UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 13, 2026

CLEARPOINT NEURO, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-34822**	**58-2394628**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
120 S. Sierra Ave., Suite 100 Solana Beach, California		**92075**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 888 287-9109

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.01 par value per share	CLPT	The Nasdaq Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On May 13, 2026, ClearPoint Neuro, Inc. (the "Company") issued a press release announcing its financial results for the first fiscal quarter ended March 31, 2026. A copy of the press release is furnished herewith as Exhibit 99.1.

The information in Item 2.02 of this Form 8-K, as well as Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

On May 13, 2026, the Company posted an updated investor presentation to its website at http://ir.stockpr.com/clearpointneuro/investor-presentations. A copy of the investor presentation is being furnished herewith as Exhibit 99.2. The Company may use the investor presentation from time to time in conversations with analysts, investors and others.

The information in Item 7.01 of this Form 8-K, as well as Exhibit 99.2 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith:

Exhibit 99.1	Press Release dated May 13, 2026
Exhibit 99.2	Investor Presentation dated May 13, 2026
Exhibit 104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CLEARPOINT NEURO, INC.

Date: May 13, 2026

By: /s/ Danilo D'Alessandro

Danilo D'Alessandro
Chief Financial Officer

Exhibit 99.1

ClearPoint Neuro Reports First Quarter 2026 Results

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

SOLANA BEACH, CA, 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=IjzOoM7l. 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	$ —


CLEARPOINT
NEURO
WHEN YOUR PATH IS UNCLEAR,
WE POINT THE WAY.
Nasdaq: CLPT
May 2026
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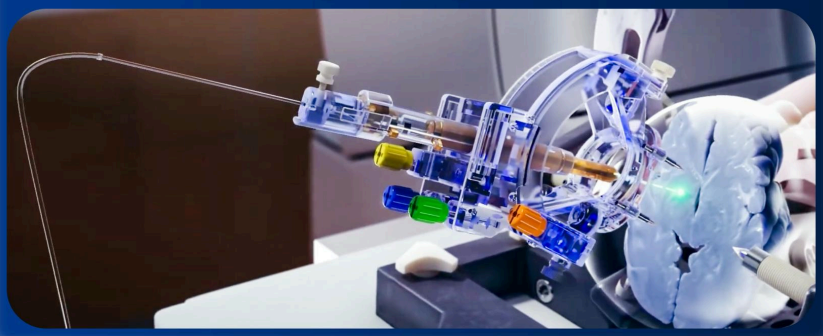
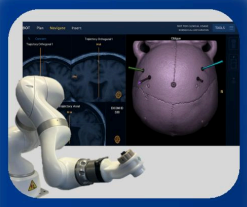
DISCLAIMER

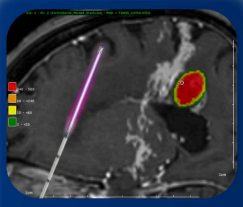
Statements in this presentation and discussion concerning ClearPoint Neuro's (the "Company's") plans, growth, and strategies may include forward-looking statements within the context of the federal securities laws. Statements regarding the Company's future events, developments and future performance; the continued development, anticipated timing, and potential commercial opportunity of the Company's pipeline of products and services under development, including its proprietary Robotic Neuro-Navigation platform System, cell and gene therapy delivery devices and routes of administration, software modeling and navigation tools, and preclinical service capabilities; the expected future role of the Company's products and services in addressing unmet needs in neurological diseases and the potential market opportunity for therapies targeting those indications; the Company's belief about the outcome of regulatory interactions with respect to its biotech Partners' therapies, the benefits of regulatory expedited review with respect to accelerating the timing of commercialization of such therapies, and the market potential for such therapies; the size of total addressable markets or the market opportunity for the Company's products and services, including for the PRISM Laser Therapy System; the Company's preclinical CRO facility, the IRRA*flow* Active Fluid Exchange System, and the Company's navigation technology; the anticipated adoption of the Company's products and services for use in the delivery of gene and cell therapies; the Company's ability to scale its operations, commercialization, and increase utilization of its products in neurosurgical centers; the Company's 4-Pillar Product pipeline; the Company's future looking 4-phase strategy; the Company's four and five pillar growth strategy for 2026 and beyond; the Company's expectations for revenues, market share, 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 pipeline 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 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 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 research and development programs and commercialization efforts; 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.

Biologics and Drug Delivery





Neuro Navigation and Robotics*



Ablation Therapy and Access

Neurocritical Management

*Robotic product is in development phase. Commercialization is subject to successful development, testing, and applicable regulatory clearance.

CLEARPOINT® NEURO

OUR COMPANY

We Enable Delivery of Both Drug and Device Therapies by Offering Precise Navigation to the Brain and Spine

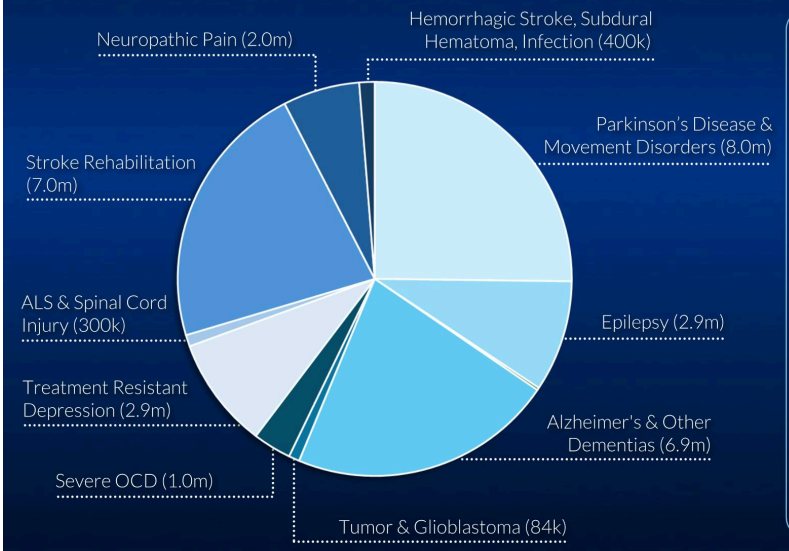
Our Unique Platform Includes Proven Clinical Products Used by Hospitals and Neurosurgeons, and Drug Development Services Used by BioPharma Partners

Our Company

The Future of Neuro Biologics and Drug Delivery **is Here Today**

More than **30 Million people** in the U.S. alone are estimated to suffer from **severe and debilitating neurological disorders.**

Neurological diseases cost Americans nearly $800 Billion annually. To reduce these costs, we must improve both the therapies and the access to care.



30 Million Patients Indicated in the U.S.

30 Million Patients
U.S. prevalence pool

<300k treated to date with minimally-invasive neurosurgery
<1% penetration

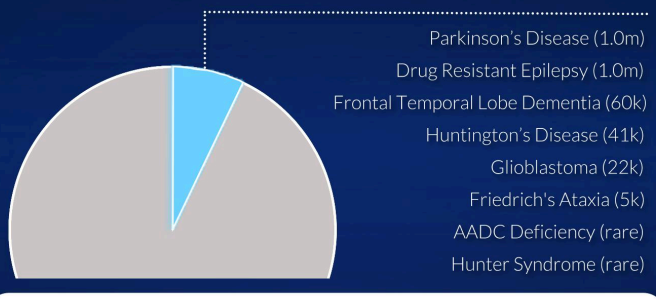
ClearPoint Neuro believes that biologics and drug delivery, including cell and gene therapies, will be the answer and that our minimally invasive tools will make these therapies accessible.

Prevalence estimates are based on publicly available sources. Categories shown are representative and may not be mutually exclusive.

Our Company

The Future of Neuro Biologics and Drug Delivery **is Here Today**

Of those 30 million patients, 2.1 million in the U.S. alone have disorders where a ClearPoint BioPharma Partner has already been accepted for FDA expedited review.



AskBio · Aspen Neuroscience · AVIADOBIO · BlueRock Therapeutics · kenai therapeutics · Neurona Therapeutics · PTC Therapeutics · REGENXBIO · SIREN Biotechnology · uniQure

ClearPoint Neuro has 60+ Active Pharma Partners, with 10+ programs accepted for FDA expedited review. In 2024, the first gene therapy delivered directly to the brain was approved.

FDA NEWS RELEASE

FDA Approves First Gene Therapy for Treatment of Aromatic L-amino Acid Decarboxylase Deficiency

For Immediate Release: November 14, 2024

The U.S. Food and Drug Administration approved Kebilidi (eladocagene exuparvovec-tneq), an adeno-associated virus vector-based gene therapy indicated for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency. Kebilidi is the first FDA-approved gene therapy for treatment of AADC deficiency.

Importantly, this gene therapy is labeled as a **combination product** with the ClearPoint SmartFlow Neuro Cannula

The FDA also authorized the SmartFlow Neuro Cannula, an infusion tube inserted into a target in the brain (parenchymal tissue), to deliver Kebilidi. The SmartFlow Neuro Cannula is currently the only FDA authorized device indicated for use to administer Kebilidi. The FDA granted authorization of the SmartFlow Neuro Cannula to ClearPoint Neuro, Inc.

Our Company

Our 4-Phase Strategy Positions ClearPoint for Decades of Growth

2010 – 2019

1 | DESIGN. DISCOVERY.

EXTEND OUR LEAD WITH A UNIQUE DRUG DELIVERY ECOSYSTEM DESIGNED FOR CELL AND GENE THERAPY

Our one-of-a-kind drug delivery platform including neuro navigation, predictive modeling, co-labeled delivery devices, infusion monitoring software and expert clinical case support has become the leading choice by biopharma developers

2020 – 2025

2 | FUNDED. FOUNDATION.

GROW OUR ACTIVE INSTALLED BASE OF 150+ LEADING GLOBAL INSTITUTIONS AND ADD PROCEDURAL CAPACITY

With more than $100m of capital invested over the past 5 years, our large commercial footprint, rapidly expanding installed base, high-capacity manufacturing, stress-tested quality system, global regulatory reach and expansive IP portfolio has given us a mature foundation on which to build

2026+

3 | FAST. FORWARD.

LEVERAGE OUR EXISTING PORTFOLIO TO PENETRATE A $1B EXISTING MARKET OPPORTUNITY TODAY

Our current products and pipeline, combined with our growing commercial reach will continue to compete in these four existing markets;

1) Biologics & drug delivery,
2) Neuro navigation & robotics,
3) Ablation therapy and access,
4) Neurocritical management,

Our next goal is to earn 20% share, generate $200m in annual revenue

2026+

4 | ESSENTIAL. EVERYWHERE.

BUILD A NEW $10B MARKET ALONGSIDE OUR 60+ BIOPHARMA PARTNERS AND DIVERSIFIED ACROSS 15+ INDICATIONS THAT INCLUDES DRUGS THAT ARE CO-LABELED WITH CLEARPOINT TECHNOLOGY

More than 10 of our partners have now been accepted for FDA expedited review and are leveraging our unique ecosystem, clinical trial experience, and proven global regulatory leadership

Our next goal is to treat just 1% of patients with these indications under expedited review, generate another $300m in annual revenue

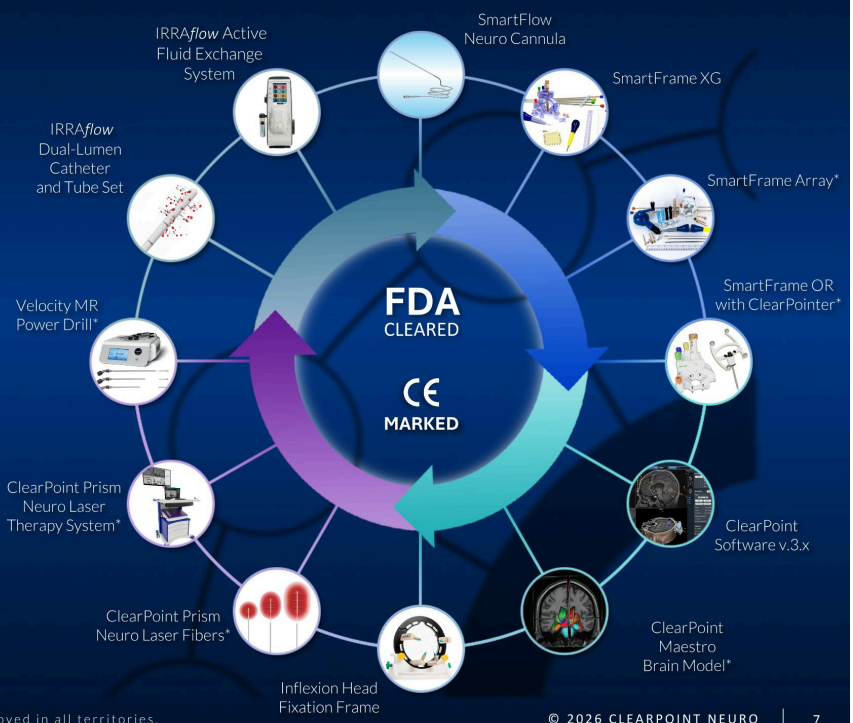
Design. Discovery.

This Unique ClearPoint Ecosystem Has Been Years in the Making

ClearPoint Neuro embraced the unmet need in neuro biologics and drug delivery and has invested more than $200m over the past 15 years to build a substantial headstart and leadership position.

This expansive platform has been used in more than 10,000 procedures to date and has regulatory approvals across 34 countries and counting.*

We are positioned to benefit from the expanded use of our delivery platform to include future cell and gene therapies, new DBS and BCI indications, second generation laser ablation therapy, and more advanced approaches to neurocritical fluid management.



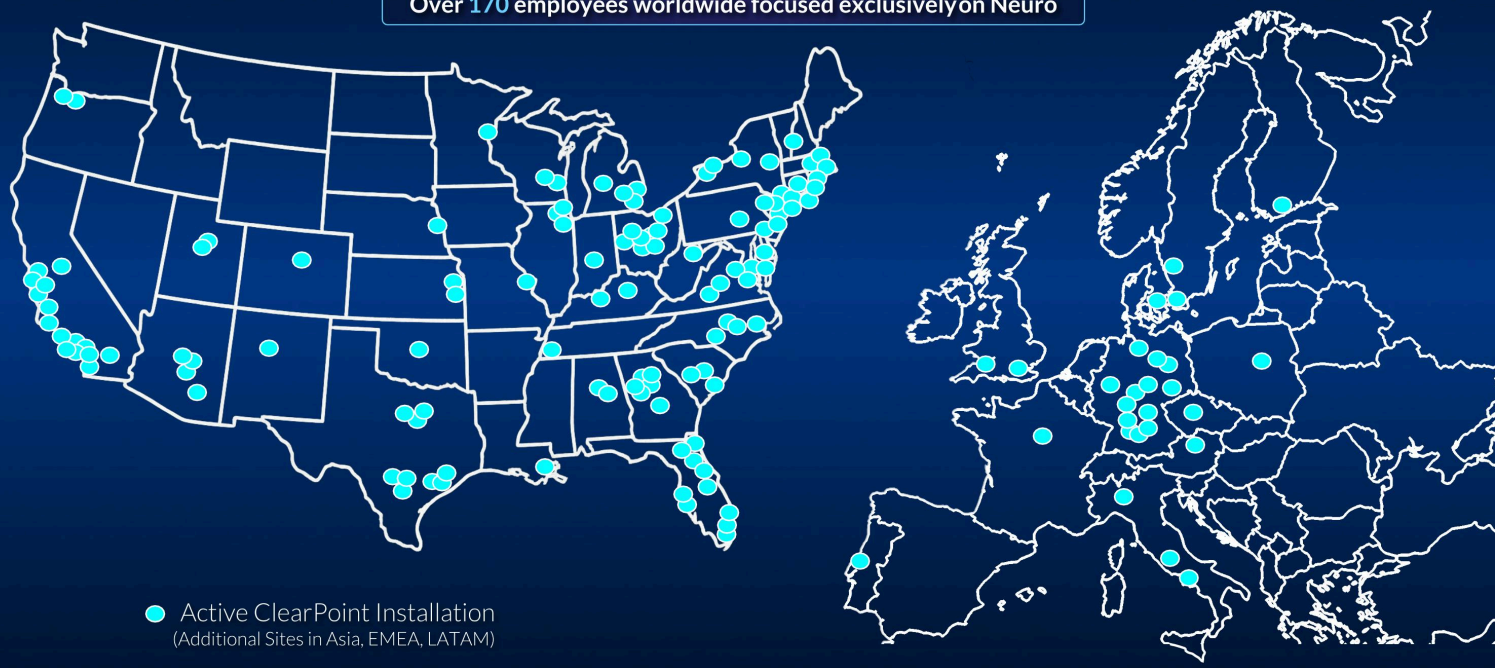
Data on file

*Not all products cleared or approved in all territories.

Funded. Foundation.

Our Installed Base Has Grown to More than 175 Active Global Centers

Over 170 employees worldwide focused exclusively on Neuro



Active ClearPoint Installation
(Additional Sites in Asia, EMEA, LATAM)

Funded. Foundation.

~50% of the Top Ranked Neurosurgery Programs use ClearPoint Technology

US News & World Report Best Neurology/Neurosurgery Hospitals 2025-2026
are recognized for excelling in the treatment of complex, high-risk neurological specialty cases.

Evaluation Criteria

45%	Outcomes
35%	Structure
12%	Process / Expert Opinion
5%	Patient Experience
3%	Public Transparency

- UCSF Medical Center
- New York-Presbyterian Hospital-Columbia and Cornell
- Rush University Medical Center
- Northwestern Memorial Hospital
- Johns Hopkins Hospital
- Hospital of University Pennsylvania
- UT Southwestern Medical Ctr
- Massachusetts General Hospital
- Stanford Health Hospital
- Cleveland Clinic
- UCLA Medical Center
- Houston Methodist Hospital
- Brigham & Women's Hospital
- Barnes-Jewish Hospital
- Cedars-Sinai Medical Center
- Mayo Clinic Arizona
- Mayo Clinic Florida
- Advent Health Orlando
- Keck Medical Center of USC
- Thomas Jefferson University
- UC Davis Medical Center
- UCSD Jacobs Medical Center
- University of Michigan
- Mount Sinai West
- University of Kansas
- Emory University Hospital
- Hackensack Meridian Health
- Corewell Beaumont University
- Yale University Hospital
- Ohio State University – Wexner
- University of Alabama at Birmingham
- University of Minnesota
- Barrow Institute
- Duke University Hospital
- University of Wisconsin, Madison
- Tampa General Hospital
- UC Irvine Medical Center
- Baptist Health Miami Hospital
- Ochsner Medical Center
- Penn State Health Milton
- Inova Fairfax Hospital
- Oregon Health & Science University
- University of Colorado Aurora
- Henry Ford Health
- University of North Carolina
- Froedtert Hospital
- Ohio Health Riverside
- University of Utah
- Georgetown University

https://health.usnews.com/best-hospitals/rankings/neurology-and-neurosurgery - Posted July 29, 2025
Methodology components and weights summarized from publicly described Best Hospitals specialty ranking methodology (2025–2026 cycle; specialty-specific adjustments may apply).

Funded. Foundation.

Stress-Tested QMS and Operations

We have invested in our Research & Development, Quality and Manufacturing infrastructure to build confidence for both hospitals and biopharma partners

We bring **medical device expertise and regulatory combination product acumen** to pharmaceutical companies

ClearPoint Neuro assets available to our partners:

- HQ & training facility in Solana Beach, CA
- Advanced Research Laboratory in Torrey Pines, CA
- R&D and manufacturing facility in Carlsbad, CA
- ISO 13485 / MDSAP / EU MDR certified QMS
- Proven audit history with pharma partners, FDA and global regulatory body inspections

Funded. Foundation.

Growth Continues Today While We Prepare for Commercial Drug Approvals

HEADQUARTERS
Solana Beach, CA

R&D, MANUFACTURING
Carlsbad, CA

ADVANCED RESEARCH LABORATORIES
Torrey Pines, CA

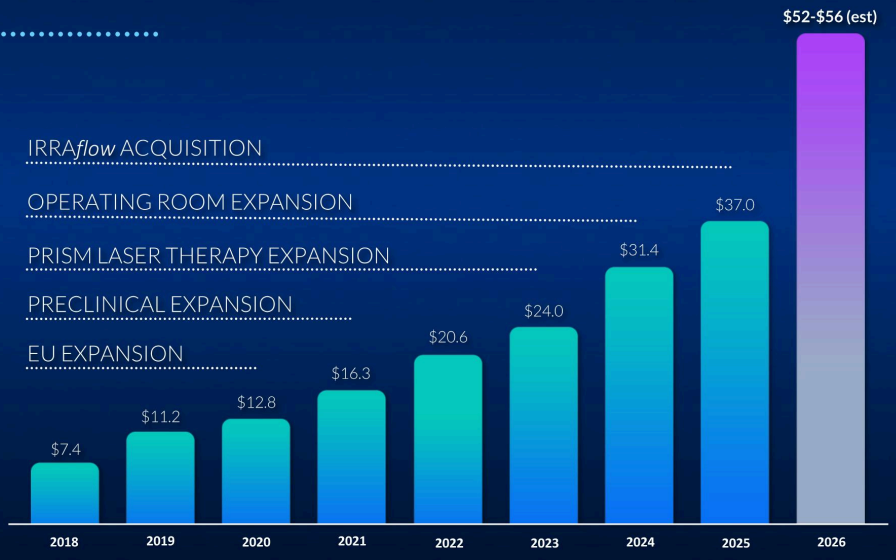
2025 REVENUE
$37.0m[A]

GROSS MARGIN
62%[B,C]

PATENTS ISSUED
130+[D]

CASH & CASH EQUIVALENTS
$35.6m[B]

EMPLOYEES
170+



*All Annual Totals in Millions

(A) For the year ended December 31, 2025
(B) Unaudited, as of, and for the quarter ended March 31, 2026
(C) For the Trailing Twelve Months (TTM)
(D) Including owned and licensed patents

Funded. Foundation.

Experienced Leadership in Place

EXECUTIVE LEADERSHIP TEAM

Proven industry operators with decades of experience in medical devices, biopharmaceuticals, and clinical research.

Joe Burnett
President & Chief Executive Officer

Danilo D'Alessandro
Chief Financial Officer

Jeremy Stigall
Chief Business Officer

Mazin Sabra
Chief Operating Officer

Paul Larson, MD
Chief Medical Officer

Ellisa Cholapranee
General Counsel

Megan Faulkenberry
Senior Vice President of Quality

Rob Korn
Senior Vice President of Sales

Mary McNamara-Cullinane
Senior Vice President of Regulatory Affairs

Tim Orr
Vice President of Software Development

Lyubomir Zagorchev, PhD
Vice President of Clinical Science & Applications

Ernesto Salegio, PhD
Vice President of Translational & Pre-Clinical Research

Fast. Forward.

Our 4-Pillar Growth Strategy

FAST. FORWARD.

Our **Fast. Forward.** 4-Pillar Growth Strategy is to **Win 20% of an Existing $1.0B Global Market Opportunity, Generate $200m in Annual Revenue,** and to **Achieve Cash Breakeven and Profitability Along the Way**

Collective $1.0B Existing Market Opportunity Today

Increasing Global Scale with Clearances in 34 Countries Worldwide*

*Not all products cleared or approved in all territories.

Fast. Forward.

Pillar 1: Pre-Commercial Biologics & Drug Delivery

CLEARPOINT ADVANCED LABORATORIES
Pre-Commercial Biologics & Drug Delivery

$300m+
Existing Market

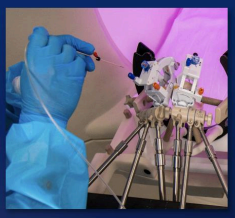
ClearPoint Neuro currently offers a boutique, neuro-focused CRO complete with device co-development services, pre-clinical testing capabilities, and validated clinical trial products to support and de-risk our more than 60 active pharma partners and generate revenue before reaching the drug commercialization stage.

Combining Services & Technology

Benchtop Testing

- Device compatibility testing
- Custom device development
- Delivery system validation
- Performance assessment

Preclinical Studies

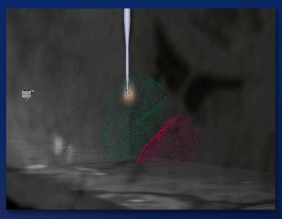


- Running preclinical studies
- Surgical planning & strategy
- Dosing & surgical expertise
- Post-procedure analysis

Hardware

Leverage Both Commercial and In-Development Delivery and Navigation Tools

Software



SmartFlow Software & Biophysical Modeling in Collaboration with NE Scientific

Fast. Forward.

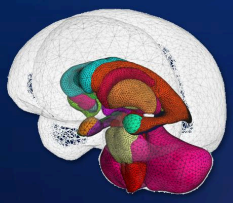
Pillar 2: Neuro Navigation & Robotics

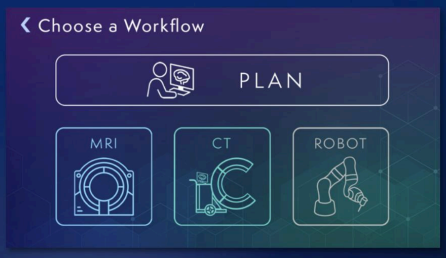
CLEARPOINT NAVIGATION SYSTEM
Neurosurgery Navigation & Robotics

$125m+
Existing Market

ClearPoint will provide unmatched flexibility by having a single pre-planning software offering several workflows deployed via either MRI, iCT and eventually Robotics. This strategy balances the consistency of delivery that biopharma partners desire with the optionality and adaptability for surgeons to choose their desired technique.

Pre-Planning & Navigation Software

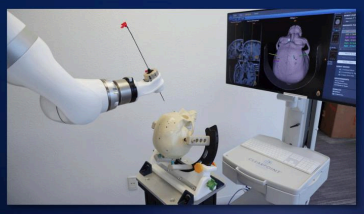




Select Optimal Delivery Method

SmartFrame XG and Accessory Kit

SmartFrame OR and ClearPointer Optical Wand



ClearPoint Robotic Platform using the KUKA LBR Robotic Arm

*Robotic product is in development phase. Commercialization is subject to successful development, testing, and applicable regulatory clearance.

Fast. Forward.

Pillar 3: Laser Therapy & Access

CLEARPOINT PRISM NEURO LASER THERAPY SYSTEM

Laser Ablation Therapy & Access

$75m+ Existing Market

ClearPoint Prism is a mobile laser therapy system featuring innovative non-cooled applicator technology that simplifies setup, reduces power and potentially ablation time, and enables efficient workflows. Surgeons can capitalize on workflow efficiency and total system accuracy when Prism is combined with ClearPoint Navigation.

The Velocity^{ALPHA} MR High Speed Surgical Drill System is a versatile cutter system designed to reduce procedure times in both the MRI suite and the operating room.

CLEARPOINT PRISM NEURO LASER THERAPY SYSTEM

With Optional ClearPoint Navigation Synergies

One Room

One System

One Team

Velocity^{ALPHA} MRI Conditional Power Drill

A Versatile Power Solution for SmartFrame in the MRI and OR

adeor MEDICAL

Fast. Forward.

Pillar 4: Neurocritical Management

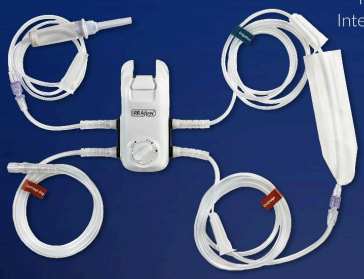
IRRA*flow*®
Neurocritical Care & Active CSF Exchange

$500m+
Existing Market

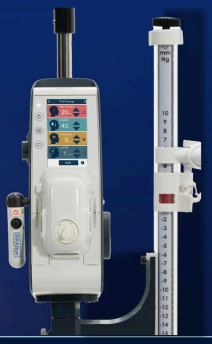
ClearPoint's recent acquisition of IRRAS expands the portfolio with a unique and disruptive solution for neurocritical care and intracranial fluid management. IRRA*flow* enables active irrigation and controlled drainage of hemorrhage, toxins, and clots to therapeutically treat intracranial pathologies.

IRRA*flow*® Active Fluid Exchange System Components

IRRA*flow* Dual-Lumen Catheter



IRRA*flow* Tube Set & Intelligent Digital Cassette



IRRA*flow* Control Unit & Drainage Collection Bag

Fast. Forward.

Clear and Continued Investment in ClearPoint's 4-Pillar Product Pipeline

	1H 2026	2H 2026	1H 2027	2H 2027	2028+
1 CLEARPOINT ADVANCED LABORATORIES	• CAL Facility Operational • Radiopharma Formulation	• MRI/CT Imaging Live • GLP Study Capable • Cell Culture Capability	• PET/SPECT Imaging Live • Radiolabeling Active • Histopathology Active	• Bioanalytic Lab Active • Pathology Lab Active • Hot Cell F-18 Radiochemistry	• Translational Models for tumor, stroke and spinal cord injury
2 CLEARPOINT NAVIGATION SYSTEM	• CE Mark for 3.x Software • Global Installed Base with OR iCT capability	• SmartFrame Accessory Kit • Pre-Clinical Robotic System Active at the CAL	• Harmony 1.0 Software • Sub-Nuclei Segmentation	• SmartFrame Duet • Maestro CT	• Harmony 2.0 Software • Robotic System • DBS/BCI Area of Activation • Non-Rigid Fusion
3 CLEARPOINT PRISM NEURO LASER THERAPY SYSTEM	• 1.5T Compatibility	• Velocity MRI Power Drill	• Philips MRI Compatibility • Interoperable 3D Damage Model	• CE Mark Prism System • 3D Thermal Modeling Study Initiated	• Predictive Ablation Software • Spine LITT Data Readout
4 IRRAflow®	• Shoreline Software • Cranial Access Bolt	• IRRA*flow* Dart • Cranial Access Bolt Kit	• ARCH RCT Data Readout • Next Gen IRRA*flow* Catheter	• Subdural Indication • IRRA*flow* Rapid Evacuation System	• VASH Trial Data Readout • CRYSTAL Registry Readout • Bedside Navigation System

Our **Fast. Forward.** 4-Pillar Growth Strategy is to **Win 20% of an Existing $1.0B Global Market Opportunity, Generate $200m in Annual Revenue,** and to **Achieve Cash Breakeven and Profitability Along the Way**

4 NEUROCRITICAL CARE & ACTIVE CSF EXCHANGE
Expand Existing Portfolio Into Multiple New Indications
Launch Shoreline Software, Cranial Bolt, IRRA*flow* Dart, Next-Gen IRRA*flow* Catheter and a Subdural Hemorrhage Catheter Kit

3 LASER ABLATION THERAPY & ACCESS
Add Ablation Coverage & AI Predictive Thermal Modeling Software
Launch MRI Conditional Power Drill for Faster Procedure Times

2 NEUROSURGERY NAVIGATION AND ROBOTICS
Expand into the Operating Room w/ 3.0 Software, ClearPoint Duet, and Robotics
Launch Maestro CT, sub-nuclei segmentation, Non-Rigid Fusion, Area-of-Activation Harmony Software

1 PRE-COMMERCIAL BIOLOGICS & DRUG DELIVERY
Expand Neuro Pre-Clinical CRO Services Portfolio and Capacity including larger GLP Study Capability
Expand Partnerships to Include Co-Development, Commercial Pricing, Drug Clinical Milestones & Royalty Based Agreements
Execute on Development Pipeline for Drug Infusion Monitoring/Modeling, Cell Therapy Actuation, Indwelling Catheters and Spinal Routes of Administration

2026+

Essential. Everywhere.

What Does it Mean to be **Essential** to Future of Cell and Gene Therapy?

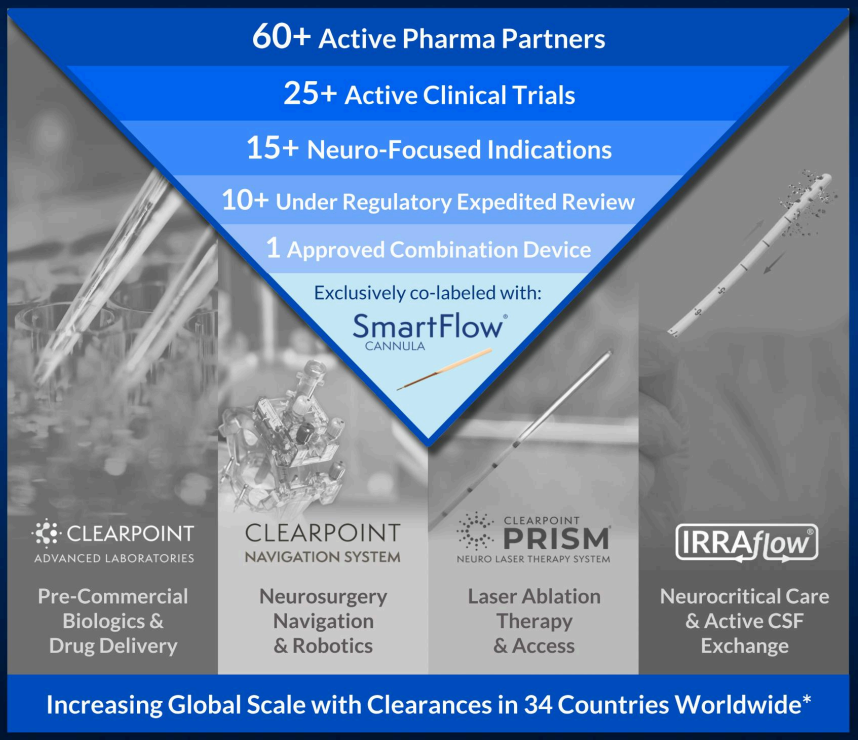
ESSENTIAL. EVERYWHERE.

It starts by being **unique**.

Our **Essential. Everywhere.** Strategy is to **build a new market from the ground up** where our unique ecosystem plays an essential role and enables 20,000 annual Cell & Gene Therapy procedures.

Our Goal is to create the capacity for 20,000 CGT patients per year and generate an additional $300m annually.

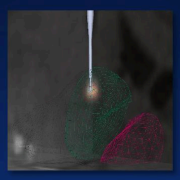
*Not all products cleared or approved in all territories.



Increasing Global Scale with Clearances in 34 Countries Worldwide*

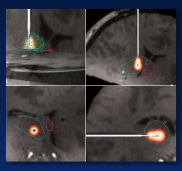
Essential. Everywhere.

Our Unique Ecosystem Will Play An Essential Role for Cell and Gene Therapy



A.I. Derived Patient and Tissue Specific Segmentation

+



Therapy and Patient Specific Biophysics Modeling Tools

+

Comprehensive Pre-Planning Navigation Software Modules

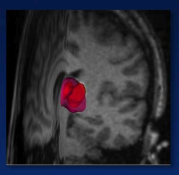
+

Flexible Options for Surgeon Selected Navigation Including Frames, Robotics

+

Multiple Biologic Specific & Co-Labeled Routes-of-Administration

+



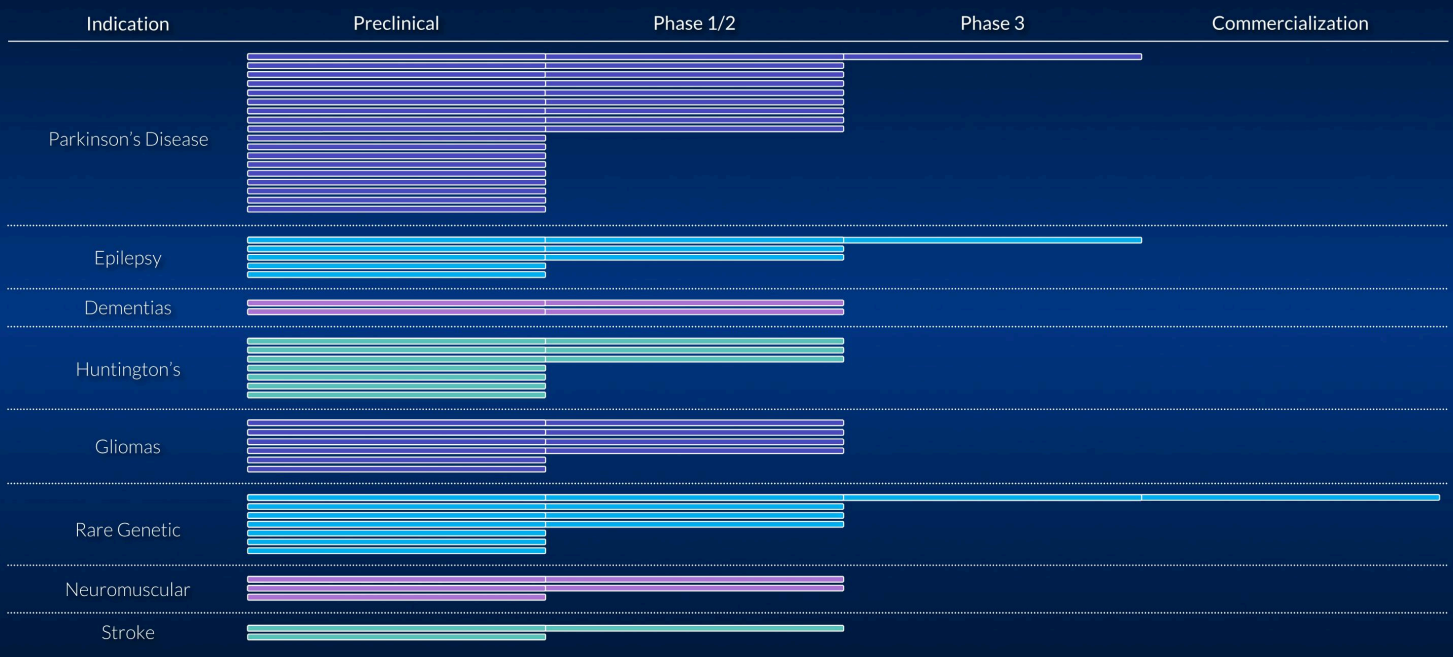
Confirmatory Volumetric Dosing Data for Quality of Delivery Documentation

Every Step Fully Supported by a Team of 30+ Expert Field-Based Clinical Specialists

All products in development phase. Commercialization is subject to successful development, testing, and applicable regulatory clearance.

Essential. Everywhere.

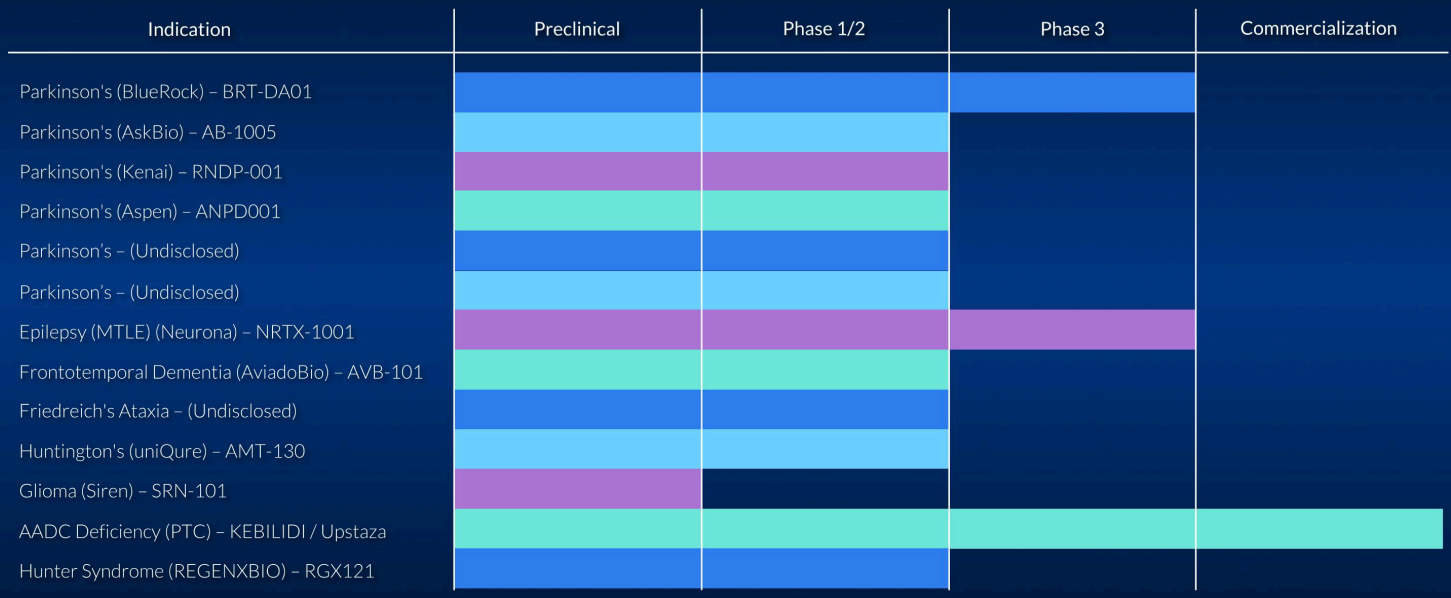
ClearPoint Neuro Has 60+ Active Pharma Partners, 25+ Active Clinical Trials



…and more than 15 additional programs that are undisclosed and in preclinical development.

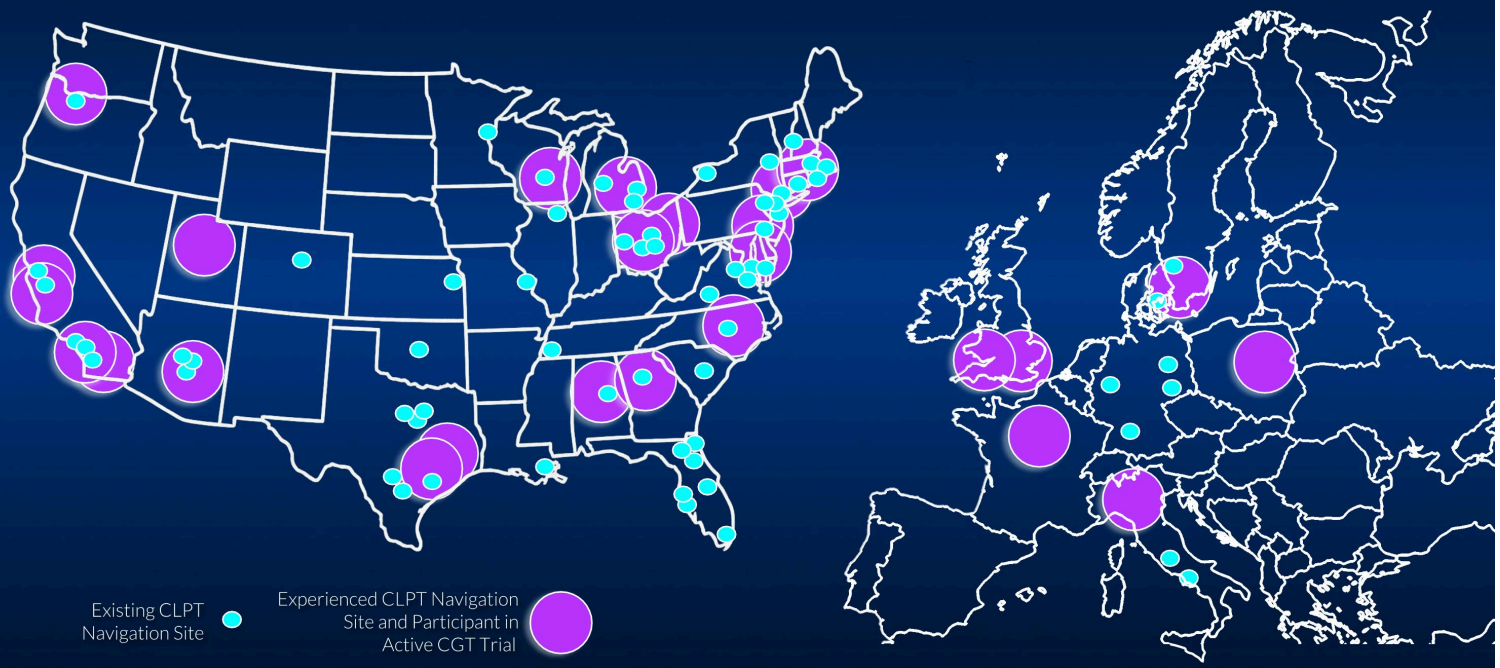
Essential. Everywhere.

10+ Programs Are Already Under FDA Expedited Review and Enrolling



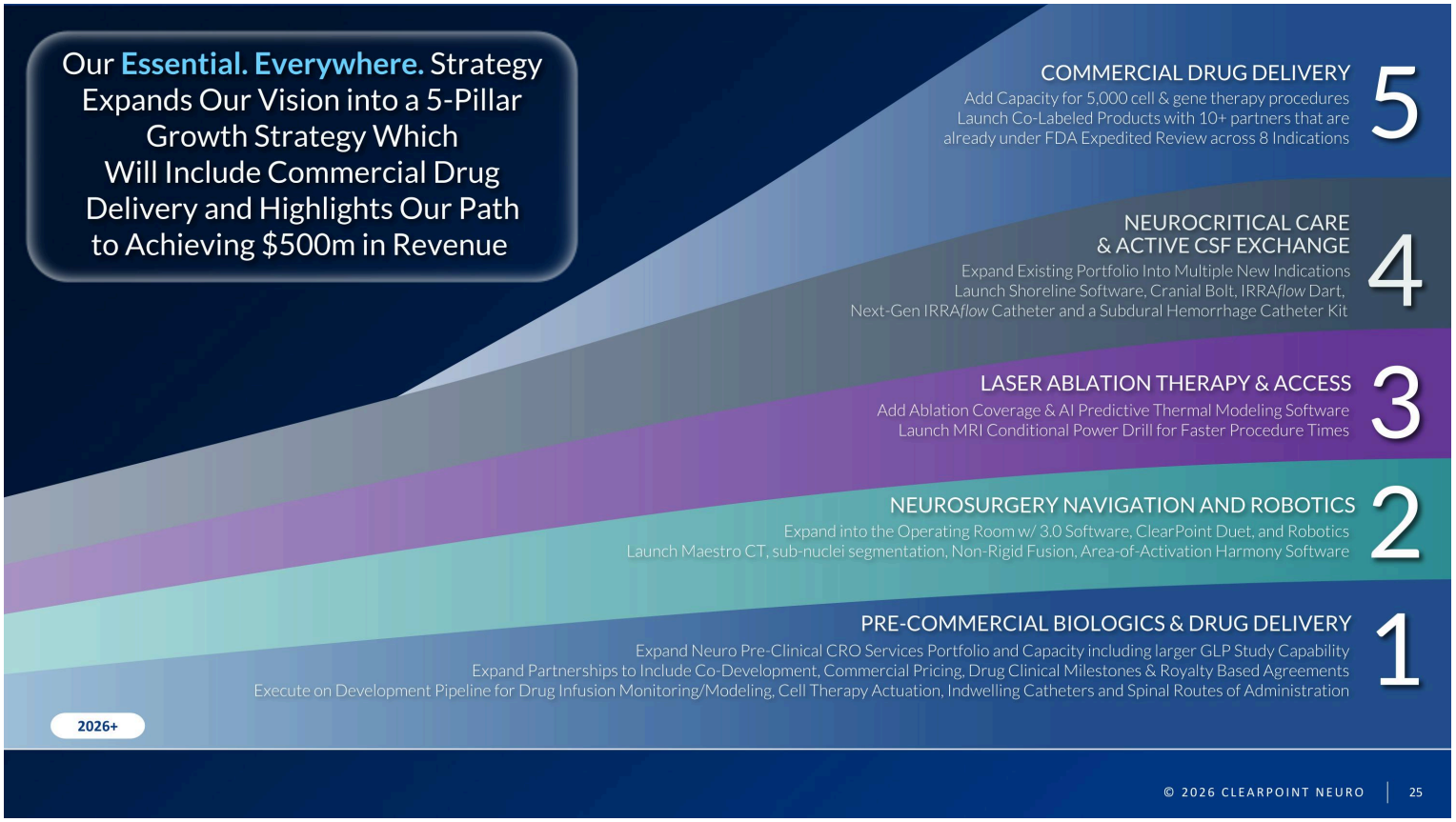
Essential. Everywhere.

Building Surgical Experience and Capacity to Prepare for Drug Commercialization



Existing CLPT Navigation Site

Experienced CLPT Navigation Site and Participant in Active CGT Trial



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