August 3, 2026

ClearPoint Neuro Reports Second Quarter 2026 Results

Positive BioPharma Partner Regulatory Progress and Early Success in Focused Ultrasound Technology Platform Expansion

SOLANA BEACH, CA / ACCESS Newswire / August 3, 2026 /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 second quarter ended June 30, 2026.

Second Quarter 2026 Highlights

- Reported second quarter revenue of $10.9 million, representing 18% overall growth, including the recently acquired IRRA*flow* Portfolio; Biologics and Drug Delivery Revenue declined 15% in the quarter, primarily due to a decrease in products shipped to biopharma customers supporting new trial initiations compared to the second quarter a year ago. This decline was partially offset by growth in preclinical service revenue in the quarter. As of July 2026, the ClearPoint Advanced Laboratories (CAL) facility is now in the Company's possession and new services revenue is expected to return the Biologics and Drug Delivery segment to growth in the third quarter;

- Multiple biopharma partners recently received positive feedback from the FDA on their potential BLA submissions, as well as other global regulatory progress, leading us to believe that additional cell and gene therapies could become available commercially by the end of 2027;

- The Company expects 10-15 clinical trials using ClearPoint Neuro technology to be enrolling patients in the next 18 months, along with approximately 10 partner clinical trial data readouts;

- The Company has entered into multiple statements of work for preclinical services at CAL, including our first statement of work involving GLP services, which we expect to complete in the first half of 2027;

- Both our in-development Robotic platform and Harmony 1.0 software were showcased at multiple neurosurgery trade shows in the second quarter; feedback from more than 50 surgeons reinforced our strategy and provided essential user input;

- Announced plans to enter the focused ultrasound market via a partnership with the SONOCARE Lab at Sungkyunkwan University, South Korea, alongside the successful intravenous delivery of tracers across the blood-brain barrier in a preclinical model using the ClearPoint Neuro prototype system; and

- Positive regulatory news has re-activated the need for commercial drug delivery readiness in 2027 leading to a reorganization of the Company's commercial structure which began in Q2 with an emphasis on installed base expansion and clinical case support.

"Establishing ClearPoint Neuro as the leading neuro cell and gene therapy delivery company has been our number one priority for the last 10 years. Over that time, we have pivoted the company vision, invested more than $200 million, built our unique ecosystem, and earned more than 60 active biopharma partners, many of whom have programs which are now under FDA expedited review," commented Joe Burnett, President and CEO at ClearPoint Neuro. "Exciting news over the past few months from our partners, global regulatory bodies, and our own product development teams have only furthered that conviction."

"First, the FDA recently reversed their guidance on a number of rare disease decisions, once again opening the door for potential partner BLA submissions later this year. This timing could yield commercial approvals as early as 2027, and as a key product and service provider to our partners, we need to ensure that we are ready. This regulatory news, combined with the planned initiation of larger phase III trials, has elevated the priority to invest in building our clinical capacity so that the ClearPoint installed base and our clinical support team are not a bottleneck. We believe the next 18 months will only increase the need for capable sites as we expect between 10 and 15 clinical trials to be enrolling, and approximately 10 data readouts to be presented, creating informative news flow on almost a monthly basis. It is important to note that progress toward commercial cell and gene therapy delivery is not just a U.S. phenomenon, and expanding our global footprint is included in these activities."

"Second, we are now in possession of the ClearPoint Advanced Laboratories, or the ‘CAL', our preclinical lab facility in Torrey Pines. Importantly we have now signed our very first statement of work for an IND enabling study involving GLP services at the CAL and we expect it to be performed in the first half of 2027."

"Third, we announced a 10-year focused ultrasound drug delivery partnership with the SONOCARE Lab at Sungkyunkwan University in South Korea, supported by preclinical proof-of-concept results demonstrating successful delivery of tracers across the blood-brain barrier. In parallel, our in-development ClearPoint Neuro robotic platform continued to advance and received valuable feedback from neurosurgeons during the quarter. Our Harmony 1.0 software, designed to control the ClearPoint drug delivery ecosystem through a single workflow, was further refined. These in-development technologies are all designed to help our partners reach the phase that will inevitably follow regulatory approval which is achieving global scale."

"As we embrace this new and important market information, our revised 2026 priorities are designed to build capacity across the full development pathway, from preclinical studies at the CAL, through larger, pivotal phase III trials, to commercial scale around the world, all hallmarks of the leading neuro drug delivery company," continued Burnett. "As a result of

these new priorities and investments, we are adjusting our 2026 revenue guidance to between $48.0 - $52.0 million as our investment will be less focused on traditional sales expansion than previously planned, and more focused on clinical case support for commercial drug delivery, global regulatory product expansion, capital equipment purchases at the CAL facility, and development of our focused ultrasound, robotics and harmony software solutions. We believe these decisions are the best way to extend our lead as the premier neuro drug delivery partner, be true to our strategy, and prepare ourselves for an exciting future."

Business Outlook

The Company estimates revenue in 2026 to be between $48.0 million and $52.0 million.

Financial Results - Quarter Ended June 30, 2026

Total revenue was $10.9 million for the three months ended June 30, 2026, and $9.2 million for the three months ended June 30, 2025, which represents an increase of $1.7 million, or 18%.

Biologics and drug delivery revenue, which include sales of disposable products and services related to customer-sponsored preclinical and clinical trials utilizing our products, decreased to $4.0 million for the three months ended June 30, 2026 from $4.7 million for the three months ended June 30, 2025. This decrease is attributable to lower product revenue due to a single customer order that occurred in the quarter of the prior year and did not recur in the current quarter.

Neurosurgery navigation and therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint and IRRA*flow* systems, increased 62% to $5.6 million for the three months ended June 30, 2026, from $3.4 million for the same period in 2025. The increase is driven by additional revenues from sales of the IRRA*flow* product as well as 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 June 30, 2026, compared to the same period in 2025.

Capital equipment and software revenue, consisting of sales of ClearPoint and IRRA*flow* reusable hardware and software and related services, increased 24% to $1.3 million for the three months ended June 30, 2026, from $1.0 million for the same period in 2025 due to an increase in placements of ClearPoint navigation capital and software, IRRA*flow* control units, and Prism laser units.

The Company achieved a gross margin of 62% on its sales for the three months ended June 30, 2026, and a gross margin of 60% in the same period in 2025. The increase in gross margin is primarily due to lower excess and obsolete inventory for the three months ended June 30, 2026, as compared to the same period in 2025.

Operating expenses were $17.0 million for the three months ended June 30, 2026, compared with $11.2 million for the same period in 2025, an increase of 51%. The increase was mainly driven by the IRRAS acquisition in November 2025, primarily through higher personnel costs resulting from the expansion of our clinical and sales teams, as well as increased occupancy costs, and travel costs.

At June 30, 2026, the Company had cash and cash equivalents totaling $29.4 million as compared to $45.9 million at December 31, 2025, with the decrease resulting from the use of $15.0 million in cash for operating activities and $2.0 million in cash paid for taxes related to the net share settlement of equity awards. We expect our operational cash burn to decrease in the second half of the year.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's second quarter 2026 results on Monday, August 3, 2026 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=FFVNbjau. 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 September 2, 2026, 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 meaning of the federal securities laws. Forward-looking statements include, among others, statements regarding: the Company's financial guidance and its expectations for revenue, operating expenses, cash and cash equivalents, operational cash burn, capital expenditures, liquidity and future capital requirements; the market opportunity for, and the expected adoption, growth and commercialization of, the Company's products and services, including its neuronavigational products, the IRRA*flow* Active Fluid Exchange System, the PRISM Laser Therapy System, and the preclinical services offered through its CRO facility (CAL); the continued development and commercialization of the Company's focused ultrasound system, robotic system and Harmony 1.0 software; the anticipated timing, scope, performance and results of preclinical services under executed statements of work; the

expected number, timing, enrollment and results of the clinical trials of the Company's biotech Partners and the timing and outcome of their regulatory submissions and any resulting commercialization; the expected benefits of the Company's commercial reorganization, its 2026 priorities and related investments, and its acquisition of IRRAS; and other statements of management's expectations, beliefs, plans, estimates or projections relating to the future. Words such as "anticipate," "believe," "expect," "intend," "plan," "may," "will," "should," "could" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these words. 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.

Specific risks which may cause the Company's actual results to differ from those expressed in or implied by forward-looking statements include: risks relating to the clinical and regulatory programs of the Company's biotech Partners, including that their trials may not commence, enroll patients or generate data readouts when expected or at all, and that the number of trials enrolling or data readouts presented may be lower than anticipated, that anticipated phase III studies may not begin on the expected timeline or at the expected scale, that positive or encouraging feedback from regulatory authorities may not be indicative of the ultimate outcome and does not ensure that any application will be submitted, accepted for review or approved, and that additional patient data may support a different interpretation than data previously released, all of which are largely outside the Company's control; risks relating to changes in the guidance, policies, leadership, staffing, funding or priorities of the FDA and other regulatory authorities, including that recent changes in FDA guidance or policy applicable to rare disease programs may be further modified, reversed, delayed or applied inconsistently; risks relating to the Company's planned entry into the focused ultrasound market, including through its arrangement with the SONOCARE Lab at Sungkyunkwan University, which may be modified or terminated or may not proceed on the expected timeline or at all, and to the development and commercialization of the Company's focused ultrasound system, robotic system and Harmony 1.0 software; risks relating to the Company's collaborations with academic and other third-party institutions, including with respect to the ownership, allocation and licensing of intellectual property developed under those arrangements; the risk that results observed in preclinical models, including the delivery of tracers across the blood-brain barrier using the Company's prototype system, are not replicated in future studies or in humans and are not predictive of clinical or commercial success; risks relating to the Company's investments in clinical capacity, including expansion of its installed base and clinical support team, which may not be completed when expected or at all and may not be sufficient to prevent capacity from becoming a limiting factor for partner trial enrollment or commercial launches; risks relating to the execution of the Company's commercial reorganization and its revised 2026 priorities and related investments, which may be disruptive, may not be implemented as planned, or may not deliver the anticipated benefits when expected or at all; risks relating to the Company's preclinical services business, including that executed statements of work may be delayed, rescheduled, reduced in scope or terminated and that the CAL facility may not achieve or maintain GLP compliance or generate revenue on the anticipated timeline; risks relating to the Company's liquidity and capital resources, including that the Company may fail to meet its publicly announced financial guidance and its ability to fund operations and capital expenditures for the period anticipated, to raise additional capital on acceptable terms, and to satisfy the covenants under its existing indebtedness; and risks relating to the

integration of IRRAS, the clearance and commercialization of the Company's own products in the United States and internationally, the Company's ability to attract and retain key personnel, and macroeconomic, geopolitical and policy conditions. For a more 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
(in thousands, except for share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Revenue:				
Product revenue	$ 7,376	$ 5,997	$ 16,178	$ 11,288
Service and other revenue	3,504	3,218	6,830	6,412
Total revenue	10,880	9,215	23,008	17,700
Cost of revenue	4,170	3,659	8,542	7,012
Gross profit	6,710	5,556	14,466	10,688
Research and development costs	4,632	3,829	9,154	7,208
Sales and marketing expenses	6,768	4,019	13,483	7,853
General and administrative expenses	5,554	3,388	10,551	7,470
Operating loss	(10,244)	(5,680)	(18,722)	(11,843)
Other income (expense):				
Other expense, net	(7)	(52)	(42)	(48)
Interest income	289	285	640	436
Interest expense	(1,413)	(365)	(2,795)	(365)
Net loss before income taxes	(11,375)	(5,812)	(20,919)	(11,820)
Income tax (benefit) expense	(38)	25	(30)	43
Net loss	$ (11,337)	$ (5,837)	$ (20,889)	$ (11,863)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.38)	$ (0.21)	$ (0.70)	$ (0.42)
Weighted average shares outstanding:				
Basic and diluted	30,166,640	28,258,305	29,858,476	27,990,102

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

	June 30, 2026 (Unaudited)	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 29,363	$ 45,923
Accounts receivable, net	8,395	6,549
Inventory, net	8,813	8,359
Prepaid expenses and other current assets	2,361	2,769
Total current assets	48,932	63,600
Property and equipment, net	2,986	2,621
Operating lease right-of-use assets	12,644	8,430
Goodwill	7,472	7,472
Intangible assets, net	12,915	13,922
Other assets	1,792	1,702
Total assets	$ 86,741	$ 97,747
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,153	$ 1,256
Accrued compensation	4,141	4,360
Other accrued liabilities	1,983	2,786
Operating lease liabilities, current portion	194	694
Contract liabilities, current portion	1,842	1,669
Total current liabilities	10,313	10,765
Operating lease liabilities, net of current portion	13,520	8,461
Contract liabilities, net of current portion	511	581
Long-term notes payable, net	50,232	49,077
Deferred tax liabilities, net	321	354
Other long-term liabilities	1,068	489
Total liabilities	75,965	69,727
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized; none issued and outstanding at June 30, 2026 and December 31, 2025	-	-
Common stock, $0.01 par value; 90,000,000 shares authorized at June 30, 2026 and December 31, 2025; 30,503,132 and 29,368,760 shares issued and outstanding at June 30, 2026 and December 31, 2025, respectively	305	294
Additional paid-in capital	245,703	238,995
Shares to be issued	2,567	5,641
Accumulated deficit	(237,799)	(216,910)
Total stockholders' equity	10,776	28,020
Total liabilities and stockholders' equity	$ 86,741	$ 97,747

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

	Six Months Ended June 30,	
	2026	2025
Cash flows from operating activities:		
Net loss	$ (20,889)	$ (11,863)
Adjustments to reconcile net loss to net cash used in operating activities:		
Allowance for credit losses (recoveries)	(95)	217
Depreciation and amortization	236	499
Amortization of intangible assets	1,007	-
Share-based compensation	4,489	4,177
Payment-in-kind interest	1,061	172
Amortization of debt issuance costs and original issue discounts	94	21
Amortization of lease right-of-use assets, net of accretion in lease liabilities	1,244	461
Deferred income taxes	(33)	-
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(1,751)	237
Inventory, net	(452)	482
Prepaid expenses and other current assets	342	(136)
Other assets	(215)	-
Accounts payable and accrued expenses	777	(1,944)
Lease liabilities	(900)	(471)
Contract liabilities	103	(576)
Net cash used in operating activities	(14,982)	(8,724)
Cash flows from investing activities:		
Purchases of property and equipment	(859)	(274)
Net cash used in investing activities	(859)	(274)
Cash flows from financing activities:		
Proceeds from offerings of common stock, net of offering costs	-	3,263
Proceeds from issuance of note payable, net of financing costs and discount	-	28,653
Proceeds from stock option exercises	603	49
Payments for taxes related to net share settlement of equity awards	(1,993)	(1,661)
Proceeds from issuance of common stock under employee stock purchase plan	546	311
Net cash (used in) provided by financing activities	(844)	30,615
Net change in cash, cash equivalents and restricted cash	(16,685)	21,617
Cash, cash equivalents and restricted cash, beginning of period	46,973	20,104
Cash, cash equivalents and restricted cash, end of period	$ 30,288	$ 41,721
Cash and cash equivalents	29,363	41,541
Restricted cash included in other current assets and other assets, non-current	925	180
Total cash, cash equivalents and restricted cash	$ 30,288	$ 41,721
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ 30	$ 12
Interest	$ 1,061	$ 172

SOURCE: ClearPoint Neuro, Inc.

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