

November 10, 2020



ClearPoint Neuro Reports Third Quarter 2020 Results

Revenue Reaches a Record \$3.5 million

IRVINE, Calif., Nov. 10, 2020 (GLOBE NEWSWIRE) -- ClearPoint Neuro, Inc. (Nasdaq: CLPT), a medical device company with a portfolio of products focused on enabling therapies for neurological disorders, today announced financial results for its third fiscal quarter ended September 30, 2020.

Third Quarter 2020 Highlights

- Reported record total revenue of \$3.5 million, a 20% increase over the same quarter last year
- Increased biologics and drug delivery revenue to \$1.5 million, a 162% increase over the same quarter last year, driven by new clinical service relationships
- Supported 200 cases in the quarter

“This quarter’s results, with a return to double-digit growth, underscores the dedication and focus of the entire ClearPoint Neuro team,” commented Joe Burnett, President and CEO of ClearPoint Neuro. “As elective procedures increased in the third quarter, our manufacturing employees in our Irvine, CA facility and our Clinical Specialist team on the front lines worked diligently to provide best-in-class support. I’m pleased that hospitals have prioritized our team’s access to support cases, enabling the best service possible. As a result, I am proud to disclose that we supported 200 cases in the quarter. While there remains uncertainty due to the pandemic, our team is being proactive in redeploying our resources to further our engineering efforts and investing in our people and our pipeline of future products and services.

“As we look to the conclusion of the year, we believe that total revenue for 2020, absent a resumption of a partial or full suspension of elective procedures due to the progression of the COVID-19 pandemic, will be in a range of \$12.0 million to \$12.5 million, which would represent growth over the prior year of between 7% to 11%,” continued Burnett. “Nonetheless, it should be kept in mind that our case volume currently represents approximately 80% of our pre-pandemic estimates, and, while hospitals are willing to treat very sick patients, many of these patients are in a high-risk category for COVID-19 based on age or other conditions. As a result, patients, rather than hospitals, are more likely to make the decision to postpone procedures.”

Third Quarter 2020 Financial Results

Total revenues were a record \$3.5 million in the third quarter of 2020, compared to \$2.9 million for the third quarter of 2019, an increase of 20%.

Functional neurosurgery navigation revenue, which consists of disposable product commercial sales related to cases utilizing the ClearPoint® system, decreased 1% to \$1.8 million for the third quarter 2020, from \$1.9 million for the same period in 2019. This decrease reflects the continuing effects of the COVID-19 pandemic, in which elective surgical procedures that were postponed or cancelled at the outset of the pandemic have resumed, albeit at volumes that have not yet reached pre-pandemic activity.

Biologics and drug delivery revenues, which include sales of disposable products and services related to customer-sponsored clinical trials utilizing the ClearPoint system, increased 162% to \$1.5 million for the third quarter 2020, from \$0.6 million for the same period in 2019. This increase was due to the establishment of additional relationships with biologic and drug delivery companies that included period-based retainers for ClearPoint Neuro's clinical services in support of such companies' clinical trials.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, decreased 48% to \$0.2 million for the third quarter 2020, from \$0.4 million for the same period in 2019. While revenues from this product line historically have varied from quarter to quarter, the Company believes that many hospitals have postponed capital equipment acquisition activities due to the COVID-19 pandemic.

The Company achieved a gross margin of 80% on its sales for the third quarter 2020, compared to a gross margin of 66% for the same period in 2019. This increase was due primarily to a shift in the mix of revenues by line of business that resulted in service revenues, which bear higher gross margins in comparison to other product lines, representing a greater contribution to total sales for the third quarter 2020, relative to the same period in 2019.

Operating expenses for the third quarter 2020 were \$4.1 million, a 43% increase from operating expenses of \$2.9 million for the same period in 2019. This increase was comprised of: (a) research and development costs, which increased 59% due primarily to increases in headcount and increased project activity; (b) sales and marketing expenses, which increased 40%, due primarily to increases in headcount of the Company's clinical specialist team; and (c) general and administrative expenses, which increased 33%, due primarily to an increase in company-wide share-based compensation, and a reduction of the allocation of shared departmental resources to production due to the reduced manufacturing activity as an effect of the COVID-19 pandemic.

Operating loss for the third quarter 2020 was \$1.3 million, compared with \$0.9 million for the same period in 2019.

Cash and cash equivalent balances at September 30, 2020 were \$14.7 million.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's 2020 third quarter financial results today at 4:30 p.m. Eastern time (1:30 p.m. Pacific time) that may be accessed by visiting the Company's website at www.clearpointneuro.com and selecting "Investors", "News / Events / Presentations", "Events".

Investors and analysts who would like to participate in the conference call may do so via telephone at (877) 407-9034, or at (201) 493-6737 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 10, 2020 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 60 active clinical sites in the United States. The Company's SmartFlow[®] cannula is being used in partnership or evaluation with 25 individual biologics and drug delivery companies in various stages from preclinical research to late stage regulatory trials. To date, more than 4,000 cases have been performed and supported by the Company's field-based clinical specialist team which offers support and services for our 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 COVID-19 and the measures adopted to contain its spread; future revenues 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 estimates regarding the sufficiency of the Company's cash resources. 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, 2019, and the Company's Quarterly Report on Form 10-Q for the three months ended June 30, 2020, 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, 2020, which the Company intends to file with the Securities

and Exchange Commission on or before November 16, 2020.

Contact:

Harold A. Hurwitz, Chief Financial Officer
(949) 900-6833
info@clearpointneuro.com

Jacqueline Keller, Vice President, Marketing
(949) 900-6833
info@clearpointneuro.com

CLEARPOINT NEURO, INC.
Condensed Consolidated Balance Sheets

	September 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,665,597	\$ 5,695,722
Accounts receivable, net	1,449,333	1,089,917
Inventory, net	3,534,643	3,240,218
Prepaid expenses and other current assets	492,886	357,227
Total current assets	<u>20,142,459</u>	<u>10,383,084</u>
Property and equipment, net	327,055	447,162
Operating lease rights of use	294,583	374,218
Software license inventory	571,800	504,400
Licensing rights	487,640	135,000
Other assets	23,380	82,573
Total assets	<u>\$ 21,846,917</u>	<u>\$ 11,926,437</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,064,121	\$ 965,783
Accrued compensation	1,210,356	1,408,292
Other accrued liabilities	487,768	328,460
Operating lease liabilities, current portion	108,923	113,520
Deferred product and service revenue	767,969	1,016,892
Paycheck Protection Program loan payable, current portion	73,985	-
Total current liabilities	<u>3,713,122</u>	<u>3,832,947</u>
Accrued interest	-	959,659
Operating lease liabilities, net of current portion	205,468	276,669
Deferred product and service revenue, net of current portion	108,816	197,862
2020 senior secured convertible notes payable, net	16,848,396	-
2010 junior secured notes payable, net	-	2,072,583
Paycheck Protection Program loan payable, net of current portion	822,015	-
Total liabilities	<u>21,697,817</u>	<u>7,339,720</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at September 30, 2020 and December 31, 2019	-	-
Common stock, \$0.01 par value; 200,000,000 shares authorized; 15,881,404 shares issued and outstanding at September 30, 2020; and 15,235,308 issued and outstanding at December 31, 2019	158,814	152,353
Additional paid-in capital	117,930,011	117,173,984
Accumulated deficit	(117,939,725)	(112,739,620)
Total stockholders' equity	<u>149,100</u>	<u>4,586,717</u>
Total liabilities and stockholders' equity	<u>\$ 21,846,917</u>	<u>\$ 11,926,437</u>

CLEARPOINT NEURO, INC.
Condensed Consolidated Statements of Operations
(Unaudited)

	For The Three Months Ended September 30,	
	2020	2019
Revenues:		
Product revenues	\$ 2,333,550	\$ 2,594,428
Service and other revenues	1,185,637	333,038
Total revenues	3,519,187	2,927,466
Cost of revenues	718,787	983,042
Research and development costs	1,209,048	761,881
Sales and marketing expenses	1,492,948	1,063,143
General and administrative expenses	1,369,900	1,029,929
Operating loss	(1,271,496)	(910,529)
Other income (expense):		
Other income (expense), net	(11,491)	728
Interest expense, net	(201,245)	(213,167)
Net loss	\$ (1,484,232)	\$ (1,122,968)
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.09)	\$ (0.08)
Weighted average shares outstanding:		
Basic and diluted	15,724,401	14,053,508

	For The Nine Months Ended September 30,	
	2020	2019
Revenues:		
Product revenues	\$ 6,030,005	\$ 6,952,575
Service and other revenues	3,082,558	1,053,807
Total revenues	9,112,563	8,006,382
Cost of revenues	2,276,927	2,899,837
Research and development costs	2,860,877	2,044,224
Sales and marketing expenses	3,915,920	3,246,912
General and administrative expenses	4,013,493	2,991,305
Operating loss	(3,954,654)	(3,175,896)
Other income (expense):		
Other income (expense), net	(5,360)	8,100
Interest expense, net	(1,240,091)	(726,292)
Net loss	\$ (5,200,105)	\$ (3,894,088)
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.33)	\$ (0.31)
Weighted average shares outstanding:		
Basic and diluted	15,556,231	12,477,790

CLEARPOINT NEURO, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	For The Nine Months Ended September 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	\$ (5,200,105)	\$ (3,894,088)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	170,057	105,310
Share-based compensation	762,488	576,012
Amortization of debt issuance costs and original issue discounts	855,598	523,969
Amortization of lease rights of use, net of accretion in lease liabilities	74,734	76,871
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(359,416)	(895,189)
Inventory, net	(323,075)	(908,413)
Prepaid expenses and other current assets	(135,658)	(150,589)
Other assets	59,193	11,899
Accounts payable and accrued expenses	59,711	1,506,279
Accrued interest	(959,661)	-
Lease liabilities	(70,896)	(82,448)
Deferred revenue	(337,969)	746,682
Net cash flows from operating activities	(5,404,999)	(2,383,705)
Cash flows from investing activities:		
Purchases of property and equipment	-	(10,190)
Acquisition of licensing rights	(441,341)	(150,000)
Net cash flows from investing activities	(441,341)	(160,190)
Cash flows from financing activities:		
Proceeds from issuance of 2020 senior secured convertible notes, net of financing costs and discount	16,757,871	-
Proceeds from issuance of Paycheck Protection Program loan	896,000	-
Proceeds from private placement of common stock, net of offering costs	-	7,427,848
Proceeds from stock option and warrant exercises	-	387,426
Repayment of notes payable	(2,837,656)	(2,137,344)
Net cash flows from financing activities	14,816,215	5,677,930
Net change in cash and cash equivalents	8,969,875	3,134,035
Cash and cash equivalents, beginning of period	5,695,722	3,101,133
Cash and cash equivalents, end of period	<u>\$ 14,665,597</u>	<u>\$ 6,235,168</u>
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	\$ -	\$ -
Interest	\$ 1,399,182	\$ 82,621



Source: ClearPoint Neuro, Inc.