

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 forwardlooking 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 forwardlooking 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 Th	e Three Mo Septembe	Months Ended ber 30,	
	20)23	2022	
Revenue:				
Product revenue	\$	2,410 \$	•	
Service and other revenue		3,352	2,016	
Total revenue		5,762	5,146	
Cost of revenue		2,489	1,467	
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		2,900	2,398	
Operating loss		(4,897)	(3,795)	
Other expense:				
Other expense, net		(12)	(25)	
Interest income, net		100	32	
Net loss	\$	(4,809) \$	(3,788)	
Net loss per share attributable to common stockholders:				
Basic and diluted	\$	(0.20) \$	(0.15)	
Weighted average shares used in computing net loss per share:				
Basic and diluted	24 6	30,181	24,497,636	
	For Th		onths Ended	
		Septembe	er 30,	
Revenue				
Revenue:	20	Septembe	er 30, 2022	
Product revenue		September 223	er 30, 2022 9,750	
Product revenue Service and other revenue	\$	7,377 \$ 9,768	er 30, 2022 9,750 5,627	
Product revenue Service and other revenue Total revenue	\$	7,377 \$ 9,768 17,145	er 30, 2022 9,750 5,627 15,377	
Product revenue Service and other revenue Total revenue Cost of revenue	\$	7,377 \$ 9,768 17,145 7,544	er 30, 2022 9,750 5,627 15,377 5,212	
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit	\$	7,377 \$ 9,768 17,145 7,544 9,601	9,750 5,627 15,377 5,212 10,165	
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit Research and development costs	\$	7,377 \$ 9,768 17,145 7,544 9,601 9,057	9,750 5,627 15,377 5,212 10,165 7,967	
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit Research and development costs Sales and marketing expenses	\$	7,377 \$ 9,768 17,145 7,544 9,601 9,057 9,248	9,750 5,627 15,377 5,212 10,165 7,967 6,826	
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit Research and development costs Sales and marketing expenses General and administrative expenses	\$	7,377 \$ 9,768 17,145 7,544 9,601 9,057 9,248 9,036	9,750 5,627 15,377 5,212 10,165 7,967 6,826 7,235	
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit Research and development costs Sales and marketing expenses General and administrative expenses Operating loss	\$	7,377 \$ 9,768 17,145 7,544 9,601 9,057 9,248	9,750 5,627 15,377 5,212 10,165 7,967 6,826 7,235	
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit Research and development costs Sales and marketing expenses General and administrative expenses Operating loss Other expense:	\$	7,377 \$ 9,768 17,145 7,544 9,601 9,057 9,248 9,036 (17,740)	9,750 5,627 15,377 5,212 10,165 7,967 6,826 7,235 (11,863)	
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit Research and development costs Sales and marketing expenses General and administrative expenses Operating loss Other expense: Other expense, net	\$	7,377 \$ 9,768 17,145 7,544 9,601 9,057 9,248 9,036 (17,740) (25)	9,750 5,627 15,377 5,212 10,165 7,967 6,826 7,235 (11,863)	
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit Research and development costs Sales and marketing expenses General and administrative expenses Operating loss Other expense: Other expense, net Interest income (expense), net	\$	7,377 \$ 9,768 17,145 7,544 9,601 9,057 9,248 9,036 (17,740) (25) 295	er 30, 2022 9,750 5,627 15,377 5,212 10,165 7,967 6,826 7,235 (11,863) (22) (165)	
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit Research and development costs Sales and marketing expenses General and administrative expenses Operating loss Other expense: Other expense, net Interest income (expense), net Net loss	\$	7,377 \$ 9,768 17,145 7,544 9,601 9,057 9,248 9,036 (17,740) (25)	er 30, 2022 9,750 5,627 15,377 5,212 10,165 7,967 6,826 7,235 (11,863) (22) (165)	
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit Research and development costs Sales and marketing expenses General and administrative expenses Operating loss Other expense: Other expense, net Interest income (expense), net Net loss Net loss per share attributable to common stockholders:	\$	7,377 \$ 9,768 17,145 7,544 9,601 9,057 9,248 9,036 (17,740) (25) 295 (17,470) \$	9,750 5,627 15,377 5,212 10,165 7,967 6,826 7,235 (11,863) (22) (165) (12,050)	
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit Research and development costs Sales and marketing expenses General and administrative expenses Operating loss Other expense: Other expense, net Interest income (expense), net Net loss Net loss per share attributable to common stockholders: Basic and diluted	\$	7,377 \$ 9,768 17,145 7,544 9,601 9,057 9,248 9,036 (17,740) (25) 295	9,750 5,627 15,377 5,212 10,165 7,967 6,826 7,235 (11,863) (22) (165) (12,050)	
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit Research and development costs Sales and marketing expenses General and administrative expenses Operating loss Other expense: Other expense, net Interest income (expense), net Net loss Net loss per share attributable to common stockholders:	\$ \$ \$ \$	7,377 \$ 9,768 17,145 7,544 9,601 9,057 9,248 9,036 (17,740) (25) 295 (17,470) \$	9,750 5,627 15,377 5,212 10,165 7,967 6,826 7,235 (11,863) (22) (165) (12,050)	

CLEARPOINT NEURO, INC.

Consolidated Balance Sheets

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

	·	tember 30, 2023 naudited)	Dec	cember 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	\$	43,837	\$	55,490
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	\$	43,837	\$	55,490
Total habilities and stockholders equity	Ψ	70,001	Ψ	55,430

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	\$	_	\$	_
	Ψ		Ψ	054
Interest	\$	554	\$	351

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Investor Relations

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Source: ClearPoint Neuro, Inc.