

# ClearPoint Neuro Reports Second Quarter 2023 Results

### Biologics & Drug Delivery growing +40%; Company Reaffirms 2023 Revenue Forecast

SOLANA BEACH, Calif., Aug. 08, 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 second quarter ended June 30, 2023.

#### **Second Quarter Highlights**

- Reported record quarterly revenue of \$6.0 million, a 14% year-over-year increase;
- Increased biologics and drug delivery revenue to \$3.4 million, a 40% year-over-year increase;
- Announced an example of a milestone-based biologics and drug delivery agreement whereby ClearPoint would earn cash compensation based on the successful progression of a drug candidate through the clinical and regulatory process;
- Installed multiple new PRISM laser therapy units and continued the limited market release in the U.S.;
- Completed construction on the manufacturing clean room at the Carlsbad, California facility;
- Cash and cash equivalents totaled \$26.5 million as of June 30, 2023.

#### **Business Outlook**

The Company reaffirms its full year 2023 revenue outlook of between \$25.0 and \$27.0 million.

"We are pleased with our result for the second quarter as we have returned to double-digit growth and delivered record revenue stemming primarily from the launch of new services in the biologics and drug delivery space which grew more than 40%," commented Joe Burnett, President and CEO at ClearPoint Neuro. "As we look ahead to the second half of 2023, we expect to demonstrate progress toward our continued growth and scale by 1) accelerating revenue growth; 2) adding meaningful strategic and milestone-based biologics and drug delivery agreements; 3) expanding our PRISM limited market release to multiple new

centers; 4) executing as many as five FDA submissions directly or through partnerships for new products; and 5) completing the qualification of our new manufacturing clean room facility in Carlsbad, California and producing sellable product. We believe these milestones will contribute to a reduction in operational cash burn compared to the first half of 2023 with continued revenue growth in biologics and drug delivery being the primary driver."

#### Financial Results – Quarter Ended June 30, 2023

Total revenue was \$6.0 million for the three months ended June 30, 2023, and \$5.2 million for the three months ended June 30, 2022, which represents an increase of \$0.8 million, or 14%.

Functional neurosurgery navigation and therapy revenue, remained relatively consistent at \$2.2 million for the three months ended June 30, 2023 and 2022.

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 40% to \$3.4 million for the three months ended June 30, 2023, from \$2.4 million for the same period in 2022. This increase is attributable to a \$1.8 million increase in service revenue, partially offset by \$0.9 million decrease in product revenue.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, decreased 38% to \$0.4 million for the three months ended June 30, 2023, from \$0.6 million for the same period in 2022 as a result of fewer placements of ClearPoint capital and software.

Gross margin for the three months ended June 30, 2023, was 53%, as compared to a gross margin of 63% for the three months ended June 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 product sales 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.

Operating expenses for the second quarter of 2023 were \$10.3 million, compared to \$7.5 million for the second 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 product development costs.

At June 30, 2023, the Company had cash and cash equivalents and short-term investments totaling \$26.5 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 \$10.8 million.

#### **Teleconference Information**

Investors and analysts are invited to listen to a live broadcast review of the Company's 2023 second quarter on Tuesday, August 8, 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=n0kx7ZK0. Investors and analysts who would like to participate in the conference call via telephone may do so at (888) 437-3179, 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, 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 <a href="https://ir.clearpointneuro.com/">https://ir.clearpointneuro.com/</a>.

#### **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 the COVID-19 pandemic, global instability, supply chain disruptions, labor shortages, and macroeconomic and inflationary conditions; future revenue from sales of the Company's ClearPoint Neuro Navigation System and other new products offered by the Company; the Company's ability to market, commercialize and achieve broader market acceptance for the Company's ClearPoint Neuro Navigation System and other new products offered by the Company; the ability of our biologics and drug delivery partners to achieve commercial success, including their use of our products and services in their delivery of therapies; risks inherent in the research and development, and regulatory approval of new products; and risks in the process of developing and establishing manufacturing operations in a new facility. 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 March 31, 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 June 30, 2023, which the Company intends to file with the Securities and Exchange Commission on or before August 14, 2023.

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

For The	Three	<b>Months</b>	<b>Ended</b>			
June 30,						

		oune so,			
	2023			2022	
Revenue:					
Product revenue	\$	2,337	\$	3,457	
Service and other revenue		3,613		1,743	
Total revenue		5,950		5,200	
Cost of revenue		2,824		1,945	
Gross profit		3,126		3,255	
Research and development costs		3,605		2,411	
Sales and marketing expenses		3,474		2,387	
General and administrative expenses		3,178		2,661	
Operating loss		(7,131)		(4,204)	
Other expense:					
Other expense, net		(2)		(8)	
Interest income (expense), net		81		(91)	
Net loss	\$	(7,052)	\$	(4,303)	
Net loss per share attributable to common stockholders:					
Basic and diluted	\$	(0.29)	\$	(0.18)	
Weighted average shares used in computing net loss per share:					
Basic and diluted		24,583,712		23,985,577	

#### For The Six Months Ended June 30.

	Julie 30,			
		2023		2022
Revenue:				
Product revenue	\$	4,967	\$	6,620
Service and other revenue		6,416		3,611
Total revenue		11,383		10,231
Cost of revenue		5,055		3,746
Gross profit		6,328		6,485
Research and development costs		6,628		5,312
Sales and marketing expenses		6,407		4,404
General and administrative expenses		6,136		4,837
Operating loss		(12,843)		(8,068)
Other expense:				
Other (expense) income, net		(13)		3
Interest income (expense), net		195		(197)
Net loss	\$	(12,661)	\$	(8,262)
Net loss per share attributable to common stockholders:				
Basic and diluted	\$	(0.52)	\$	(0.35)
Weighted average shares used in computing net loss per share:				
Basic and diluted		24,583,439		23,834,847

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

	June 30, 2023 (Unaudited)		December 31, 2022	
ASSETS				
Current assets:				
Cash and cash equivalents	\$ 26,464	\$	27,615	
Short-term investments, at amortized cost	_		9,874	
Accounts receivable, net	2,799		2,665	
Inventory, net	9,204		9,303	
Prepaid expenses and other current assets	2,244		1,723	
Total current assets	40,711		51,180	
Property and equipment, net	1,360		806	
Operating lease, right-of-use assets	3,956		1,895	
Software license inventory	407		450	
Licensing rights	1,051		1,028	
Other assets	156		131	
Total assets	\$ 47,641	\$	55,490	
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$ 1,273	\$	272	
Accrued compensation	2,339		2,824	
Other accrued liabilities	1,373		2,065	
Operating lease liabilities, current portion	493		561	
Deferred product and service revenue, current portion	724		1,066	
Total current liabilities	 6,202		6,788	
Operating lease liabilities, net of current portion	3,855		1,532	
Deferred product and service revenue, net of current portion	253		390	
2020 senior secured convertible note payable, net	9,921		9,893	
Total liabilities	 20,231		18,603	
Commitments and contingencies			_	
Stockholders' equity:				
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and				
outstanding at June 30, 2023 and December 31, 2022	_		_	
Common stock, \$0.01 par value; 90,000,000 shares authorized at June 30, 2023 and 200,000,000 shares authorized at December 31, 2022; 24,627,674 shares issued and outstanding at June 30, 2023; and 24,578,983 issued and outstanding at				
December 31, 2022	246		246	
Additional paid-in capital	190,192		187,008	
Accumulated deficit	(163,028)		(150,367)	
Total stockholders' equity	27,410		36,887	
Total liabilities and stockholders' equity	\$ 47,641	\$	55,490	

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

For The	Six	Months	Ended			
June 30,						

	June 30,			
		2023		2022
Cash flows from operating activities:				
Net loss	\$	(12,661)	\$	(8,262)
Adjustments to reconcile net loss to net cash flows from operating activities:				
Allowance for credit losses (recoveries)		454		(10)
Depreciation and amortization		285		187
Share-based compensation		2,952		1,779
Amortization of debt issuance costs and original issue discounts		28		27
Amortization of lease right-of-use, net of accretion in lease liabilities		325		267
Accretion of discounts on short-term investments		(126)		(23)
Increase (decrease) in cash resulting from changes in:				
Accounts receivable		(588)		(1,001)
Inventory, net		94		(1,786)
Prepaid expenses and other current assets		(438)		(1,010)
Other assets		(25)		30
Accounts payable and accrued expenses		(282)		679
Lease liabilities		(293)		(261)
Deferred revenue		(480)		134
Net cash flows from operating activities		(10,755)		(9,250)
Cash flows from investing activities:				
Purchases of property and equipment		(461)		(145)
Acquisition of licensing rights		(167)		(116)
Purchase of short-term investments		_		(21,590)
Proceeds from maturities of short-term investments		40.000		
		10,000		
Net cash flows from investing activities		9,372		(21,851)
Cash flows from financing activities:				
Proceeds from stock option and warrant exercises		_		256
Payments for taxes related to net share settlement of equity awards		(82)		_
Proceeds from issuance of common stock under employee stock purchase plan		314		260
Net cash flows from financing activities		232		516
Net change in cash and cash equivalents		(1,151)		(30,585)
Cash and cash equivalents, beginning of period		27,615		54,109
Cash and cash equivalents, end of period	\$	26,464	\$	23,524
SUPPLEMENTAL CASH FLOW INFORMATION				
Cash paid for:				
Income taxes	\$	_	\$	
Interest	\$	369	\$	207

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Source: ClearPoint Neuro, Inc.