

November 6, 2025



ClearPoint Neuro Announces Agreement to Acquire IRRAS

Acquisition Will Further Expand the Potential of ClearPoint Neuro's Drug Delivery Portfolio While Immediately Adding New Indications and Commercial Scale Across a \$0.5 Billion Market for the Treatment of Intracranial Bleeding

SOLANA BEACH, CALIFORNIA / [ACCESS Newswire](#) / November 6, 2025 /ClearPoint Neuro, Inc. (Nasdaq:CLPT) (the "Company"), a global device, cell, and gene therapy-enabling company offering precise navigation to the brain and spine, today announced the acquisition of San Diego based, IRRAS Holdings, Inc., a medical technology company focused on neurocritical care, with an emphasis on treatments for intracerebral hemorrhage, chronic subdural hematoma, and other conditions requiring intracranial fluid management. Its cornerstone product is the IRRAS^{flow}® system, an FDA-cleared and CE-marked platform which integrates continuous irrigation, aspiration, and real-time intracranial pressure monitoring. The IRRAS^{flow} system is also intended for the delivery of physician directed fluids¹ and has the demonstrated potential to be used for targeted intracranial drug delivery, with the investigational administration of antibiotics and antithrombotic agents having been reported in clinical literature. The deal brings more than 50 active customers to the ClearPoint Neuro installed base and 10 additional patent families.

The IRRAS^{flow} system has been cited in more than 30 peer-reviewed publications, highlighting the device's clinical benefits, including reduction in catheter occlusions, the potential to reduce infection rates, and shorter treatment times, which may equate to lower hospital costs.

"This is a very strategic merger transaction for ClearPoint Neuro, and we believe this addition is complementary to our vision as we continue to become the world's premier neuro drug delivery partner for the biopharma community," commented Joe Burnett, President and CEO at ClearPoint Neuro.

"There are three important strategic rationales that make the IRRAS team and portfolio a perfect fit for this next phase of ClearPoint Neuro," continued Mr. Burnett. "First, the IRRAS^{flow} catheter, a proprietary disposable dual-lumen catheter, will immediately give ClearPoint Neuro access to a large existing market in the treatment of intracerebral hemorrhage, chronic subdural hematoma, and other conditions requiring intracranial fluid management. It is estimated these clinical presentations represent up to approximately 400,000 procedures annually in the United States alone and close to a \$0.5 billion existing

global market opportunity which ClearPoint Neuro now gains access to. Second, the design of the indwelling and flexible IRRAS catheter provides ClearPoint Neuro with a launching point for the design of a longer duration infusion cannula that may open up additional biopharma partners, especially in the oncology space, who often require a device that allows multiple infusions over an extended duration, potentially in an outpatient setting. Our goal is to become a true one-stop shop for cell, gene, and other therapy delivery that are directed by our same biopharma and neurosurgery call points. Third, the combined entity is expected to immediately gain operational scale with an expansive commercial team including marketing, sales, and clinical specialists that will now include more than 40 additional professionals across the United States. This merger with IRRAS will deliver a new pillar of growth for the Company and is expected to extend our lead in neuro drug delivery."

"We are incredibly proud of what the IRRAS team has accomplished thus far in de-risking the platform, earning FDA Clearance and CE Mark approvals, launching multiple generations of technology while incorporating surgeon and nursing feedback, and building an installed base of more than 50 customers and growing 83% in the first 9 months of 2025 to an estimated \$9.0 million revenue run-rate," commented Will Martin, President and CEO of IRRAS. "We are very excited to accelerate this next phase of commercialization alongside the ClearPoint Neuro team with a scaled sales organization and a collective reach to offer solutions for functional neurosurgery, neuro critical care, and intracranial drug delivery. Our investors at IRRAS are excited to continue this journey as shareholders in the combined ClearPoint Neuro company moving forward."

Based on management's current forecasts for ClearPoint Neuro's business and our assessment of the IRRAS business, the total 2026 combined revenue for the two companies is expected to be in the range of \$54.0 to \$60.0 million. As with all forward-looking statements, this estimate is subject to revision based on updated information, including that arising through the post-closing integration of IRRAS. Our guidance for future financial performance is based on management's current expectations and is subject to the risks inherent in the business, which may cause the Company's actual results to differ materially from those expressed in or implied by forward-looking statements.

About the Proposed Merger and Principal Transaction Terms

Upon closing, the Company will deliver closing consideration of \$5,000,000 in cash and 1,325,000 shares of Company common stock. The agreement also provides for the Company to pay a revenue share on net sales of certain IRRAS products for specific periods. The closing of the merger is subject to a number of conditions, including approval of the transaction by IRRAS shareholders, and is expected to be completed in the fourth quarter of 2025. The Company intends to deliver shares of common stock that may be sold following the closing pursuant to an effective registration statement. Additional information regarding the terms of the transaction will be provided in the Company's Current Report on Form 8-K expected to be filed with the Securities and Exchange Commission on November 6, 2025.

About ClearPoint Neuro

ClearPoint Neuro is a device, cell, and gene therapy-enabling company offering precise navigation to the brain and spine. The Company uniquely provides both established clinical products as well as preclinical development services for controlled drug and device delivery.

The Company's flagship product, the ClearPoint Neuro Navigation System, has FDA clearance and is CE-marked. ClearPoint Neuro is engaged with healthcare and research centers in North America, Europe, Asia, and South America. The Company is also partnered with the most innovative pharmaceutical/biotech companies, academic centers, and contract research organizations, providing solutions for direct central nervous system delivery of therapeutics in preclinical studies and clinical trials worldwide. To date, thousands of 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 worldwide. For more information, please visit www.clearpointneuro.com.

Forward-Looking Statements

Statements in this press release 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, including, but not limited to the closing of proposed transaction with IRRAS Holdings, Inc.; the market potential for the use of IRRAS products in drug delivery and the regulatory approval of the IRRAS products for such indications; the prospective benefits of the proposed transaction; approval of the proposed transaction by IRRAS Holdings, Inc. shareholders; the successful integration of IRRAS Holdings, Inc. into the Company; the size of total addressable markets or the market opportunity for the IRRAS products; the Company's expectation for revenues for the IRRAS products; the Company's expectations for operating expenses and the adequacy of cash and cash equivalent balances to support operations and meet the future obligations of the combined entity; 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. These forward-looking statements are based on management's current expectations and are subject to the risks inherent in the business, which 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 possibility that the closing of the IRRAS transaction is delayed or does not occur at all because conditions to the transaction are not obtained or satisfied on a timely basis or at all; the possibility that the anticipated benefits of the IRRAS transaction are not realized when expected or at all; expenditures or assumed liabilities that may be incurred as a result of the proposed transaction; the Company's failure to integrate IRRAS into its business in accordance with expectations; deviations from the expected market potential and clinical benefit of the IRRAS products; future revenue from sales of the IRRAS products; the Company's ability to market, commercialize and achieve broader market acceptance for the IRRAS products; risks in the development, marketing, or regulatory approval of the IRRAS products for use in specific drug delivery applications; diversion of management's attention on the IRRAS proposed transaction; the Company's ability to attract and retain key employees after the consummation of the transaction; macroeconomic and inflationary conditions; regulatory and policy uncertainty; the introduction of or changes in tariffs, sanctions, or trade barriers; changes in monetary policy; geopolitical trends, such as protectionism and economic nationalism; the Company's expectations, projections and estimates regarding expenses, future revenue, capital requirements, and the availability of and the need for additional financing; and the ability of the Company to manage the growth of its business. For a detailed description of the Company's risks and uncertainties, you are encouraged to review its documents filed with the SEC including the Company's recent filings on Form 8-K, Form 10-K and Form 10-Q. You are cautioned not to place undue reliance on forward-looking

statements, which speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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¹ IRRAflow Active Fluid Exchange System Instructions for Use, Document Number 7001151 Rev. H, Release Date 2025-07-11.

SOURCE: ClearPoint Neuro, Inc.

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