

November 9, 2023



ClearPoint Neuro Reports Third Quarter 2023 Results

Biologics & Drug Delivery Growing 55%; Q3 Operational Cash Burn of \$1.8M

SOLANA BEACH, Calif., Nov. 09, 2023 (GLOBE NEWSWIRE) -- 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 third quarter ended September 30, 2023.

Third Quarter Highlights

- Reported quarterly revenue of \$5.8 million, a 12% year-over-year increase;
- Increased biologics and drug delivery revenue to \$3.5 million, a 55% year-over-year increase;
- Operational cash burn of \$1.8 million, the lowest quarterly burn since 2020;
- Entered into new strategic biologics and drug delivery agreements, including additional milestone-based agreement;
- Submitted three new stereotactic products to the FDA for 510(k) clearance;
- Submitted one 510(k) clearance to the FDA for updated software that allows the ClearPoint Navigation Software to incorporate the Maestro Brain Model;
- Completed the transition to the new manufacturing facility in Carlsbad, California, which is now producing and shipping sellable product to customers;
- Cash and cash equivalents totaled \$24.3 million as of September 30, 2023.

Business Outlook

- With additional focus on near-term investments that drive profitable growth, the company now forecasts 2023 total revenue between \$23.0 and \$25.0 million representing growth between 11% and 18% for the year.

"The third quarter was productive for the team as we continued to grow double digits while meaningfully reducing our operational cash burn," commented Joe Burnett, President and CEO at ClearPoint Neuro. "We believe that our long-term vision and strategy remain unchanged, however we are committed to focusing our near-term activities on profitable

growth as our third quarter demonstrated. Despite reducing our quarterly operational cash burn to the lowest level since 2020, we were still able to execute multiple new strategic biologics and drug delivery agreements, expand our PRISM laser therapy system to new centers, execute multiple new product FDA submissions, and complete the transition of manufacturing to our new facility in Carlsbad, California ahead of schedule, improving gross margin and eliminating redundant costs heading into 2024.”

Financial Results – Quarter Ended September 30, 2023

Total revenue was \$5.8 million for the three months ended September 30, 2023, and \$5.1 million for the three months ended September 30, 2022, which represents an increase of \$0.6 million, or 12%.

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 55% to \$3.5 million for the three months ended September 30, 2023, from \$2.2 million for the same period in 2022.

Functional neurosurgery navigation and therapy revenue, decreased 21% to \$1.9 million for the three months ended September 30, 2023, from \$2.4 million for the same period in 2022. The decrease is driven primarily by lower service revenue of \$0.3 million as a result of pausing a co-development program with one of our Brain Computer Interface partners.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, decreased 26% to \$0.4 million for the three months ended September 30, 2023, from \$0.5 million for the same period in 2022.

Gross margin for the three months ended September 30, 2023, was 57%, as compared to a gross margin of 71% for the three months ended September 30, 2022. The 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 prior year as we launch new services and increase our presence in this space. Increased costs related to the transition to the new manufacturing facility have also contributed to the decrease in gross margin compared to prior year.

Operating expenses for the third quarter of 2023 were \$8.2 million, compared to \$7.5 million for the third 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, offset slightly by lower research and development costs.

At September 30, 2023, the Company had cash and cash equivalents and short-term investments totaling \$24.3 million as compared to \$37.5 million at December 31, 2022, with the decrease resulting primarily from the use of cash in operating activities of \$12.6 million.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company’s 2023 third quarter on Thursday, November 9, 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=dhaAzhXA>. Investors and

analysts who would like to participate in the conference call via telephone may do so at (800) 715-9871, or at (646) 307-1963 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 9, 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 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 over 65 sites in North America, Europe, and South America. ClearPoint Neuro is partnered with more than 50 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, more than 6,000 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 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, 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 macroeconomic and inflationary conditions, global instability, supply chain disruptions, and labor shortages; future revenue from sales of the Company's hardware and software products and biologics and drug delivery consulting services; the Company's ability to market, commercialize and achieve broader market acceptance for the Company's hardware and software products and service offerings, including our biologics and drug delivery partners' use of our products and services in their delivery of therapies; our biologics and drug delivery partners' ability to fund their business activities, conduct further research and development, and achieve success in their studies and clinical trials; and risks inherent in the research and 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 June 30, 2023, 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, 2023, which the Company intends to file with the

Securities and Exchange Commission on or before November 14, 2023.

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

	For The Three Months Ended September 30,	
	2023	2022
Revenue:		
Product revenue	\$ 2,410	\$ 3,130
Service and other revenue	3,352	2,016
Total revenue	<u>5,762</u>	<u>5,146</u>
Cost of revenue	<u>2,489</u>	<u>1,467</u>
Gross profit	3,273	3,679
Research and development costs	2,429	2,654
Sales and marketing expenses	2,841	2,422
General and administrative expenses	<u>2,900</u>	<u>2,398</u>
Operating loss	(4,897)	(3,795)
Other expense:		
Other expense, net	(12)	(25)
Interest income, net	100	32
Net loss	<u>\$ (4,809)</u>	<u>\$ (3,788)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	<u>\$ (0.20)</u>	<u>\$ (0.15)</u>
Weighted average shares used in computing net loss per share:		
Basic and diluted	24,630,181	24,497,636
	For The Nine Months Ended September 30,	
	2023	2022
Revenue:		
Product revenue	\$ 7,377	\$ 9,750
Service and other revenue	9,768	5,627
Total revenue	<u>17,145</u>	<u>15,377</u>
Cost of revenue	<u>7,544</u>	<u>5,212</u>
Gross profit	9,601	10,165
Research and development costs	9,057	7,967
Sales and marketing expenses	9,248	6,826
General and administrative expenses	<u>9,036</u>	<u>7,235</u>
Operating loss	(17,740)	(11,863)
Other expense:		
Other expense, net	(25)	(22)
Interest income (expense), net	295	(165)
Net loss	<u>\$ (17,470)</u>	<u>\$ (12,050)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	<u>\$ (0.71)</u>	<u>\$ (0.50)</u>
Weighted average shares used in computing net loss per share:		
Basic and diluted	24,599,191	24,058,205

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

	September 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 24,342	\$ 27,615
Short-term investments, at amortized cost	—	9,874
Accounts receivable, net	2,424	2,665
Inventory, net	8,987	9,303
Prepaid expenses and other current assets	1,557	1,723
Total current assets	37,310	51,180
Property and equipment, net	1,355	806
Operating lease, right-of-use assets	3,689	1,895
Software license inventory	405	450
Licensing rights	969	1,028
Other assets	109	131
Total assets	<u>\$ 43,837</u>	<u>\$ 55,490</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 789	\$ 272
Accrued compensation	2,288	2,824
Other accrued liabilities	953	2,065
Operating lease liabilities, current portion	384	561
Deferred product and service revenue, current portion	1,175	1,066
Total current liabilities	5,589	6,788
Operating lease liabilities, net of current portion	3,695	1,532
Deferred product and service revenue, net of current portion	524	390
2020 senior secured convertible note payable, net	9,935	9,893
Total liabilities	19,743	18,603
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at September 30, 2023 and December 31, 2022	—	—
Common stock, \$0.01 par value; 90,000,000 shares authorized at September 30, 2023 and 200,000,000 shares authorized at December 31, 2022; 24,625,670 shares issued and outstanding at September 30, 2023; and 24,578,983 issued and outstanding at December 31, 2022	246	246
Additional paid-in capital	191,685	187,008
Accumulated deficit	(167,837)	(150,367)
Total stockholders' equity	24,094	36,887
Total liabilities and stockholders' equity	<u>\$ 43,837</u>	<u>\$ 55,490</u>

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

	For The Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (17,470)	\$ (12,050)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for credit losses (recoveries)	903	(92)
Depreciation and amortization	443	224
Share-based compensation	4,536	2,954
Amortization of debt issuance costs and original issue discounts	42	41
Amortization of lease right-of-use, net of accretion in lease liabilities	590	400
Accretion of discounts on short-term investments	(126)	(159)
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(662)	(982)
Inventory, net	263	(3,318)
Prepaid expenses and other current assets	241	(1,150)
Other assets	22	31
Accounts payable and accrued expenses	(1,023)	1,255
Lease liabilities	(553)	(400)
Deferred revenue	243	144
Net cash flows from operating activities	(12,551)	(13,102)
Cash flows from investing activities:		
Purchases of property and equipment	(696)	(214)
Acquisition of licensing rights	(167)	(678)
Purchase of short-term investments	—	(21,590)
Proceeds from maturities of short-term investments	10,000	—
Net cash flows from investing activities	9,137	(22,482)
Cash flows from financing activities:		
Proceeds from stock option and warrant exercises	—	263
Payments for taxes related to net share settlement of equity awards	(173)	(336)
Proceeds from issuance of common stock under employee stock purchase plan	314	260
Net cash flows from financing activities	141	187
Net change in cash and cash equivalents	(3,273)	(35,397)
Cash and cash equivalents, beginning of period	27,615	54,109
Cash and cash equivalents, end of period	\$ 24,342	\$ 18,712

SUPPLEMENTAL CASH FLOW INFORMATION

Cash paid for:

Income taxes	\$ —	\$ —
Interest	\$ 554	\$ 351

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Source: ClearPoint Neuro, Inc.