

November 7, 2024



ClearPoint Neuro Reports Third Quarter 2024 Results

Achieved Record Revenue and Growth of 41%; Operational Cash Burn Reduced to \$1.2 Million

SOLANA BEACH, CA / ACCESSWIRE / November 7, 2024 /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 third quarter ended September 30, 2024.

Third Quarter Highlights

- Reported quarterly revenue of \$8.1 million, a 41% year-over-year increase;
- Accelerated growth of SmartFrame OR™ platform and ClearPoint Prism® Laser Therapy System, contributing to record navigation and device revenue of \$2.9 million, a 53% year-over-year increase;
- Overall product revenue, including biologics and drug delivery, more than doubled year-over-year, growing 127% to \$5.5 million;
- Activated five new global centers in the third quarter for a total of 19 new centers so far this year; approximately three times our historic activation rate;
- Continued patient enrollment in numerous cell and gene therapy trials for partners selected in FDA expedited review programs across multiple indications;
- Full early repayment of the principal amount and interest on a \$10 million convertible note leaving the Company with no outstanding debt as of September 30, 2024;
- Quarterly operational cash burn reduced to \$1.2 million, a 33% year-over-year decrease; and
- Reported cash and cash equivalents totaling \$21.6 million as of September 30, 2024.

"The third quarter of 2024 was another example of continued execution of our four-pillar growth strategy, yielding another record revenue quarter, 41% topline growth, and further reduction in operational cash burn as we scale the business," commented Joe Burnett, President and CEO at ClearPoint Neuro. "Our growth continues to be fueled by (i) our 2024

new-product introductions including the SmartFrame OR Navigation system expanding our footprint into the Operating Room, (ii) the ongoing adoption of the PRISM laser therapy system expanding our participation in an existing therapy segment, and (iii) the expansion of our pre-clinical capabilities increasing the depth of our biopharma relationships as we work to co-develop tools and techniques to enhance neuro drug delivery. We expect all three of these new growth vectors to continue into 2025 and to be complemented by additional FDA and CE Mark submissions in the months ahead. The expanding range of our versatile and innovative portfolio of products and services, well beyond MRI Navigation, has been very well received and is evidenced by our accelerated customer activation rate in 2024. We currently have more than 90 active global customers, and a strong pipeline of potential new global activation sites for 2025 and beyond."

Business Outlook

The Company reaffirms its full year 2024 revenue outlook of between \$30.0 and \$33.0 million.

Financial Results - Quarter Ended September 30, 2024

Total revenue was \$8.1 million for the three months ended September 30, 2024, in comparison to \$5.8 million for the three months ended September 30, 2023, representing an increase of \$2.4 million, or 41%.

Biologics and Drug Delivery revenue, which includes sales of services and disposable products related to customer-sponsored preclinical and clinical trials utilizing our products, increased 27% to \$4.4 million for the three months ended September 30, 2024, from \$3.5 million for the same period in 2023. Our overall revenue growth is attributable to a \$1.6 million increase in product revenue resulting from higher demand for disposables as multiple partners progress in their trials, partially offset by a decrease of \$0.7 million in service and other revenue due to a reduction in the number of preclinical studies performed.

Neurosurgery Navigation and Therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 49% to \$2.9 million for the three months ended September 30, 2024, from \$1.9 million for the same period in 2023. The increase is driven by higher product revenue of \$1.0 million resulting from newly activated accounts, increased case count, and new product offerings, including the SmartFrame OR and Prism Laser Therapy, during the three months ended September 30, 2024, compared to the same period in 2023.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software and related services, increased 133% to \$0.8 million for the three months ended September 30, 2024, from \$0.4 million for the same period in 2023 due to an increase in the placements of ClearPoint navigation capital and software and Prism laser units. The total number of newly activated accounts increased by five in the quarter and to nineteen for the full year which represents approximately three times the historic activation rate.

Gross margin for the three months ended September 30, 2024, was 60% compared to a gross margin of 57% for the three months ended September 30, 2023.

Operating expenses for the third quarter of 2024 were \$10.0 million, compared to \$8.2 million for the third quarter of 2023. The increase was mainly driven by higher personnel costs and product development costs, partially offset by lower bad debt expense as a result of recoveries.

At September 30, 2024, the Company had cash and cash equivalents totaling \$21.6 million as compared to \$23.1 million at December 31, 2023, with the decrease resulting from the full repayment of debt of \$10.0 million and the use of cash in operating activities of \$7.7 million in the nine month period ending September 30, 2024, partially offset by the net proceeds from the public offering of common stock of \$16.2 million in the first quarter of 2024.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's 2024 third quarter on Thursday, November 7, 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=YI0JL1Mt>. Investors and analysts who would like to participate in the conference call via telephone may do so at (888) 428-7458, or at (862) 298-0702 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 December 7, 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 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 preclinical 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 preclinical 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 ability to maintain its current relationships with biologics and drug delivery partners or enter into new relationships with such partners; 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, 2023, and the Company's Quarterly Report on Form 10-Q for the three months ended June 30, 2024, both of which have been filed with the Securities and Exchange Commission, and the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2024, which the Company intends to file with the Securities and Exchange Commission on or before November 14, 2024. The Company does not assume any obligation to update these forward-looking statements.

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CLEARPOINT NEURO, INC.

Consolidated Statements of Operations

(Unaudited)

(in thousands, except for share and per share data)

	For The Three Months Ended September 30,	
	2024	2023
Revenue:		
Product revenue	\$ 5,474	\$ 2,410
Service and other revenue	<u>2,648</u>	<u>3,352</u>
Total revenue	8,122	5,762
Cost of revenue	<u>3,275</u>	<u>2,489</u>
Gross profit	4,847	3,273
Research and development costs	3,315	2,429
Sales and marketing expenses	3,549	2,841
General and administrative expenses	<u>3,155</u>	<u>2,900</u>
Operating loss	(5,172)	(4,897)
Other income (expense):		
Other expense, net	(11)	(12)
Interest income, net	<u>209</u>	<u>100</u>
Net loss	<u>\$ (4,974)</u>	<u>\$ (4,809)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	<u>\$ (0.18)</u>	<u>\$ (0.20)</u>
Weighted average shares used in computing net loss per share:		
Basic and diluted	<u>27,591,623</u>	<u>24,630,181</u>

	For The Nine Months Ended September 30,	
	2024	2023
Revenue:		
Product revenue	\$ 14,053	\$ 7,377
Service and other revenue	<u>9,566</u>	<u>9,768</u>
Total revenue	23,619	17,145
Cost of revenue	<u>9,259</u>	<u>7,544</u>
Gross profit	14,360	9,601
Research and development costs	9,060	9,057
Sales and marketing expenses	10,673	9,248
General and administrative expenses	<u>8,769</u>	<u>9,036</u>
Operating loss	(14,142)	(17,740)
Other income (expense):		
Other expense, net	(32)	(25)
Interest income, net	<u>646</u>	<u>295</u>
Net loss	<u>\$ (13,528)</u>	<u>\$ (17,470)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	<u>\$ (0.50)</u>	<u>\$ (0.71)</u>
Weighted average shares used in computing net loss per share:		
Basic and diluted	<u>26,840,119</u>	<u>24,599,191</u>

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

	September 30, 2024 (Unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 21,573	\$ 23,140
Accounts receivable, net	3,875	3,211
Inventory, net	7,059	7,911
Prepaid expenses and other current assets	1,823	1,910
Total current assets	34,330	36,172
Property and equipment, net	1,695	1,389
Operating lease, right-of-use assets	3,210	3,564
Software license inventory	198	386
Licensing rights	612	1,041
Other assets	148	109
Total assets	\$ 40,193	\$ 42,661
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 955	\$ 393
Accrued compensation	3,635	2,947
Other accrued liabilities	1,176	1,053
Operating lease liabilities, current portion	536	424
Deferred product and service revenue, current portion	1,252	2,613
Total current liabilities	7,554	7,430
Operating lease liabilities, net of current portion	3,158	3,568
Deferred product and service revenue, net of current portion	480	541
2020 senior secured convertible note payable, net	-	9,949
Total liabilities	11,192	21,488
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at September 30, 2024 and December 31, 2023	-	-
Common stock, \$0.01 par value; 90,000,000 shares authorized at September 30, 2024 and December 31, 2023; 27,588,819 shares issued and outstanding at September 30, 2024; and 24,652,729 issued and outstanding at December 31, 2023	276	247
Additional paid-in capital	214,709	193,382
Accumulated deficit	(185,984)	(172,456)
Total stockholders' equity	29,001	21,173
Total liabilities and stockholders' equity	\$ 40,193	\$ 42,661

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

	For The Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (13,528)	\$ (17,470)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for credit losses (recoveries)	(507)	903
Depreciation and amortization	740	443
Share-based compensation	5,204	4,536
Amortization of debt issuance costs and original issue discounts	51	42
Amortization of lease right-of-use, net of accretion in lease liabilities	692	590
Accretion of discounts on short-term investments	-	(126)
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(157)	(662)
Inventory, net	434	263
Prepaid expenses and other current assets	88	241
Other assets	(40)	22
Accounts payable and accrued expenses	1,373	(1,023)
Lease liabilities	(635)	(553)
Deferred revenue	(1,422)	243
Net cash flows from operating activities	(7,707)	(12,551)
Cash flows from investing activities:		
Purchases of property and equipment	(12)	(696)
Acquisition of licensing rights	-	(167)
Proceeds from maturities of short-term investments	-	10,000
Net cash flows from investing activities	(12)	9,137
Cash flows from financing activities:		
Proceeds from public offering of common stock, net of offering costs	16,183	-
Repayment of 2020 senior secured convertible note	(10,000)	-
Proceeds from stock option exercises	21	-
Payments for taxes related to net share settlement of equity awards	(340)	(173)
Proceeds from issuance of common stock under employee stock purchase plan	288	314
Net cash flows from financing activities	6,152	141
Net change in cash and cash equivalents	(1,567)	(3,273)
Cash and cash equivalents, beginning of period	23,140	27,615
Cash and cash equivalents, end of period	\$ 21,573	\$ 24,342

SUPPLEMENTAL CASH FLOW INFORMATION

Cash paid for:

Income taxes	\$ -	\$ -
Interest	\$ 480	\$ 554

SOURCE: ClearPoint Neuro, Inc.

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