

**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): February 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 February 12, 2020, ClearPoint Neuro, Inc. (formerly MRI Interventions, Inc.) (the “Company”) issued a press release announcing its financial performance for the fourth fiscal quarter and fiscal year ended December 31, 2019. 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, 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	Press Release, dated February 12, 2020

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: February 12, 2020

MRI INTERVENTIONS, INC.

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



ClearPoint Neuro Reports 53% Increase in 2019 Revenue

Fourth quarter revenue grows 41%, fifth consecutive quarter of revenue growth

IRVINE, CA, February 12, 2020 – ClearPoint Neuro, Inc. (Nasdaq: CLPT) (formerly, MRI Interventions, Inc.; the “Company”) today announced financial results for its fourth fiscal quarter and full year ended December 31, 2019.

2019 Full Year and Fourth Quarter Highlights

- Achieved full-year 2019 revenue of \$11.2 million, representing 53% year-over year growth.
 - Functional neurosurgery revenue increased 29% to \$6.9 million.
 - Biologics and drug delivery revenue increased 116% to \$2.6 million.
 - Capital equipment sales and related service revenue increased 104% to \$1.7 million
 - Increased to 60 active surgical centers utilizing the ClearPoint® system.
 - Supported a record 801 cases, an increase of 20%.
 - Reduced cash burn from operations to \$2.8 million.
- Increased 2019 fourth quarter revenue 41% on a year-over-year basis to a record \$3.2 million.
- Reduced cash burn from operations in the 2019 fourth quarter to \$466,000.

“We believe that 2019 exhibited a true inflection point in our Company’s history,” commented Joe Burnett, President and CEO of ClearPoint Neuro. “We delivered growth in all four segments of our business, driven by the performance of our commercial and clinical specialist teams that exceeded our plan. We made significant progress across our portfolio of navigation and therapy programs that we expect will result in U.S. FDA submission or market introduction of several new products in 2020, a testament to our development and operations teams. In transactions completed in May 2019 and January 2020, we secured more than \$25 million of financing from strategic partners that strengthened our balance sheet and facilitated us becoming a Nasdaq-listed company, an accomplishment driven by our finance and legal teams. The culmination of these successes enabled us to win multiple new biologics and gene therapy partnerships that we believe will lead to exciting new applications. It is not a coincidence that the totality of these achievements led us to change our corporate name to ClearPoint Neuro. We feel we are truly a new company, with an exciting future ahead.”

Financial Results – Year Ended December 31, 2019

Total revenues were approximately \$11.2 million and \$7.4 million for the years ended December 31, 2019 and 2018, respectively, an increase of 53% year-over-year.

Functional neurosurgery revenue, which consists of disposable product sales related to cases utilizing the ClearPoint system, increased 29% to \$6.9 million for 2019, from \$5.3 million in 2018. The increase was due primarily to a record 801 cases utilizing the ClearPoint Neuro Navigation System in 2019, an increase of 20% from 670 cases in 2018.

Biologics and drug delivery revenue, which include sales of disposable products and services related to customer-sponsored clinical trials and services, increased 116% to \$2.6 million for 2019, from \$1.2 million in 2018. This increase was due primarily to the growth of both clinical services and product sales during 2019.

Capital equipment sales and related service revenue, consisting of sales of ClearPoint reusable hardware and software, and related service revenue, increased to \$1.7 million for 2019, from \$813,000 in 2018, due primarily to an increase in sales of ClearPoint systems, which historically have varied from quarter to quarter.

Gross margin for the year ended December 31, 2019 was 66%, as compared to 67% in 2018. The slight decrease was due primarily to an increased contribution from lower margin capital equipment sales, substantially offset by an increased contribution from sales of services, which bear higher margins relative to other lines of revenue.

Research and development costs were \$2.9 million in 2019, compared to \$2.3 million in 2018, an increase of 26%, resulting primarily from increases in product development costs and departmental compensation. Sales and marketing expenses were \$4.8 million for the year ended December 31, 2019, compared to \$3.5 million in 2018, an increase of 35%, resulting primarily from increases in incentive-based compensation tied to increased sales and expansion of the Company's team of clinical specialists. General and administrative expenses were \$4.3 million for both 2019 and 2018.

Financial Results – Three Months Ended December 31, 2019

Functional neurosurgery revenue increased 7% to \$1.7 million for the three months ended December 31, 2019, from \$1.6 million for the same period in 2018. The increase was primarily due to an expanded customer base and increased utilization by our existing customers of MRI scanner availability.

Biologics and drug delivery revenue increased 99% to \$1.1 million for the three months ended December 31, 2019, from \$540,000 for the fourth quarter of 2018.

Capital equipment sales and related service revenue increased to \$446,000 for the three months ended December 31, 2019, versus \$174,000 in the fourth quarter of 2018, which, as previously mentioned, can vary from quarter to quarter.

Gross margin for the three months ended December 31, 2019 was 71%, a slight increase from gross margin of 70% for the same period in 2018, primarily due to an increased contribution from higher margin services.

Research and development costs were \$880,000 for three months ended December 31, 2019, compared to \$481,000 for the same period in 2018, an increase of 83%. Sales and marketing expenses were \$1.5 million for the three months ended December 31, 2019, compared to \$879,000 for the same period in 2018, an increase of 72%, attributable primarily to increases in incentive compensation tied to increased sales, and in the expansion of the Company's team of clinical specialists. General and administrative expenses were \$1.3 million for the three months ended December 31, 2019, compared to \$1.2 million for the same period in 2018, an increase of 8%.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's 2019 fourth quarter and full year 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 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 February 26, 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, 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 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® 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.

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; 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, 2018, and its Quarterly Report on Form 10-Q for the three months ended September 30, 2019, both of which have been filed with the Securities and Exchange Commission, as well as the Company's Annual Report on Form 10-K for the year ended December 31, 2019, which the Company intends to file with the Securities and Exchange Commission on or before March 30, 2020.

Contact:

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MRI INTERVENTIONS, INC.
Consolidated Statements of Operations

	Three Months Ended	
	December 31,	
	2019	2018
Revenues:		
Product revenues	\$ 2,523,789	\$ 1,994,019
Service and other revenues	686,766	282,504
Total revenues	3,210,555	2,276,523
Cost of revenues	933,044	689,088
Research and development costs	880,334	481,293
Sales and marketing expenses	1,508,604	878,997
General and administrative expenses	1,308,630	1,206,169
Operating loss	(1,420,057)	(979,024)
Other income (expense):		
Other income (loss), net	3,229	(920)
Interest expense, net	(228,874)	(237,996)
Net loss	\$ (1,645,702)	\$ (1,217,940)
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.11)	\$ (0.11)
Weighted average shares outstanding:		
Basic and diluted	15,165,193	11,012,208
	Years Ended December 31,	
	2019	2018
Revenues:		
Product revenues	\$ 9,476,364	\$ 6,685,020
Service and other revenues	1,740,573	668,246
Total revenues	11,216,937	7,353,266
Cost of revenues	3,832,884	2,433,069
Research and development costs	2,922,279	2,310,139
Sales and marketing expenses	4,755,516	3,532,040
General and administrative expenses	4,299,936	4,325,786
Operating loss	(4,593,678)	(5,247,768)
Other income (expense):		
Gain on change in fair value of derivative liabilities	—	64,318
Other income, net	9,054	364
Interest expense, net	(955,166)	(980,383)
Net loss	\$ (5,539,790)	\$ (6,163,469)
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.42)	\$ (0.56)
Weighted average shares outstanding:		
Basic and diluted	13,155,163	10,928,213

MRI INTERVENTIONS, INC.
Consolidated Balance Sheets

	December 31,	
	2019	2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 5,695,722	\$ 3,101,133
Accounts receivable, net	1,089,917	1,233,896
Inventory, net	3,240,218	2,105,976
Prepaid expenses and other current assets	357,227	213,684
Total current assets	<u>10,383,084</u>	<u>6,654,689</u>
Property and equipment, net	447,162	377,706
Operating lease rights of use	374,218	—
Software license inventory	504,400	801,900
Other assets	217,573	22,538
Total assets	<u>\$ 11,926,437</u>	<u>\$ 7,856,833</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 965,783	\$ 500,929
Accrued compensation	1,408,292	764,960
Other accrued liabilities	328,460	390,838
Operating lease liabilities, current portion	113,520	—
Deferred product and service revenues	1,214,754	350,963
Total current liabilities	<u>4,030,809</u>	<u>2,007,690</u>
Accrued interest	959,659	857,500
Operating lease liabilities	276,669	—
2010 junior secured notes payable, net of unamortized discount of \$765,073 and \$1,459,209 at December 31, 2019 and 2018, respectively	2,072,583	1,540,791
2014 junior secured notes payable, net of unamortized discount and deferred issuance costs aggregating \$35,149 at December 31, 2018	—	1,939,850
Total liabilities	<u>7,339,720</u>	<u>6,345,831</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized at December 31, 2019 and 2018; none issued and outstanding at December 31, 2019 and 2018	—	—
Common stock, \$0.01 par value; 200,000,000 shares authorized at December 31, 2019 and 2018; 15,235,308 and 11,018,364 shares issued and outstanding at December 31, 2019 and 2018, respectively	152,353	110,183
Additional paid-in capital	117,173,984	108,600,405
Accumulated deficit	(112,739,620)	(107,199,586)
Total stockholders' equity	<u>4,586,717</u>	<u>1,511,002</u>
Total liabilities and stockholders' equity	<u>\$ 11,926,437</u>	<u>\$ 7,856,833</u>

MRI INTERVENTIONS, INC.
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (5,539,790)	\$ (6,163,469)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	143,604	109,439
Share-based compensation	799,110	1,231,379
Expenses paid through the issuance of common stock	—	77,500
Gain on change in fair value of derivative liabilities	—	(64,318)
Amortization of debt issuance costs and original issue discounts	729,287	562,529
Amortization of lease right of use assets, net of accretion in lease liabilities	106,956	—
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	143,979	(284,481)
Inventory	(1,024,612)	122,220
Prepaid expenses and other current assets	(143,543)	(20,957)
Other assets	14,965	(10,897)
Accounts payable and accrued expenses	1,165,724	(284,322)
Lease liability	(108,985)	—
Deferred revenue	863,791	94,785
Net cash flows from operating activities	(2,849,514)	(4,630,592)
Cash flows from investing activities:		
Purchases of property and equipment	(10,190)	(63,490)
Acquisition of licensing rights	(150,000)	—
Net cash flows from investing activities	(160,190)	(63,490)
Cash flows from financing activities:		
Proceeds from private offering, net of offering costs	7,427,847	—
Prepayment of offering costs in connection with January 2020 private placement	(75,000)	—
Proceeds from exercise of warrants	388,790	505,384
Principal repayment of 2014 and 2010 notes	(2,137,344)	(2,000,000)
Net cash flows from financing activities	5,604,293	(1,494,616)
Net change in cash and cash equivalents	2,594,589	(6,188,698)
Cash and cash equivalents, beginning of year	3,101,133	9,289,831
Cash and cash equivalents, end of year	\$ 5,695,722	\$ 3,101,133

SUPPLEMENTAL CASH FLOW INFORMATION

Cash paid for:

Income taxes	\$ —	\$ —
Interest	\$ 316,558	\$ 210,722