

---

---

**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, 2023

---

**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, CA 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, 2023, ClearPoint Neuro, Inc. (the “Company”) issued a press release announcing its financial results for the fourth fiscal quarter and full year ended December 31, 2022. 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, 2023](#)

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, 2023

**CLEARPOINT NEURO, INC.**

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



## **ClearPoint Neuro Reports Fourth Quarter and Full-Year 2022 Results**

### **Company Reports Record Revenues**

SOLANA BEACH, CA, March 1, 2023 – 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, 2022.

#### **2022 Full Year and Fourth Quarter Highlights**

- Reported fourth quarter 2022 revenue of \$5.2 million, a 21% year-over-year increase compared with the fourth quarter of 2021;
- Reported revenue of \$20.6 million for the full year 2022, an increase of 26% over 2021 and representing the eighth consecutive year of growth;
- Increased biologics and drug delivery revenue to \$9.1 million for the full year 2022, a 34% increase over 2021;
- Added multiple new biologics and drug delivery partners in the quarter to bring the total to more than 50; and
- Cash and short-term investments totaled \$37.5 million as of December 31, 2022.

#### **Business Outlook**

“We are pleased with our performance in 2022, growing revenue 26% year-over-year, achieving FDA clearance for key new products, adding services and capabilities to support our more than 50 biologics partners, and executing against all four pillars of our growth strategy,” commented Joe Burnett, President and CEO at ClearPoint Neuro. “We continue to expect growth of more than 20% in 2023, given the competitiveness of our laser system and the cadence of our pharma partners’ continuing progress through the global regulatory process for new gene and cell therapies. We are reiterating our 2023 revenue forecast of between \$25 and \$27 million.”

#### **Financial Results - Year Ended December 31, 2022**

Total revenue was \$20.6 million and \$16.3 million for the years ended December 31, 2022 and 2021, respectively.

Functional neurosurgery navigation and therapy revenue increased to \$9.1 million during the year ended December 31, 2022 from \$8.1 million for the same period in 2021. This increase is primarily driven by \$1.5 million of service revenue related to development services for the year ended December 31, 2022, compared to \$0.4 million for the same period in 2021.

Biologics and drug delivery revenue, which include sales of disposable products and services related to customer-sponsored pre-clinical and clinical trials utilizing our products, increased 34% to \$9.1 million for the year ended December 31, 2022, from \$6.8 million for the same period in 2021. This increase is attributable to a \$2.0 million increase in service and license revenue and \$0.3 million increase in product revenue for the year

---

ended December 31, 2022, due to expanded commitments from our current biologics and drug delivery partners as well as an increase in new partners.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, increased 61% to \$2.3 million for the year ended December 31, 2022, from \$1.4 million for the same period in 2021. This increase is due primarily to an increase in the placements of ClearPoint capital and software.

The Company achieved a gross margin of 66% on its sales for 2022, compared to a gross margin of 68% for 2021. This decrease in gross margin was due primarily to an increase in indirect labor costs in 2022 as compared to 2021 as well as an increase in excess and obsolete inventory reserves.

Operating expenses were \$29.9 million for the full year 2022, compared with \$24.5 million for 2021. The increase was mainly driven by an increase in personnel-related expenses, including share-based compensation, as we increased headcount to fund the expansion of the research and development, clinical, and support organizations.

#### **Financial Results – Quarter Ended December 31, 2022**

Total revenue was \$5.2 million for the three months ended December 31, 2022, and \$4.3 million for the three months ended December 31, 2021, which represents an increase of \$0.9 million, or 21%.

Functional neurosurgery navigation and therapy revenue increased 7% to \$2.3 million for the three months ended December 31, 2022, from \$2.1 million for the same period in 2021. The growth was driven by higher service revenue.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored pre-clinical and clinical trials utilizing our products, increased 37% to \$2.3 million for the three months ended December 31, 2022, from \$1.7 million for the same period in 2021. This increase is attributable to a \$0.7 million increase in service revenue, partially offset by a slight decrease in product revenue.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, increased 25% to \$0.6 million for the three months ended December 31, 2022, from \$0.5 million for the same period in 2021 due to an increase in the placements of ClearPoint capital and software.

Gross margin for the three months ended December 31, 2022, was 64%, as compared to a gross margin of 77% for the three months ended December 31, 2021. The decrease in gross margin was due primarily to higher overhead expenses and inventory reserves.

Operating expenses for the fourth quarter of 2022 were \$7.8 million, compared to \$7.3 million for the fourth quarter of 2021. The increase was mainly driven by the increase in headcount across the organization and share-based compensation.

At December 31, 2022, the Company had cash and cash equivalents and short-term investments totaling \$37.5 million compared to \$54.1 million at December 31, 2021, with the decrease resulting primarily from the use of cash in operating activities of \$16.2 million.

#### **Teleconference Information**

Investors and analysts are invited to listen to a live broadcast review of the Company's fourth quarter and full year 2022 on Wednesday, March 1, 2023 at 4:30 p.m. Eastern time (1:30 p.m. Pacific time), which may be accessed online here: <https://event.choruscall.com/mediaframe/webcast.html?webcastid=KFYSIHDo>. Investors and analysts who would like to participate in the conference call via telephone may do so at (877) 407-9034, or at (202) 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 March 31, 2023, 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 Investor Relations website at <https://ir.clearpointneuro.com/>.

### **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, 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 more than 65 sites in North America, Europe, and South America. ClearPoint Neuro is partnered with more than 50 biologics/pharmaceutical companies, academic centers, and contract research organizations, providing solutions for direct CNS delivery of therapeutics in pre-clinical studies and clinical trials worldwide. To date, more than 5,000 procedures have been performed and supported by the Company's field-based clinical specialist team, which offers support and services to our customers and partners. For more information, please visit [www.clearpointneuro.com](http://www.clearpointneuro.com).

### **Forward-Looking Statements**

Statements in this press release and in the teleconference referenced above concerning the Company's revenue expectations, plans, growth and strategies may be forward-looking statements within the context of the federal securities laws. Statements regarding the Company's future events, developments and future performance, the size of total addressable markets or the market opportunity for the Company's products and services, 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, global instability, supply chain disruptions, labor shortages, and macroeconomic and inflationary conditions; future revenue from sales of the Company's ClearPoint Neuro Navigation System and other new products offered by the Company; the Company's ability to market, commercialize and achieve broader market acceptance for the Company's ClearPoint Neuro Navigation System and other new products offered by the Company; the ability of our biologics and drug delivery partners to achieve commercial success, including their use of our products and services in their delivery of therapies; and risks inherent in the research, development, and regulatory approval 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, 2021, and the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2022, 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, 2022, which the Company intends to file with the Securities and Exchange Commission on or before March 31, 2023.

### **Contact:**

Danilo D'Alessandro, Chief Financial Officer  
(949) 900-6833  
[info@clearpointneuro.com](mailto:info@clearpointneuro.com)

Caroline Corner, Investor Relations  
[ir@clearpointneuro.com](mailto:ir@clearpointneuro.com)

---

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

	<b>Years Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
Revenue:		
Product revenue	\$ 12,789	\$ 11,913
Service and other revenue	7,762	4,386
Total revenue	20,551	16,299
Cost of revenue	7,020	5,176
Gross profit	13,531	11,123
Research and development costs	10,894	9,281
Sales and marketing expenses	9,358	7,217
General and administrative expenses	9,611	7,999
Operating loss	(16,332)	(13,374)
Other income (expense):		
Other expense, net	(22)	(63)
Interest expense, net	(81)	(973)
Net loss	\$ (16,435)	\$ (14,410)
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.68)	\$ (0.69)
Weighted average shares outstanding:		
Basic and diluted	24,181,854	20,734,236

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

	December 31,	
	2022	2021
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 27,615	\$ 54,109
Short-term investments	9,874	—
Accounts receivable, net	2,665	2,337
Inventory, net	9,303	4,938
Prepaid expenses and other current assets	1,723	508
Total current assets	51,180	61,892
Property and equipment, net	806	539
Operating lease rights of use	1,895	2,241
Software license inventory	450	519
Licensing rights	1,028	265
Other assets	131	125
Total assets	\$ 55,490	\$ 65,581
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 272	\$ 427
Accrued compensation	2,824	2,604
Other accrued liabilities	2,065	537
Operating lease liabilities, current portion	561	507
Deferred product and service revenue, current portion	1,066	678
Total current liabilities	6,788	4,753
Operating lease liabilities, net of current portion	1,532	1,939
Deferred product and service revenue, net of current portion	390	264
2020 senior secured convertible note payable, net	9,893	9,838
Total liabilities	18,603	16,794
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized at December 31, 2022 and 2021; none issued and outstanding at December 31, 2022 and 2021	—	—
Common stock, \$0.01 par value; 200,000,000 shares authorized at December 31, 2022 and 2021; 24,578,983 and 23,665,991 shares issued and outstanding at December 31, 2022 and 2021, respectively	246	237
Additional paid-in capital	187,008	182,482
Accumulated deficit	(150,367)	(133,932)
Total stockholders' equity	36,887	48,787
Total liabilities and stockholders' equity	\$ 55,490	\$ 65,581



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

	<b>Years Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
Cash flows from operating activities:		
Net loss	\$ (16,435)	\$ (14,410)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for doubtful accounts	(117)	202
Depreciation and amortization	244	159
Share-based compensation	4,126	2,078
Payment-in-kind interest	—	325
Amortization of debt issuance costs and original issue discounts	55	100
Amortization of lease right of use assets, net of accretion in lease liabilities	533	533
Accretion of discounts on short-term investments	(284)	—
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(211)	(658)
Inventory, net	(4,421)	(1,714)
Prepaid expenses and other current assets	(1,216)	(264)
Other assets	(6)	(66)
Accounts payable and accrued expenses	1,591	1,285
Lease liability	(541)	(432)
Deferred revenue	515	165
Net cash flows from operating activities	(16,167)	(12,697)
Cash flows from investing activities:		
Purchases of property and equipment	(253)	(168)
Acquisition of licensing rights	(893)	—
Purchase of short-term investments	(21,590)	—
Proceeds from maturities of short-term investments	12,000	—
Net cash flows from investing activities	(10,736)	(168)
Cash flows from financing activities:		
Proceeds from public offering of common stock, net of offering costs	—	46,785
Proceeds from stock option and warrant exercises	268	465
Proceeds from issuance of common stock under employee stock purchase plan	477	224
Payments for taxes related to net share settlement of equity awards	(336)	(599)
Net cash flows from financing activities	409	46,875
Net change in cash and cash equivalents	(26,494)	34,010
Cash and cash equivalents, beginning of year	54,109	20,099
Cash and cash equivalents, end of year	\$ 27,615	\$ 54,109

**SUPPLEMENTAL CASH FLOW INFORMATION**

**Cash paid for:**

Income taxes	\$ —	\$ —
Interest	\$ 523	\$ 597