May 13, 2026

ClearPoint Neuro Reports First Quarter 2026 Results

Record Revenue Achieved Including 25% Organic Growth in Devices and 43% Overall Growth

SOLANA BEACH, CA / ACCESS Newswire / May 13, 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 first quarter ended March 31, 2026.

First Quarter 2026 Highlights

- Reported first quarter revenue of $12.1 million, including $2.3 million of IRRA*flow* revenue, representing 43% overall growth and 16% year-over-year total organic growth compared with the first quarter of 2025;
- The activated installed base across all ClearPoint technology including IRRA*flow* systems now includes over 175 global centers;
- Achievement of measurable revenue and cost synergies through the continuing integration of the IRRA*flow* product portfolio and team;
- Continued clinical trial and regulatory progress across more than 60 active biopharma partners;
- FDA clearance and successful completion of the first clinical procedure utilizing the Velocity Alpha MR High Speed Surgical Drill System;
- Received Medical Device License (MDL) from Health Canada for the ClearPoint Neuro Navigation System, covering both MRI-guidance and iCT guidance workflows with first cases now scheduled;
- Completion of the first commercial drug delivery case utilizing ClearPoint technology in the Asia-Pacific region;
- Gross margin expanded to 64%; and
- Reported cash and cash equivalents totaling $35.6 million as of March 31, 2026.

"Our team is off to a strong start in 2026 with forward progress across our entire four-pillar growth strategy," commented Joe Burnett, President and CEO at ClearPoint Neuro. "While record revenue achievement and 25% organic devices growth made the headline, there is no shortage of meaningful strategic progress across the entire organization. This includes highlights from each pillar: multiple new drug routes-of-administration tested for the first time at the ClearPoint Advanced Laboratories, expansion of our navigation installed base globally, FDA clearance of the Velocity Alpha MR conditional drill that has now been used clinically for the first time, and the integration of the entire IRRA*flow* portfolio into the ClearPoint Neuro commercial and operations teams which will lead to meaningful revenue and cost synergies in the second half of 2026. We continue to believe that these four pillars will each contribute double digit growth in 2026, and represent a solid foundation on which to build our commercial cell and gene therapy delivery business in the future. Individual drug development programs of course come with inherent risk, however if you look across our entire portfolio of more than 60 partners and programs, every quarter we see partners getting funded or acquired, we see INDs being approved, we see more patients being recruited and enrolled in regulatory trials, and we see our partners getting closer and closer to pivotal data readouts. With more than 60 shots on goal across this portfolio, and having worked closely with the amazing teams doing this drug development, we feel more than ever that global approvals are not a matter of if, but when."

Business Outlook

The Company estimates revenue in 2026 to be between $52.0 million and $56.0 million.

Financial Results - Quarter Ended March 31, 2026

Total revenue was $12.1 million for the three months ended March 31, 2026, and $8.5 million for the three months ended March 31, 2025, which represents an increase of $3.6 million, or 43%.

Biologics and drug delivery revenue, which include sales of disposable products and services related to customer-sponsored preclinical and clinical trials utilizing our products, increased slightly to $4.8 million for the three months ended March 31, 2026 from $4.7 million for the three months ended March 31, 2025.Of note the construction of the new CAL facility (ClearPoint Advanced Laboratories) is continuing, which is designed to the bring the CAL's capacity to the level expected in the years ahead.

Neurosurgery navigation, therapy and access revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint and IRRA*flow* systems, increased 80% to $5.9 million for the three months ended March 31, 2026, from $3.3 million for the same period in 2025. The increase is driven by additional revenues from sales of the IRRA*flow* product of 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 March 31, 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 177% to $1.4 million for the three months ended March 31, 2026, from $0.5 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 64% on its sales for the three months ended March 31, 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 March 31, 2026, as compared to the same period in 2025.

Operating expenses were $16.2 million for the three months ended March 31, 2026, compared with $11.3 million for the same period in 2025, an increase of 44%. The increase was mainly driven by higher personnel costs as a result of the expanded team due to the acquisition of IRRAS which occurred in November 2025, as well as increased occupancy costs and travel costs.

At March 31, 2026, the Company had cash and cash equivalents totaling $35.6 million as compared to $45.9 million at December 31, 2025, with the decrease resulting from the use of $8.0 million in cash for operating activities and $2.0 million in cash paid for taxes related to the net share settlement of equity awards. The Company expects cost synergies resulting from the acquisition of IRRAS to contribute to a reduction in cash burn in the second half of 2026 and believes that the asset integration could potentially be cash neutral for the full year 2027.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's first quarter 2026 results on Wednesday, May 13, 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=IjzOoM7I. 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 June 12, 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 context of the federal securities laws. Statements regarding the Company's future events, developments and future performance; the market opportunity and rate of sales and revenue growth for the Company's products and services, including for the Company's preclinical CRO facility and its products and services, the Company's neuronavigational products, the IRRA*flow* Active Fluid Exchange System, and the PRISM Laser Therapy System; the Company's expectations for achieving key growth drivers for its sales including its ability to expand its commercial organization, receive regulatory approval for its products in new geographies, activate additional customer sites, generate clinical and economic data to support and expand the adoption rate for its products, and its development of new products; the Company's ability to successfully develop new products for gene and cell therapy delivery; the adoption of the Company's products and services for use in the delivery of gene and cell therapies; the regulatory approval and commercialization of cell and gene therapies being developed by the Company's biotech Partners; the Company's expectations regarding its four-pillar growth strategy, including its belief that each pillar will contribute double-digit growth in 2026; the Company's expectations regarding future revenue and cost synergies from the integration of the IRRA*flow* product portfolio and team, including the expectation that IRRAS integration could be cash neutral for the full year 2027; the Company's expectations for the ClearPoint Advanced Laboratories (CAL) facility, including anticipated future study capacity; the Company's expectations regarding international regulatory approvals, including the Medical Device License from Health Canada and the scheduling of future cases; the Company's expectations regarding the Velocity Alpha MR High Speed Surgical Drill System and the PRISM Laser Therapy System, including their clinical adoption and commercial potential; the Company's expectations that global regulatory approvals of cell and gene therapies by its biotech Partners are a matter of timing rather than outcome; and 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 products and the investment and timeline required to expand such services, which could divert resources from

the Company's other business operations; 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 integration of IRRAS into its business; the risk that the Company's four-pillar growth strategy may not achieve double-digit growth across each pillar as anticipated due to market, competitive, or operational factors; the risk that expected revenue and cost synergies from the IRRAS integration, including the expectation of cash neutrality for the full year 2027, may not be achieved on the anticipated timeline or at all; risks related to the construction, completion, and operational ramp up of the CAL facility, including the possibility that study capacity may not scale as expected; risks related to obtaining and maintaining international regulatory approvals, including approvals from Health Canada, and the Company's ability to successfully commercialize its products in new geographies; risks related to the clinical adoption and commercial success of the Velocity Alpha MR High Speed Surgical Drill System and other newly cleared products; 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 instability, 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 business activity, including its research and development programs and the expansion of its commercial organization; 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.

Contact:

Investor Relations:
Danilo D'Alessandro, Chief Financial Officer
(888) 287-9109 ext. 3
ir@clearpointneuro.com

CLEARPOINT NEURO, INC.
Consolidated Statements of Operations
(in thousands, except for share and per share data)

	For the Three Months Ended March 31,	
	2026	2025
Revenue:		
Product revenue	$ 8,802	$ 5,291
Service and other revenue	3,326	3,194
Total revenue	12,128	8,485
Cost of revenue	4,372	3,353
Gross profit	7,756	5,132
Research and development costs	4,522	3,379
Sales and marketing expenses	6,715	3,834
General and administrative expenses	4,997	4,082
Operating loss	(8,478)	(6,163)
Other income (expense):		
Other (expense) income, net	(35)	4
Interest income	351	151
Interest expense	(1,382)	-
Net loss before income taxes	(9,544)	(6,008)
Income tax expense	8	18
Net loss	$ (9,552)	$ (6,026)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.32)	$ (0.22)
Weighted average shares outstanding:		
Basic and diluted	29,546,889	27,718,918

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

	March 31, 2026 (Unaudited)	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 35,593	$ 45,923
Accounts receivable, net	8,662	6,549
Inventory, net	8,573	8,359
Prepaid expenses and other current assets	2,049	2,769
Total current assets	54,877	63,600
Property and equipment, net	2,914	2,621
Operating lease, right-of-use assets	13,088	8,430
Goodwill	7,472	7,472
Intangible assets, net	13,419	13,922
Other assets	1,646	1,702
Total assets	$ 93,416	$ 97,747
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,330	$ 1,256
Accrued compensation	2,977	4,360
Other accrued liabilities	2,125	2,786
Operating lease liabilities, current portion	234	694
Contract liabilities, current portion	1,814	1,669
Total current liabilities	9,480	10,765
Operating lease liabilities, net of current portion	13,710	8,461
Contract liabilities, net of current portion	608	581
Long-term notes payable, net	49,644	49,077
Deferred tax liabilities, net	354	354
Other long-term liabilities	779	489
Total liabilities	74,575	69,727
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized; none issued and outstanding at March 31, 2026 and December 31, 2025	-	-
Common stock, $0.01 par value; 90,000,000 shares authorized at March 31, 2026 and December 31, 2025; 29,986,639 and 29,368,760 shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively	300	294
Additional paid-in capital	239,468	238,995
Shares to be issued	5,535	5,641
Accumulated deficit	(226,462)	(216,910)
Total stockholders' equity	18,841	28,020
Total liabilities and stockholders' equity	$ 93,416	$ 97,747

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

	Three Months Ended March 31,	
	2026	2025
Cash flows from operating activities:		
Net loss	$ (9,552)	$ (6,026)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for credit losses (recoveries)	(95)	217
Depreciation and amortization	86	103
Amortization of intangible assets	504	-
Share-based compensation	2,218	1,908
Payment-in-kind interest	525	-
Amortization of debt issuance costs and original issue discounts	42	-
Amortization of lease right of use assets, net of accretion in lease liabilities	523	231
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(2,019)	846
Inventory, net	(125)	78
Prepaid expenses and other current assets	653	168
Other assets	(71)	-
Accounts payable and accrued expenses	(437)	(2,882)
Lease liabilities	(391)	(234)
Contract liabilities	172	(581)
Net cash flows from operating activities	(7,967)	(6,172)
Cash flows from investing activities:		
Purchases of property and equipment	(645)	(183)
Net cash flows from investing activities	(645)	(183)
Cash flows from financing activities:		
Payment of At-The-Market offering costs	-	(78)
Proceeds from stock option exercises	148	21
Payments for taxes related to net share settlement of equity awards	(1,993)	(1,305)
Net cash flows from financing activities	(1,845)	(1,362)
Net change in cash, cash equivalents and restricted cash	(10,457)	(7,717)
Cash, cash equivalents and restricted cash, beginning of period	46,973	20,104
Cash, cash equivalents and restricted cash, end of period	$ 36,516	$ 12,387
Cash and cash equivalents	35,593	12,387
Restricted cash included in other current assets and other assets, non-current	923	-
Total cash, cash equivalents and restricted cash	$ 36,516	$ 12,387
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ -	$ -
Interest	$ 525	$ -

SOURCE: ClearPoint Neuro, Inc.

View the original press release on ACCESS Newswire