

March 12, 2024



ClearPoint Neuro Reports Fourth Quarter and Full-Year 2023 Results

Release Includes Commentary on Early 2024 Progress

SOLANA BEACH, Calif., March 12, 2024 (GLOBE NEWSWIRE) -- ClearPoint Neuro, Inc. (Nasdaq: CLPT) (the "Company"), a global device, cell, and gene therapy-enabling company offering precise navigation to the brain and spine, today announced financial results for its fourth quarter and full-year ended December 31, 2023.

2023 Full Year and Fourth Quarter Highlights

- Reported fourth quarter 2023 revenue of \$6.8 million, a 32% year-over-year increase compared with the fourth quarter of 2022;
- Reported revenue of \$24.0 million for the full year 2023, an increase of 17% over 2022 and representing the ninth consecutive year of growth;
- Increased biologics and drug delivery revenue to \$13.6 million for the full year 2023, a 49% increase over 2022;
- Completed Certification of Carlsbad development and manufacturing facility and shut down of Irvine manufacturing facility; and
- Cash burn of \$1.2 million in the fourth quarter, bringing cash and cash equivalents to \$23.1 million as of December 31, 2023.

2024 Operational Highlights

- Six new hospital customers already added since the beginning of the year;
- Received 510(k) clearance for Smartframe OR™ Stereotactic System;
- First-in-Human cases performed using ClearPoint 2.2 Software and ClearPoint Array 1.2 Parallel Trajectory Software;
- First product approved under European MDR and products shipped to Europe from new Carlsbad development and manufacturing facility;
- Validation Papers for ClearPoint Maestro and ClearPoint PRISM products published in peer-reviewed journals;
- Completed a public offering of common stock, resulting in gross proceeds of approximately \$15 million; and

- Reaffirming 2024 revenue guidance to be between \$28.0 million and \$32.0 million.

Business Outlook

“We are pleased to confirm our fourth quarter 2023 performance which included record revenue of \$6.8 million, over 30% topline growth, and a reduction in our quarterly cash burn to only \$1.2 million, our lowest since 2020,” commented Joe Burnett, President and CEO at ClearPoint Neuro. “In just the first two months of 2024 we have already achieved some key strategic milestones including multiple FDA clearances and first-in-human procedures, first shipments to EU countries from our new Carlsbad facility and under EU-MDR certification, publication of key validation papers in peer-reviewed journals supporting both our navigation software and laser therapy system, and activation of more new clinical customers in the first quarter than in all of 2023.

“As a result,” continued Burnett, “we have been able to complete an important equity offering of approximately \$15 million which solidifies our balance sheet for our pharma partners and will allow us to retire our entire outstanding debt in the next 12 months. It was very encouraging to perform this capital raise alongside many other biotech companies in the past few weeks, highlighting renewed investment into this important and exciting gene and cell therapy space. We continue to look with confidence at 2024 and reaffirm our 2024 revenue guidance to be in the range of \$28.0 million - \$32.0 million.”

Financial Results - Year Ended December 31, 2023

Total revenue was \$24.0 million and \$20.6 million for the years ended December 31, 2023 and 2022, respectively.

Biologics and drug delivery revenue, which include sales of disposable products and services related to customer-sponsored preclinical and clinical trials utilizing our products, increased 49% to \$13.6 million for the year ended December 31, 2023, from \$9.1 million for the same period in 2022. This increase is attributable to a \$6.0 million increase in service revenue related to new preclinical studies and services entered into with our partners for the year ended December 31, 2023, compared to the same period in 2022, partially offset by a \$1.5 million decrease in product revenue.

Functional neurosurgery navigation and therapy revenue which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, decreased 7% to \$8.5 million during the year ended December 31, 2023, from \$9.1 million for the same period in 2022. The decrease is driven by lower service revenue of \$0.6 million as a result of pausing a co-development program with one of our Brain Computer Interface partners for the year ended December 31, 2023, compared to the same period in 2022.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, decreased 21% to \$1.8 million for the year ended December 31, 2023, from \$2.3 million for the same period in 2022, due primarily to a decrease in the placements of ClearPoint capital and software.

The Company achieved a gross margin of 57% on its sales for 2023, compared to a gross margin of 66% for 2022. This decrease in gross margin was primarily due to an increase in biologics and drug delivery preclinical services, which, to date, have had a lower margin than

in prior years, as we launch new services and increase our presence in this space. Increased costs related to the transition to the new manufacturing facility also contributed to the decrease in gross margin compared to the prior year.

Operating expenses were \$36.1 million for the full year 2023, compared with \$29.9 million for 2022. 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, as well as an increase in the allowance for credit losses.

Financial Results – Quarter Ended December 31, 2023

Total revenue was \$6.8 million for the three months ended December 31, 2023, and \$5.2 million for the three months ended December 31, 2022, which represents an increase of \$1.6 million, or 32%.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored preclinical and clinical trials utilizing our products, increased 76% to \$4.1 million for the three months ended December 31, 2023, from \$2.3 million for the same period in 2022. This increase is attributable to a \$1.8 million increase in service revenue, partially offset by a slight decrease in product revenue.

Functional neurosurgery navigation and therapy revenue decreased 11% to \$2.0 million for the three months ended December 31, 2023, from \$2.3 million for the same period in 2022. The decrease was driven by lower service revenue.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, increased 23% to \$0.7 million for the three months ended December 31, 2023, from \$0.6 million for the same period in 2022.

Gross margin for the three months ended December 31, 2023, was 59%, as compared to a gross margin of 64% for the three months ended December 31, 2022. The decrease in gross margin was due primarily to an increase in biologics and drug delivery preclinical services, which, to date, have had a lower margin than in prior years, as we launch new services and increase our presence in this space.

Operating expenses for the fourth quarter of 2023 were \$8.7 million, compared to \$7.8 million for the fourth quarter of 2022. The increase was mainly driven by the increase in headcount across the organization and share-based compensation as well as an increase in the allowance for credit losses.

At December 31, 2023, the Company had cash and cash equivalents and short-term investments totaling \$23.1 million compared to \$37.5 million at December 31, 2022, with the decrease resulting primarily from the use of cash in operating activities of \$13.7 million.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's fourth quarter and full year 2023 on Tuesday, March 12, 2024 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=198rn5GM>. 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 April 12, 2024, 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 is a device, cell, and gene therapy-enabling company offering precise navigation to the brain and spine. The Company uniquely provides both established clinical products as well as pre-clinical development services for controlled drug and device delivery. The Company's flagship product, the ClearPoint Neuro Navigation System, has FDA clearance and is CE-marked. ClearPoint Neuro is engaged with healthcare and research centers in North America, Europe, Asia, and South America. The Company is also partnered with the most innovative pharmaceutical/biotech 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, thousands of 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 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, the size of total addressable markets or the market opportunity for the Company's products and services, the Company's expectation for revenues, operating expenses, the adequacy of cash and cash equivalent balances to support operations and meet future obligations, 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. These forward-looking statements are based on management's current expectations and are subject to the risks inherent in the business, which 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: global and political instability, supply chain disruptions, labor shortages, and macroeconomic and inflationary conditions; future revenue from sales of the Company's products and services; the Company's ability to market, commercialize and achieve broader market acceptance for new products and services offered by the Company; the ability of our biologics and drug delivery partners to achieve commercial success, including their use of the Company's products and services in their delivery of therapies; the Company's expectations, projections and estimates regarding expenses, future revenue, capital requirements, and the availability of and the need for additional financing; the Company's ability to obtain additional funding to support its research and development programs; the ability of the Company to manage the growth of its business; the Company's ability to attract and retain its key employees; 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, 2022, and the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2023, 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, 2023, which the Company intends to file with the Securities and Exchange Commission on or before March 31, 2024. The Company does not assume any obligation to update these forward-looking statements.

CLEARPOINT NEURO, INC.

Consolidated Statements of Operations
(Dollars in thousands, except for share and per share data)

	Years Ended December 31,	
	2023	2022
Revenue:		
Product revenue	\$ 10,603	\$ 12,789
Service and other revenue	13,352	7,762
Total revenue	<u>23,955</u>	<u>20,551</u>
Cost of revenue	<u>10,341</u>	<u>7,020</u>
Gross profit	13,614	13,531
Research and development costs	11,709	10,894
Sales and marketing expenses	12,595	9,358
General and administrative expenses	<u>11,756</u>	<u>9,611</u>
Operating loss	(22,446)	(16,332)
Other income (expense):		
Other expense, net	(29)	(22)
Interest income (expense), net	<u>386</u>	<u>(81)</u>
Net loss	\$ (22,089)	\$ (16,435)
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.90)	\$ (0.68)
Weighted average shares outstanding:		
Basic and diluted	24,605,212	24,181,854

CLEARPOINT NEURO, INC.

Consolidated Balance Sheets
(Dollars in thousands, except for share and per share data)

	December 31,	
	2023	2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 23,140	\$ 27,615
Short-term investments	—	9,874
Accounts receivable, net	3,211	2,665
Inventory, net	7,911	9,303
Prepaid expenses and other current assets	1,910	1,723
	36,172	51,180
Total current assets		
Property and equipment, net	1,389	806
Operating lease rights of use	3,564	1,895
Software license inventory	386	450
Licensing rights	1,041	1,028
Other assets	109	131
Total assets	\$ 42,661	\$ 55,490
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 393	\$ 272
Accrued compensation	2,947	2,824
Other accrued liabilities	1,053	2,065
Operating lease liabilities, current portion	424	561
Deferred product and service revenue, current portion	2,613	1,066
Total current liabilities	7,430	6,788
Operating lease liabilities, net of current portion	3,568	1,532
Deferred product and service revenue, net of current portion	541	390
2020 senior secured convertible note payable, net	9,949	9,893
Total liabilities	21,488	18,603
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized at December 31, 2023 and 2022; none issued and outstanding at December 31, 2023 and 2022	—	—
Common stock, \$0.01 par value; 90,000,000 shares authorized at December 31, 2023 and 200,000,000 shares authorized at December 31, 2022; 24,652,729 and 24,578,983 shares issued and outstanding at December 31, 2023 and 2022, respectively	247	246
Additional paid-in capital	193,382	187,008
Accumulated deficit	(172,456)	(150,367)
Total stockholders' equity	21,173	36,887
Total liabilities and stockholders' equity	\$ 42,661	\$ 55,490

CLEARPOINT NEURO, INC.

Consolidated Statements of Cash Flows
(Dollars in thousands)

	Years Ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (22,089)	\$ (16,435)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for credit losses (recoveries)	1,258	(117)
Depreciation and amortization	626	244
Share-based compensation	6,079	4,126
Amortization of debt issuance costs and original issue discounts	57	55
Amortization of lease right of use assets, net of accretion in lease liabilities	831	533
Accretion of discounts on short-term investments	(126)	(284)
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(1,804)	(211)
Inventory, net	1,246	(4,421)
Prepaid expenses and other current assets	(113)	(1,216)
Other assets	22	(6)
Accounts payable and accrued expenses	(649)	1,591
Lease liability	(755)	(541)
Deferred revenue	1,697	515
Net cash flows from operating activities	(13,720)	(16,167)
Cash flows from investing activities:		
Purchases of property and equipment	(717)	(253)
Acquisition of licensing rights	(334)	(893)
	—	(21,590)
Purchase of short-term investments		
Proceeds from maturities of short-term investments	10,000	12,000
Net cash flows from investing activities	8,949	(10,736)
Cash flows from financing activities:		
Proceeds from stock option and warrant exercises	—	268
Proceeds from issuance of common stock under employee stock purchase plan	506	477
Payments for taxes related to net share settlement of equity awards	(210)	(336)
Net cash flows from financing activities	296	409
Net change in cash and cash equivalents	(4,475)	(26,494)
Cash and cash equivalents, beginning of year	27,615	54,109
Cash and cash equivalents, end of year	\$ 23,140	\$ 27,615

SUPPLEMENTAL CASH FLOW INFORMATION

Cash paid for:

Income taxes	\$ —	\$ —
Interest	\$ 743	\$ 523

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Source: ClearPoint Neuro, Inc.