

**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 11, 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)

120 S. Sierra Ave., Suite 100
Solana Beach, California
(Address of principal executive offices, zip code)

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

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

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 11, 2021, ClearPoint Neuro, Inc. (the "Company") issued a press release announcing its financial performance for the first fiscal quarter ended March 31, 2021. 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 May 11, 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: May 11, 2021

CLEARPOINT NEURO, INC.

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



ClearPoint Neuro Reports Record Revenue in First Quarter 2021 Results, Announces FDA Clearance of the SmartFrame ‘Array’

SOLANA BEACH, CA, May 11, 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 first quarter ended March 31, 2021.

First Quarter Highlights

- Reported first quarter 2021 revenue of \$4.0 million, an increase of 29% compared to the first quarter of 2020.
- Increased biologics and drug delivery revenue to \$1.7 million in the first quarter of 2021, a 61% year-over-year increase.
- Added biologics and drug delivery relationships bringing current count of active partners to approximately 30.
- Case volume rebounded to 214 cases in the quarter versus prior estimates of 190-200 cases for the quarter, with certain cases successfully attended remotely via a pilot support program.
- Completed a public offering of common stock, resulting in net proceeds of approximately \$46.8 million.
- Achieved FDA Clearance for the SmartFrame Array™, the new and flexible Navigation system designed for use both the MRI Suite and Operating Room.
- The Company estimates revenue to be between \$16.0 and \$17.5 million for the 2021 calendar year.

“Our goal for the past year has been to exit the pandemic stronger than when we entered it,” commented Joe Burnett, President and CEO of ClearPoint Neuro. “I am so proud of this team for recognizing the importance of what our company is doing for patients, leading by example, and getting stronger each day. We had an excellent quarter across our entire business, including functional neurosurgery cases and disposables, biologics and drug delivery products and services, as well as capital sales, despite significant hospital budget constraints and access. Most importantly, we continue to add amazing members to this team, enabled by a successful public equity offering in February, resulting in a cash balance of nearly \$65.0 million at the end of the first quarter. For the first time in our history, we have the team and resources to execute against our strategic plan and become a premier platform neurosurgery company across multiple indications, especially gene and stem cell therapy delivery.”

Financial Results – Quarter Ended March 31, 2021

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

Functional neurosurgery navigation revenue, which consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 10% to \$1.9 million for the three months ended March 31, 2021, from \$1.7 million for the same period in 2020. This increase reflects the resumption in the three months ended March 31, 2021, of elective surgical procedures, which were postponed or cancelled during the three months ended March 31, 2020, due to the effects of the COVID-19 pandemic. Case volume increased each month in the quarter.

Biologics and drug delivery revenue, which include sales of disposable products and services related to customer-sponsored clinical trials utilizing our products, increased 61% to \$1.7 million for the three months ended March 31, 2021, from \$1.0 million for the same period in 2020, due primarily to the resumption of clinical trial activities that led to increased sales of biologics and drug delivery products.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, increased 31% to \$0.5 million for the three months ended March 31, 2021, from \$0.3 million for the same period in 2020. While revenue from this product line historically has varied from quarter to quarter, the Company believes that the increase represents the partial resumption of hospitals’ capital equipment acquisition activities following the onset of the COVID-19 pandemic. While hospital budget constraints caused by the pandemic continue to be a real headwind, the current funnel of potential installs is larger than it has ever been in the Company’s history.

Gross margin for the three months ended March 31, 2021 was 65%, compared to 70% for the same period in 2020. This decrease was due primarily to: (a) a greater contribution in the first quarter of 2020 to total sales of service revenue, which provide higher gross margins in comparison to other product lines, due to the adverse effects during the 2020 period of the COVID-19 pandemic on hospitals’ purchases of products, as discussed above; and (b) a greater portion of overhead allocated to cost of revenue resulting from larger production output volume during the three months ended March 31, 2021, relative to the same period in 2020.

Research and development costs were \$1.6 million for the three months ended March 31, 2021, compared to \$0.8 million for the same period in 2020, an increase of \$0.8 million, or 91%. Sales and marketing expenses were \$1.6 million for the three months ended March 31, 2021, compared to \$1.3

million for the same period in 2019, an increase of \$0.3 million, or 21%. Both of these increases reflect additions in key areas to the Company's team, as it builds the infrastructure necessary to expand product lines, launch new indications, and comply with global standards as installations take place around the world. General and administrative expenses were \$1.7 million for the three months ended March 31, 2021, compared to \$1.3 million for the same period in 2020, an increase of \$0.4 million, or 30%. This increase was due primarily to increases in insurance, occupancy costs, and incentive-based and share-based compensation.

At March 31, 2021, the Company had cash and cash equivalents totaling \$64.9 million as compared to \$20.1 million at December 31, 2020, with the increase resulting primarily from the completion of a public offering of its common stock in February 2021.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's 2021 first quarter 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 June 11, 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 approximately 30 individual biologics and drug delivery companies in various stages – from preclinical research to late-stage regulatory trials. To date, more than 4,500 cases have been performed and supported by the Company's field-based clinical specialist team, which offers support and services for the Company's 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 revenue 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, 2020, 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, 2021, which the Company intends to file with the Securities and Exchange Commission on or before May 17, 2021.

Contact:

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

	For The Three Months Ended	
	March 31,	
	2021	2020
Revenue:		
Product revenue	\$ 3,162	\$ 2,179
Service and other revenue	868	937
Total revenue	4,030	3,116

Cost of revenue	1,416	932
Research and development costs	1,563	818
Sales and marketing expenses	1,575	1,299
General and administrative expenses	1,657	1,276
Operating loss	(2,181)	(1,209)
Other expense:		
Other expense, net	(25)	(4)
Interest expense, net	(332)	(842)
Net loss	<u>\$ (2,538)</u>	<u>\$ (2,055)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	<u>\$ (0.13)</u>	<u>\$ (0.13)</u>
Weighted average shares outstanding:		
Basic and diluted	<u>18,852,828</u>	<u>15,438,276</u>

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

	March 31, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 64,858	\$ 20,099
Accounts receivable, net	2,004	1,881
Inventory, net	3,266	3,238
Prepaid expenses and other current assets	254	244
Total current assets	<u>70,382</u>	<u>25,462</u>
Property and equipment, net	292	319
Operating lease rights of use	2,613	2,736
Software license inventory	589	589
Licensing rights	331	353
Other assets	56	59
Total assets	<u>\$ 74,263</u>	<u>\$ 29,518</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 727	\$ 300
Accrued compensation	990	1,595
Other accrued liabilities	473	349
Operating lease liabilities, current portion	430	394
Deferred product and service revenue	501	562
Total current liabilities	<u>3,121</u>	<u>3,200</u>
Operating lease liabilities, net of current portion	2,327	2,446
Deferred product and service revenue, net of current portion	318	215
2020 senior secured convertible notes payable, net	24,515	21,280
Total liabilities	<u>30,281</u>	<u>27,141</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at March 31, 2021 and December 31, 2020	—	—
Common stock, \$0.01 par value; 200,000,000 shares authorized; 20,678,280 shares issued and outstanding at March 31, 2021; and 17,047,584 issued and outstanding at December 31, 2020	207	170
Additional paid-in capital	165,835	121,729
Accumulated deficit	(122,060)	(119,522)
Total stockholders' equity	<u>43,982</u>	<u>2,377</u>
Total liabilities and stockholders' equity	<u>\$ 74,263</u>	<u>\$ 29,518</u>

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

	For The Three Months Ended March 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (2,538)	\$ (2,055)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	15	58
Share-based compensation	320	228
Payment-in-kind interest	94	—
Amortization of debt issuance costs and original issue discounts	35	787

Amortization of lease rights of use, net of accretion in lease liabilities	133	25
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(123)	105
Inventory, net	47	(365)
Prepaid expenses and other current assets	(10)	169
Other assets	3	70
Accounts payable and accrued expenses	(54)	(161)
Accrued interest	—	(960)
Lease liabilities	(94)	(23)
Deferred revenue	41	(209)
Net cash flows from operating activities	<u>(2,131)</u>	<u>(2,331)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(40)	—
Acquisition of licensing rights	—	(441)
Net cash flows from investing activities	<u>(40)</u>	<u>(441)</u>
Cash flows from financing activities:		
Proceeds from issuance of 2020 senior secured convertible notes, net of financing costs and discount	—	16,890
Proceeds from public offering of common stock, net of offering costs	46,785	—
Proceeds from stock option and warrant exercises	145	—
Repayment of notes payable	—	(2,838)
Net cash flows from financing activities	<u>46,930</u>	<u>14,052</u>
Net change in cash and cash equivalents	44,759	11,280
Cash and cash equivalents, beginning of period	20,099	5,696
Cash and cash equivalents, end of period	<u>\$ 64,858</u>	<u>\$ 16,976</u>

SUPPLEMENTAL CASH FLOW INFORMATION

Cash paid for:		
Income taxes	<u>\$ —</u>	<u>\$ —</u>
Interest	<u>\$ 214</u>	<u>\$ 1,043</u>