

August 7, 2024



ClearPoint Neuro Reports Second Quarter 2024 Results

Second Quarter Revenue Growth +32%; Record Revenue Achieved

SOLANA BEACH, Aug. 07, 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 second quarter ended June 30, 2024.

Second Quarter Highlights

- Reported quarterly revenue of \$7.9 million, a 32% year-over-year increase;
- Product revenue across all segments more than doubled, and grew 112% to \$4.9 million;
- Increased Biologics and Drug Delivery revenue to \$4.3 million, a 28% year-over-year increase;
- Full market release of SmartFrame OR™ platform and ClearPoint Prism® Laser Therapy System contributing to record navigation and device revenue of \$2.6 million and 34% growth versus the prior quarter;
- Activated six new global centers in the second quarter for a total of fourteen new centers so far this year;
- Partners advancing through preclinical and clinical review with seven pharmaceutical partners receiving expedited FDA review designation;
- Approval of SmartFlow® Cannula for commercial use in Taiwan by the Taiwan Food and Drug Administration;
- Operational cash burn reduced to \$2.7 million, a 47% year-over-year decrease;
- Cash and cash equivalents totaled \$32.8 million as of June 30, 2024.

"This has been the strongest quarter in our history both from a financial standpoint as well as continued execution of our four-pillar growth strategy," commented Joe Burnett, President and CEO at ClearPoint Neuro. "In the second quarter of 2024, we were excited to achieve double-digit growth from all four pillars including Biologics and Drug Delivery, Neurosurgery Navigation, Therapy and Access Products, and achieving global scale through capital placements and customer activations. This has led to record quarterly revenue of \$7.9

million, record product revenue of \$4.9 million, gross margins rising to 63%, and an operating cash burn reduction of 47% year over year. We expect to be well poised to continue this growth across all of our segments as we:

- Expand our biologics and drug delivery services and customers,
- Add long-term strategic agreements with pharmaceutical partners,
- Assist our biotech partners as they continue first-in-human study initiations,
- Continue our expansion into the operating room with SmartFrame OR,
- Expand our installed base of the PRISM Laser Therapy System under full market release, and
- Activate new capital customers by working through our sizable funnel of prospective customers.

As a result of our strong first half of 2024, we are raising our revenue guidance to between \$30.0 and \$33.0 million for the year 2024.”

Business Outlook

The Company is raising its full year 2024 revenue outlook to between \$30.0 and \$33.0 million.

Financial Results – Quarter Ended June 30, 2024

Total revenue was \$7.9 million for the three months ended June 30, 2024, and \$6.0 million for the three months ended June 30, 2023, which represents an increase of \$1.9 million, or 32%.

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 28% to \$4.3 million for the three months ended June 30, 2024, from \$3.4 million for the same period in 2023. This increase is attributable to a \$1.3 million increase in product revenue as a result of increased demand for disposables as multiple partners progress in their trials, partially offset by a decrease of \$0.4 million in service and other revenue, during the three months ended June 30, 2024, compared to the same period in 2023.

Neurosurgery Navigation and Therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 17% to \$2.6 million for the three months ended June 30, 2024, from \$2.2 million for the same period in 2023. The increase is driven by higher product revenue of \$0.8 million as a result of increased case volume, new capital placements, and new product offerings (SmartFrame OR and Prism) during the three months ended June 30, 2024, compared to the same period in 2023. This is partially offset by a decrease of \$0.4 million in service and other revenue primarily as a result of pausing a co-development program with one of our Brain Computer Interface partners, during the three months ended June 30, 2024, compared to the same period in 2023.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, increased 148% to \$0.9 million for the three

months ended June 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.

Gross margin for the three months ended June 30, 2024, was 63% compared to a gross margin of 53% for the three months ended June 30, 2023. The increase in gross margin was primarily due to lower costs for the three months ended June 30, 2024 due to the transition to the new manufacturing facility which was occurring in 2023, and higher volumes for the three months ended June 30, 2024.

Operating expenses for the second quarter of 2024 were \$9.7 million, compared to \$10.3 million for the second quarter of 2023. The decrease was mainly driven by lower product development costs and bad debt expense, partially offset by higher sales and marketing personnel expense.

At June 30, 2024, the Company had cash and cash equivalents totaling \$32.8 million as compared to \$23.1 million at December 31, 2023, with the increase resulting from the net proceeds from the public offering of common stock of \$16.2 million in the first quarter, partially offset by the use of cash in operating activities of \$6.5 million in the six month period ending June 30, 2024.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's 2024 second quarter on Wednesday, August 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=u0rzWezB>. 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 September 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 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 March 31, 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 June 30, 2024, which the Company intends to file with the Securities and Exchange Commission on or before August 14, 2024. The Company does not assume any obligation to update these forward-looking statements.

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

	For The Three Months Ended June 30,	
	2024	2023
Revenue:		
Product revenue	\$ 4,944	\$ 2,337
Service and other revenue	2,914	3,613
Total revenue	7,858	5,950
Cost of revenue	2,870	2,824
Gross profit	4,988	3,126
Research and development costs	3,120	3,605
Sales and marketing expenses	3,834	3,474
General and administrative expenses	2,773	3,178
Operating loss	(4,739)	(7,131)
Other expense:		
Other income (expense), net	5	(2)
Interest income, net	326	81
Net loss	<u>\$ (4,408)</u>	<u>\$ (7,052)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	<u>\$ (0.16)</u>	<u>\$ (0.29)</u>
Weighted average shares used in computing net loss per share:		
Basic and diluted	27,468,378	24,583,712

	For The Six Months Ended June 30,	
	2024	2023
Revenue:		
Product revenue	\$ 8,579	\$ 4,967
Service and other revenue	6,918	6,416
Total revenue	15,497	11,383
Cost of revenue	5,984	5,055
Gross profit	9,513	6,328
Research and development costs	5,745	6,628
Sales and marketing expenses	7,124	6,407
General and administrative expenses	5,614	6,136
Operating loss	(8,970)	(12,843)
Other expense:		
Other expense, net	(21)	(13)
Interest income, net	437	195
Net loss	<u>\$ (8,554)</u>	<u>\$ (12,661)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	<u>\$ (0.32)</u>	<u>\$ (0.52)</u>
Weighted average shares used in computing net loss per share:		
Basic and diluted	26,460,237	24,583,439

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

	June 30, 2024 (Unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 32,845	\$ 23,140
Accounts receivable, net	3,475	3,211
Inventory, net	8,031	7,911
Prepaid expenses and other current assets	2,205	1,910
Total current assets	46,556	36,172
Property and equipment, net	1,545	1,389
Operating lease, right-of-use assets	3,330	3,564
Software license inventory	236	386
Licensing rights	758	1,041
Other assets	149	109
Total assets	\$ 52,574	\$ 42,661
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 822	\$ 393
Accrued compensation	2,996	2,947
Other accrued liabilities	1,302	1,053
Operating lease liabilities, current portion	516	424
Deferred product and service revenue, current portion	1,079	2,613
2020 senior secured convertible note payable, net	9,979	—
Total current liabilities	16,694	7,430
Operating lease liabilities, net of current portion	3,302	3,568
Deferred product and service revenue, net of current portion	446	541
2020 senior secured convertible note payable, net	—	9,949
Total liabilities	20,442	21,488
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at June 30, 2024 and December 31, 2023	—	—
Common stock, \$0.01 par value; 90,000,000 shares authorized at June 30, 2024 and December 31, 2023; 27,588,812 shares issued and outstanding at June 30, 2024; and 24,652,729 issued and outstanding at December 31, 2023	276	247
Additional paid-in capital	212,866	193,382
Accumulated deficit	(181,010)	(172,456)
Total stockholders' equity	32,132	21,173
Total liabilities and stockholders' equity	\$ 52,574	\$ 42,661

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

	For The Six Months Ended June 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (8,554)	\$ (12,661)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for credit losses (recoveries)	(507)	454
Depreciation and amortization	476	285
Share-based compensation	3,300	2,952
Amortization of debt issuance costs and original issue discounts	29	28
Amortization of lease right-of-use, net of accretion in lease liabilities	461	325
Accretion of discounts on short-term investments	—	(126)
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	244	(588)
Inventory, net	(320)	94
Prepaid expenses and other current assets	(294)	(438)
Other assets	(39)	(25)
Accounts payable and accrued expenses	726	(282)
Lease liabilities	(401)	(293)
Deferred revenue	(1,629)	(480)
Net cash flows from operating activities	<u>(6,508)</u>	<u>(10,755)</u>
Cash flows from investing activities:		
Purchases of property and equipment	—	(461)
Acquisition of licensing rights	—	(167)
Proceeds from maturities of short-term investments	—	10,000
Net cash flows from investing activities	<u>—</u>	<u>9,372</u>
Cash flows from financing activities:		
Proceeds from public offering of common stock, net of offering costs	16,183	—
Proceeds from stock option exercises	21	—
Payments for taxes related to net share settlement of equity awards	(279)	(82)
Proceeds from issuance of common stock under employee stock purchase plan	288	314
Net cash flows from financing activities	<u>16,213</u>	<u>232</u>
Net change in cash and cash equivalents	9,705	(1,151)
Cash and cash equivalents, beginning of period	23,140	27,615
Cash and cash equivalents, end of period	<u>\$ 32,845</u>	<u>\$ 26,464</u>

SUPPLEMENTAL CASH FLOW INFORMATION

Cash paid for:

Income taxes	\$ —	\$ —
Interest	<u>\$ 370</u>	<u>\$ 369</u>

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