

ClearPoint Neuro Reports Third Quarter 2021 Results

Record Revenue Achieved; Company Reaffirms 2021 Revenue Forecast

SOLANA BEACH, Calif., Nov. 09, 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 third quarter ended September 30, 2021.

Third Quarter Highlights

- Reported record revenue of \$4.6 million, a 30% year-over-year increase;
- Increased biologics and drug delivery revenue to \$2.1 million, a 39% year-over-year increase:
- Achieved additional biologics and drug delivery relationships, bringing current count of active partners to approximately 40;
- Initiated development program for a navigation and delivery system for Brain-Computer Interfaces;
- Supported 227 cases despite the impact of the Delta variant on elective procedures, a 14% year-over-year increase; and
- Launched Patient Education Program to increase awareness around DBS options, including awake MER-guided procedures and MRI-guided procedures under general anesthesia.

Business Outlook

- The Company continues to estimate total case volume support 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 continued to execute against our four-pillar growth strategy in the third quarter and celebrated a number of successes along the way," commented Joe Burnett, President and CEO. "First, we achieved record revenue in both Functional Neurosurgery Navigation and Biologics & Drug Delivery, yielding total revenue of \$4.6 M which represents year-over-year growth of 30% growth. These results are in spite of the

postponement of numerous elective procedures due to the rise of the Delta Variant which adversely impacted case volume in August and September. The majority of our impacted centers have again scheduled cases starting in October. Our Biologics and Drug Delivery Team, driven by the expansion of pre-clinical services and placements in Europe have added additional pharma partners to our 'active' list, bringing the total number of active relationships to approximately 40. We have started development of our navigation system for Brain Computer Interface placements, leveraging the ClearPoint platform and expect to have functional prototypes for pre-clinical testing in the second half of 2022. We also made progress across all of our previously announced development programs, with timeline estimates remaining intact. Very importantly, we utilized a portion of the capital we raised last February to invest in innovation and expand our market presence by hiring 18 talented engineers, programmers, researchers, and clinical specialists. Our ability to attract talent I believe demonstrates the excitement our team generates, and the recognition of the important work that we are doing."

Financial Results – Quarter Ended September 30, 2021

Total revenue was \$4.6 million for the three months ended September 30, 2021, and \$3.5 million for the three months ended September 30, 2020, which represents an increase of \$1.1 million, or 30%.

Functional neurosurgery navigation revenue, which consists of disposable product commercial sales and services related to cases utilizing the ClearPoint system, increased 17% to \$2.2 million for the three months ended September 30, 2021, from \$1.8 million for the same period in 2020.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored clinical trials utilizing our products, increased 39% to \$2.1 million for the three months ended September 30, 2021, from \$1.5 million for the same period in 2020. This increase was due to (a) a higher number of biologic and drug delivery partners and (b) the resumption of investments in pre-clinical research and clinical trials by our biologics and drug delivery customers.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, increased 78% to \$0.4 million for the three months ended September 30, 2021, from \$0.2 million for the same period in 2020.

Gross margin for the three months ended September 30, 2021, was 68%, as compared with gross margin of 74% for the same period in 2020. This decrease in gross margin was due primarily to increases in the reserve for excess and obsolete inventory and in overhead costs allocated to cost of sales during the three months ended September 30, 2021 as compared to the same period in 2020.

Research and development costs were \$2.6 million for the three months ended September 30, 2021, compared to \$1.1 million for the same period in 2020, an increase of \$1.5 million, or 130%. This increase was due primarily to increases in personnel costs due to growth in headcount, and product and software development costs, both resulting from our efforts to expand the applications of our technological platforms. Sales and marketing expenses were \$1.8 million for the three months ended September 30, 2021, compared to \$1.5 million for the same period in 2020, an increase of \$0.3 million, or 22%. This increase was due

primarily to increases in personnel costs resulting from increases in headcount, travel expenses, and marketing activities. General and administrative expenses were \$2.4 million for the three months ended September 30, 2021, compared to \$1.3 million for the same period in 2020, an increase of \$1.2 million, or 95%. This increase was due primarily to increases in personnel costs, share-based compensation and various professional and consulting fees.

At September 30, 2021, the Company had cash and cash equivalents totaling \$57.7 million as compared to \$20.1 million at December 31, 2020, with the increase resulting primarily from the completion of a public offering of the Company's common stock in February 2021.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's 2021 third quarter on Tuesday, November 9, 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 (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 December 9, 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 40 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 5,000 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 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, 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 June 30, 2021, 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, 2021, which the Company intends to file with the Securities and Exchange Commission on or before November 15, 2021.

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

For The Three Months Ended

		September 30,		
		2021	2020	
Revenue:			_	
Product revenue	\$	3,338 \$	2,371	
Service and other revenue	<u></u>	1,236	1,148	
Total revenue		4,574	3,519	
Cost of revenue		1,486	903	
Gross profit		3,088	2,616	
Research and development costs		2,630	1,143	
Sales and marketing expenses		1,826	1,493	
General and administrative expenses	<u></u>	2,436	1,252	
Operating loss		(3,804)	(1,272)	
Other expense:				
Other income (expense), net		62	(11)	
Interest expense, net		(238)	(201)	
Net loss	\$	(3,980)\$	(1,484)	
Net loss per share attributable to common stockholders:				
Basic and diluted	\$	(0.18)\$	(0.09)	
Weighted average shares used in computing net loss per share:				
Basic and diluted		22,522,460	15,724,401	

For The Nine Months Ended September 30,

	 2021	2020	
Revenues:	 		
Product revenues	\$ 8,863 \$	6,186	
Service and other revenues	3,154	2,927	
Total revenues	 12,017	9,113	
Cost of revenues	4,015	2,636	
Gross profit	 8,002	6,477	
Research and development costs	6,251	2,774	
Sales and marketing expenses	5,081	3,916	
General and administrative expenses	6,062	3,742	
Operating loss	 (9,392)	(3,955)	
Other income (expense):			
Other (expense), net	(60)	(5)	
Interest expense, net	(809)	(1,240)	
Net loss	\$ (10,261)	(5,200)	
Net loss per share attributable to common stockholders:	 		
Basic and diluted	\$ (0.50)\$	(0.33)	
Weighted average shares used in computing net loss per share:	 		
Basic and diluted	 20,545,080	15,556,231	

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

		September 30, 2021 (Unaudited)		December 31, 2020	
ASSETS					
Current assets:	•	57.054	•	00.000	
Cash and cash equivalents	\$	57,651	\$	20,099	
Accounts receivable, net		2,559		1,881	
Inventory, net		3,943		3,238	
Prepaid expenses and other current assets		842		244	
Total current assets		64,995		25,462	
Property and equipment, net		450		319	
Operating lease rights of use		2,365		2,736	
Software license inventory		519		589	
Licensing rights		287		353	
Other assets		86		59	
Total assets	\$	68,702	\$	29,518	
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Carrone nationals.	\$	777	\$	300	
Accounts payable	Ψ		Ψ		
Accrued compensation		1,804		1,595	
Other accrued liabilities		1,081		349	
Operating lease liabilities, current portion		486		394	
Deferred product and service revenue		440		562	
Total current liabilities		4,588		3,200	
Operating lease liabilities, net of current portion		2,071		2,446	
Deferred product and service revenue, net of current portion		310		215	
2020 senior secured convertible notes payable, net		17,613		21,280	
Total liabilities	·	24,582		27,141	
Commitments and contingencies		_			
Stockholders' equity:					
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at September 30, 2021 and December 31, 2020		-		-	
Common stock, \$0.01 par value; 200,000,000 shares authorized; 22,855,187 shares issued and outstanding at September 30, 2021; and 17,047,584 issued and					
outstanding at December 31, 2020		229		170	
Additional paid-in capital		173,674		121,729	
Accumulated deficit		(129,783)		(119,522)	
Total stockholders' equity		44,120		2,377	
Total liabilities and stockholders' equity	\$	68,702	\$	29,518	

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

For The Nine Months Ended September 30,

		2021		2020
Cash flows from operating activities:	_			
Net loss	\$	(10,261)	\$	(5,200)
Adjustments to reconcile net loss to net cash flows from operating activities:				
Allowance for doubtful accounts		170		13
Depreciation and amortization		113		170
Share-based compensation		1,153		762
Payment-in-kind interest		285		-
Amortization of debt issuance costs and original issue discounts		73		856
Amortization of lease rights of use, net of accretion in lease liabilities		400		75
Increase (decrease) in cash resulting from changes in:				
Accounts receivable		(848)		(373)
Inventory, net		(682)		(323)
Prepaid expenses and other current assets		(599)		(136)
Other assets		(28)		59
Accounts payable and accrued expenses		1,418		60
Accrued interest		-		(960)
Lease liabilities		(312)		(71)
Deferred revenue		(27)		(338)
Net cash flows from operating activities		(9,145)		(5,406)
Cash flows from investing activities:				
Purchases of property and equipment		(130)		-
Acquisition of licensing rights		-		(441)
Net cash flows from investing activities		(130)		(441)
Cash flows from financing activities:	-			
Proceeds from issuance of 2020 senior secured convertible notes, net of financing				
costs and discount		-		16,758
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		584		-
Payments for taxes related to net share settlement of equity awards		(542)		-
Repayment of notes payable		-		(2,838)
Net cash flows from financing activities		46,827		14,816
Net change in cash and cash equivalents		37,552		8,969
Cash and cash equivalents, beginning of period		20,099		5,696
Cash and cash equivalents, end of period	\$	57,651	\$	14,665
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SUPPLEMENTAL CASH FLOW INFORMATION				
Cash paid for:	Φ.		Φ	
Income taxes	\$	-	\$	4 000
Interest	\$	495	\$	1,399

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Source: ClearPoint Neuro, Inc.