

**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):
March 4, 2021

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 March 4, 2021, ClearPoint Neuro, Inc. (the "Company") issued a press release announcing its financial performance for the fourth fiscal quarter and full year ended December 31, 2020. A copy of the press release is furnished herewith as Exhibit 99.1.

The information in Item 2.02 of this 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith:

Exhibit 99.1 [Press Release dated March 4, 2021](#)

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: March 4, 2021

CLEARPOINT NEURO, INC.

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



ClearPoint Neuro Reports Fourth Quarter and Full-Year 2020 Results Company Reports Record Revenues

IRVINE, CA, March 4, 2021 – ClearPoint Neuro, Inc. (Nasdaq: CLPT) (the “Company”), a global therapy-enabling platform company providing navigation and delivery to the brain, today announced financial results for its fourth quarter and full-year ended December 31, 2020.

2020 Full Year and Fourth Quarter Highlights

- Reported fourth quarter 2020 revenue of \$3.7 million, an increase of 16% compared with the fourth quarter of 2019. Reported revenue of \$12.8 million for 2020, a 14% increase over 2019 and representing the sixth consecutive year of growth.
- Increased biologics and drug delivery revenue to \$5.0 million in 2020, a 109% increase over 2019, driven by service revenue.
- Supported 682 cases in 2020 despite the continued challenges posed by the COVID-19 pandemic.
- Completed a convertible note financing facility under which notes aggregating \$25.0 million were issued, and ended 2020 with cash and cash equivalents totaling \$20.1 million.

“Our goal throughout the last 12 months was to exit the COVID-19 pandemic in a stronger position than we started, and I believe we are doing just that,” commented Joe Burnett, President and CEO of ClearPoint Neuro. “Despite still dealing with COVID-related closures and postponements, we are stronger than we have ever been as it relates to our strategy, our partners, our portfolio, and our pipeline of potential new customers. We now have a strong balance sheet to match, which will allow our talented team to relentlessly execute on our strategy. We are proud of the growth we showed in 2020, particularly in our biologics and drug delivery business, and most importantly, proud of the close to 700 patients we helped treat throughout the year, in spite of the COVID-19 pandemic.

“As we continue to see closures and postponements related to ICU bed capacity due to the COVID-19 pandemic, we are not yet in a position to give a forecast for 2021,” continued Burnett. “We are, however, very encouraged that hospitals that have been closed to elective procedures for several months in states such as Massachusetts, California, Texas, Arizona, Oklahoma and Kansas, have started to schedule patients for March and April, and we expect to return to pre-COVID procedure volume in the second half of 2021.”

Financial Results – Year Ended December 31, 2020

Total revenues were approximately \$12.8 million and \$11.2 million for the years ended December 31, 2020 and 2019, respectively.

Functional neurosurgery navigation and therapy revenues, which consist of disposable product commercial sales related to cases utilizing the ClearPoint system and related services, decreased 12% to \$6.3 million for 2020 from \$7.1 million for 2019. This decrease primarily reflects the continuing effects of the COVID-19 pandemic. Although vaccinations to combat the COVID-19 virus have commenced, and elective surgical procedures that were postponed or cancelled at the outset of the pandemic have resumed, such resumption is at volumes that have not yet reached pre-pandemic activity.

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Biologics and drug delivery revenue, which include sales of services related to customer-sponsored clinical trials utilizing the ClearPoint system and of related disposable products, increased 109% to \$5.0 million for 2020, from \$2.4 million for 2019. This increase was due primarily to an increase from 2019 to 2020 of approximately \$2.7 million, or 302%, in biologics and drug delivery services.

Capital equipment revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, decreased 10% to \$1.5 million for 2020, as compared with \$1.7 million for 2019. While revenues from this product line historically have varied from quarter to quarter, the Company believes that many hospitals have postponed capital equipment acquisition activities due to the COVID-19 pandemic.

The Company achieved a gross margin of 71% on its sales for 2020, compared to a gross margin of 65% for 2019. This increase 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 2020, relative to 2019.

Research and development costs were \$4.7 million for 2020, compared to \$2.8 million in 2019, an increase of 67%, resulting primarily from cost increases in compensation, collaborative research, and intellectual property, including amortization of acquired license rights. Sales and marketing

expenses were \$5.4 million for 2020, compared to \$4.8 million for the same period in 2019, an increase of 13%, resulting primarily from an increase in base compensation costs, attributable primarily to headcount increases in the Company's clinical and marketing teams, that were partially offset by decreases in travel costs and incentive-based compensation. General and administrative expenses were \$5.3 million for 2020, compared to \$4.3 million for 2019, an increase of 22%, resulting primarily from increases in compensation, consisting primarily of stock-based compensation and officer transition costs, occupancy costs and legal fees.

Financial Results – Three Months Ended December 31, 2020

Total revenues were approximately \$3.7 million and \$3.2 million for the three months ended December 31, 2020 and 2019, respectively.

Functional neurosurgery navigation and therapy product and service revenues decreased 5% to \$1.6 million for the fourth quarter of 2020 from \$1.7 million for the same period in 2019, due primarily to the previously mentioned continuing effects of the COVID-19 pandemic.

Biologics and drug delivery revenue increased 40% to \$1.5 million for the fourth quarter of 2020, from \$1.1 million for the same period in 2019, due primarily to an increase in biologics and drug delivery services of approximately 81% from the fourth quarter of 2019 to the same period of 2020.

Capital equipment product and related service revenue increased 41% to \$0.6 million for the fourth quarter of 2020, as compared with \$0.4 million for the same period in 2019, due primarily to an increase in systems placement in the fourth quarter of 2020, relative to the same period in 2019.

The Company realized a gross margin of 61% on its sales for the fourth quarter of 2020, compared to a gross margin of 69% for the same period in 2019, due primarily to a one-time, year-to-date reclassification of certain costs, previously classified during 2020 as operating expenses, as cost of revenues.

Research and development costs were \$1.8 million for the fourth quarter of 2020, compared to \$0.8 million for the same period in 2019, an increase of 120%, resulting primarily from cost increases in compensation, collaborative research, and intellectual property, including amortization of acquired license rights. Sales and marketing expenses were \$1.5 million for the fourth quarter of each of 2020 and 2019, due primarily to decreases in travel costs and incentive-based compensation being substantially offset by increases in compensation costs due to headcount increases in the Company's clinical and marketing teams. General and administrative expenses were \$1.3 million for the fourth quarter of each of 2020 and 2019, resulting primarily from increases in compensation costs, occupancy costs and legal fees being offset by the one-time reclassification of costs mentioned above.

At December 31, 2020, the Company had cash and cash equivalents totaling approximately \$20.1 million, resulting primarily from the issuance of senior secured convertible notes in January and December 2020 in the aggregate amount of \$25 million, which resulted in net proceeds to the Company totaling approximately \$24.3 million. From the proceeds of the January 2020 note issuance, the Company repaid and retired notes issued in 2010 having an aggregate principal amount of approximately \$2.8 million and accrued interest of approximately \$0.9 million at the date of repayment.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's 2020 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 [online here](#) or 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 April 3, 2021 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 over 60 active clinical sites in the United States, Canada, and Europe. The Company's SmartFlow[®] cannula is being used in partnership or evaluation with 25 individual biologics and drug delivery companies in various stages from preclinical research to late-stage regulatory trials. To date, more than 4,000 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: the impact of the COVID-19 pandemic and the measures adopted to contain its spread; future revenues from sales of the

Company's ClearPoint Neuro Navigation System products; and the Company's ability to market, commercialize and achieve broader market acceptance for the Company's ClearPoint Neuro Navigation System products. 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, and the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2020, both of which have been filed with the Securities and Exchange Commission, and the Company's Annual Report on Form 10-K for the year ended December 31, 2020, which the Company intends to file with the Securities and Exchange Commission on or before March 31, 2021.

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CLEARPOINT NEURO, INC.
Consolidated Statements of Operations
(Dollars in thousands, except for per share data)

	Three Months Ended December 31,	
	2020	2019
Revenues:		
Product revenues	\$ 2,759	\$ 2,558
Service and other revenues	957	652
Total revenues	<u>3,716</u>	<u>3,210</u>
Cost of revenues	1,432	1,011
Research and development costs	1,825	830
Sales and marketing expenses	1,468	1,509
General and administrative expenses	<u>1,256</u>	<u>1,282</u>
Operating loss	(2,265)	(1,422)
Other income (expense):		
Other income, net	887	3
Interest expense, net	<u>(204)</u>	<u>(229)</u>
Net loss	<u>\$ (1,582)</u>	<u>\$ (1,648)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	<u>\$ (0.09)</u>	<u>\$ (0.11)</u>
Weighted average shares outstanding:		
Basic and diluted	<u>16,723,597</u>	<u>15,165,193</u>

	Years Ended December 31,	
	2020	2019
Revenues:		
Product revenues	\$ 8,789	\$ 9,796
Service and other revenues	4,040	1,421
Total revenues	<u>12,829</u>	<u>11,217</u>
Cost of revenues	3,709	3,942
Research and development costs	4,686	2,810
Sales and marketing expenses	5,384	4,756
General and administrative expenses	<u>5,270</u>	<u>4,303</u>
Operating loss	(6,220)	(4,594)
Other income (expense):		
Other income, net	882	9
Interest expense, net	<u>(1,444)</u>	<u>(955)</u>
Net loss	<u>\$ (6,782)</u>	<u>\$ (5,540)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	<u>\$ (0.43)</u>	<u>\$ (0.42)</u>
Weighted average shares outstanding:		
Basic and diluted	<u>15,849,667</u>	<u>13,155,163</u>

CLEARPOINT NEURO, INC.
Consolidated Balance Sheets
(Dollars in thousands, except for per share data)

	December 31,	
	2020	2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 20,099	\$ 5,696
Accounts receivable, net	1,881	1,090
Inventory, net	3,238	3,240
Prepaid expenses and other current assets	244	358
Total current assets	<u>25,462</u>	<u>10,384</u>
Property and equipment, net	319	447
Operating lease rights of use	2,858	374
Software license inventory	589	504
Licensing rights	353	—
Other assets	59	218
Total assets	<u>\$ 29,640</u>	<u>\$ 11,927</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 300	\$ 966
Accrued compensation	1,595	1,408
Other accrued liabilities	349	328
Operating lease liabilities, current portion	429	114
Deferred product and service revenues	562	1,017
Total current liabilities	<u>3,235</u>	<u>3,833</u>
Accrued interest	—	960
Operating lease liabilities, net of current portion	2,533	277
Deferred product and service revenues, net of current portion	215	198
2020 senior secured convertible notes payable, net	21,280	—
2010 secured notes payable, net	—	2,073
Total liabilities	<u>27,263</u>	<u>7,341</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized at December 31, 2020 and 2019; none issued and outstanding at December 31, 2020 and 2019	—	—
Common stock, \$0.01 par value; 200,000,000 shares authorized at December 31, 2020 and 2019; 17,047,584 and 15,235,308 shares issued and outstanding at December 31, 2020 and 2019, respectively	170	152
Additional paid-in capital	121,729	117,174
Accumulated deficit	<u>(119,522)</u>	<u>(112,740)</u>
Total stockholders' equity	2,377	4,586
Total liabilities and stockholders' equity	<u>\$ 29,640</u>	<u>\$ 11,927</u>

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

	Years Ended December 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	\$ (6,782)	\$ (5,540)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	334	144
Share-based compensation	1,090	799
Payment-in-kind interest	3	—
Forgiveness of PPP loan	(896)	—
Amortization of debt issuance costs and original issue discounts	890	729
Amortization of lease right of use assets, net of accretion in lease liabilities	219	107
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(791)	144
Inventory	(25)	(1,025)
Prepaid expenses and other current assets	113	(144)
Other assets	24	15
Accounts payable and accrued expenses	(459)	1,166
Accrued interest	(960)	—
Lease liability	(131)	(109)
Deferred revenue	(437)	864
Net cash flows from operating activities	<u>(7,808)</u>	<u>(2,850)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(41)	(10)
Acquisition of licensing rights	(441)	(150)
Net cash flows from investing activities	<u>(482)</u>	<u>(160)</u>
Cash flows from financing activities:		
Proceeds from issuance of 2020 senior secured convertible notes, net of financing costs and discount	24,258	—
Prepayment of offering costs in connection with issuance of 2020 senior secured convertible notes	—	(75)
Proceeds from private offering, net of offering costs	—	7,428

Proceeds from issuance of Paycheck Protection Program loan	896	—
Proceeds from stock option and warrant exercises	377	389
Repayment of notes payable	(2,838)	(2,137)
Net cash flows from financing activities	<u>22,693</u>	<u>5,605</u>
Net change in cash and cash equivalents	14,403	2,595
Cash and cash equivalents, beginning of year	5,696	3,101
Cash and cash equivalents, end of year	<u>\$ 20,099</u>	<u>\$ 5,696</u>

SUPPLEMENTAL CASH FLOW INFORMATION

Cash paid for:

Income taxes	\$ —	\$ —
Interest	\$ 1,578	\$ 317