

November 8, 2022



ClearPoint Neuro Reports Third Quarter 2022 Results

Company Reaffirms 2022 Revenue Forecast

SOLANA BEACH, Calif., Nov. 08, 2022 (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, 2022.

Third Quarter Highlights

- Reported quarterly revenue of \$5.1 million, a 13% year-over-year increase;
- Partner PTC Therapeutics' gene therapy treatment Upstaza™ was granted full marketing authorization by the European Commission. Upstaza will be administered with the Company's SmartFlow® Neuro Cannula;
- Added multiple new biologics and drug delivery partners in the quarter to bring the total to approximately 50;
- Announced multiple FDA clearances: the ClearPoint Maestro™ Brain Model, the ClearPoint Prism™ Neuro Laser Therapy System and the 2.1 version of the ClearPoint Neuro Navigation software; and
- Cash and short-term investments totaled \$40.5 million as of September 30, 2022.

Business Outlook

- The Company reaffirms its full year 2022 revenue outlook of between \$21.0 and \$22.0 million.

"The ClearPoint Neuro Team has continued to execute against our four-pillar growth strategy in the third quarter and remain on track to achieve our previously announced strategic and financial goals for the year," commented Joe Burnett, President and CEO.

"We achieved another strong quarter for revenue despite a historically high case cancellation rate and hospital supply chain disruptions. Our Biologics and Drug Delivery team added multiple new pharma and academic partners bringing our total to approximately 50 and keeping pace at approximately one new partner each month. Three new products were cleared by the FDA in the quarter and are in the process of being deployed in limited market

releases before the end of the year. We have now installed a record 10 new systems globally year to date and have the largest active capital funnel in our history.

Particularly of note, the European Commission granted marketing authorization for Upstaza to our partner PTC Therapeutics. Upstaza is the first marketed gene therapy approved anywhere in the world to be dosed by direct infusion into the brain. Consistent with our long term strategy, the Summary of Product Characteristics for Upstaza specifically includes the ClearPoint SmartFlow Neuro Cannula as the device used for minimally invasive infusion of the gene therapy. We believe the approval of Upstaza, delivered with ClearPoint's cannula, demonstrates the viability and potential of our drug delivery partnerships.

At present, we are reaffirming our prior guidance of revenue between \$21.0 and \$22.0 million for the year and continue to maintain a strong balance sheet with over \$40 million in cash and short-term investments enabling the continuation of our four-pillar growth strategy.”

Financial Results – Quarter Ended September 30, 2022

Total revenue was \$5.1 million for the three months ended September 30, 2022, and \$4.6 million for the three months ended September 30, 2021, which represents an increase of \$0.6 million, or 13%.

Functional neurosurgery navigation and therapy revenue, increased 12% to \$2.4 million for the three months ended September 30, 2022, from \$2.2 million for the same period in 2021. The growth was driven by higher service revenue.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored clinical trials utilizing our products, increased 9% to \$2.2 million for the three months ended September 30, 2022, from \$2.1 million for the same period in 2021. This increase is attributable to a \$0.5 million increase in service revenue, partially offset by \$0.3 million decrease in product revenue.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, increased 32% to \$0.5 million for the three months ended September 30, 2022, from \$0.4 million for the same period in 2021 due to an increase in the placements of ClearPoint capital and software.

Gross margin for the three months ended September 30, 2022, was 72%, as compared to a gross margin of 66% for the three months ended September 30, 2021. The increase in gross margin was due primarily to an increased contribution of service revenue, which carries a higher gross margin relative to product revenue and by lower overhead expenses.

Operating expenses for the third quarter of 2022 were \$7.5 million, compared to \$6.8 million for the third quarter of 2021. The increase was mainly driven by the increase in headcount across the organization and share based compensation.

At September 30, 2022, the Company had cash and cash equivalents and short-term investments totaling \$40.5 million as compared to \$54.1 million at December 31, 2021, with the decrease resulting primarily from the use of cash in operating activities of \$13.1 million.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's 2022 third quarter on Tuesday, November 8, 2022 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=LADbDbTi>. Investors and analysts who would like to participate in the conference call via telephone may do so at (888) 272-8703, or at (713) 936-6995 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 8, 2022, 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 <https://ir.clearpointneuro.com/>.

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 50 pharmaceutical and biotech companies, academic institutions, and contract research organizations 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, 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 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, 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; 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, 2021, and the Company's Quarterly Report on Form 10-Q for the three

months ended June 30, 2022, 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, 2022, which the Company intends to file with the Securities and Exchange Commission on or before November 14, 2022.

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

	For The Three Months Ended September 30,	
	2022	2021
Revenue:		
Product revenue	\$ 3,130	\$ 3,338
Service and other revenue	2,016	1,236
Total revenue	<u>5,146</u>	<u>4,574</u>
Cost of revenue	<u>1,434</u>	<u>1,533</u>
Gross profit	3,712	3,041
Research and development costs	2,453	2,601
Sales and marketing expenses	2,139	1,808
General and administrative expenses	<u>2,915</u>	<u>2,436</u>
Operating loss	(3,795)	(3,804)
Other expense:		
Other (expense) income, net	(25)	62
Interest income (expense), net	32	(238)
Net loss	<u>\$ (3,788)</u>	<u>\$ (3,980)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	<u>\$ (0.15)</u>	<u>\$ (0.18)</u>
Weighted average shares used in computing net loss per share:		
Basic and diluted	24,497,636	22,522,460

	For The Nine Months Ended September 30,	
	2022	2021
Revenue:		
Product revenue	\$ 9,750	\$ 8,863
Service and other revenue	5,627	3,154
Total revenue	<u>15,377</u>	<u>12,017</u>
Cost of revenue	<u>5,162</u>	<u>4,078</u>
Gross profit	10,215	7,939
Research and development costs	7,270	6,208
Sales and marketing expenses	6,171	5,061
General and administrative expenses	<u>8,637</u>	<u>6,062</u>
Operating loss	(11,863)	(9,392)
Other expense:		
Other expense, net	(22)	(60)
Interest expense, net	<u>(165)</u>	<u>(809)</u>
Net loss	<u>\$ (12,050)</u>	<u>\$ (10,261)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	<u>\$ (0.50)</u>	<u>\$ (0.50)</u>
Weighted average shares used in computing net loss per share:		
Basic and diluted	24,058,205	20,545,080

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

	September 30, 2022	December 31, 2021
	<u>(Unaudited)</u>	<u></u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 18,712	\$ 54,109
Short-term investments	21,749	—
Accounts receivable, net	3,411	2,337
Inventory, net	8,284	4,938
Prepaid expenses and other current assets	1,658	508
Total current assets	<u>53,814</u>	<u>61,892</u>
Property and equipment, net	629	539
Operating lease rights of use	1,866	2,241
Software license inventory	485	519
Licensing rights	850	265
Other assets	94	125
Total assets	<u>\$ 57,738</u>	<u>\$ 65,581</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,387	\$ 427
Accrued compensation	2,187	2,604
Other accrued liabilities	1,249	537
Operating lease liabilities, current portion	537	507
Deferred product and service revenue, current portion	735	678
Total current liabilities	<u>6,095</u>	<u>4,753</u>
Operating lease liabilities, net of current portion	1,535	1,939
Deferred product and service revenue, net of current portion	351	264
2020 senior secured convertible note payable, net	9,879	9,838
Total liabilities	<u>17,860</u>	<u>16,794</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, \$0.01 par value; 200,000,000 shares authorized; 24,500,832 shares issued and outstanding at September 30, 2022; and 23,665,991 issued and outstanding at December 31, 2021	245	237
Additional paid-in capital	185,615	182,482
Accumulated deficit	(145,982)	(133,932)
Total stockholders' equity	<u>39,878</u>	<u>48,787</u>
Total liabilities and stockholders' equity	<u>\$ 57,738</u>	<u>\$ 65,581</u>

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

	For The Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (12,050)	\$ (10,261)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for doubtful accounts	(92)	170
Depreciation and amortization	224	113
Share-based compensation	2,954	1,153
Payment-in-kind interest	—	285
Amortization of debt issuance costs and original issue discounts	41	73
Amortization of lease rights of use, net of accretion in lease liabilities	400	400
Accretion of discounts on short-term investments	(159)	—
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(982)	(848)
Inventory, net	(3,318)	(682)
Prepaid expenses and other current assets	(1,150)	(599)
Other assets	31	(28)
Accounts payable and accrued expenses	1,255	1,418
Lease liabilities	(400)	(312)
Deferred revenue	144	(27)
Net cash flows from operating activities	<u>(13,102)</u>	<u>(9,145)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(214)	(130)
Acquisition of licensing rights	(678)	—
Purchase of short-term investments	(21,590)	—
Net cash flows from investing activities	<u>(22,482)</u>	<u>(130)</u>
Cash flows from financing activities:		
Proceeds from public offering of common stock, net of offering costs	—	46,785
Proceeds from stock option and warrant exercises	263	584
Proceeds from issuance of common stock under employee stock purchase plan	260	—
Payments for taxes related to net share settlement of equity awards	(336)	(542)
Net cash flows from financing activities	<u>187</u>	<u>46,827</u>
Net change in cash and cash equivalents	<u>(35,397)</u>	<u>37,552</u>
Cash and cash equivalents, beginning of period	54,109	20,099
Cash and cash equivalents, end of period	<u>\$ 18,712</u>	<u>\$ 57,651</u>

SUPPLEMENTAL CASH FLOW INFORMATION

Cash paid for:

Income taxes	\$ —	\$ —
Interest	\$ 351	\$ 495

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Source: ClearPoint Neuro, Inc.