales and marketing expenses	2,422,972	2,183,769
General and administrative expenses	2,643,592	1,961,322
Operating loss	(2,683,158)	(2,265,317)
Other income (expense):		
Other income, net	6,131	7,322
Interest expense, net	(1,038,846)	(513,125)
Net loss	$ (3,715,873)	$ (2,771,120)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.24)	$ (0.24)
Weighted average shares outstanding:		
Basic and diluted	15,471,222	11,676,872

See accompanying notes to Condensed Consolidated Financial Statements.

CLEARPOINT NEURO, INC.
(formerly MRI Interventions, Inc.)
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

For The Six Months Ended June 30, 2020

	Common Stock		Additional Paid-in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balances, January 1, 2020	15,235,308	$ 152,353	$ 117,173,984	$ (112,739,620)	$ 4,586,717
Issuances of common stock:					
Share-based compensation	9,696	97	227,871	—	227,968
Warrant exercises (cashless)	262,145	2,621	(2,621)	—	—
Net loss for the period	—	—	—	(2,054,825)	(2,054,825)
Balances, March 31, 2020	15,507,149	155,071	117,399,234	(114,794,445)	2,759,860
Issuances of common stock:					
Share-based compensation	5,538	56	240,961	—	241,017
Net loss for the period	—	—	—	(1,661,048)	(1,661,048)
Balances, June 30, 2020	15,512,687	$ 155,127	$ 117,640,195	$ (116,455,493)	$ 1,339,829

For The Six Months Ended June 30, 2019

	Common Stock		Additional Paid-in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balances, January 1, 2019	11,018,364	$ 110,183	$ 108,600,405	$ (107,199,586)	$ 1,511,002
Cumulative adjustment for adoption of new accounting standard	—	—	—	(244)	(244)
Issuances of common stock:					
Share-based compensation	28,462	285	152,301	—	152,586
Warrant exercises	20,381	204	(204)	—	—
Net loss for the period	—	—	—	(1,220,725)	(1,220,725)
Balances, March 31, 2019	11,067,207	110,672	108,752,502	(108,420,555)	442,619
Issuances of common stock:					
Share-based compensation	3,251	32	203,962	—	203,994
Warrant exercises	189,407	1,894	381,182	—	383,076
May 2019 private placement, net of offering costs of $94,162	2,426,455	24,265	7,403,583	—	7,427,848
Net loss for the period	—	—	—	(1,550,395)	(1,550,395)
Balances, June 30, 2019	13,686,320	$ 136,863	$ 116,741,229	$ (109,970,950)	$ 6,907,142

See accompanying notes to Condensed Consolidated Financial Statements.

CLEARPOINT NEURO, INC.
(formerly MRI Interventions, Inc.)
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	For The Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (3,715,873)	$ (2,771,120)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	116,026	69,600
Share-based compensation	468,985	356,580
Amortization of debt issuance costs and original issue discounts	821,301	363,465
Amortization of lease rights of use, net of accretion in lease liabilities	49,782	51,255
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(73,746)	(137,931)
Inventory, net	(313,476)	(201,503)
Prepaid expenses and other current assets	(180,712)	(216,953)
Other assets	70,134	11,899
Accounts payable and accrued expenses	93,347	716,222
Accrued interest	(959,661)	—
Lease liabilities	(48,280)	(50,285)
Deferred revenue	(366,341)	389,201
Net cash flows from operating activities	(4,038,514)	(1,419,570)
Cash flows from investing activities:		
Acquisition of licensing rights	(441,341)	(150,000)
Net cash flows from investing activities	(441,341)	(150,000)
Cash flows from financing activities:		
Proceeds from issuance of 2020 senior secured convertible notes, net of financing costs and discount	16,757,871	—
Proceeds from issuance of Paycheck Protection Program loan	896,000	—
Proceeds from private placement of common stock	—	7,522,010
Proceeds from stock option warrant exercises	—	383,075
Repayment of notes payable	(2,837,656)	(1,975,000)
Net cash flows from financing activities	14,816,215	5,930,085
Net change in cash and cash equivalents	10,336,360	4,360,515
Cash and cash equivalents, beginning of period	5,695,722	3,101,133
Cash and cash equivalents, end of period	$ 16,032,082	$ 7,461,648
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ —	$ —
Interest	$ 1,043,371	$ 164,157

NON-CASH TRANSACTIONS:

- During the six months ended June 30, 2020 Company recorded net sales of ClearPoint reusable components having an aggregate net book value of $47,686 that had previously been transferred from inventory to loaned systems, which are included in property and equipment in the accompanying condensed consolidated balance sheets. During the six months ended June 30, 2019, the Company recorded net transfers of ClearPoint reusable components having an aggregate net book value of $163,321 from loaned systems to inventory.

- On January 1, 2019, the Company adopted the provisions of Topic 842 within the Accounting Standards Codification, which resulted in the establishment of operating lease right-of-use assets and operating lease liabilities, each in the aggregate amount of $480,395 (see Note 6).

- In connection with the 2019 PIPE (see Note 7), the Company incurred approximately $94,000 of issuance costs that were unpaid and included in accounts payable at June 30, 2019.

See accompanying notes to Condensed Consolidated Financial Statements.

ClearPoint Neuro, Inc.
(formerly MRI Interventions, 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 and heart 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. The Company's ClearTrace® system is a product candidate that is designed to allow catheter-based minimally invasive procedures in the heart to be performed in an MRI suite. Although still a product candidate, the Company has reduced its efforts to commercialize the ClearTrace system.

On February 12, 2020, the Company changed its corporate name from MRI Interventions, Inc. to ClearPoint Neuro, Inc., pursuant to a Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware. In addition, effective as of February 12, 2020, the Company's Board of Directors adopted the Second and Amended Restated Bylaws, to reflect the name change of the Company. No other changes were made to the Company's certificate of incorporation or bylaws. In connection with the Company's name change, effective as of the opening of trading on February 12, 2020, the Company's shares of common stock commenced trading on the Nasdaq Capital Market under the symbol "CLPT."

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 financial markets and 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. The rapid development and fluidity of the situation precludes any prediction as to the ultimate impact COVID-19 will have on the Company's business, financial condition, results of operation and cash flows, which will depend largely on future developments directly or indirectly relating to the duration and scope of the COVID-19 outbreak in the United States.

Liquidity

The Company has incurred net losses since its inception, which has resulted in a cumulative deficit at June 30, 2020 of $116 million. In addition, the Company's use of cash from operations amounted to $4.0 million for the six months ended June 30, 2020 and $2.8 million for the year ended December 31, 2019. 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.

As discussed in Note 7, in May 2019, the Company entered into a Securities Purchase Agreement with certain accredited investors under which such investors purchased 2,426,455 shares of the Company's common stock at $3.10 per share (the "2019 PIPE), resulting in proceeds of approximately $7.5 million, before deducting offering expenses aggregating approximately $94,000.

In addition, as discussed in Note 5, in January 2020, the Company entered into a Securities Purchase Agreement with two investors under which the Company issued to such investors an aggregate principal amount of $17.5 million of floating rate secured convertible notes (the "2020 Secured Notes"), resulting in proceeds, net of financing costs paid and payable, and a commitment fee paid to one of the investors, of approximately $16.8 million. From the net proceeds received from the issuance of the 2020 Secured 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.

Also, as discussed in Note 5, in April 2020, the Company received $896,000 in proceeds through a loan funded under the Payroll Protection Program as part of the CARES Act. Management's plan during the period in which the Company is affected by the COVID-19 pandemic is to retain the Company's employee base and, pending the ultimate duration and impact of the COVID-19 pandemic and by using the funds for the purposes described under the terms of the loan, consider whether to repay the loan in conformity with its terms or request that all or a portion of the loan, as applicable under its terms, be ultimately forgiven. However, there is no assurance that the Company would be successful in obtaining such forgiveness.

Based on the foregoing, in management's opinion, cash and cash equivalent balances at June 30, 2020, when combined with the proceeds from issuance of the 2020 Secured Notes (after repayment of the 2010 Secured Notes) and receipt of the proceeds from the loan funded under the Payroll Protection Program, 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, 2019 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 United States Securities and Exchange Commission ("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, revenues, 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 2019 Form 10-K. The accompanying condensed consolidated balance sheet as of December 31, 2019 has been derived from the audited consolidated financial statements at that date but does not include all information and footnotes required by GAAP for a complete set of financial statements. The results of operations for the three and six months ended June 30, 2020 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

In June 2019 and February 2020, the Company entered into 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 certain license agreements, the Company paid an aggregate $591,341 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.

Revenue Recognition

The Company's revenues are comprised primarily of: (1) product revenues resulting from the sale of functional neurosurgical products, and drug delivery and biologic products; (2) product revenues resulting from the sale of ClearPoint capital equipment; (3) revenues resulting from the rental, service, installation, training and shipping related to ClearPoint capital equipment; and (4) clinical case support revenues 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. This process 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. 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 product, biologics and drug delivery systems product, and therapy product sales:* Revenues from the sale of functional neurosurgery 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), are 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 sales*

  - *Capital equipment sales preceded by evaluation periods:* The predominance of capital equipment 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 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 sales not preceded by evaluation periods:* Revenue from sales of capital equipment 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 sales described above, the Company's determination of the point in time at which to recognize revenue represents that point at which the customer has legal title, physical possession, and the risks and rewards of ownership, and the Company has a present right to payment.

- *Functional neurosurgery and related services:* Revenues from functional neurosurgery and related services are recognized over the period of time such services are rendered.

- *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.

  - *Therapy services:* The Company recognizes revenue for such services at the point in time that the performance obligation has been satisfied.

- *Capital equipment-related services:*

  - *Equipment service:* Revenue from service of ClearPoint capital equipment 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 rental and service revenues 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 sales as described above, fees for installation, training and shipping in connection with sales of capital equipment 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. Installation, training and shipping fees related to capital equipment 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 products, biologics and drug delivery systems products, and capital equipment 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, 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 its cash and cash equivalents on deposit with financial institutions in the U.S. insured by the Federal Deposit Insurance Corporation. At June 30, 2020, the Company had approximately $7.9 million in bank balances that were in excess of the insured limits.

Information with respect to accounts receivable from those customers who comprised more than 10% of accounts receivable at June 30, 2020 and December 31, 2019 is as follows:

	June 30, 2020	December 31, 2019
Customer – 1	—	12%

Information with respect to customers that accounted for sales in excess of 10% of total sales in the three-month periods ended June 30, 2020 and 2019 is as follows:

	June 30,	
	2020	2019
Customer – 1	22%	—

Information with respect to customers that accounted for sales in excess of 10% of total sales in the six-month periods ended June 30, 2020 and 2019 is as follows:

	June 30,	
	2020	2019
Customer – 1	21%	—

Prior to granting credit, the Company performs credit evaluations of its customers' financial condition, and generally does not require collateral from its customers. The Company will provide an allowance for doubtful accounts when collections become doubtful. The allowance for doubtful accounts at June 30, 2020 and December 31, 2019 was approximately $32,000 and $29,000, respectively.

The Company is subject to risks common to emerging companies in the medical device industry, including, but not limited to: new technological innovations; acceptance and competitiveness of its products; dependence on key personnel; dependence on key suppliers; 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.

3. Revenue Recognition

Revenue by Service Line

	Three Months Ended June 30,	
	2020	**2019**
Products:		
Disposable products:		
Functional neurosurgery	$ 1,049,015	$ 1,690,122
Biologics and drug delivery	406,955	244,949
Therapy	21,300	17,830
Capital equipment	115,800	241,293
Total product revenue	1,593,070	2,194,194
Services:		
Capital equipment and other	123,998	243,954
Biologics and drug delivery	760,714	168,250
Total service revenue	884,712	412,204
Total revenue	$ 2,477,782	$ 2,606,398

	Six Months Ended June 30,	
	2020	**2019**
Products:		
Disposable products:		
Functional neurosurgery	$ 2,733,424	$ 3,294,767
Biologics and drug delivery	580,330	529,859
Therapy	78,800	17,830
Capital equipment	303,901	515,692
Total product revenue	3,696,455	4,358,148
Services:		
Capital equipment and other	280,493	455,156
Biologics and drug delivery	1,616,428	265,611
Total service revenue	1,896,121	720,767
Total revenue	$ 5,593,376	$ 5,078,915

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-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 are classified as deferred revenue.

  During the three and six months ended June 30, 2020, the Company recognized capital equipment-related service revenue of approximately $89,000 and $210,000, respectively, which was previously included in deferred revenue in the accompanying condensed consolidated balance sheet at December 31, 2019.

In September 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 $127,600, of which $83,000 and $102,000 are included in deferred revenue in the accompanying June 30, 2020 and December 31, 2019 condensed consolidated balance sheets, respectively.

Also, in September 2019, the Company entered into a Letter of Intent, followed by a related Statement of Work (together with the Letter of Intent, the "Project Documents") in November 2019, with a customer which is a stockholder and whose then Chief Operating Officer was a member of the Company's Board of Directors (and was subsequently replaced with the customer's Chief Development Officer), 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 $500,000; and (b) quarterly service fees of $500,000 commencing in the fourth quarter of 2019. 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 $250,000. During the six months ended June 30, 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 $100,000 and $200,000 during the three and six months ended June 30, 2020, respectively. The Company recognizes as revenue each of the upfront payments described in this paragraph in proportional relationship to the transaction prices of the performance obligations contained in the related agreements, 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, approximately $429,000 and $625,000 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 June 30, 2020 and December 31, 2019, respectively.

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. The transaction price of the software is recognized as revenue upon its installation and comprised approximately $143,000 and $172,000 of unbilled accounts receivable at June 30, 2020 and December 31, 2019, respectively.

Remaining Performance Obligations

The Company's contracts with customers, other than capital equipment-related service agreements discussed below, are predominantly of terms less than one year. Accordingly, the transaction price of remaining performance obligations related to such contracts at June 30, 2020 are not material.

Revenue with respect to remaining performance obligations related to capital equipment-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 $672,000 at June 30, 2020. The Company expects to recognize this revenue within the next three years.

4. Inventory

Inventory consists of the following as of:

	June 30, 2020	December 31, 2019
Raw materials and work in process	$ 1,761,658	$ 1,495,190
Software licenses	210,000	332,500
Finished goods	1,627,322	1,412,528
Inventory, net, included in current assets	3,598,980	3,240,218
Software licenses – non-current	506,800	504,400
Total	$ 4,105,780	$ 3,744,618

5. Notes Payable

2020 Secured Notes

On January 29, 2020 (the "Closing Date"), the Company completed a financing transaction (the "2020 Financing Transaction") with two investors (the "2020 Convertible Noteholders"), whereby the Company issued an aggregate principal amount of $17,500,000 of the 2020 Secured Notes pursuant to a Securities Purchase Agreement (the "SPA") dated January 11, 2020. Unless earlier converted or redeemed, the 2020 Secured 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 (x) the three (3)-month London Interbank Offered Rate ("LIBOR") and (y) two percent (2%), plus (ii) a margin of 2% on the outstanding balance of the 2020 Secured Notes, payable quarterly on the first business day of each calendar quarter. The 2020 Secured Notes 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. Prior to maturity, the 2020 Convertible Noteholders will have the right to convert all or any portion of the outstanding balance of their notes, including any accrued but unpaid interest, into shares of the Company's common stock at a conversion price of $6.00 per share, subject to certain adjustments as set forth in the 2020 Secured Notes. The 2020 Secured Notes are secured by all the assets of the Company.

Pursuant to the terms and subject to the conditions of the SPA, at any time on or prior to January 11, 2022, the Company shall have the right, but not the obligation, to request that one of the 2020 Convertible Noteholders purchase an additional $5,000,000 in aggregate principal amount of Second Closing Notes (as defined in the SPA) and an additional $10,000,000 in aggregate principal amount of additional Third Closing Notes (as defined in the SPA) (together, the "Additional Convertible Notes"), provided that such 2020 Convertible Noteholder has the right, but not the obligation, to purchase such notes. As of June 30, 2020, the Company had made no requests of the 2020 Convertible Noteholder to purchase any of the Additional Convertible Notes. The terms of the Additional Convertible Notes are the same as the terms of the 2020 Secured Notes, except that: (a) the Additional Convertible Notes would bear interest at a rate equal to the sum of (i) the greater of (x) the three (3)-month LIBOR and (y) 2%, plus (ii) a margin of 7% on their outstanding balance; and (b) only 70% of the Additional Convertible Notes' principal amount outstanding would be convertible into shares of the Company's common stock.

The carrying amount of the 2020 Secured Notes in the accompanying June 30, 2020 condensed consolidated balance sheet is presented net of: (a) financing costs, comprised of commissions and legal expenses, having an unamortized balance of $408,631; and (b) a discount, comprised of a commitment fee paid to one of the 2020 Convertible Noteholders, having an unamortized balance amounting to $277,270 at that date. The unamortized balance of the financing costs and the discount are charged to interest expense over the term of the 2020 Secured Notes under the effective interest method.

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 an individual to attend and observe 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 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 its first fiscal quarter of 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 $920,000, resulted in the full retirement of the 2010 Secured Notes.

Payroll Protection Program Loan

In April 2020, the Company received $896,000 in proceeds through an unsecured loan funded under the Payroll Protection Program as part of the CARES Act, which was enacted by the U.S. Congress in response to the COVID-19 pandemic. The loan has a two-year term, bears an interest at rate of 1% per annum, and is payable monthly from November 2020 through the remainder of the note's term in equal monthly installments of principal and interest amounting to $50,424.18. Management's plan during the period in which the Company is affected by the COVID-19 pandemic is to retain its employee base and, pending the ultimate duration and impact of the COVID-19 pandemic and by using the funds for the purposes described under the terms of the loan, consider whether to repay the loan in conformity with its terms or request that all or a portion of the loan, as applicable under its terms, be ultimately forgiven. However, there is no assurance that the Company would be successful in obtaining such forgiveness.

2010 Secured Notes

The indebtedness outstanding under the 2010 Secured Notes at December 31, 2019 was $2.8 million. As discussed above, during the first fiscal quarter of 2020, the Company repaid in full the aggregate outstanding principal amount of the 2010 Secured Notes, together with accrued interest. The Company's Chairman of its Board of Directors and one of the Company's officers held 2010 Secured Notes purchased at the date of original issuance having an aggregate principal balance of $197,000.

The carrying amount of the 2010 Secured Notes in the accompanying December 31, 2019 condensed consolidated balance sheet is presented net of a discount, having an unamortized balance amounting to $765,073 at that date, arising from shares issued to the noteholders at issuance of the 2010 Secured Notes. During the six months ended June 30, 2020, the unamortized balance of this discount was charged to interest expense upon the Company's repayment of the 2010 Secured Notes.

Scheduled Notes Payable Maturities

Scheduled principal payments as of June 30, 2020 with respect to notes payable are summarized as follows:

Years ending December 31,	
2020	$ 73,984
2021	446,504
2022	375,512
2023	—
2024	—
Thereafter	17,500,000
Total scheduled principal payments	18,396,000
Less: Unamortized financing costs and discount	(685,901)
Total	$ 17,710,099

6. Leases

The Company leases office space in Irvine, California that houses its headquarters 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 Mississauga, Ontario, Canada for its software development personnel. The lease term commenced on August 1, 2018, is set to expire in July 2021, and provides for automatic one-year renewals at the Company's option. Both office leases are classified as operating leases in conformity with the provisions of Topic 842.

The lease costs included in general and administrative expenses were $28,219 and $28,617 for the three months ended June 30, 2020 and 2019, respectively, and were $56,438 and $55,620 for the six months ended June 30, 2020 and 2019, respectively.

7. Stockholders' Equity

2019 Private Placement

On May 9, 2019, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain accredited investors (collectively, the "Investors") for the private placement of 2,426,455 shares of the Company's common stock at $3.10 per share. The Company received aggregate gross proceeds of approximately $7.5 million, before deducting offering expenses aggregating approximately $94,000.

The Purchase Agreement also contains representations and warranties by the Company and the Investors and covenants of the Company and the Investors (including indemnification from the Company in the event of breaches of its representations and warranties), certain information rights and other rights, obligations and restrictions, which the Company believes are customary for transactions of this type.

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. The following is information regarding the number of shares issued to directors as payment for director fees in lieu of cash for the three and six months ended June 30, 2020 and 2019:

Three Months Ended June 30,	
2020	**2019**
9,832	8,841

Six Months Ended June 30,	
2020	**2019**
19,563	17,739

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 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 440,995 shares have been awarded and option grants, net of options terminated, expired or forfeited, of 1,175,679 shares were outstanding as of June 30, 2020. Accordingly, 1,339,576 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 six months ended June 30, 2020 is summarized below:

	Shares	Weighted-average Exercise price per share	Intrinsic Value[1]
Outstanding at January 1, 2020	1,639,167	$ 9.87	$ 2,892,027
Granted	84,445	4.14	26,512
Exercised	(833)	1.74	
Outstanding at June 30, 2020	1,722,779	$ 9.59	$ 867,568

(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 June 30, 2020, there was unrecognized compensation expense of $948,807 related to outstanding stock options and shares of restricted stock, which is expected to be recognized over a weighted average period of 1.44 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 six months ended June 30, 2020 was as follows:

	Shares	Weighted-average Exercise price per share	Intrinsic Value[1]
Outstanding at January 1, 2020	5,532,267	$ 4.00	$ 10,470,008
Exercised	(428,532)	2.20	
Outstanding at June 30, 2020	5,103,735	$ 4.15	$ 2,717,201

(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 2019 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 neurological procedures. In addition, in 2011, we also obtained CE marking approval for our ClearPoint system, which enables us to sell our ClearPoint system in the European Union. The majority of our product revenues for the three and six months ended June 30, 2020 relate to sales of our ClearPoint system products. 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 June 30, 2020, we had accumulated losses of approximately $116 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 COVID-19 as a 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. In June 2020, the National Bureau of Economic Research officially declared that the United States economy has fallen into a recession. Although much of the United States economy is now in the process of reopening, the COVID-19 pandemic is intensifying in many areas of the country. The rapid development and fluidity of the situation precludes any prediction as to the ultimate impact COVID-19 will have on the Company's business, financial condition, results of operation and cash flows, which will depend largely on future developments directly or indirectly relating to the duration and scope of the COVID-19 outbreak in the United States.

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 neurosurgical products reflected in the accompanying Condensed Consolidated Financial Statements appearing elsewhere in this Quarter 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 and six months ended June 30, 2020, the ClearPoint system was used in 127 and 308 cases, respectively, as compared to 197 and 372 cases during the same respective periods in 2019, representing decreases of 36% for the comparative three-month periods and 17% for the comparative six-month periods. Consistent with the discussion in the section "Results of Operations –Revenues," these increases were lower, relative to the quarterly year-over-year increases we experienced prior to the onset of the COVID-19 pandemic, which we attribute to the COVID-19 pandemic.

    - Number of "Active Surgical Centers" – For purposes of analyzing this performance indicator, an Active Surgical 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 neurosurgical product is sold to such hospitals for their use in cases. In addition to signifying growth, the number of Active Surgical Centers, when analyzed in conjunction with case volume data, further informs targeted sales and marketing activities and confirms where these activities have led to increased penetration of our product lines. As of June 30, 2020, the ClearPoint system was used in more than 60 Active Surgical Centers, as compared to more than 50 such centers as of the same date in 2019.

- 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 revenues from sales of products and services to these Partners in support of their clinical trials are 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 the use of our products and services in delivering our Partners' therapies. At each of June 30, 2020 and 2019, we had commercial relationships with approximately 20 Partners, with acquisition activity in the biotechnology space during the year between these dates being substantially offset by new relationships we entered into over that same period.

- Therapy products – We do not expect meaningful revenue from therapy products in 2020 and are targeting a limited market release of such products in 2021. 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 Surgical 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 2020 we expect to take the first steps in leveraging the CE Marks we have for our ClearPoint system and SmartFlow cannula to establish 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 Surgical Centers and number of biologics and drug delivery Partners.

Revenues

In 2010, we received 510(k) clearance from the FDA to market our ClearPoint system in the U.S. for general neurological procedures. Future revenues from sales of our ClearPoint platform products and services are 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 revenues from the sale of functional neurosurgical products is an important part of our business model for our ClearPoint system. We anticipate that, over time, recurring revenues will constitute an increasing percentage of our total revenues as we leverage installations of our ClearPoint system to generate recurring sales of our functional neurosurgical products. Our product revenues were approximately $1.6 million and $3.7 million for the three and six months ended June 30, 2020, respectively, and predominantly related to our ClearPoint system.

In addition, we expect that, over time, service revenues will constitute an increasing portion of our total revenues based on: (a) leveraging current and future installations of ClearPoint systems, as discussed above, so as to result in an increase in functional neurosurgical service revenues; and (b) increasing biologics and drug delivery service revenues 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 revenues were approximately $885,000 and $1.9 million for the three and six months ended June 30, 2020, respectively.

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 Revenues

Cost of revenues includes the direct costs associated with the assembly and purchase of components for functional neurosurgical products, drug delivery and biologic products, non-neurosurgical therapy products, and ClearPoint capital equipment which we have sold, and for which we have recognized the revenue in accordance with our revenue recognition policy. Cost of revenues 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 revenues 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 June 30, 2020, we have incurred approximately $58 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 or six months ended June 30, 2020 as compared to the critical accounting policies described in our 2019 Form 10-K.

Results of Operations

Three Months Ended June 30, 2020 Compared to the Three Months Ended June 30, 2019

	Three Months Ended June 30,		
	2020	2019	Percentage Change
Product revenues	$ 1,593,070	$ 2,194,194	(27%)
Service and other revenues	884,712	412,204	115%
Total revenues	2,477,782	2,606,398	(5%)
Cost of revenues	640,805	1,030,316	(38%)
Research and development costs	822,301	697,803	18%
Sales and marketing expenses	1,124,378	1,143,056	(2%)
General and administrative expenses	1,365,084	1,028,291	33%
Other income (expense):			
Other income, net	10,851	1,693	541%
Interest expense, net	(197,113)	(259,020)	(24%)
Net loss	$ (1,661,048)	$ (1,550,395)	7%

Revenues. Total revenues were $2.5 million for the three months ended June 30, 2020, and $2.6 million for the three months ended June 30, 2019, which represents a decrease of $129,000, or 5%.

Functional neurosurgery revenue, which consists of disposable product commercial sales related to cases utilizing the ClearPoint system, decreased 38% to $1.0 million for the three months ended June 30, 2020, from $1.7 million for the same period in 2019. This decrease was due to the effects of the COVID-19 pandemic, in which elective surgical procedures, historically representing approximately 80% of our ClearPoint system case volume, were postponed or cancelled. Although elective surgeries have been resumed, albeit at reduced levels, or the resumption is being considered, in certain areas of the U.S., we are unable to determine the extent to which such factors as the timing, adoption or viability of such resumption will impact our revenue. Accordingly, we are unable to determine the length of time that the COVID-19 pandemic will adversely affect our product revenues. There were no increases in functional neurosurgery product prices during the period between the three months ended June 30, 2020 and the same period in 2019 that would be reasonably expected to affect a typical customer order.

Biologics and drug delivery revenues, which include sales of disposable products and services related to customer-sponsored clinical trials utilizing the ClearPoint system, increased 183% to $1.2 million for the three months ended June 30, 2020, from $413,000 for the same period in 2019. This increase was due primarily to an increase, during the quarter ended June 30, 2020, relative to the same period in 2019, in biologic and drug delivery service revenues of $592,000. This increase in biologics and drug delivery service revenues is attributable to the establishment of additional relationships with biologic and drug delivery companies that included period-based retainers for clinical services in support of such companies' respective clinical trials. Also contributing to the increase in biologics and drug delivery revenues was an increase of $162,000 in related product revenues that was also attributable to the establishment of additional relationships with biologic and drug delivery companies who ordered product for their clinical trials. These increases 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 pandemic, future biologics and drug delivery revenues could be adversely impacted. In this context, however, it should be noted that the terms of our product sales do not provide the customer with a right of return for any reason other than for defective product or product that does not conform to a customer's specifications. There were no increases in biologics and drug delivery product prices during the period between the three months ended June 30, 2020 and the same period in 2019 that would be reasonably expected to affect a typical customer order.

Capital equipment revenue, consisting of sales of ClearPoint reusable hardware and software, decreased 52% to $116,000 for the three months ended June 30, 2020, from $241,000 for the same period in 2019. While revenues from this product line historically have varied from quarter to quarter, we believe that many hospitals have postponed capital equipment acquisition activities, which continued postponement we believe will be contingent upon the prevalence and duration of the COVID-19 pandemic. There were no increases in capital equipment product prices during the period between the three months ended June 30, 2020 and the same period in 2019 that would be reasonably expected to affect a typical customer order.

Capital equipment-related services, consisting of fees for capital equipment rental, service, installation, training and shipping, decreased 49% to $124,000 for the three months ended June 30, 2020, from $244,000 for the same period in 2019. The decrease was due primarily to decreases in fees related to capital equipment sales, which were partially offset by an increase in equipment service contracts.

Cost of Revenues. Cost of revenues was $641,000, representing a gross margin of 74%, for the three months ended June 30, 2020, and was $1.0 million, representing a gross margin of 60%, for the three months ended June 30, 2019. This increase in gross margin was due primarily to a shift in the mix of revenues by line of business that resulted in service revenues, which bear higher gross margins in comparison to other product lines, representing a greater contribution to total sales for the three months ended June 30, 2020, relative to the same period in 2019. Also contributing to the improvement in gross margin was a lower allocation of overhead costs to sales for the three months ended June 30, 2020 as compared to the same period in 2019, resulting from the reduced sales volume during such 2020 period as compared to the same period in 2019, and a reduction in the allowance for excess and obsolete inventory. While we believe that these factors may prevail during the period that precautionary measures are in effect due to the COVID-19 pandemic, we also believe there is a possibility that gross margin may erode from its current level in the event that the mix of revenues and overhead allocations return to historical norms.

Research and Development Costs. Research and development costs were $822,000 for the three months ended June 30, 2020, compared to $698,000 for the same period in 2019, an increase of $124,000, or 18%. The increase was due primarily to increases in personnel costs of $84,000 due to increases in headcount and compensation, license amortization costs of $30,000 resulting primarily from licensing rights acquired in 2020, and outside consulting costs of $41,000 in connection with enhancements to the Company's quality system.

Sales and Marketing Expenses. Sales and marketing expenses were $1.1 million for each of the three months ended June 30, 2020 and 2019. A decrease during the three months ended June 30, 2020 as compared to the same period in 2019 in travel and entertainment expenses of $137,000, resulting primarily from reduced activity due to the COVID-19 pandemic, was offset by an increase in personnel costs of $189,000, resulting primarily from headcount increases in our clinical and marketing teams, the effect of which was partially offset by a decrease in incentive compensation from reduced sales volume due to the COVID-19 pandemic.

General and Administrative Expenses. General and administrative expenses were $1.4 million for the three months ended June 30, 2020, compared to $1.0 million for the same period in 2019, an increase of $337,000, or 33%. This increase was due primarily to increases in share-based compensation of $37,000, professional fees of $106,000 and insurance costs of $20,000, and a $104,000 reduction of allocation of shared departmental resources to production due to the reduced manufacturing activity as an effect of the COVID-19 pandemic.

Interest Expense. Net interest expense for the three months ended June 30, 2020 was $197,000, compared with $259,000 for the same period in 2019. This decrease was primarily due to a $160,000 decrease in the amortization of the discount associated with the 2010 Secured Notes, which were repaid and retired during the fiscal quarter ended March 31, 2020, and to the repayment, in June 2019, of secured notes issued in 2014. This decrease was partially offset by a $111,000 increase in interest expense associated with the 2020 Secured Notes issued in January 2020. 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.

Six Months Ended June 30, 2020 Compared to the Six Months Ended June 30, 2019

	Six Months Ended June 30,		
	2020	2019	Percentage Change
Product revenues	$ 3,696,455	$ 4,358,148	(15%)
Service and other revenues	1,896,921	720,767	163%
Total revenues	5,593,376	5,078,915	10%
Cost of revenues	1,558,141	1,916,798	(19%)
Research and development costs	1,651,829	1,282,343	29%
Sales and marketing expenses	2,422,972	2,183,769	11%
General and administrative expenses	2,643,593	1,961,322	35%
Other income (expense):			
Other income, net	6,131	7,322	(16%)
Interest expense, net	(1,038,846)	(513,125)	102%
Net loss	$ (3,715,874)	$ (2,771,120)	34%

Revenues. Total revenues were $5.6 million for the six months ended June 30, 2020, and $5.1 million for the six months ended June 30 31, 2019, which represents an increase of $514,000, or 10%.

Functional neurosurgery revenue, which consists of disposable product commercial sales related to cases utilizing the ClearPoint system, decreased 17% to $2.7 million for the six months ended June 30, 2020, from $3.3 million for the same period in 2019. This decrease was due to the effects of the COVID-19 pandemic, in which elective surgical procedures, historically representing approximately 80% of our ClearPoint system case volume, were postponed or cancelled. Although elective surgeries have been resumed, or the resumption is being considered, in certain areas of the U.S., we are unable to determine the extent to which such factors as the timing, adoption or viability of such resumption will impact our revenue. Accordingly, we are unable to determine the length of time that the COVID-19 pandemic will adversely affect our product revenues. There were no increases in functional neurosurgery product prices during the period between the six months ended June 30, 2020 and the same period in 2019 that would be reasonably expected to affect a typical customer order.

Biologics and drug delivery revenues, which include sales of disposable products and services related to customer-sponsored clinical trials utilizing the ClearPoint system, increased 176% to $2.2 million for the six months ended June 30, 2020, from $795,000 for the same period in 2019. This increase was due primarily to an increase, during the six months ended June 30, 2020, relative to the same period in 2019, in biologic and drug delivery service revenues of $1.4 million. This increase in biologics and drug delivery service revenues is attributable to the establishment of additional relationships with biologic and drug delivery companies that included period-based retainers for clinical services in support of such companies' respective clinical trials. 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 pandemic, future biologics and drug delivery revenues could be adversely impacted. In this context, however, it should be noted that the terms of our product sales do not provide the customer with a right of return for any reason other than for defective product or product that does not conform to a customer's specifications. There were no increases in biologics and drug delivery product prices during the period between the six months ended June 30, 2020 and the same period in 2019 that would be reasonably expected to affect a typical customer order.

Capital equipment revenue, consisting of sales of ClearPoint reusable hardware and software, decreased 41% to $304,000 for the six months ended June 30, 2020, from $516,000 for the same period in 2019. While revenues from this product line historically have varied from quarter to quarter, we believe that many hospitals have postponed capital equipment acquisition activities, which postponement we believe to be contingent upon the prevalence and duration of the COVID-19 pandemic. There were no increases in capital equipment product prices during the period between the six months ended June 30, 2020 and the same period in 2019 that would be reasonably expected to affect a typical customer order.

Capital equipment-related services, consisting of fees for capital equipment rental, service, installation, training and shipping, decreased 38% to $280,000 for the six months ended June 30, 2020, from $455,000 for the same period in 2019. The decrease was due primarily to decreases in fees related to capital equipment sales, which were partially offset by an increase in equipment service contracts.

Cost of Revenues. Cost of revenues was $1.6 million, representing a gross margin of 72%, for the six months ended June 30, 2020, and was $1.9 million, representing a gross margin of 62%, for the six months ended June 30, 2019. This increase in gross margin was due primarily to a shift in the mix of revenues by line of business that resulted in service revenues, which bear higher gross margins in comparison to other product lines, representing a greater contribution to total sales for the six months ended June 30, 2020, relative to the same period in 2019. Also contributing to the improvement in gross margin was a lower allocation of overhead costs to sales for the six months ended June 30, 2020 as compared to the same period in 2019, resulting from the reduced sales volume during such 2020 period as compared to the same period in 2019, and a reduction in the allowance for excess and obsolete inventory. While we believe that these factors may prevail during the period that precautionary measures are in effect due to the COVID-19 pandemic, we also believe there is a possibility that gross margin may erode from its current level in the event that the mix of revenues and overhead allocations return to historical norms.

Research and Development Costs. Research and development costs were $1.7 million for the six months ended June 30, 2020, compared to $1.3 million for the same period in 2019, an increase of $369,000, or 29%. The increase was due primarily to increases in personnel costs of $171,000 due to increases in headcount and compensation, intellectual property costs of $109,000 due to increased project activity, license amortization costs of $59,000 resulting primarily from licensing rights acquired in 2020, and outside consulting costs of $84,000 in connection with enhancements to the Company's quality system and pre-commercial license fees of $23,000 resulting from an increase in project activity. Partially offsetting these increases was a decrease in other product development costs of $63,000.

Sales and Marketing Expenses. Sales and marketing expenses were $2.4 million for the six months ended June 30, 2020 and $2.2 million for the same period in 2019. The increase was due primarily to increases in personnel costs of $428,000 resulting from headcount increase in our clinical and marketing teams, and meeting costs of $75,000. These increases were partially offset by decreases during the six months ended June 30, 2020 as compared to the same period in 2019 in travel and entertainment expenses of $173,000 and incentive compensation costs of $203,000, both decreases resulting from reduced activity due to the COVID-19 pandemic.

General and Administrative Expenses. General and administrative expenses were $2.6 million for the six months ended June 30, 2020, compared to $2.0 million for the same period in 2019, an increase of $682,000, or 35%. This increase was due primarily to increases in share-based compensation of $187,000, professional fees of $212,000, insurance costs of $37,000, and a $155,000 reduction of allocation of shared departmental resources to production due to the reduced manufacturing activity as an effect of the COVID-19 pandemic. These increases were partially offset by a $53,000 decrease in license expense.

Interest Expense. Net interest expense for the six months ended June 30, 2020 was $1.0 million, compared with $513,000 for the same period in 2019. This increase was primarily due to a $458,000 increase in the amortization of the discount associated with the 2010 Secured Notes, which were repaid and retired during the six months ended June 30, 2020, and interest expense associated with the issuance of the 2020 Secured Notes in January 2020. These increases were partially offset by interest incurred during the six months ended June 30, 2019 related to secured notes issued in 2014 and repaid in June 2019. 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 June 30, 2020 of $116 million. In addition, our use of cash from operations amounted to $4.0 for the six months ended June 30, 2020 and $2.8 million for the year ended December 31, 2019. 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.

As discussed in Note 7 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report, in May 2019, we entered into the 2019 PIPE under which such investors purchased 2,426,455 shares of our common stock at $3.10 per share, resulting in proceeds of approximately $7.5 million, before deducting offering expenses aggregating approximately $94,000. In addition, as discussed in Note 5 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report, in January 2020, we issued the 2020 Secured Notes, resulting in proceeds, net of financing costs paid and payable, and a commitment fee to one of the investors, of approximately $16.8 million. From the net proceeds received from the issuance of the 2020 Secured 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. Also, as discussed in Note 5 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report, in April 2020 we received $896,000 in proceeds through a loan funded under the Payroll Protection Program as part of the CARES Act. Management's plan during the period in which we are affected by the COVID-19 pandemic is to retain our employee base and, pending the ultimate duration and impact of the COVID-19 pandemic and by using the funds for the purposes described under the terms of the loan, consider whether to repay the loan in conformity with its terms or request that all or a portion of the loan, as applicable under its terms, be ultimately forgiven. However, there is no assurance that we would be successful in obtaining such forgiveness. Based on the foregoing, in management's opinion, cash and cash equivalent balances at June 30, 2020, when combined with the proceeds from issuance of the 2020 Secured Notes (after repayment of the 2010 Secured Notes) and receipt of the proceeds from the loan funded under the Payroll Protection Program, are sufficient to support our operations and meet our obligations for at least the next twelve months.

Cash Flows

Cash activity for the six months ended June 30, 2020 and 2019 is summarized as follows:

	Six Months Ended June 30,	
	2020	**2019**
Cash used in operating activities	$ (4,038,514)	$ (1,419,570)
Cash used in investing activities	(441,341)	(150,000)
Cash provided by financing activities	14,816,215	5,930,085
Net change in cash and cash equivalents	$ 10,336,360	$ 4,360,515

Net Cash Flows from Operating Activities. We used $4.0 million and $1.4 million of cash for operating activities during the six months ended June 30, 2020 and 2019, respectively.

During the six months ended June 30, 2020, uses of cash in operating activities primarily consisted of: (i) our $3.7 million net loss; (ii) increases in accounts receivable of $74,000, inventory of $313,000, and prepaid expenses and other current assets of $181,000; and (iii) decreases in accrued interest of $960,000, lease liabilities of $48,000, and deferred revenue of $366,000. These uses were partially offset by: (a) a decrease in other assets of $70,000; (b) an increase in accounts payable and accrued expenses of $93,000; and (c) net non-cash expenses included in our net loss aggregating $1.5 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.

During the six months ended June 30, 2019, uses of cash in operating activities primarily consisted of: (i) our $2.8 million net loss; (ii) increases in accounts receivable of $138,000, inventory of $202,000, and prepaid expenses and other current assets of $217,000; and (iii) a decrease in lease liabilities of $50,000. These uses were partially offset by: (a) a decrease in other assets of $12,000; (b) increases in accounts payable and accrued expenses of $716,000 and in deferred revenue of $389,000; and (c) net non-cash expenses included in our net loss aggregating $841,000 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 six months ended June 30, 2020 and 2019 were $441,000 and $150,000, respectively, and consisted of acquisitions of medical device license rights.

Net Cash Flows from Financing Activities. Net cash flows from financing activities for the six months ended June 30, 2020 consisted of the proceeds, net financing costs and discount paid as of that date, of $16.8 million received from the issuance of the 2020 Secured Notes, and the proceeds of $896,000 from the Payroll Protection Program loan. The proceeds from these activities were partially offset by the repayment of the 2010 Secured Notes amounting to $2.8 million. The 2020 Secured Notes, the Payroll Protection Act Loan and the repayment of the 2010 Secured Notes are described in Note 5 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report.

Net cash flows from financing activities for the six months ended June 30, 2019 consisted of proceeds from cash proceeds of: (a) $7.5 million received from the sale of shares of our common stock under the terms of the 2019 PIPE as described in Note 7 to the condensed consolidated financial statements included elsewhere in this Quarterly Report; and (b) $383,000 received from warrant exercises. These proceeds were partially offset by the $2.0 million repayment, in June 2019, of secured notes that otherwise would have been due in September 2019.

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, revenues 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 sensitivity, which is affected by changes in the general level of U.S. interest rates, because all 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.

Foreign Currency Risk

To date, we have not recorded a significant amount of sales in currencies other than U.S. dollars, and have only limited business transactions in foreign currencies. We do not currently engage in hedging or similar transactions to reduce our foreign currency risks, which at present, are not material. We believe we have no material exposure to risk from changes in foreign currency exchange rates at this time. We will continue to monitor and evaluate our internal processes relating to foreign currency exchange, including the potential use of hedging strategies.

ITEM 4. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

We have established disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act"). Our disclosure controls and procedures are designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others within our organization. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of June 30, 2020 to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer as appropriate, to allow timely decisions regarding required disclosure. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of June 30, 2020.

Changes in Internal Control Over Financial Reporting

During the quarter ended June 30, 2020, 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.

Except as noted below, there have been no material changes to the risk factors disclosed in our 2019 Form 19-K under Item 1A. "Risk Factors."

The COVID-19 pandemic and mitigation efforts to control the spread of the disease have and are expected to continue to materially impact our business, and our financial condition, results of operations and cash flows could be materially adversely affected by factors relating to COVID-19.

On March 11, 2020, the World Health Organization characterized COVID-19 as a pandemic, and on March 13, 2020, the President of the United States proclaimed that the COVID-19 outbreak in the United States constitutes 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 represents approximately 80% of the procedures utilizing our products and services. Furthermore, the business shutdowns and the disruptions to financial markets caused by COVID-19 pandemic has led to recessionary conditions in the economy in the short term, which could negatively impact our business, as hospitals curtail and reduce capital and overall spending.

The ongoing COVID-19 pandemic and restrictions intended to prevent its spread could have significant adverse impacts on our business, financial condition, results of operations and cash flows in a variety of ways that are difficult to predict. Such adverse impacts will depend on, among other factors:

- federal, state, local and industry-initiated efforts that may adversely affect the ability to perform elective surgeries;
- disruptions to the supply chain of critical components;
- severe and prolonged disruption and instability in the financial markets, including the debt and equity capital markets, which have already experienced and may continue to experience significant volatility, or deteriorations in credit and financing conditions, which may affect our ability to access capital necessary to fund our business operations or refinance maturing debt on a timely basis, on attractive terms or at all, which would adversely affect our ability to meet liquidity and capital expenditure requirements;
- sustained stock market volatility that negatively affects the market price of our securities, including market conditions unrelated to our operating performance or prospects;
- our ability to manage our business to the extent our management or personnel are impacted in significant numbers by the COVID-19 pandemic and are not willing, available or allowed to conduct work; and
- our ability to ensure business continuity in the event our continuity of operations plan is not effective or improperly implemented during the COVID-19 pandemic.

The ongoing COVID-19 pandemic and the current economic, financial and capital markets environment present material risks and uncertainties for us. However, the rapid development and fluidity of the situation precludes any prediction as to the ultimate impact COVID-19 will have on our business, financial condition, results of operation and cash flows, which will depend largely on future developments directly or indirectly relating to the duration and scope of the COVID-19 outbreak in the United States. To the extent the COVID-19 pandemic adversely affects our business, financial condition, results of operation and cash flows, it may also have the effect of heightening many of the other risks described in the "Risk Factors" section of our 2019 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
10.1	ClearPoint Neuro, Inc. Third Amended and Restated 2013 Incentive Compensation Plan (incorporated by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A (File No. 001-34822) filed with the SEC on April 20, 2020)
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: August 13, 2020

CLEARPOINT NEURO, INC.

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

By: /s/ Harold A. Hurwitz
Harold A. Hurwitz
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

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

I, Joseph M. Burnett, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarter ended June 30, 2020, of ClearPoint Neuro, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 13, 2020

/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, Harold A. Hurwitz, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarter ended June 30, 2020, of ClearPoint Neuro, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 13, 2020

/s/ Harold A. Hurwitz
Harold A. Hurwitz
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 Harold A. Hurwitz, certifies pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934 and Section 1350 of Chapter 63 of Title 18 of the United States Code, that (1) this quarterly report on Form 10-Q for the quarter ended June 30, 2020, of ClearPoint Neuro, Inc. (the "Company") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934, and (2) the information contained in this quarterly report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 13, 2020

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

/s/ Harold A. Hurwitz
Harold A. Hurwitz
Chief Financial Officer