

August 8, 2022



## **ClearPoint Neuro, Inc. Announces Appointment of Mary McNamara-Cullinane as Vice President of Regulatory Affairs**

SOLANA BEACH, Calif., Aug. 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 that Mary McNamara-Cullinane has joined the Company as Vice President of Regulatory Affairs. Ms. McNamara-Cullinane will report directly to Joe Burnett, ClearPoint Neuro's Chief Executive Officer, and serve as a member of the Company's senior leadership team.

"We are thrilled to welcome Mary to our team as we fully expect her leadership and experience in Regulatory Affairs will contribute immediately to our partners and to patients globally," commented Joe Burnett, President and CEO at ClearPoint Neuro. "Our mission at ClearPoint continues to attract talented professionals capable of building teams and achieving scale, not for where we are today, but for where we are headed tomorrow. Mary is a perfect example of an experienced functional leader capable of defining a Regulatory Strategy and putting the people and processes in place to execute. The Regulatory Affairs function will be one of our biggest strengths as we support our growing portfolio of pharma and device partners and our global installed base."

Ms. McNamara-Cullinane brings to the Company over 25 years of experience in the healthcare and life sciences field. Her global regulatory and clinical affairs expertise includes regulation of radiology, urology, physical medicine, orthopedic, neurological wound care, digital health, IVDs, dental medical devices, and combination products. She has authored over 200 submissions including 510(k)s, RFDs, Breakthrough Device Designations, 513(g)s, IDEs, and PMAs. Mary is also a frequent podium speaker and panelist on a range of topics including MedTech, regulatory affairs, and women in healthcare. Before joining the Company, she was Senior Vice President of Regulatory Affairs at Alira Health. Prior to that, Ms. McNamara-Cullinane served as Principal of MMC Regulatory Consulting and has held senior leadership positions at Intrinsic Therapeutics and Echo Therapeutics. Ms. McNamara-Cullinane holds a Bachelor of Arts Degree from Massachusetts College of Liberal Arts, a Post-Graduate degree in Cardiovascular Health and Biochemistry from Northeastern University, and a Master of Public Health from Southern New Hampshire University.

"ClearPoint's growth hinges on new product introductions and geographic expansion, both of which require a strong regulatory strategy and team," stated Mary McNamara-Cullinane. "I am delighted to support the Company's impactful mission and help bring meaningful

neurosurgical innovation to patients around the world.”

## **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 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](http://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 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.

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