

ClearPoint Neuro Reports Fourth Quarter and Full-Year 2022 Results

Company Reports Record Revenues

SOLANA BEACH, Calif., March 01, 2023 (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 fourth quarter and full-year ended December 31, 2022.

2022 Full Year and Fourth Quarter Highlights

- Reported fourth quarter 2022 revenue of \$5.2 million, a 21% year-over-year increase compared with the fourth quarter of 2021;
- Reported revenue of \$20.6 million for the full year 2022, an increase of 26% over 2021 and representing the eighth consecutive year of growth;
- Increased biologics and drug delivery revenue to \$9.1 million for the full year 2022, a 34% increase over 2021;
- Added multiple new biologics and drug delivery partners in the quarter to bring the total to more than 50; and
- Cash and short-term investments totaled \$37.5 million as of December 31, 2022.

Business Outlook

"We are pleased with our performance in 2022, growing revenue 26% year-over-year, achieving FDA clearance for key new products, adding services and capabilities to support our more than 50 biologics partners, and executing against all four pillars of our growth strategy," commented Joe Burnett, President and CEO at ClearPoint Neuro. "We continue to expect growth of more than 20% in 2023, given the competitiveness of our laser system and the cadence of our pharma partners' continuing progress through the global regulatory process for new gene and cell therapies. We are reiterating our 2023 revenue forecast of between \$25 and \$27 million."

Financial Results - Year Ended December 31, 2022

Total revenue was \$20.6 million and \$16.3 million for the years ended December 31, 2022

and 2021, respectively.

Functional neurosurgery navigation and therapy revenue increased to \$9.1 million during the year ended December 31, 2022 from \$8.1 million for the same period in 2021. This increase is primarily driven by \$1.5 million of service revenue related to development services for the year ended December 31, 2022, compared to \$0.4 million for the same period in 2021.

Biologics and drug delivery revenue, which include sales of disposable products and services related to customer-sponsored pre-clinical and clinical trials utilizing our products, increased 34% to \$9.1 million for the year ended December 31, 2022, from \$6.8 million for the same period in 2021. This increase is attributable to a \$2.0 million increase in service and license revenue and \$0.3 million increase in product revenue for the year ended December 31, 2022, due to expanded commitments from our current biologics and drug delivery partners as well as an increase in new partners.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, increased 61% to \$2.3 million for the year ended December 31, 2022, from \$1.4 million for the same period in 2021. This increase is due primarily to an increase in the placements of ClearPoint capital and software.

The Company achieved a gross margin of 66% on its sales for 2022, compared to a gross margin of 68% for 2021. This decrease in gross margin was due primarily to an increase in indirect labor costs in 2022 as compared to 2021 as well an increase in excess and obsolete inventory reserves.

Operating expenses were \$29.9 million for the full year 2022, compared with \$24.5 million for 2021. The increase was mainly driven by an increase in personnel-related expenses, including share-based compensation, as we increased headcount to fund the expansion of the research and development, clinical, and support organizations.

Financial Results – Quarter Ended December 31, 2022

Total revenue was \$5.2 million for the three months ended December 31, 2022, and \$4.3 million for the three months ended December 31, 2021, which represents an increase of \$0.9 million, or 21%.

Functional neurosurgery navigation and therapy revenue increased 7% to \$2.3 million for the three months ended December 31, 2022, from \$2.1 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 pre-clinical and clinical trials utilizing our products, increased 37% to \$2.3 million for the three months ended December 31, 2022, from \$1.7 million for the same period in 2021. This increase is attributable to a \$0.7 million increase in service revenue, partially offset by a slight decrease in product revenue.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, increased 25% to \$0.6 million for the three months ended December 31, 2022, from \$0.5 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 December 31, 2022, was 64%, as compared to a gross margin of 77% for the three months ended December 31, 2021. The decrease in gross margin was due primarily to higher overhead expenses and inventory reserves.

Operating expenses for the fourth quarter of 2022 were \$7.8 million, compared to \$7.3 million for the fourth quarter of 2021. The increase was mainly driven by the increase in headcount across the organization and share-based compensation.

At December 31, 2022, the Company had cash and cash equivalents and short-term investments totaling \$37.5 million compared to \$54.1 million at December 31, 2021, with the decrease resulting primarily from the use of cash in operating activities of \$16.2 million.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's fourth quarter and full year 2022 on Wednesday, March 1, 2023 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=KFYSIHDo. Investors and analysts who would like to participate in the conference call via telephone may do so at (877) 407-9034, or at (202) 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 March 31, 2023, 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 Relations 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, 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 more than 65 sites in North America, Europe, and South America. ClearPoint Neuro is partnered with more than 50 biologics/pharmaceutical companies, academic centers, 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 procedures have been performed and supported by the Company's field-based clinical specialist team, which offers support and services to our customers and partners. 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 revenue expectations, plans, growth and strategies may be 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, development, and regulatory approval 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 September 30, 2022, both of which have been filed with the Securities and Exchange Commission, and the Company's Annual Report on Form 10-K for the year ended December 31, 2022, which the Company intends to file with the Securities and Exchange Commission on or before March 31, 2023.

CLEARPOINT NEURO, INC.

Consolidated Statements of Operations (Dollars in thousands, except for per share data)

Years Ended December 31,			
 2022		2021	
\$ 12,789	\$	11,913	
7,762		4,386	
 20,551		16,299	
7,020		5,176	
 13,531		11,123	
10,894		9,281	
9,358		7,217	
9,611		7,999	
 (16,332)		(13,374)	
(22)		(63)	
(81)		(973)	
\$ (16,435)	\$	(14,410)	
\$ (0.68)	\$	(0.69)	
24,181,854		20,734,236	
\$	\$ 12,789 7,762 20,551 7,020 13,531 10,894 9,358 9,611 (16,332) (22) (81) \$ (16,435)	\$ 12,789 \$ 7,762 20,551 7,020 13,531 10,894 9,358 9,611 (16,332) (22) (81) \$ (16,435) \$ \$ (0.68) \$	

CLEARPOINT NEURO, INC.

Consolidated Balance Sheets (Dollars in thousands, except for per share data)

December 31,

	2022		2021	
ASSETS		LVLL		2021
Current assets:				
Cash and cash equivalents	\$	27,615	\$	54,109
Short-term investments	*	9,874	*	_
Accounts receivable, net		2,665		2,337
Inventory, net		9,303		4,938
Prepaid expenses and other current assets		1.723		508
Total current assets		51,180		61,892
Property and equipment, net		806		539
Operating lease rights of use		1,895		2,241
Software license inventory		450		519
Licensing rights		1,028		265
Other assets		131		125
Total assets	\$	55,490	\$	65,581
l oldi dassets	Ψ	00,100	Ψ	00,001
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	272	\$	427
Accrued compensation		2,824		2,604
Other accrued liabilities		2,065		537
Operating lease liabilities, current portion		561		507
Deferred product and service revenue, current portion		1,066		678
Total current liabilities		6,788		4,753
Operating lease liabilities, net of current portion		1,532		1,939
Deferred product and service revenue, net of current portion		390		264
2020 senior secured convertible note payable, net		9,893		9,838
Total liabilities	-	18,603		16,794
Commitments and contingencies		10,000		10,704
Stockholders' equity:				
Preferred stock, \$0.01 par value; 25,000,000 shares authorized at December 31, 2022 and 2021; none issued and outstanding at December 31, 2022 and 2021		_		_
Common stock, \$0.01 par value; 200,000,000 shares authorized at December 31, 2022 and 2021; 24,578,983 and 23,665,991 shares issued and outstanding at				
December 31, 2022 and 2021, respectively		246		237
Additional paid-in capital		187,008		182,482
Accumulated deficit		(150,367)		(133,932)
Total stockholders' equity		36,887	-	48,787
Total liabilities and stockholders' equity	\$	55,490	\$	65,581

CLEARPOINT NEURO, INC.

Consolidated Statements of Cash Flows (Dollars in thousands)

	Years Ended December 31,			
		2022		2021
Cash flows from operating activities:				
Net loss	\$	(16,435)	\$	(14,410)
Adjustments to reconcile net loss to net cash flows from operating activities:				
Allowance for doubtful accounts		(117)		202
Depreciation and amortization		244		159
Share-based compensation		4,126		2,078
Payment-in-kind interest		_		325
Amortization of debt issuance costs and original issue discounts		55		100
Amortization of lease right of use assets, net of accretion in lease liabilities		533		533
Accretion of discounts on short-term investments		(284)		_
Increase (decrease) in cash resulting from changes in:				
Accounts receivable		(211)		(658)
Inventory, net		(4,421)		(1,714)
Prepaid expenses and other current assets		(1,216)		(264)
Other assets		(6)		(66)
Accounts payable and accrued expenses		1,591		1,285
Lease liability		(541)		(432)
Deferred revenue		515		165
Net cash flows from operating activities		(16,167)		(12,697)
Cash flows from investing activities:				
Purchases of property and equipment		(253)		(168)
Acquisition of licensing rights		(893)		_
Purchase of short-term investments		(21,590)		_
Proceeds from maturities of short-term investments		12,000		_
Net cash flows from investing activities		(10,736)		(168)
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		268		465
Proceeds from issuance of common stock under employee stock purchase plan		477		224
Payments for taxes related to net share settlement of equity awards		(336)		(599)
Net cash flows from financing activities		409		46,875
Net change in cash and cash equivalents		(26,494)		34,010
Cash and cash equivalents, beginning of year		54,109		20,099
Cash and cash equivalents, end of year	\$	27,615	\$	54,109
SUPPLEMENTAL CASH FLOW INFORMATION				
Cash paid for:	¢		æ	
Income taxes	D		Φ	
Interest	\$	523	\$	597

Contact:

Danilo D'Alessandro, Chief Financial Officer

(949) 900-6833

info@clearpointneuro.com

Caroline Corner, Investor Relations



Source: ClearPoint Neuro, Inc.