

ClearPoint Neuro Reports Second Quarter 2021 Results

Record Case Volume Supported Clinically During the Quarter

SOLANA BEACH, Calif., Aug. 10, 2021 (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, 2021.

Second Quarter Highlights

- Reported revenue of \$3.4 million, a 38% year-over-year increase;
- Clinical team supported a record 249 cases, a 98% year-over- year increase;
- Increased biologics and drug delivery revenue to \$1.4 million, a 19% year-over-year increase;
- Added biologics and drug delivery relationships bringing current count of active partners to approximately 35 from approximately 30 in Q1 2021; and
- Announced FDA clearance of the SmartFrame Array and performed first human cases.

Business Outlook

- The Company continues to estimate total case volume supported to be in the range of 900 – 1000 for 2021; and
- The Company continues to estimate revenue to be between \$16.0 and \$17.5 million for 2021.

"The ClearPoint Neuro team enjoyed multiple significant successes in the 2021 second quarter, headlined by our record case volume result, which demonstrated a return to prepandemic levels a quarter ahead of schedule," commented Joe Burnett, the Company's President and Chief Executive Officer. "Also encouraging has been the resumption of clinical and pre-clinical activities by our biologics and drug delivery partners who have resumed labbased activities and enrollment in human clinical trials, which we believe puts the regulatory pathway for their therapies back on track. We are currently working with more than 30 partners in the drug delivery space and expect to add additional partners in the second half of 2021. Further, our development and production teams remain on track for all the programs we announced in February, which keeps our planned timelines and key milestones on schedule. While we are monitoring the impact of the new Delta wave of COVID-19 cases, which has again started to put pressure on elective procedures at several customer sites as

hospital ICU beds fill up, we believe our biologics and drug delivery business will make up for any potential impact in the second half and we continue to estimate that the range of cases supported by our clinical team will be in a range of 900 – 1000, and that our revenues will be in a range of \$16.0 - \$17.5 million for 2021."

Financial Results – Quarter Ended June 30, 2021

Total revenue was \$3.4 million for the three months ended June 30, 2021, and \$2.5 million for the three months ended June 30, 2020, which represents an increase of \$0.9 million, or 38%.

Functional neurosurgery navigation revenue, which consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 74% to \$1.9 million for the three months ended June 30, 2021, from \$1.1 million for the same period in 2020. This increase reflects the resumption in the three months ended June 30, 2021, of elective surgical procedures, which were postponed or cancelled during the three months ended June 30, 2020, due to the effects of the COVID-19 pandemic.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored clinical trials utilizing our products, increased 19% to \$1.4 million for the three months ended June 30, 2021, from \$1.2 million for the same period in 2020. This increase was due to an increase, during the quarter ended June 30, 2021, relative to the same period in 2020, in biologic and drug delivery service revenue of \$0.2 million, and an increase in biologic and drug delivery product revenue of \$0.04 million.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, were \$0.2 million for each of the three months ended June 30, 2021. Revenue from this product line historically has varied from quarter to quarter, and overall, the Company believes that hospitals' capital equipment acquisition activities remain at a low level, relative to the acquisition activity prior to the onset in 2020 of the COVID-19 pandemic.

Gross margin for the three months ended June 30, 2021, was 67%, as compared with gross margin of 68% for the same period in 2020. This decrease in gross margin was due primarily to a decreased contribution, during the three months ended June 30, 2021, as compared to the same period in 2020, from service revenue, which carries a higher gross margin relative to product lines, substantially offset by an increased contribution from functional neurosurgery navigation disposable product sales, which carry a higher gross margin relative to other product lines.

Research and development costs were \$2.1 million for the three months ended June 30, 2021, compared to \$0.8 million for the same period in 2020, an increase of \$1.3 million, or 161%. The increase was due primarily to increases in personnel costs due to growth in headcount, and software development and product development costs. Sales and marketing expenses were \$1.6 million for the three months ended June 30, 2021, compared to \$1.1 million for the same period in 2020, an increase of \$0.5 million, or 42%. This increase was due primarily to increases in marketing personnel costs resulting from increases in headcount, and a commensurate increase in marketing activities including our expansion into Europe. General and administrative expenses were \$2.0 million for the three months ended June 30, 2021, compared to \$1.2 million for the same period in 2020, an increase of

\$0.8 million, or 63%. This increase was due primarily to increases in state franchise taxes, share-based compensation, occupancy costs, insurance and professional fees related primarily to public company reporting.

At June 30, 2021, the Company had cash and cash equivalents totaling \$61.5 million as compared to \$20.1 million at December 31, 2020, with the increase resulting primarily from the completion of a public offering of its common stock in February 2021.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's 2021 second quarter on Tuesday, August 10, 2021 at 4:30 p.m. Eastern time (1:30 p.m. Pacific time) which may be accessed <u>online here</u>. Investors and analysts who would like to participate in the conference call via telephone may do so at (877) 407-9034, or at (201) 493-6737 if calling from outside the U.S. or Canada and then entering conference I.D. number 13721705.

For those who cannot access the live broadcast, a replay will be available shortly after the completion of the call until September 10, 2021, 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 website at www.clearpointneuro.com, on the "Investor Relations" page.

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, neuro-aspiration, 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 60 active sites in the United States, Canada, and Europe. ClearPoint Neuro is partnered with approximately 35 biologics/pharmaceutical companies and academic centers, providing solutions for direct CNS delivery of therapeutics in pre-clinical studies and clinical trials worldwide. To date, more than 4,500 cases have been performed and supported by the Company's field-based clinical specialist team, which offers support and services to our customers and partners. For more information, please visit www.clearpointneuro.com.

Forward-Looking Statements

Statements herein 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, 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 the COVID-19 pandemic and the measures adopted to contain its spread; future revenue from sales of the Company's ClearPoint Neuro Navigation System products; the Company's ability to market, commercialize and achieve broader market

acceptance for the Company's ClearPoint Neuro Navigation System products; and risks inherent in the research and development 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, 2020, and the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2021, both of which has 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, 2021, which the Company intends to file with the Securities and Exchange Commission on or before August 16, 2021.

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

For The Three Months Ended June 30. 2021 2020 Revenue: Product revenue \$ 2,363 \$ 1,636 1,050 Service and other revenue 842 3,413 Total revenue 2,478 Cost of revenue 1,123 802 2,290 1,676 Gross profit 2,123 812 Research and development costs Sales and marketing expenses 1,592 1,125 General and administrative expenses 1,982 1,214 (3,407)(1,475)Operating loss Other expense: Other (expense) income, net (96)11 Interest expense, net (240)(197)(3,743)(1,661)Net loss per share attributable to common stockholders: Basic and diluted (0.17)(0.11)Weighted average shares used in computing net loss per share:

21,523,393

15,504,169

Basic and diluted

For The Six Months Ended June 30,

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	2021		2020	
Revenues:				
Product revenues	\$	5,525	\$	3,814
Service and other revenues		1,918		1,779
Total revenues		7,443		5,593
Cost of revenues		2,539		1,733
Gross profit		4,904		3,860
Research and development costs		3,687		1,631
Sales and marketing expenses		3,167		2,423
General and administrative expenses		3,638		2,490
Operating loss		(5,588)		(2,684)
Other income (expense):				
Other (expense) income, net		(122)		6
Interest expense, net		(571)		(1,038)
Net loss	\$	(6,281)	\$	(3,716)
Net loss per share attributable to common stockholders:				
Basic and diluted	\$	(0.31)	\$	(0.24)
Weighted average shares used in computing net loss per share:				
Basic and diluted		20,195,488		15,471,222

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

	June 30, 2021 (Unaudited)		2021 2020	
ASSETS				
Current assets:	_		_	
Cash and cash equivalents	\$	61,524	\$	20,099
Accounts receivable, net		2,407		1,881
Inventory, net		3,575		3,238
Prepaid expenses and other current assets		1,003		244
Total current assets		68,509		25,462
Property and equipment, net		349		319
Operating lease rights of use		2,489		2,736
Software license inventory		519		589
Licensing rights		309		353
Other assets		151		59
Total assets	\$	72,326	\$	29,518
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	1,252	\$	300
Accrued compensation		1,411		1,595
Other accrued liabilities		892		349
Operating lease liabilities, current portion		462		394
Deferred product and service revenue		368		562
Total current liabilities		4,385		3,200
Operating lease liabilities, net of current portion		2,203		2,446
Deferred product and service revenue, net of current portion		268		215
2020 senior secured convertible notes payable, net		17,504		21,280
Total liabilities		24,360		27,141
Commitments and contingencies				
Stockholders' equity:				
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at June 30, 2021 and December 31, 2020		-		-
Common stock, \$0.01 par value; 200,000,000 shares authorized; 22,322,344 shares issued and outstanding at June 30, 2021; and 17,047,584 issued and				
outstanding at December 31, 2020		223		170
Additional paid-in capital		173,546		121,729
Accumulated deficit		(125,803)		(119,522)
Total stockholders' equity		47,966		2,377
Total liabilities and stockholders' equity	\$	72,326	\$	29,518

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

For The Six Months Ended June 30,

	Julie Ju,		
	2021		2020
Cash flows from operating activities:			
Net loss	\$ (6,281)	\$	(3,716)
Adjustments to reconcile net loss to net cash flows from operating activities:			
Allowance for doubtful accounts	92		2
Depreciation and amortization	62		116
Share-based compensation	567		469
Payment-in-kind interest	189		-
Amortization of debt issuance costs and original issue discounts	54		821
Amortization of lease rights of use, net of accretion in lease liabilities	267		50
Increase (decrease) in cash resulting from changes in:			
Accounts receivable	(617)		(76)
Inventory, net	(304)		(313)
Prepaid expenses and other current assets	(760)		(181)
Other assets	(93)		70
Accounts payable and accrued expenses	1,312		93
Accrued interest	-		(960)
Lease liabilities	(195)		(48)
Deferred revenue	(142)		(366)
Net cash flows from operating activities	(5,849)		(4,039)
Cash flows from investing activities:			
Purchases of property and equipment	(5)		-
Acquisition of licensing rights	-		(441)
Net cash flows from investing activities	 (5)		(441)
Cash flows from financing activities:			
Proceeds from issuance of 2020 senior secured convertible notes, net of financing			16,758
costs and discount			,
	-		
Proceeds from issuance of Paycheck Protection Program loan	-		896
Proceeds from public offering of common stock, net of offering costs	46,785		-
Proceeds from stock option and warrant exercises	494		-
Repayment of notes payable			(2,838)
Net cash flows from financing activities	 47,279		14,816
Net change in cash and cash equivalents	41,425		10,336
Cash and cash equivalents, beginning of period	20,099		5,696
Cash and cash equivalents, end of period	\$ 61,524	\$	16,032
SUPPLEMENTAL CASH FLOW INFORMATION			
Cash paid for:			
Income taxes	\$ -	\$	-
Interest	\$ 353	\$	1,043

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Source: ClearPoint Neuro, Inc.