

August 9, 2022



ClearPoint Neuro Reports Second Quarter 2022 Results

Record Quarterly Revenue Achieved; Company Reaffirms 2022 Revenue Forecast

SOLANA BEACH, Calif., Aug. 09, 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 second quarter ended June 30, 2022.

Second Quarter Highlights

- Reported record quarterly revenue of \$5.2 million, a 52% year-over-year increase;
- Partner PTC Therapeutics received a positive opinion for its gene therapy treatment Upstaza™. from the European Medicines Agency's Committee for Medicinal Products for Human Use. Upstaza, which was granted full marketing authorization by the European Commission in July 2022, will be administered with the Company's SmartFlow® Neuro Cannula;
- Increased biologics and drug delivery revenue to \$2.4 million, a 73% year-over-year increase;
- Added multiple new biologics and drug delivery partners in the quarter to bring the total to more than 45;
- Installed four additional systems in the quarter bringing the total to 8 new installations year-to-date;
- Achieved Medical Device Single Audit Program (MDSAP) certification paving the way for additional international regulatory submissions in support of pharmaceutical partners; and
- Cash and short-term investments totaled \$45.1 million as of June 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 second quarter,” commented Joe Burnett, President and CEO. “We achieved another record quarter for revenue and over 50% growth despite an elevated case cancellation rate and supply chain disruptions. Our biologics and drug delivery business led the way and became our largest segment with product and service revenue growing at more than 70%. The team also added multiple new pharma and academic partners bringing our total to more than 45 and keeping pace at approximately one new partner each month. Our ClearPoint Navigation system was installed at four additional centers bringing the total new centers to eight in 2022 across the U.S. and Europe. Our product development team continues to execute on our pipeline and has additional products being reviewed by global regulatory bodies.

Particularly of note, the European Commission granted marketing authorization for Upstaza to our partner PTC Therapeutics. Upstaza is the first 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.”

Financial Results – Quarter Ended June 30, 2022

Total revenue was \$5.2 million for the three months ended June 30, 2022, and \$3.4 million for the three months ended June 30, 2021, which represents an increase of \$1.8 million, or 52%.

Functional neurosurgery navigation and therapy revenue, increased 17% to \$2.2 million for the three months ended June 30, 2022, from \$1.9 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 73% to \$2.4 million for the three months ended June 30, 2022, from \$1.4 million for the same period in 2021. This increase is attributable to a \$0.8 million increase in product revenue and \$0.2 million increase in service revenue.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, increased 282% to \$0.6 million for the three months ended June 30, 2022, from \$0.2 million for the same period in 2021 due to an increase in the sale of ClearPoint systems.

Gross margin for the three months ended June 30, 2022, was 63%, as compared to a gross margin of 67%, for the three months ended June 30, 2021. The decrease in gross margin was due primarily to an increase in overhead expenses, excess and obsolete reserves, and product mix.

Operating expenses for the second quarter of 2022 were \$7.5 million, compared to \$5.7 million for the second quarter of 2021. The increase was mainly driven by the increase in

headcount across the organization, product development expenses and share based compensation.

At June 30, 2022, the Company had cash and cash equivalents and short-term investments totaling \$45.1 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 \$9.3 million.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's 2022 second quarter on Tuesday, August 9, 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=LzXg7k1V>. Investors and analysts who would like to participate in the conference call via telephone may do so at (888) 437-3179, or at (404) 267-0369 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 September 9, 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 more than 45 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, 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; 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 March 31, 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 June 30, 2022, which the Company intends to file with the Securities and Exchange Commission on or before August 15, 2022.

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

	For The Three Months Ended June 30,	
	2022	2021
Revenue:		
Product revenue	\$ 3,457	\$ 2,363
Service and other revenue	1,743	1,050
Total revenue	<u>5,200</u>	<u>3,413</u>
Cost of revenue	<u>1,943</u>	<u>1,139</u>
Gross profit	3,257	2,274
Research and development costs	2,284	2,109
Sales and marketing expenses	2,187	1,590
General and administrative expenses	<u>2,990</u>	<u>1,982</u>
Operating loss	(4,204)	(3,407)
Other expense:		
Other expense, net	(8)	(96)
Interest expense, net	<u>(91)</u>	<u>(240)</u>
Net loss	<u>\$ (4,303)</u>	<u>\$ (3,743)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	<u>\$ (0.18)</u>	<u>\$ (0.17)</u>
Weighted average shares used in computing net loss per share:		
Basic and diluted	23,985,577	21,523,393

	For The Six Months Ended June 30,	
	2022	2021
Revenue:		
Product revenue	\$ 6,620	\$ 5,525
Service and other revenue	3,611	1,918
Total revenue	10,231	7,443
Cost of revenue	3,728	2,555
Gross profit	6,503	4,888
Research and development costs	4,817	3,673
Sales and marketing expenses	4,032	3,165
General and administrative expenses	5,722	3,638
Operating loss	(8,068)	(5,588)
Other expense:		
Other income (expense), net	3	(122)
Interest expense, net	(197)	(571)
Net loss	\$ (8,262)	\$ (6,281)
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.35)	\$ (0.31)
Weighted average shares used in computing net loss per share:		
Basic and diluted	23,834,847	20,195,488

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

	June 30, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 23,524	\$ 54,109
Short-term investments	21,613	—
Accounts receivable, net	3,348	2,337
Inventory, net	6,639	4,938
Prepaid expenses and other current assets	1,517	508
Total current assets	56,641	61,892
Property and equipment, net	689	539
Operating lease rights of use	1,992	2,241
Software license inventory	504	519
Licensing rights	320	265
Other assets	94	125
Total assets	<u>\$ 60,240</u>	<u>\$ 65,581</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,592	\$ 427
Accrued compensation	1,814	2,604
Other accrued liabilities	870	537
Operating lease liabilities, current portion	532	507
Deferred product and service revenue, current portion	675	678
Total current liabilities	5,483	4,753
Operating lease liabilities, net of current portion	1,671	1,939
Deferred product and service revenue, net of current portion	401	264
2020 senior secured convertible notes payable, net	9,865	9,838
Total liabilities	17,420	16,794
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Common stock, \$0.01 par value; 200,000,000 shares authorized; 24,480,600 shares issued and outstanding at June 30, 2022; and 23,665,991 issued and outstanding at December 31, 2021	245	237
Additional paid-in capital	184,769	182,482
Accumulated deficit	(142,194)	(133,932)
Total stockholders' equity	42,820	48,787
Total liabilities and stockholders' equity	<u>\$ 60,240</u>	<u>\$ 65,581</u>

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

	For The Six Months Ended June 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (8,262)	\$ (6,281)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for doubtful accounts	(10)	92
Depreciation and amortization	187	62
Share-based compensation	1,779	567
Payment-in-kind interest	—	189
Amortization of debt issuance costs and original issue discounts	27	54
Amortization of lease rights of use, net of accretion in lease liabilities	267	267
Accretion of discounts on short-term investments	(23)	—
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(1,001)	(617)
Inventory, net	(1,786)	(304)
Prepaid expenses and other current assets	(1,010)	(760)
Other assets	30	(93)
Accounts payable and accrued expenses	679	1,312
Lease liabilities	(261)	(195)
Deferred revenue	134	(142)
Net cash flows from operating activities	(9,250)	(5,849)
Cash flows from investing activities:		
Purchases of property and equipment	(145)	(5)
Acquisition of licensing rights	(116)	—
Purchase of short-term investments	(21,590)	—
Net cash flows from investing activities	(21,851)	(5)
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	256	494
Proceeds from issuance of common stock under employee stock purchase plan	260	—
Net cash flows from financing activities	516	47,279
Net change in cash and cash equivalents	(30,585)	41,425
Cash and cash equivalents, beginning of period	54,109	20,099
Cash and cash equivalents, end of period	\$ 23,524	\$ 61,524

SUPPLEMENTAL CASH FLOW INFORMATION

Cash paid for:		
Income taxes	\$ —	\$ —
Interest	\$ 207	\$ 353

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Source: ClearPoint Neuro, Inc.