

ClearPoint Neuro Reports Second Quarter 2020 Results

Revenue Reaches \$2.5 million Amid COVID-19 Pandemic

IRVINE, Calif., Aug. 12, 2020 (GLOBE NEWSWIRE) -- ClearPoint Neuro, Inc. (Nasdaq: CLPT) today announced financial results for its second fiscal quarter and six months ended June 30, 2020.

Financial Results - Three Months Ended June 30, 2020

Total revenues for the quarter were approximately \$2.5 million and \$2.6 million for the three months ended June 30, 2020 and 2019, respectively, a decrease of 5%.

Functional neurosurgery revenue, which consists of disposable product commercial sales related to cases utilizing the ClearPoint system, decreased 38% to \$1.0 million for the three months ended June 30, 2020, from \$1.7 million for the same period in 2019. This decrease was due to the effects of the COVID-19 pandemic, in which elective surgical procedures, historically representing more than 80% of the Company's ClearPoint system case volume, were temporarily suspended commencing in the second half of March 2020 and which have not yet returned to pre-pandemic levels.

Biologics and drug delivery revenues, which include sales of disposable products and services related to customer-sponsored clinical trials utilizing the ClearPoint system, increased 183% to \$1.2 million for the three months ended June 30, 2020, from \$413,000 for the same period in 2019. This increase in biologics and drug delivery service revenues is attributable to the establishment of additional relationships with biologic and drug delivery companies that included period-based retainers for clinical services in support of such companies' respective clinical trials.

Capital equipment revenue, consisting of sales of ClearPoint reusable hardware and software, as well as service contracts related to capital equipment, decreased 51% to \$240,000 for the three months ended June 30, 2020, from \$485,000 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, which continued postponement the Company believes will be contingent upon the prevalence and duration of the COVID-19 pandemic.

Gross margin for the three months ended June 30, 2020 was 74%, as compared to 60% for

the same period in 2019. This increase was driven primarily by the greater contribution of services to total revenue during the three months ended June 30, 2020, as compared to the same period in 2019.

Operating expenses for the three months ended June 30, 2020 were \$3.3 million, a 15% 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 18% resulting primarily from increases in personnel costs; and (b) general and administrative expenses, which increased 33% resulting primarily from an increase in professional fees and a decrease in the allocation of shared departmental resources to production due to reduced manufacturing activity during the 2020 second quarter. These increases were partially offset by a decrease of 2% in sales and marketing expenses, resulting primarily from a decrease in items attributable to the effects of the COVID-19 pandemic, such as incentive-based compensation and travel, which was partially offset by headcount increases in the Company's clinical and marketing teams.

Operating loss for the three months ended June 30, 2020 was \$1.5 million, as compared with \$1.3 million for the same period in 2019.

Cash and cash equivalent balances at June 30, 2020 were \$16.0 million.

"The second quarter of 2020 was significantly affected by the COVID-19 pandemic, which adversely impacted sales across all of our business lines," commented Joe Burnett, President and Chief Executive Officer of ClearPoint Neuro. "More than 80% of our procedures are deemed 'elective,' which generally resulted in the postponement or cancellation of such procedures to give our hospital customers the capacity for treating critical COVID-19 patients, which resulted in the completion of only 11 ClearPoint cases in April. As elective procedures resumed in certain cities, May case volume increased to 44 cases and June volume followed at 71 cases, representing approximately 90% of our prepandemic volume. Similarly, new capital placements and evaluations were effectively put on hold in the 2020 second quarter as hospitals dealt with the influx of COVID-19 patients. This said, I am immeasurably proud of our clinical support team who stood shoulder-to-shoulder with our hospital customers and ensured that cases in which the use of our ClearPoint System was integral in patient treatment were supported during the pandemic.

"On a more positive note, our biologics and drug delivery business increased 183% to \$1.2 million, which we believe demonstrates that our strategy in this space continues to drive new business and to provide diversification in our revenue stream. While our customersponsored clinical trials cases were postponed as a result of the pandemic, our pre-clinical planning and clinical services continued to progress where possible.

"The pervasiveness of the pandemic continues to result in uncertainty as to the timing of the resumption to pre-pandemic levels of elective procedures, capital placements and customer-sponsored clinical trials. Accordingly, we are not yet providing a forecast for the balance of 2020. While we do not expect elective procedures to decline to the level seen in April, we anticipate, and have observed, that hospitals in cities struggling with COVID-19 cases will suspend elective procedures to ensure ventilator access and bed capacity. Furthermore, it should be noted that patients flow through a diagnostic and treatment process before they are referred to surgery. Accordingly, it follows that diagnostic work-ups delayed in March and April will cause the resulting surgeries to be similarly delayed.

"While we view the current situation as a temporary setback, our team continues to work tirelessly to execute on our four-pillar growth strategy, staying true to our course."

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's 2020 second quarter and six months 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" / "IR Calendar."

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 August 26, 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 more than 20 individual biologics and drug delivery companies in various stages from preclinical research to late stage regulatory trials. To date, more than 3,500 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 March 31, 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 June 30, 2020, which the Company intends to file with the Securities and Exchange Commission on or before August 14, 2020.

Contact:

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

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

CLEARPOINT NEURO, INC.
Condensed Consolidated Balance Sheets

	June 30, 2020 (Unaudited)		December 31, 2019	
ASSETS				
Current assets:				
Cash and cash equivalents	\$	16,032,082	\$	5,695,722
Accounts receivable, net		1,163,663		1,089,917
Inventory, net		3,598,980		3,240,218
Prepaid expenses and other current assets	_	537,940		357,227
Total current assets		21,332,665		10,383,084
Property and equipment, net		342,584		447,162
Operating lease rights of use		321,155		374,218
Software license inventory		506,800		504,400
Licensing rights		517,207		135,000
Other assets		12,438		82,573
Total assets	\$	23,032,849	\$	11,926,437
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	1,491,377	\$	965,783
Accrued compensation		969,877		1,408,292
Other accrued liabilities		334,627		328,460
Operating lease liabilities, current portion		110,914		113,520
Deferred product and service revenue		620,126		1,016,892
Paycheck Protection Program loan payable, current portion		296,677		-
Total current liabilities	_	3,823,598	_	3,832,947
Accrued interest		-		959,659
Operating lease liabilities, net of current portion		227,714		276,669
Deferred product and service revenue, net of current portion		228,286		197,862
2020 senior secured convertible notes payable, net		16,814,099		-
2010 junior secured notes payable, net		-		2,072,583
Paycheck Protection Program loan payable, net of current portion		599,323		-
Total liabilities	_	21,693,020	_	7,339,720
Commitments and contingencies	_		_	.,,.
Stockholders' equity:				
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at June 30, 2020 and December 31, 2019		_		
Common stock, \$0.01 par value; 200,000,000 shares authorized; 15,512,687 shares		-		-
issued and outstanding at June 30, 2020; and 15,235,308 issued and outstanding at		455.467		450.050
December 31, 2019		155,127		152,353
Additional paid-in capital		117,640,195		117,173,984
Accumulated deficit	_	(116,455,493)	_	(112,739,620)
Total stockholders' equity	_	1,339,829	_	4,586,717
Total liabilities and stockholders' equity	\$_	23,032,849	\$_	11,926,437

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

For The Three Months Ended June 30,

	2020		2019
\$	1,593,070	\$	2,194,194
	884,712		412,204
_	2,477,782		2,606,398
	640,805		1,030,316
	822,301		697,803
	1,124,378		1,143,056
	1,365,084		1,028,291
	(1,474,786)		(1,293,068)
	10,851		1,693
	(197,113)		(259,020)
\$	(1,661,048)	\$	(1,550,395)
=		_	
\$	(0.11)	\$	(0.13)
=		_	
=	15,504,169	_	12,302,667
	\$ =	\$ 1,593,070 884,712 2,477,782 640,805 822,301 1,124,378 1,365,084 (1,474,786) 10,851 (197,113) \$ (1,661,048)	\$ 1,593,070 \$ 884,712 2,477,782 640,805 822,301 1,124,378 1,365,084 (1,474,786) 10,851 (197,113) \$ (1,661,048) \$ \$ (0.11) \$ \$

For The Six Months Ended June 30,

		Julie 30,		
		2020		2019
Revenues:			_	
Product revenues	\$	3,696,455	\$	4,358,148
Service and other revenues		1,896,921		720,767
Total revenues		5,593,376		5,078,915
Cost of revenues		1,558,141		1,916,798
Research and development costs		1,651,829		1,282,343
Sales and marketing expenses		2,422,972		2,183,769
General and administrative expenses		2,643,592		1,961,322
Operating loss		(2,683,158)		(2,265,317)
Other income (expense):				
Other income, net		6,131		7,322
Interest expense, net		(1,038,846)		(513,125)
Net loss	\$	(3,715,873)	\$	(2,771,120)
Net loss per share attributable to common stockholders:			-	
Basic and diluted	\$	(0.24)	\$_	(0.24)
Weighted average shares outstanding:	_		_	
Basic and diluted	_	15,471,222	_	11,676,872

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

For The Six Months Ended June 30,

	Julie 30,			
		2020		2019
Cash flows from operating activities:				
Net loss	\$	(3,715,873)	\$	(2,771,120)
Adjustments to reconcile net loss to net cash flows from operating activities:		,		
Depreciation and amortization		116,026		69,600
Share-based compensation		468,985		356,580
Amortization of debt issuance costs and original issue discounts		821,301		363,465
Amortization of lease rights of use, net of accretion in lease liabilities		49,782		51,255
Increase (decrease) in cash resulting from changes in:				
Accounts receivable		(73,746)		(137,931)
Inventory, net		(313,476)		(201,503)
Prepaid expenses and other current assets		(180,712)		(216,953)
Other assets		70,134		11,899
Accounts payable and accrued expenses		93,347		716,222
Accrued interest		(959,661)		-
Lease liabilities		(48,280)		(50,285)
Deferred revenue		(366,341)		389,201
Net cash flows from operating activities		(4,038,514)		(1,419,570)
Cash flows from investing activities:				
Acquisition of licensing rights		(441,341)		(150,000)
Net cash flows from investing activities		(441,341)		(150,000)
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		· -		7,522,010
Proceeds from stock option warrant exercises		_		383,075
Repayment of notes payable		(2,837,656)		(1,975,000)
Net cash flows from financing activities		14,816,215		5,930,085
Net change in cash and cash equivalents		10,336,360		4,360,515
Cash and cash equivalents, beginning of period		5,695,722		3,101,133
Cash and cash equivalents, end of period	\$	16,032,082	\$	7,461,648
Cash and cash equivalence, and or period	Ť		Ť	.,,
SUPPLEMENTAL CASH FLOW INFORMATION				
Cash paid for:				
Income taxes	\$	-	\$	-
Interest	\$	1,043,371	\$	164,157
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Source: ClearPoint Neuro, Inc.