November 6, 2025

ClearPoint Neuro Reports Third Quarter 2025 Results

Site Readiness Continues for Specialized Treatment Centers Envisioned to Support a Growing Number of Cell and Gene Therapy Trial Patients and Later Commercialization

SOLANA BEACH, CA / 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 financial results for its third quarter ended September 30, 2025.

Third Quarter Highlights

- Continued to provide supply, development, and strategic support to more than 60 active biopharma partners, including nine partner programs accepted for FDA expedited review, with many partners sharing updates on their scientific and regulatory progress at the 2025 ESGCT Annual Congress in Seville, Spain;
- Completed transition to the new Pre-clinical CRO Facility named ClearPoint Advanced Laboratories (CAL) located in Torrey Pines, California, which became operational and already began running preclinical studies early in Q4 2025;
- Announced the development and demonstration of the Company's prototype Robotic Neuro-Navigation System, which is being designed to enable the ClearPoint Neuro Navigation software to operate the KUKA LBR Med Robotic Arm to support all minimally invasive cranial surgical procedures including cell and gene therapy infusions, laser catheter placement, biopsy workflows, deep brain stimulation, and stereotactic EEG lead placements;
- Received FDA 510(k) clearance expanding compatibility of the ClearPoint PRISM Laser Therapy System with 1.5T MRI guidance in addition to the previously cleared 3T MRI guidance, opening up more than 50% of the existing market for neuro LITT;
- Announced several expanded regulatory approvals for product use in Canada, Hong Kong, and Taiwan, bringing the total number of international clearances for key therapy delivery products to 34 countries worldwide;
- Announced a signed agreement for the acquisition of IRRAS Holdings, Inc., which will

expand the Company's footprint into the neurocritical care space and allow the Company to leverage an expanded commercial channel;

- Activated 5 new global customers in the third quarter;
- Reported quarterly revenue of $8.9 million, a 9% year-over-year increase compared with the third quarter of 2024 and reaffirmed the prior 2025 full year forecast narrowing the expected revenue range to between $36.0 million and $38.0 million; and
- Reported cash and cash equivalents totaling $38.2 million as of September 30, 2025.

"This is one of the most exciting times in the history of our company as we make progress across all four of our existing growth pillars and announce a plan to evolve them in line with our latest strategic direction," commented Joe Burnett, President and CEO of ClearPoint Neuro. "We are laying the groundwork for realizing the full potential of ClearPoint Neuro as we enable our 60 plus biopharma partners to progress through the regulatory process in the United States and beyond. The scientific data emerging from several of our cell and gene therapy partners who have been selected for expedited review by the FDA has been encouraging. As we have seen from recent news, the regulatory pathway and timelines for our biopharma partners remain areas of active learning. We at ClearPoint Neuro recognize the urgency of bringing transformative therapies to patients in need and remain focused on collaborating with our partners to support their development, while also remaining committed to the highest standards of quality, safety, and consistency in therapy delivery. To advance this effort, we plan to activate additional sites to support cell and gene therapy trials and eventual commercialization with our drug delivery ecosystem. Our highest priority with the neurosurgical community is to work hand-in-hand with our biopharma partners and to identify the first 35-40 specialized treatment centers which can add 5,000 patients a year in capacity. We believe that this added site capacity using ClearPoint Neuro's technology is crucial to standardize delivery and create consistency across sites for these new-to-world cell and gene therapies. The intent is that these experienced clinical trial sites will become the commercial deployment sites of the future, all using the ClearPoint Neuro ecosystem for MRI, CT, and Robotic Navigation, a portfolio of cannula-based routes-of-administration, quality control infusion modeling and monitoring, and expert clinical support. We believe that commercial drug delivery is the largest future revenue stream for ClearPoint Neuro, and we have only just begun to unlock its full potential."

"However, our excitement does not begin and end with these future cell and gene therapy launches," continued Mr. Burnett. "Our existing four pillars of growth, which will also be evolved to include IRRAS upon the closing of the acquisition, will give ClearPoint Neuro access to an existing total market valued at more than $0.5 billion, and a practical portfolio that we believe will allow us to increase our market share in each and every one of those pillars."

"In Pillar One, Biologics and Drug Delivery, we achieved a huge milestone of activating our new ClearPoint Advanced Laboratories facility (CAL). In Q3, the team focused on setting up the new facility, establishing the foundation, writing protocols, and obtaining the various necessary certifications. We have now completed our first preclinical study for a pharmaceutical sponsor at the new facility, showing that we are officially open for business. This new facility, located in the Torrey Pines biotech region, has three potential growth vectors that we expect to monetize over the coming years as CAL allows us to 1) add

capacity for much larger studies, approximately five times our prior capacity, 2) perform higher value/higher margin GLP studies including pivotal toxicology studies, and 3) offer additional services to biopharma partners increasing the potential offerings and comprehensiveness of the facility. For perspective, we have already bid out studies for 2026 and 2027 that reflect the expanded scope and greater sophistication of our new facility, which in turn results in higher value offerings for the Company. This is a huge success for the entire team to get the new facility running in such a short period of time. We expect our Biologics and Drug Delivery revenue to drive double digit growth in the fourth quarter and expand further in 2026 and 2027."

"In Pillars Two and Three, Neurosurgery Navigation and Laser Therapy, we have continued the successful full market releases for new products, which, like in Pillar One, are designed to increase share in these existing markets. Our ClearPoint 3.0 software has now been installed at more than 50 centers in the United States and is enabling ClearPoint Neuro procedures to be performed in both the MRI suite and the operating room using CT, all with the same system. In total, we activated five new customers in the quarter. Our PRISM Laser Therapy system just received FDA clearance expanding to compatibility with 1.5 Tesla powered magnets, opening up approximately 50% of the neuro LITT market in the United States. We expect the first installations of the 1.5 Tesla labeled product in the fourth quarter. Both 1.5T and 3.0T PRISM Laser Therapy systems have also been submitted for CE Mark approval which we expect in the second half of 2026. We also unveiled a prototype of our proprietary Robotic Neuro-Navigation System that is being designed to support all minimally invasive cranial procedures, including cell and gene therapy infusions, laser catheter placement, biopsy workflows, deep brain stimulation, and stereotactic EEG lead placements, which will make ClearPoint Neuro the only company with one software platform that can deploy navigation in three different arenas: MRI, iCT, and Robotics. This prototype received excellent early development feedback at the 75th Annual Congress of Neurological Surgeons (CNS) in Los Angeles this past month."

"In addition to advancing our existing pillars of growth, we are expanding our presence beyond the United States, with regulatory clearances now spanning 34 countries, including recent approvals in Canada, Taiwan, and Hong Kong. By making it possible for our biopharma partners to standardize and simplify every possible aspect of the surgical workflow for delivering their therapies across many geographies, we hope to reduce barriers to adoption and give our partners' therapies improved chances to succeed on a global stage."

"With the announcement of the signing of our agreement to acquire IRRAS Holdings, Inc., we expect to introduce a new fourth pillar of growth. This fourth pillar will be focused on cranial irrigation and aspiration, and will allow us to enter the substantial intracranial hemorrhage market with a potentially disruptive product in the EVD space, and gain scale by effectively doubling the size of our commercial organization. We believe that, across our evolved four growth pillars, we will have a credible path to cash breakeven and profitability without including our largest potential market of commercial cell and gene therapies in the years ahead."

Business Outlook

The Company reaffirmed its full-year guidance, narrowing the expected revenue range to between $36.0 million and $38.0 million.

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 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.

Financial Results - Quarter Ended September 30, 2025

Total revenue was $8.9 million for the three months ended September 30, 2025, and $8.1 million for the three months ended September 30, 2024, which represents an increase of $0.7 million, or 9%.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored preclinical and clinical trials, stayed relatively consistent at $4.4 million for the three months ended September 30, 2025 and 2024. Service and other revenue increased $0.7 million due to new studies performed for our partners in the three months ended September 30, 2025, offset by a decrease in product revenue due to timing of the pharmaceutical partners' clinical and preclinical trials.

Neurosurgery navigation and therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 20% to $3.4 million for the three months ended September 30, 2025, from $2.9 million for the same period in 2024. The increase is driven by higher sales of Prism Laser Therapy, and the introduction of our 3.0 operating room navigation software, which has positively impacted procedural volumes in the operating room during the three months ended September 30, 2025, compared to the same period in 2024.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software and related services, increased 25% to $1.0 million for the three months ended September 30, 2025, from $0.8 million for the same period in 2024 due to an increase in the sale of hardware and rental revenue.

The Company achieved a gross margin of 63% on its sales for the three months ended September 30, 2025, as compared to 60% in the same period in 2024. The increase in gross margin was primarily due to higher margins on biologics and drug delivery service revenue and mix of product sold for the three months ended September 30, 2025, as compared to the same period in 2024.

Operating expenses were $10.9 million for the three months ended September 30, 2025, compared with $10.0 million for same period in 2024, an increase of 9%. The increase was mainly driven by higher product and software development costs, professional services fees, and personnel-related expenses, including share-based compensation, as we increased headcount to fuel the expansion of the research and development, clinical, and support organizations.

At September 30, 2025, the Company had cash and cash equivalents totaling $38.2 million as compared to $20.1 million at December 31, 2024, with the increase resulting from the net

proceeds of the note payable and stock offering of $32.0 million, partially offset by the use of $11.8 million in cash for operating activities.

On November 5, 2025, the Company entered into an agreement to access an additional $20.0 million in funding under its existing note financing arrangement with Oberland Capital, conditioned upon the closing of the Company's transaction to acquire IRRAS Holdings, Inc., and other customary closing conditions. The Company expects to use the additional funding to support integration activities, enhance working capital, and fund new growth initiatives for the combined business operations.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's 2025 third quarter results on Thursday, November 6, 2025 at 5:00 p.m. Eastern time (2:00 p.m. Pacific time) which may be accessed online here: https://event.choruscall.com/mediaframe/webcast.html?webcastid=60S23gGB . Investors and analysts who would like to participate in the conference call via telephone may do so at (877) 407-9034, or at (201) 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 December 4, 2025, 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 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 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; the Company's belief about the outcome of regulatory interactions with respect to its biotech Partners' therapies, the timing of commercialization of such therapies, and the market potential for such therapies; the continued development and commercial potential of the Company's proprietary Robotic Neuro-Navigation platform System; the size of total addressable markets or the market

opportunity for the Company's products and services, including for the PRISM Laser Therapy System and the Company's preclinical CRO facility; the consummation of IRRAS Holdings, Inc. transaction and the market potential for IRRAS products; the anticipated adoption of the Company's products and services for use in the delivery of gene and cell therapies; the Company's expectations for revenues, operating expenses, and 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 Company's biotech Partners' risks related to the ongoing conduct of their clinical studies, including the risk that such trials will be unable to demonstrate data sufficient to support further clinical development or regulatory approval; the risk that more patient data becomes available that results in a different interpretation then the data already released for gene and cell therapies; risks related to interactions with regulatory authorities, which may affect the initiation, timing and progress of clinical trials and pathways to regulatory approval of the biotech Partners' therapies; the limitation or modification of the FDA's eligibility and criteria for its expedited review programs with respect to such therapies; the commercialization and acceptance of gene and cell therapies; the Company's biotech Partner's continued use of the Company's products and services in their delivery of gene and cell therapies; the Company's ability to maintain its current relationships with its biotech Partners or enter into relationships with new partners; the Company's ability to continue to build and maintain the infrastructure and personnel needed to allow for widespread adoption of intracranial administration of gene and cell therapies; risks inherent in the research, development, and regulatory approval of the Company's new products; the future market for preclinical services and the investment required to expand such services, which could divert resources from the Company's other business operations; 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; the Company's failure to integrate IRRAS into its business in accordance with expectations; deviations from the expected market potential of the IRRAS products; diversion of management's attention on the IRRAS proposed 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 ability to market, commercialize and achieve broader market acceptance for new products and services offered by the Company; the availability of additional funding to support the Company's research and development programs; the ability of the Company to manage the growth of its business; and the Company's ability to attract and retain its key employees. 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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CLEARPOINT NEURO, INC.
Consolidated Statements of Operations
(Unaudited)
(in thousands, except for share and per share data)

	For the Three Months Ended September 30,	
	2025	2024
Revenue:		
Product revenue	$ 5,361	$ 5,474
Service and other revenue	3,500	2,648
Total revenue	8,861	8,122
Cost of revenue	3,261	3,275
Gross profit	5,600	4,847
Research and development costs	3,452	3,315
Sales and marketing expenses	3,838	3,549
General and administrative expenses	3,586	3,141
Operating loss	(5,276)	(5,158)
Other income (expense):		
Other expense, net	(64)	(11)
Interest (expense) income, net	(543)	209
Net loss before income taxes	(5,883)	(4,960)
Income tax expense	(8)	(14)
Net loss	$ (5,891)	$ (4,974)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.21)	$ (0.18)
Weighted average shares outstanding:		
Basic and diluted	28,427,574	27,591,623

	For the Nine Months Ended September 30,	
	2025	2024
Revenue:		
Product revenue	$ 16,649	$ 14,053
Service and other revenue	9,912	9,566
Total revenue	26,561	23,619
Cost of revenue	10,273	9,259
Gross profit	16,288	14,360
Research and development costs	10,660	9,060
Sales and marketing expenses	11,691	10,673
General and administrative expenses	11,056	8,725
Operating loss	(17,119)	(14,098)
Other income (expense):		
Other expense, net	(112)	(32)
Interest (expense) income, net	(472)	646
Net loss before income taxes	(17,703)	(13,484)
Income tax expense	(51)	(44)
Net loss	$ (17,754)	$ (13,528)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.63)	$ (0.50)
Weighted average shares outstanding:		
Basic and diluted	28,137,528	26,840,119

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

	September 30, 2025 (Unaudited)	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,221	$ 20,104
Accounts receivable, net	4,000	4,713
Inventory, net	6,583	6,863
Prepaid expenses and other current assets	2,525	1,683
Total current assets	51,329	33,363
Property and equipment, net	2,114	2,005
Operating lease, right-of-use assets	5,955	3,086
Other assets	959	735
Total assets	$ 60,357	$ 39,189
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 723	$ 1,340
Accrued compensation	3,516	4,885
Other accrued liabilities	1,748	1,450
Operating lease liabilities, current portion	347	557
Contract liabilities, current portion	1,719	2,121
Total current liabilities	8,053	10,353
Operating lease liabilities, net of current portion	6,195	3,011
Contract liabilities, net of current portion	769	436
Long-term note payable, net	29,203	-
Other long-term liabilities	263	-
Total liabilities	44,483	13,800
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized; none issued and outstanding at September 30, 2025 and December 31, 2024	-	-
Common stock, $0.01 par value; 90,000,000 shares authorized at September 30, 2025 and December 31, 2024; 28,428,176 and 27,617,415 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	284	276
Additional paid-in capital	224,714	216,483
Accumulated deficit	(209,124)	(191,370)
Total stockholders' equity	15,874	25,389
Total liabilities and stockholders' equity	$ 60,357	$ 39,189

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

	For the Nine Months Ended September 30,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (17,754)	$ (13,528)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for credit losses (recoveries)	217	(507)
Depreciation and amortization	565	740
Share-based compensation	6,199	5,204
Payment-in-kind interest	490	-
Amortization of debt issuance costs and original issue discounts	60	51
Amortization of lease right of use assets, net of accretion in lease liabilities	821	692
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	497	(157)
Inventory, net	(16)	434
Prepaid expenses and other current assets	(696)	88
Other assets	(192)	(40)
Accounts payable and accrued expenses	(1,251)	1,373
Lease liabilities	(716)	(635)
Contract liabilities	(69)	(1,422)
Net cash flows from operating activities	(11,845)	(7,707)
Cash flows from investing activities:		
Purchases of property and equipment	(473)	(12)
Net cash flows from investing activities	(473)	(12)
Cash flows from financing activities:		
Proceeds from offerings of common stock, net of offering costs	3,263	16,183
Proceeds from issuance of note payable, net of financing costs and discount	28,653	-
Repayment of 2020 senior secured convertible note	-	(10,000)
Proceeds from stock option exercises	49	21
Payments for taxes related to net share settlement of equity awards	(1,661)	(340)
Proceeds from issuance of common stock under employee stock purchase plan	311	288
Net cash flows from financing activities	30,615	6,152
Net change in cash, cash equivalents and restricted cash	18,297	(1,567)
Cash, cash equivalents and restricted cash, beginning of period	20,104	23,140
Cash, cash equivalents and restricted cash, end of period	$ 38,401	$ 21,573
Cash and cash equivalents	38,221	21,573
Restricted cash included in other assets, non-current	180	-
Total cash, cash equivalents and restricted cash	$ 38,401	$ 21,573
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ 69	$ 41
Interest	$ 490	$ 480

SOURCE: ClearPoint Neuro, Inc.

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