

**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 1, 2022

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 92075
(Address of principal executive offices, zip code)

(888) 287-9109
(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 1, 2022, ClearPoint Neuro, Inc. (the "Company") issued a press release announcing its financial results for the fourth fiscal quarter and full year ended December 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 March 1, 2022](#)

Exhibit 104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 1, 2022

CLEARPOINT NEURO, INC.

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



ClearPoint Neuro Reports Fourth Quarter and Full-Year 2021 Results **Company Reports Record Revenues**

SOLANA BEACH, CA, March 1, 2022 – 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, 2021.

2021 Full Year and Fourth Quarter Highlights

- Reported fourth quarter 2021 revenue of \$4.3 million, an increase of 15% compared with the fourth quarter of 2020. Reported revenue of \$16.3 million for the full year 2021, a 27% increase over 2020 and representing the seventh consecutive year of growth.
- Increased biologics and drug delivery revenue to \$6.8 million for the full year 2021, a 31% increase over 2020.
- Supported 929 cases in 2021 despite the continued challenges posed by the COVID-19 pandemic.
- Completed a public offering of common stock in February 2021, resulting in net proceeds of approximately \$46.8 million, and ended 2021 with cash and cash equivalents totaling \$54.1 million.

“We are excited to close the books on a successful, yet unpredictable 2021, as we overcame elective procedure disruptions and supply chain issues to reach record levels for case volume and revenue,” commented Joe Burnett, President and CEO at ClearPoint Neuro. “Our company has made progress across all four of our growth pillars in the past year which I believe shows that our strategy has set a strong foundation which we will continue to build on in the years ahead.”

“Pillar One: Biologics and Drug Delivery

- Added approximately 15 new pharma and academic partners
- Hired a dedicated pharma support team and supplied new pre-clinical and clinical services
- Continue to believe a first commercial gene therapy delivered by ClearPoint Neuro technology is possible in 2022

Pillar Two: Functional Neurosurgery Navigation for Deep-Brain Stimulation and Brain-Computer Interfaces (BCI)

- Achieved record revenue and case volume despite Delta and Omicron variant impact on elective procedures
- Achieved FDA clearance for ClearPoint ‘Array’ and submitted the Array pre-planning software module to the FDA for review
- Began direct-to-patient education on the benefits of DBS, both awake and asleep workflows
- Began development of a BCI navigation system for the Operating Room in collaboration with BlackRock Neurotech

Pillar Three: Therapy and Access Products

- Submitted complete laser solution to the FDA in collaboration with CLS in Sweden
- Expect first clinical cases of the neuro-laser product in the second half of 2022

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- Received first inventory of our operating room drill solution from adeor in Germany and built successful MRI-Conditional drill prototypes for use in the MRI suite

Pillar Four: Achieve Global Scale

- Hired our first European based employees and installed our first three sites in the EU with ClearPoint Systems
- Achieved regulatory clearance for our existing portfolio in Israel
- Successfully passed our first audits in continuation of the EU MDR migration to ensure supply to CE Mark Countries around the world”

“Our balance sheet remains strong with more than \$54 million in cash and equivalents on hand to fund operations for years to come. We continue to expect revenue in 2022 in the range of \$20 to \$22 million. During 2021, we also hired several highly accomplished new team members who will help accelerate execution of our four-pillar strategy.”

Financial Results – Year Ended December 31, 2021

Total revenues were approximately \$16.3 million and \$12.8 million for the years ended December 31, 2021 and 2020, respectively.

Functional neurosurgery navigation and therapy revenue increased 30% to \$8.1 million during the year ended December 31, 2021 from \$6.2 million for the same period in 2020. This increase reflects the resumption in 2021 of elective surgery procedures, which were postponed or cancelled during 2020 due to the effects of the COVID-19 pandemic.

Biologics and drug delivery revenue, which include sales of disposable products and services related to customer-sponsored clinical trials utilizing our

products, increased 31% to \$6.8 million for the year ended December 31, 2021, from \$5.2 million for the same period in 2020.

Capital equipment and software revenue stayed relatively consistent at \$1.4 million for the years 2021 and 2020.

The Company achieved a gross margin of 69% on its sales for 2021, compared to a gross margin of 71% for 2020. This decrease in gross margin was due primarily to an increase in overhead allocated to costs of sales in 2021 as compared to 2020.

Operating expenses were \$24.7 million for the full year 2021, compared to \$15.3 million for 2020. The increase was mainly driven by an increase in personnel-related expenses as we increased headcount to fund the expansion of the research and development, clinical and support organizations.

Financial Results – Three Months Ended December 31, 2021

Total revenue was \$4.3 million for the three months ended December 31, 2021 and \$3.7 million for the three months ended December 31, 2020, which represents an increase of \$0.6 million or 15%.

Functional neurosurgery navigation revenue increased 37% to \$2.1 million for the fourth quarter of 2021 from \$1.6 million for the same period in 2020.

Biologics and drug delivery revenue increased 10% to \$1.7 million for the fourth quarter of 2021, from \$1.5 million for the same period in 2020.

Capital equipment product and related service revenue decreased 28% to \$0.5 million for the fourth quarter of 2021, as compared with \$0.6 million for the same period in 2020.

The Company realized a gross margin of 77% on its sales for the fourth quarter of 2021, compared to a gross margin of 61% for the same period in 2020, due primarily to a one-time reclassification of certain costs, previously classified as operating expenses to cost of revenues performed in Q4 2020 and due to lower excess and obsolete inventory reserves taken in the fourth quarter of 2021.

Operating expenses for the fourth quarter of 2021 were \$7.3 million, compared to \$4.5 million for the fourth quarter of 2020. The increase was mainly driven by the increase in headcount and the increased investments in research and development.

On December 31, 2021, the Company had cash and cash equivalents totaling \$54.1 million as compared to \$20.1 million on December 31, 2020, with the increase resulting primarily from the completion of a public offering of the Company's common stock in February 2021.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's fourth quarter and full year 2021 financial results on Tuesday, March 1, 2022 at 4:30 p.m. Eastern time (1:30 p.m. Pacific time) which may be accessed online here: <https://themediiframe.com/mediaframe/webcast.html?webcastid=ZSukJDu1>. Investors and analysts who would like to participate in the conference call via telephone may do so 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 Thursday, March 31, 2022 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 approximately 60 active sites in the United States, Canada, and Europe. ClearPoint Neuro is partnered with approximately 40 biologics/pharmaceutical companies and academic centers, providing solutions for direct CNS delivery of therapeutics in pre-clinical studies and clinical trials worldwide. To date, more than 5,000 cases have been performed and supported by the Company's field-based clinical specialist team, which offers support and services to our customers and partners worldwide. For more information, please visit www.clearpointneuro.com.

Forward-Looking Statements

Statements in this press release and in the teleconference referenced above 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; the Company's ability to market, commercialize and achieve broader market acceptance for the Company's ClearPoint Neuro Navigation System products; and risks inherent in the research and development of new 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, and the Company's Quarterly Report on Form 10-Q for the three months ended

September 30, 2021, 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, 2021, which the Company intends to file with the Securities and Exchange Commission on or before March 31, 2022.

Contact:

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

	December 31,	
	2021	2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 54,109	\$ 20,099
Accounts receivable, net	2,337	1,881
Inventory, net	4,938	3,238
Prepaid expenses and other current assets	508	244
Total current assets	61,892	25,462
Property and equipment, net	539	319
Operating lease rights of use	2,241	2,736
Software license inventory	519	589
Licensing rights	265	353
Other assets	125	59
Total assets	<u>\$ 65,581</u>	<u>\$ 29,518</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 427	\$ 300
Accrued compensation	2,604	1,595
Other accrued liabilities	537	349
Operating lease liabilities, current portion	507	394
Deferred product and service revenue, current portion	678	562
Total current liabilities	4,753	3,200
Operating lease liabilities, net of current portion	1,939	2,446
Deferred product and service revenue, net of current portion	264	215
2020 senior secured convertible notes payable, net	9,838	21,280
Total liabilities	16,794	27,141
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized at December 31, 2021 and 2020; none issued and outstanding at December 31, 2021 and 2020	—	—
Common stock, \$0.01 par value; 200,000,000 shares authorized at December 31, 2021 and 2020; 23,665,991 and 17,047,584 shares issued and outstanding at December 31, 2021 and 2020, respectively	237	170
Additional paid-in capital	182,482	121,729
Accumulated deficit	(133,932)	(119,522)
Total stockholders' equity	48,787	2,377
Total liabilities and stockholders' equity	<u>\$ 65,581</u>	<u>\$ 29,518</u>

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

	Years Ended December 31,	
	2021	2020
Revenue:		
Product revenue	\$ 11,913	\$ 8,832
Service and other revenue	4,386	3,997

Total revenue	16,299	12,829
Cost of revenue	5,008	3,709
Gross profit	11,291	9,120
Research and development costs	8,985	4,686
Sales and marketing expenses	6,919	5,384
General and administrative expenses	8,761	5,270
Operating loss	(13,374)	(6,220)
Other income (expense):		
Other (expense) income, net	(63)	882
Interest expense, net	(973)	(1,444)
Net loss	\$ (14,410)	\$ (6,782)
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.69)	\$ (0.43)
Weighted average shares outstanding:		
Basic and diluted	20,734,236	15,849,667

CLEARPOINT NEURO, INC.

Consolidated Statements of Cash Flows

(Dollars in thousands)

	Years Ended December 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (14,410)	\$ (6,782)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for doubtful accounts	202	27
Depreciation and amortization	159	334
Share-based compensation	2,078	1,090
Payment-in-kind interest	325	3
Forgiveness of PPP loan	—	(896)
Amortization of debt issuance costs and original issue discounts	100	890
Amortization of lease right of use assets, net of accretion in lease liabilities	533	216
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(658)	(818)
Inventory	(1,714)	(25)
Prepaid expenses and other current assets	(264)	113
Other assets	(66)	25
Accounts payable and accrued expenses	1,285	(459)
Accrued interest	—	(960)
Lease liability	(432)	(128)
Deferred revenue	165	(437)
Net cash flows from operating activities	(12,697)	(7,807)
Cash flows from investing activities:		
Purchases of property and equipment	(168)	(41)
Acquisition of licensing rights	—	(441)
Net cash flows from investing activities	(168)	(482)
Cash flows from financing activities:		
Proceeds from issuance of 2020 senior secured convertible notes, net of financing costs and discount	—	24,258
Proceeds from issuance of Paycheck Protection Program loan	—	896
Proceeds from public offering of common stock, net of offering costs	46,785	—
Proceeds from stock option and warrant exercises	465	376
Proceeds from issuance of common stock under employee stock purchase plan	224	—
Payments for taxes related to net share settlement of equity awards	(599)	—
Repayment of notes payable	—	(2,838)
Net cash flows from financing activities	46,875	22,692
Net change in cash and cash equivalents	34,010	14,403
Cash and cash equivalents, beginning of year	20,099	5,696
Cash and cash equivalents, end of year	\$ 54,109	\$ 20,099

SUPPLEMENTAL CASH FLOW INFORMATION

Cash paid for:

Income taxes	\$ —	\$ —
Interest	\$ 597	\$ 1,578