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ClearPoint Neuro Reports Fourth Quarter and Full Year 2022 Preliminary Revenue Results and Guidance for Full Year 2023 Revenue

SOLANA BEACH, Calif., Jan. 11, 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 preliminary, unaudited financial results for its fourth quarter and full year ended December 31, 2022.

Fourth Quarter 2022 Preliminary Unaudited Financial Highlights

- Preliminary unaudited revenue of $5.2 million, a 21% year-over-year increase;
- Increased biologics and drug delivery revenue to $2.3 million, a 37% year-over-year increase;
- Increased functional neurosurgery products and services to $2.3 million, a 7% year-over-year increase;
- Cash burn of approximately $3.0 million in the fourth quarter. The Company had approximately $37.5 million in cash, cash equivalents and short-term investments at December 31, 2022.

Full Year 2022 Preliminary Unaudited Financial Highlights

- Achieved preliminary unaudited record revenue of $20.6 million, a 26% year-over-year increase, versus most recent guidance of $21.0 - $22.0 million;
- Increased biologics and drug delivery revenue to $9.1 million, a 34% year-over-year increase;
- Increased functional neurosurgery products and services revenue to $9.1 million, a 13% year-over-year increase;
- Added multiple new biologics and drug delivery partners in the year to bring the total to more than 50 partners.

Business Outlook and Planned Value Creating Milestones

- The Company estimates revenue in 2023 to be between $25.0 million and $27.0

million, representing growth between 22% and 31%;

- Submission to the FDA of a Biologics License Application (BLA) by PTC Therapeutics for Upstaza™, using the ClearPoint SmartFlow® Cannula, for minimally invasive infusion of the gene therapy;
- Initiation of multiple pharmaceutical partner clinical trials globally;
- Expansion of the installed base to approximately 10 additional centers worldwide;
- Revenue growth from international customers driven by 8 active centers installed in the E.U. and U.K.;
- Commercialization of the ClearPoint PRISM™ Neuro Laser Therapy System and expansion into limited market release centers;
- Completion of Phase 1 safety study in Lund, Sweden, for the use of PRISM™ to treat brain lesions;
- Up to 8 FDA submissions for new hardware and software products in our portfolio;
- Production of first devices at our new expanded manufacturing facility in California.

“Our team made tremendous progress toward our four-pillar growth strategy in 2022 and finished the year with approximately 26% growth in revenue, driven by the 34% revenue growth in our biologics and drug delivery business, and 11 new centers installed worldwide,” commented Joe Burnett, President and CEO of ClearPoint Neuro. “While recognized revenue in the fourth quarter was below our expectations based on timing and delivery for certain products and services, our backlog of received purchase orders grew to the highest level in our history setting us up for a strong 2023. We are forecasting revenue for 2023 in the range of $25.0 million to $27.0 million, representing growth of between 22% and 31% percent. Our team has done a great job managing our cash position in the past year by pausing less crucial programs while continuing to invest in our supply chain to ensure product availability to hospitals and our pharmaceutical partners. As a result, our cash burn in the fourth quarter was approximately $3.0 million, which was the lowest in several quarters, bringing our current cash, cash equivalents, and short-term investments balance at year end to approximately $37.5 million.”

The preliminary unaudited financial results described in the press release are estimates only and subject to revision until we report our full financial results for the fourth quarter and full year 2022 during our upcoming earnings announcement.

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 the United States, Canada, and Europe. ClearPoint Neuro is partnered with more than 50 biologics/pharmaceutical companies and academic centers, 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. For more information, please visit www.clearpointneuro.com.

Forward-Looking Statements

Statements in this press release covering preliminary financial results for completed periods and expected results in future periods, and statements 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, 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.

Contact:

Danilo D'Alessandro, Chief Financial Officer
(888) 287-9109
info@clearpointneuro.com

Caroline Corner, Investor Relations
ir@clearpointneuro.com

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