

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

**FORM 8-K**

**CURRENT REPORT**

Pursuant to Section 13 OR 15(d) of the  
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 12, 2020

**CLEARPOINT NEURO, INC.**

(Exact name of registrant as specified in its charter)

**DELAWARE**  
(State or other jurisdiction  
of incorporation)

**001-34822**  
(Commission  
File Number)

**58-2394628**  
(I.R.S. Employer  
Identification Number)

**5 Musick**  
**Irvine, CA 92618**  
(Address of principal executive offices, zip code)

**(949) 900-6833**  
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

**Item 2.02. Results of Operations and Financial Condition.**

On May 12, 2020, ClearPoint Neuro, Inc. (the “Company”) issued a press release announcing its financial performance for the first fiscal quarter ended March 31, 2020 and providing an update with respect to its response to the COVID-19 pandemic. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 2.02 of this Current Report on Form 8-K, as well as Exhibit 99.1 attached hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 7.01. Regulation FD Disclosure.**

The information set forth in Item 2.02 above is incorporated by reference into this Item 7.01.

The information in Item 7.01 of this Current Report on Form 8-K, as well as Exhibit 99.1 attached hereto, shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release, dated May 12, 2020</a>

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**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 hereunto duly authorized.

Date: May 12, 2020

**MRI INTERVENTIONS, INC.**

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



## ClearPoint Neuro Reports First Quarter 2020 Results

*Company Provides Update on Effects of COVID-19 Pandemic*

IRVINE, CA, May 12, 2020 – ClearPoint Neuro, Inc. (Nasdaq: CLPT) today announced financial results for its first fiscal quarter ended March 31, 2020.

Total revenues were approximately \$3.1 million and \$2.5 million for the three months ended March 31, 2020 and 2019, respectively, an increase of 26% year-over-year.

Functional neurosurgery revenue, which consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 5% to \$1.7 million for the three months ended March 31, 2020, from \$1.6 million for the same period in 2019. This increase was lower, relative to recent quarterly year-over-year increases, due to the effects of the COVID-19 pandemic, in which elective surgical procedures, historically representing approximately 80% of the Company's ClearPoint system case volume, were temporarily suspended commencing in the second half of March 2020.

Biologics and drug delivery revenues, which include sales of disposable products and services related to customer-sponsored clinical trials utilizing the ClearPoint system, increased 169% to \$1.0 million for the three months ended March 31, 2020, from \$382,000 for the same period in 2019.

Capital equipment revenue, consisting of sales of ClearPoint reusable hardware and software, as well as fees related to capital equipment, decreased 29% to \$345,000 for the three months ended March 31, 2020, from \$486,000 for the same period in 2019.

Gross margin for the three months ended March 31, 2020 was 71%, as compared to 64% in 2019, 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 March 31, 2020, relative to the same period in 2019.

Operating expenses for the three months ended March 31, 2020 were \$3.4 million, a 33% increase from operating expenses of \$2.6 million for the same period in 2019. This increase was comprised of: (a) research and development costs, which increased 42% resulting primarily from increases in product development costs and departmental compensation; (b) sales and marketing expenses, which increased 25% resulting primarily from expansion of the Company's team of clinical specialists and marketing leadership; and (c) general and administrative expenses, which increased 37% resulting primarily from increases in share-based compensation and outside professional fees.

“We were on-track for another record quarter before the measures implemented in March 2020 to address the COVID-19 crisis resulted in the postponement of elective surgeries, historically constituting approximately 80% of our case volume,” commented Joe Burnett, President and CEO of ClearPoint Neuro. “With the significant impact felt by patients, providers and other businesses from the pandemic, it seems hollow to celebrate our pre-COVID-19 successes. Rather, we want to focus on the new reality our employees and our patients face. April 2020 has been the first month in which we experienced the full impact of the COVID-19 measures. In April, we performed a total of eleven surgical cases compared to a forecast of 80 procedures, which represents an approximate 85% reduction in case volume. The eleven cases took place at sites that perform mostly urgent tumor biopsy and ablation procedures. Hospitals that perform mostly drug delivery and deep brain stimulation procedures have had to postpone them. As a result, on April 16, 2020, we withdrew our case and revenue forecast for 2020.

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“We see a number of challenges to the resumption of elective procedures in the months ahead, which include the limited access to personal protective equipment and ventilators,” Mr. Burnett continued. “Our procedures are primarily performed under general anesthesia, thus requiring the use of ventilators. However these ventilators are currently in demand to treat COVID-19 patients. Further, even if some hospitals restart elective procedures, patients might have reluctance to enter the hospital environment because their families are not allowed to be with them.”

As previously disclosed, in January 2020, the Company completed a financing transaction with two investors whereby the Company issued an aggregate principal amount of \$17,500,000 of senior secured convertible notes, resulting in net proceeds of approximately \$16.8 million. From the net proceeds, the Company repaid principal and accrued interest aggregating \$3.8 million to retire secured notes that otherwise would have been due in October and November 2020 (the “2010 Notes”). As a result, the Company’s cash and cash equivalent balances at March 31, 2020 aggregated approximately \$17.0 million. During the quarter ended March 31, 2020, the Company’s operational cash burn was \$2.3 million, of which \$960,000 represented the payment of accrued interest related to the retirement of the 2010 Notes.

#### **Teleconference Information**

Investors and analysts are invited to listen to a live broadcast review of the Company's 2020 first quarter financial results today at 4:30 p.m. Eastern time (1:30 p.m. Pacific time) that may be accessed by visiting the Company's website at [www.clearpointneuro.com](http://www.clearpointneuro.com) and selecting “Investors” / “News” / “IR Calendar.”

Investors and analysts who would like to participate in the conference call may do so via telephone at (877) 407-9034, or at (201) 493-6737 if calling from outside the U.S. or Canada.

For those who cannot access the live broadcast, a replay will be available shortly after the completion of the call until May 28, 2020 by calling (877) 660-6853, or (201) 612-7415 if calling from outside the U.S. or Canada, and then entering conference I.D. number 413671. An online archive of the broadcast will be available on the Company's website at [www.clearpointneuro.com](http://www.clearpointneuro.com), on the “Investor Relations” page.

#### **About ClearPoint Neuro**

ClearPoint Neuro’s mission is to improve and restore quality of life to patients and their families by enabling therapies for the most complex neurological disorders with pinpoint accuracy. Applications of the Company’s current product portfolio include deep-brain stimulation, laser ablation, biopsy, neuro-aspiration, and delivery of drugs, biologics and gene therapy to the brain. The ClearPoint<sup>®</sup> Neuro Navigation System has FDA clearance, is CE-marked, and is installed in 60 active clinical sites in the United States. The Company’s SmartFlow<sup>®</sup> cannula is being used in partnership or evaluation with more than 20 individual biologics and drug delivery companies in various stages from preclinical research to late stage regulatory trials. To date, more than 3,500 cases have been performed and supported by the Company’s field-based clinical specialist team which offers support and services for our partners. For more information, please visit [www.clearpointneuro.com](http://www.clearpointneuro.com).

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### **Forward-Looking Statements**

Statements herein concerning the Company's plans, growth and strategies may include forward-looking statements within the context of the federal securities laws. Statements regarding the Company's future events, developments and future performance, as well as management's expectations, beliefs, plans, estimates or projections relating to the future, are forward-looking statements within the meaning of these laws. Uncertainties and risks may cause the Company's actual results to differ materially from those expressed in or implied by forward-looking statements. Particular uncertainties and risks include those relating to: future revenues from sales of the Company's ClearPoint Neuro Navigation System products; the Company's ability to market, commercialize and achieve broader market acceptance for the Company's ClearPoint Neuro Navigation System products; the impact of COVID-19 and the measures adopted to contain its spread; and estimates regarding the sufficiency of the Company's cash resources. More detailed information on these and additional factors that could affect the Company's actual results are described in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, which has been filed with the Securities and Exchange Commission, and the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2020, which the Company intends to file with the Securities and Exchange Commission on or before May 15, 2020.

#### **Contact:**

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**CLEARPOINT NEURO, INC.**  
Condensed Consolidated Balance Sheets

<b>ASSETS</b>	<b>March 31, 2020 (Unaudited)</b>	<b>December 31, 2019</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 16,976,329	\$ 5,695,722
Accounts receivable, net	984,866	1,089,917
Inventory, net	3,650,282	3,240,218
Prepaid expenses and other current assets	188,429	357,227
Total current assets	<u>21,799,906</u>	<u>10,383,084</u>
Property and equipment, net	389,223	447,162
Operating lease rights of use	347,685	374,218
Software license inventory	489,300	504,400
Licensing rights	546,744	135,000
Other assets	12,469	82,573
Total assets	<u>\$ 23,585,327</u>	<u>\$ 11,926,437</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,435,613	\$ 965,783
Accrued compensation	826,486	1,408,292
Other accrued liabilities	411,491	328,460
Operating lease liabilities, current portion	110,349	113,520
Deferred product and service revenue	857,813	1,016,892
Total current liabilities	<u>3,641,752</u>	<u>3,832,947</u>
Accrued interest	—	959,659
Operating lease liabilities, net of current portion	255,364	276,669
Deferred product and service revenue, net of current portion	148,150	197,862
2020 senior secured convertible notes payable, net	16,780,201	—
2010 junior secured notes payable, net	—	2,072,583
Total liabilities	<u>20,825,467</u>	<u>7,339,720</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at March 31, 2020 and December 31, 2019	—	—
Common stock, \$0.01 par value; 200,000,000 shares authorized; 15,507,149 shares issued and outstanding at March 31, 2020; and 15,235,308 issued and outstanding at December 31, 2019	155,071	152,353
Additional paid-in capital	117,399,234	117,173,984
Accumulated deficit	(114,794,445)	(112,739,620)
Total stockholders' equity	<u>2,759,860</u>	<u>4,586,717</u>
Total liabilities and stockholders' equity	<u>\$ 23,585,327</u>	<u>\$ 11,926,437</u>

**CLEARPOINT NEURO, INC.**  
**Condensed Consolidated Statements of Operations**  
**(Unaudited)**

	<b>For The Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2020</b>	<b>2019</b>
Revenues:		
Product revenues	\$ 2,103,384	\$ 2,163,953
Service and other revenues	1,012,209	308,564
Total revenues	3,115,593	2,472,517
Cost of revenues	917,336	886,481
Research and development costs	829,528	584,540
Sales and marketing expenses	1,298,594	1,040,712
General and administrative expenses	1,278,509	933,033
Operating loss	(1,208,374)	(972,249)
Other income (expense):		
Other income (expense), net	(33,304)	5,629
Interest expense, net	(813,147)	(254,105)
Net loss	<u>\$ (2,054,825)</u>	<u>\$ (1,220,725)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	<u>\$ (0.13)</u>	<u>\$ (0.11)</u>
Weighted average shares outstanding:		
Basic and diluted	<u>15,438,276</u>	<u>11,044,125</u>



**CLEARPOINT NEURO, INC.**  
**Condensed Consolidated Statements of Cash Flows**  
**(Unaudited)**

	<b>For The Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2020</b>	<b>2019</b>
Cash flows from operating activities:		
Net loss	\$ (2,054,825)	\$ (1,220,725)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	57,972	34,640
Share-based compensation	227,968	152,586
Amortization of debt issuance costs and original issue discounts	787,403	169,179
Amortization of lease rights of use, net of accretion in lease liabilities	25,077	25,630
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	105,051	(32,901)
Inventory, net	(365,430)	47,824
Prepaid expenses and other current assets	168,798	14,108
Other assets	70,135	11,899
Accounts payable and accrued expenses	(161,074)	(148,562)
Accrued interest	(959,661)	34,625
Lease liabilities	(23,019)	(26,289)
Deferred revenue	(208,791)	328,523
Net cash flows from operating activities	(2,330,396)	(609,463)
Cash flows from investing activities:		
Acquisition of licensing rights	(441,341)	—
Net cash flows from investing activities	(441,341)	—
Cash flows from financing activities:		
Proceeds from issuance of 2020 senior secured convertible notes, net of financing costs and discount	16,890,000	—
Repayment of 2010 junior secured notes payable	(2,837,656)	—
Net cash flows from financing activities	14,052,344	—
Net change in cash and cash equivalents	11,280,607	(609,463)
Cash and cash equivalents, beginning of period	5,695,722	3,101,133
Cash and cash equivalents, end of period	\$ 16,976,329	\$ 2,491,670

**SUPPLEMENTAL CASH FLOW INFORMATION**

Cash paid for:		
Income taxes	\$ —	\$ —
Interest	\$ 1,043,371	\$ 291,032