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): August 03, 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 August 3, 2026, ClearPoint Neuro, Inc. (the "Company") issued a press release announcing its financial results for the second fiscal quarter ended June 30, 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 August 3, 2026, the Company posted an updated investor presentation to its website at https://ir.clearpointneuro.com/news-events/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 August 3, 2026
Exhibit 99.2	Investor Presentation dated August 3, 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: August 3, 2026

By: /s/ Danilo D'Alessandro

Danilo D'Alessandro
Chief Financial Officer

Exhibit 99.1

ClearPoint Neuro Reports Second Quarter 2026 Results

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

SOLANA BEACH, CA, 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.

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)

	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


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

FORWARD-LOOKING STATEMENTS

Statements in this presentation and discussion concerning ClearPoint Neuro's (the "Company's") plans, growth, and strategies may include forward-looking statements within the meaning 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 System, Focused Ultrasound System, cell and gene therapy delivery devices and routes of administration, software modeling and navigation tools, and preclinical service capabilities; the anticipated timing, scope, cost and completion of the build-out, equipping, validation and qualification of the ClearPoint Advanced Laboratories facility, and the anticipated timing, performance and revenue contribution of preclinical, GLP and other services to be provided there; 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, including its revised revenue guidance for the year ending December 31, 2026, 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.

RISK FACTORS

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 than 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 Partners' 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; the Company's ability to recruit, hire, train and retain qualified clinical specialists and other personnel on the timeline and in the geographies necessary to support its partners' clinical and potential commercial programs, and the costs of doing so; risks inherent in the research, development, and regulatory approval of the Company's new pipeline products and the Company's ability to continue funding of such research, development, and regulatory approval; 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; risks relating to the Company's leased laboratory facility, including delays or cost overruns in construction, build-out, equipment delivery, installation, validation or qualification, the condition and habitability of the leased premises, and the risk that GLP or other service capabilities are not established, or do not generate revenue, when expected or at all; risks relating to the Company's collaborations with academic and other third-party institutions, including with respect to focused ultrasound, such as the risk that such collaborations do not produce commercially viable technology, that the parties disagree as to the terms of the collaboration, or that such arrangements are terminated or modified; 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 and resources in connection with the integration of IRRAS; 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 risk that the Company does not achieve its revenue guidance or other financial expectations for 2026 or future periods; 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.

THIRD PARTY INFORMATION

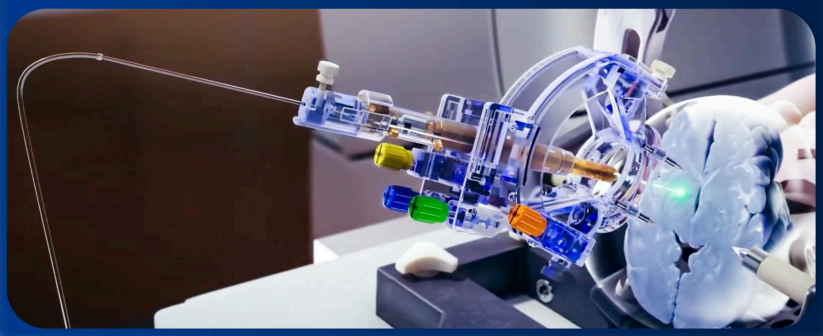
This presentation contains information concerning the Company's biotech Partners and their product candidates and clinical and regulatory programs, as well as market, industry, prevalence, cost and ranking data attributed to third parties. That information is derived from the Partners' own public disclosures and from other publicly available sources. The Company has not independently verified such information, does not adopt or endorse it, and undertakes no obligation to update it. Statements regarding the Partners' plans, expectations, submissions or timelines are the statements of those third parties and not of the Company.

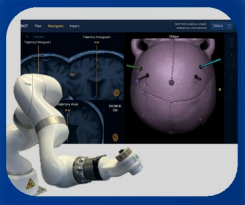
PRODUCT STATUS

Certain products and product features described in this presentation are in development and are not cleared or approved for commercial distribution in any jurisdiction. Products that are cleared or approved are not cleared or approved in all territories or for all indications described.

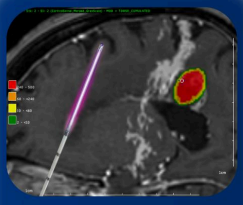
For a detailed description of the Company's risks and uncertainties, you are encouraged to review its documents filed with the SEC including the Company's recent filings on Form 8-K, Form 10-K and Form 10-Q. You are cautioned not to place undue reliance on forward-looking statements, which speak only 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 Care 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

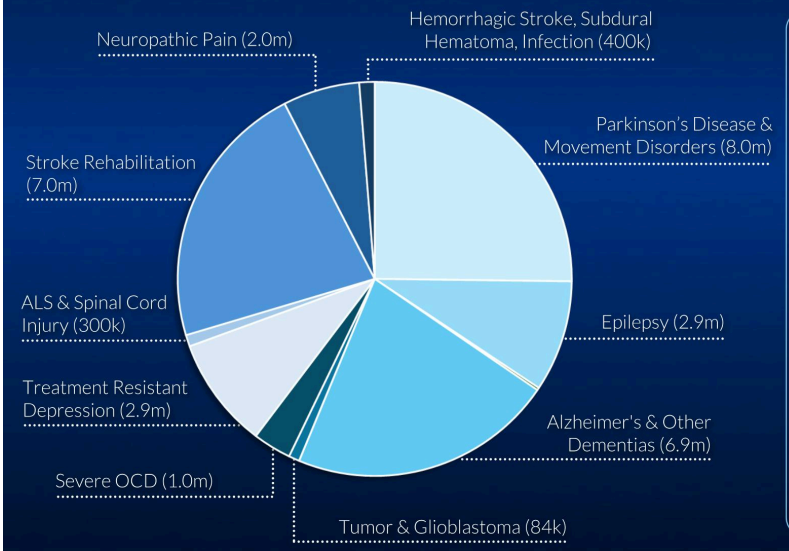
Our Unique Platform Includes Proven Clinical Products Used by Hospitals and Neurosurgeons, and Drug Development Services Used by BioPharma Partners

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

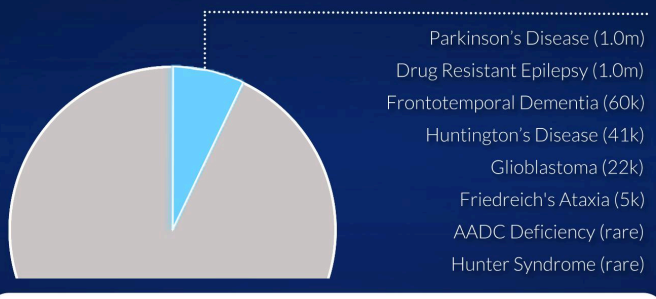
<300k treated to date with minimally-invasive neurosurgery
<1% penetration

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.

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

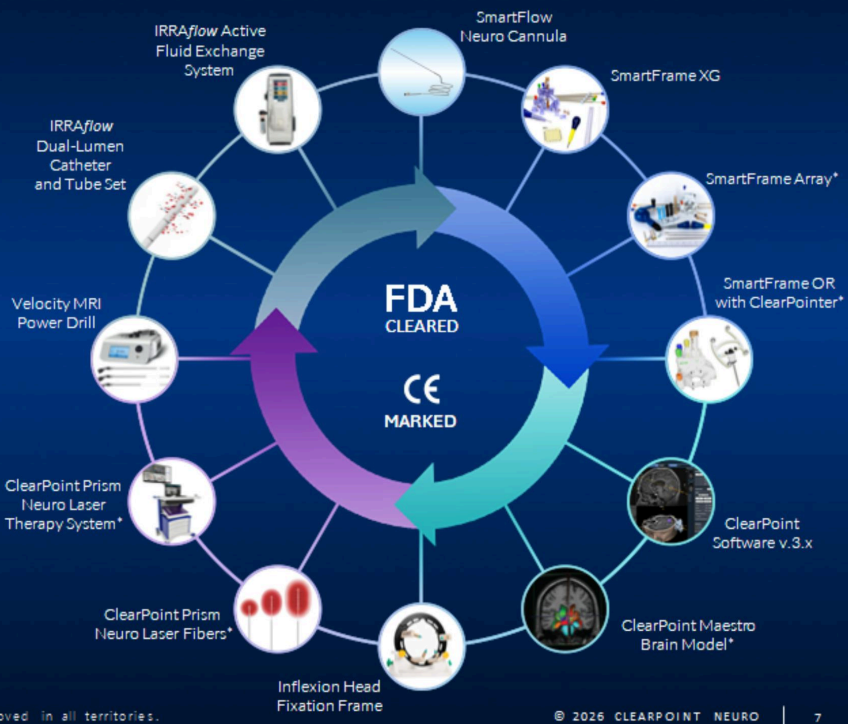
Design. Discovery.

The 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.



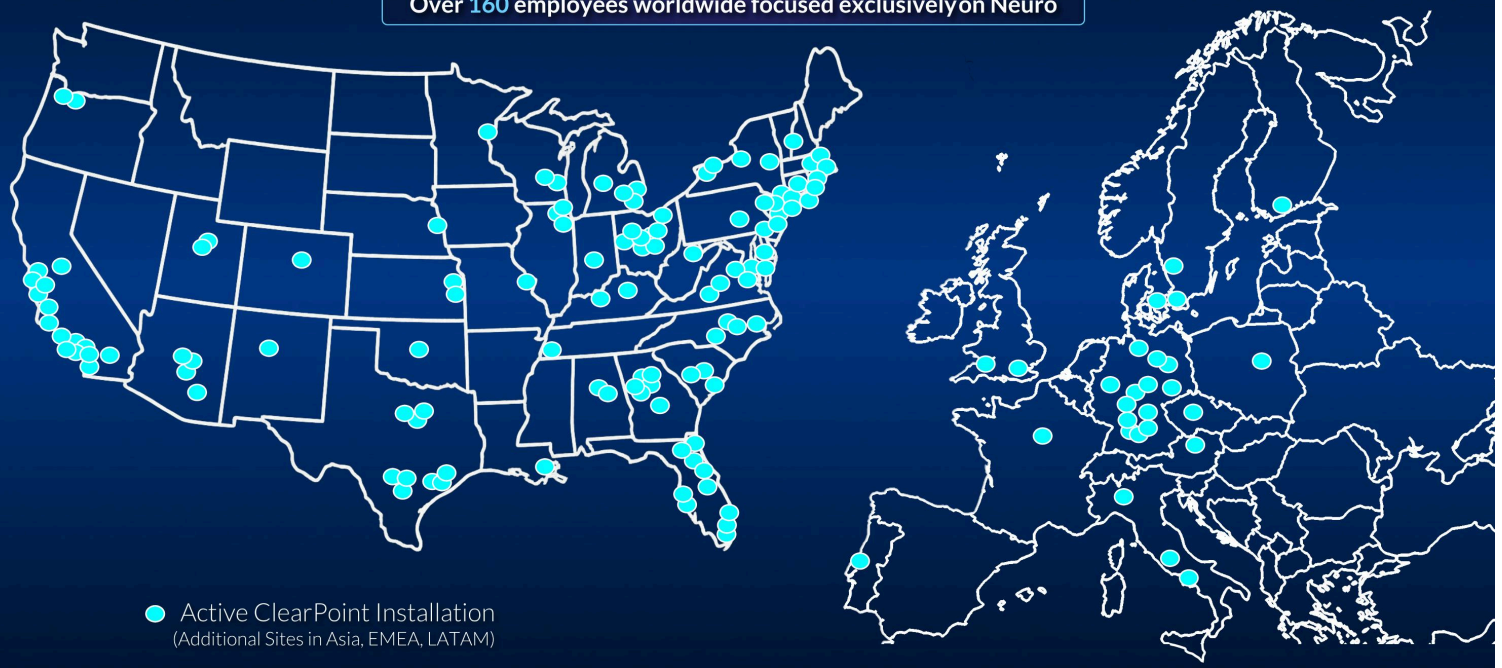
Data on file

*Not all products cleared or approved in all territories.

Funded. Foundation.

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

Over 160 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)

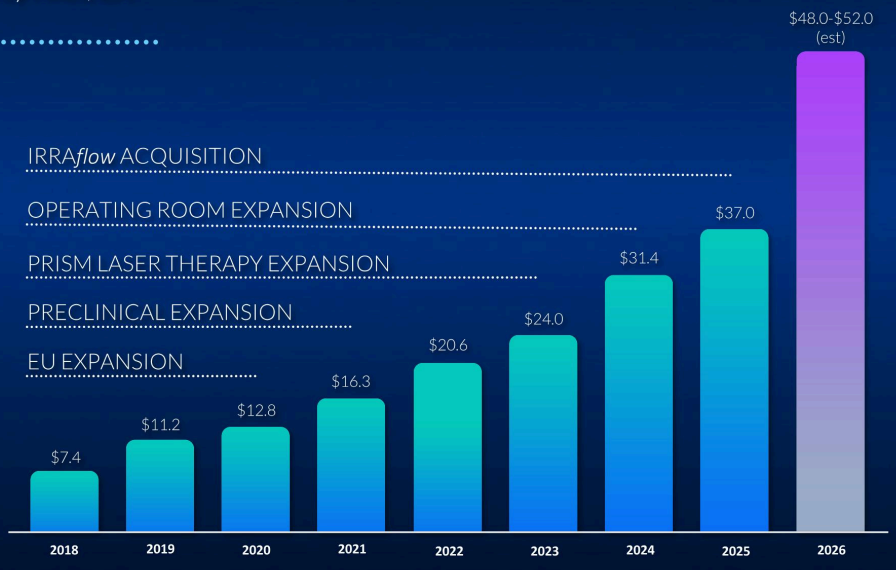
GROSS MARGIN
63% (B)

PATENTS ISSUED
130+ (C)

CASH & CASH EQUIVALENTS
$29.4m (D)

EMPLOYEES
160+

(A) For the year ended December 31, 2025
(B) Unaudited, for the trailing twelve months ended June 30, 2026
(C) Including owned and licensed patents
(D) Unaudited, as of, and for the quarter ended June 30, 2026



*All Annual Totals in Millions

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
Senior 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

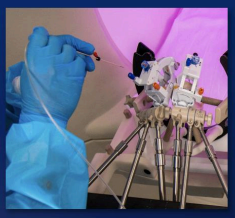
ClearPoint Neuro currently offers a boutique, neuro-focused CRO complete with device co-development services, pre-clinical testing capabilities, and validated clinical trial products to support and de-risk our more than 60 active pharma partners, and generate revenue before reaching the drug commercialization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

Combining Services & Technology

Benchtop Testing

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

Preclinical Studies

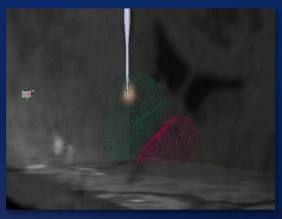


- Running preclinical studies
- Surgical planning & strategy
- Dosing & surgical expertise
- Post-procedure analysis

Hardware

Leverage Both Commercial and In-Development Delivery and Navigation Tools

Software



SmartFlow Software & Biophysical Modeling in Collaboration with NE Scientific

Fast. Forward.

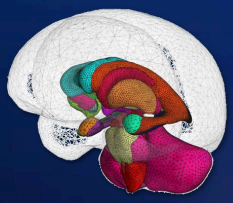
Pillar 2: Neuro Navigation & Robotics

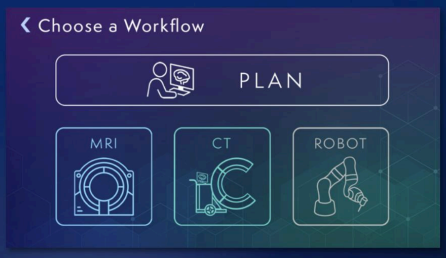
CLEARPOINT NAVIGATION SYSTEM
Neurosurgery Navigation & Robotics

$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
with iCT or MRI-guidance

ClearPoint Robotic Platform using the KUKA LBR Robotic Arm

Focused Ultrasound

*Focused Ultrasound and 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

Fast. Forward.

Pillar 4: Neurocritical Management

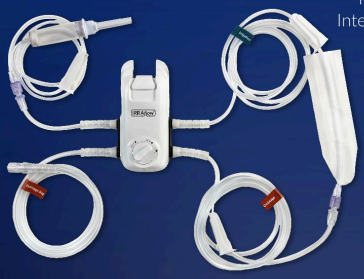
IRRA*flow*®
Neurocritical Care & Active CSF Exchange

$500m+
Existing Market

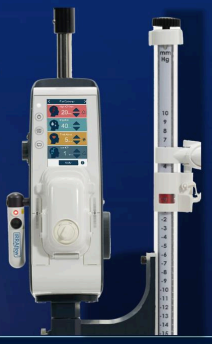
ClearPoint's recent acquisition of IRRAS expands the portfolio with a unique and disruptive solution for neurocritical care and intracranial fluid management. IRRA*flow* enables active irrigation and controlled drainage of hemorrhage, toxins, and clots to therapeutically treat intracranial pathologies.

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

	2026	2027	2028+
1 CLEARPOINT ADVANCED LABORATORIES	✓ Radiopharma Formulation ✓ MRI/CT Imaging Capable ✓ Cell Culture Capability ✓ Radiolabeling Active • Histopathology Active	• GLP Study Capable • Pre-clinical Z-Axis Bolt • Pre-Clinical Focused Ultrasound • PET/SPECT Imaging Live • MRI/CT Installed	• 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 iCT Upgrade • Publication of iCT Real-World Data	• SmartFrame Accessory Kit • Pre-Clinical Robotic System at The CAL • Harmony 1.0 Software • Sub-Nuclei Segmentation	• Harmony 2.0 Software • Robotic System • SmartFrame Duet • DBS/BCI Area of Activation • Non-Rigid Fusion • CM Segmentation
3 CLEARPOINT PRISM NEURO LASER THERAPY SYSTEM	✓ 1.5T Compatibility ✓ Velocity MRI Power Drill • ThermoGuide 3D Damage Model Export	• Harmony 1.0 Therapy Visualization • Philips MRI Compatibility	• CE Mark Prism System • Predictive Ablation Software • 3D Thermal Modeling Study Initiated • Spine LiTT Data Readout
4 IRRAflow®	✓ Next Gen Intelligent Cassette	• Cranial Access Bolt Kit • IRRA*flow* Dart • Shoreline Software • ARCH RCT Data Readout & Publication • IRRA*flow* 3.0 CE Mark (OUS)	• Subdural Indication • Rapid Evacuation System • Next Gen Catheter • 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**

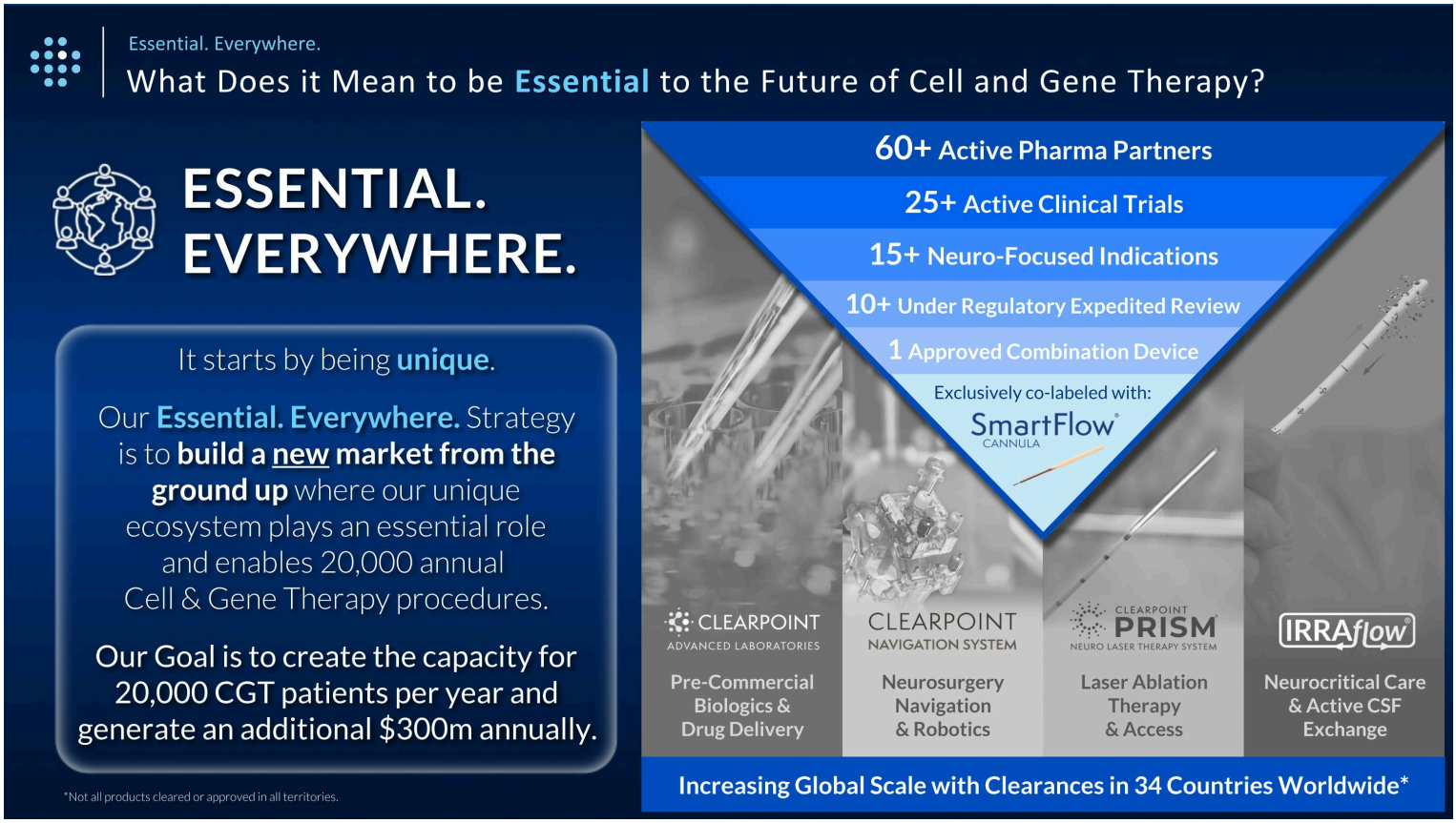
4 NEUROCRITICAL CARE & ACTIVE CSF EXCHANGE
Expand Existing Portfolio Into Multiple New Indications
Launch Shoreline Software, Cranial Bolt, IRRA*flow* Dart, Next-Gen IRRA*flow* Catheter and a Subdural Hemorrhage Catheter Kit

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

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

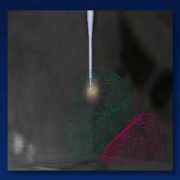
1 PRE-COMMERCIAL BIOLOGICS & DRUG DELIVERY
Expand Neuro Pre-Clinical CRO Services Portfolio and Capacity including larger GLP Study Capability
Expand Partnerships to Include Co-Development, Commercial Pricing, Drug Clinical Milestones & Royalty Based Agreements
Execute on Development Pipeline for Drug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

2026+


Essential. Everywhere.
What Does it Mean to be Essential to the 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.
60+ Active Pharma Partners
25+ Active Clinical Trials
15+ Neuro-Focused Indications
10+ Under Regulatory Expedited Review
1 Approved Combination Device
Exclusively co-labeled with:
SmartFlow
CANNULA
CLEARPOINT
ADVANCED LABORATORIES
Pre-Commercial Biologics & Drug Delivery
CLEARPOINT
NAVIGATION SYSTEM
Neurosurgery Navigation & Robotics
CLEARPOINT
PRISM
NEURO LASER THERAPY SYSTEM
Laser Ablation Therapy & Access
IRRAflow
Neurocritical Care & Active CSF Exchange
Increasing Global Scale with Clearances in 34 Countries Worldwide*

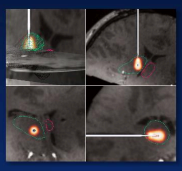
Essential. Everywhere.

Our Unique Ecosystem Will Play An Essential Role in 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

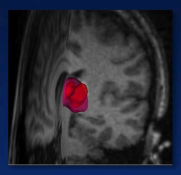
+

Flexible Options for Surgeon Selected Navigation Including Frames, Robotics

+

Multiple Biologic Specific & Co-Labeled Routes-of-Administration, including Focused Ultrasound

+



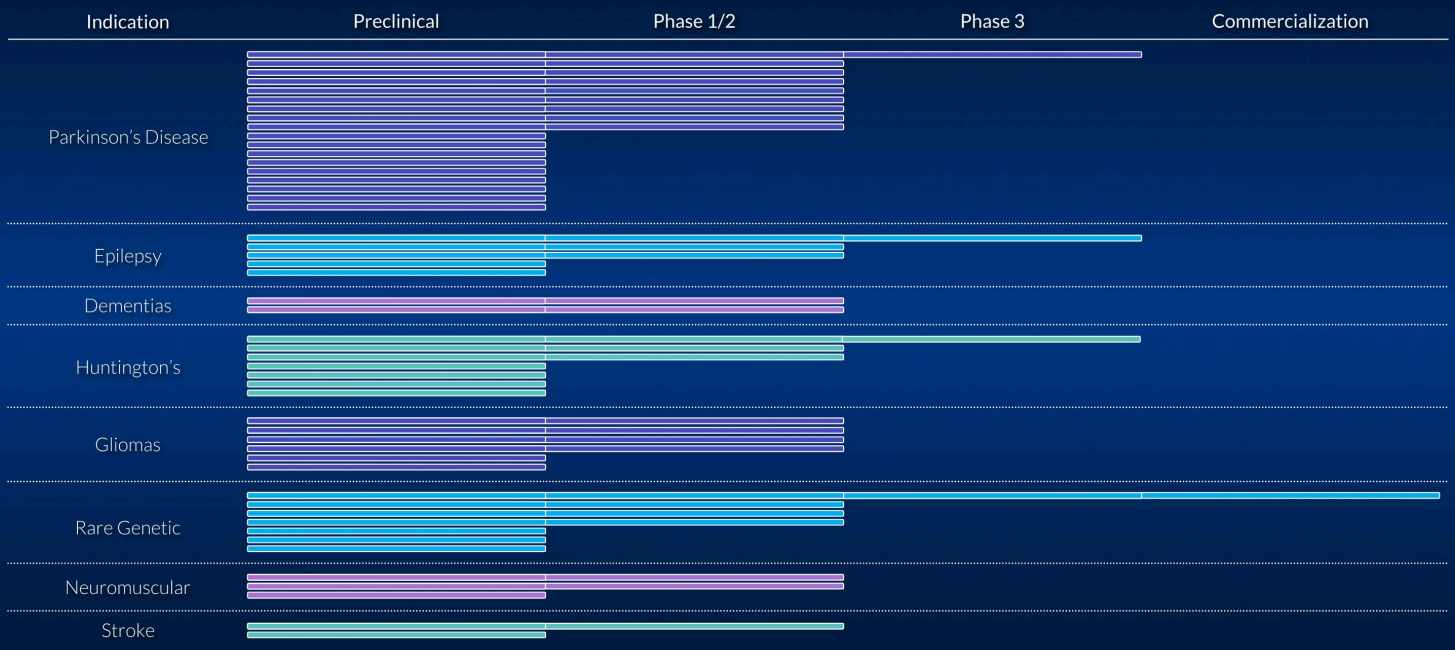
Confirmatory Volumetric Dosing Data for Quality of Delivery Documentation

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

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

Essential. Everywhere.

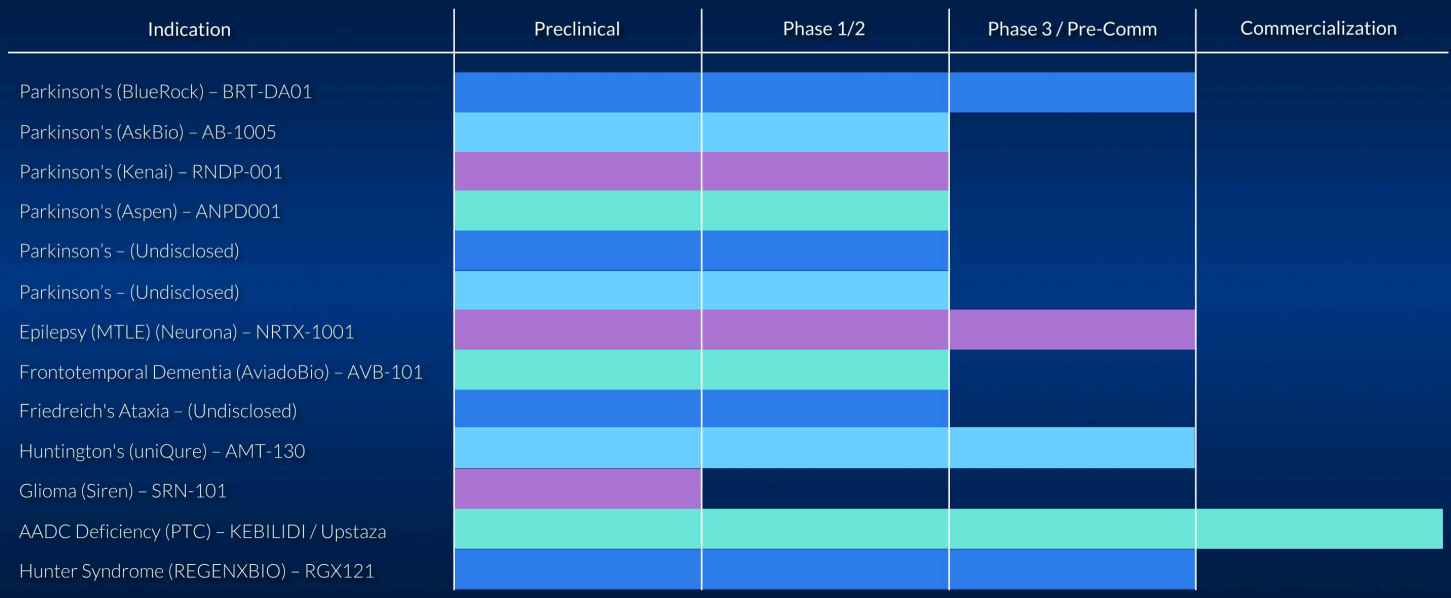
ClearPoint Neuro Has 60+ Active Pharma Partners, 25+ Active Clinical Trials



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

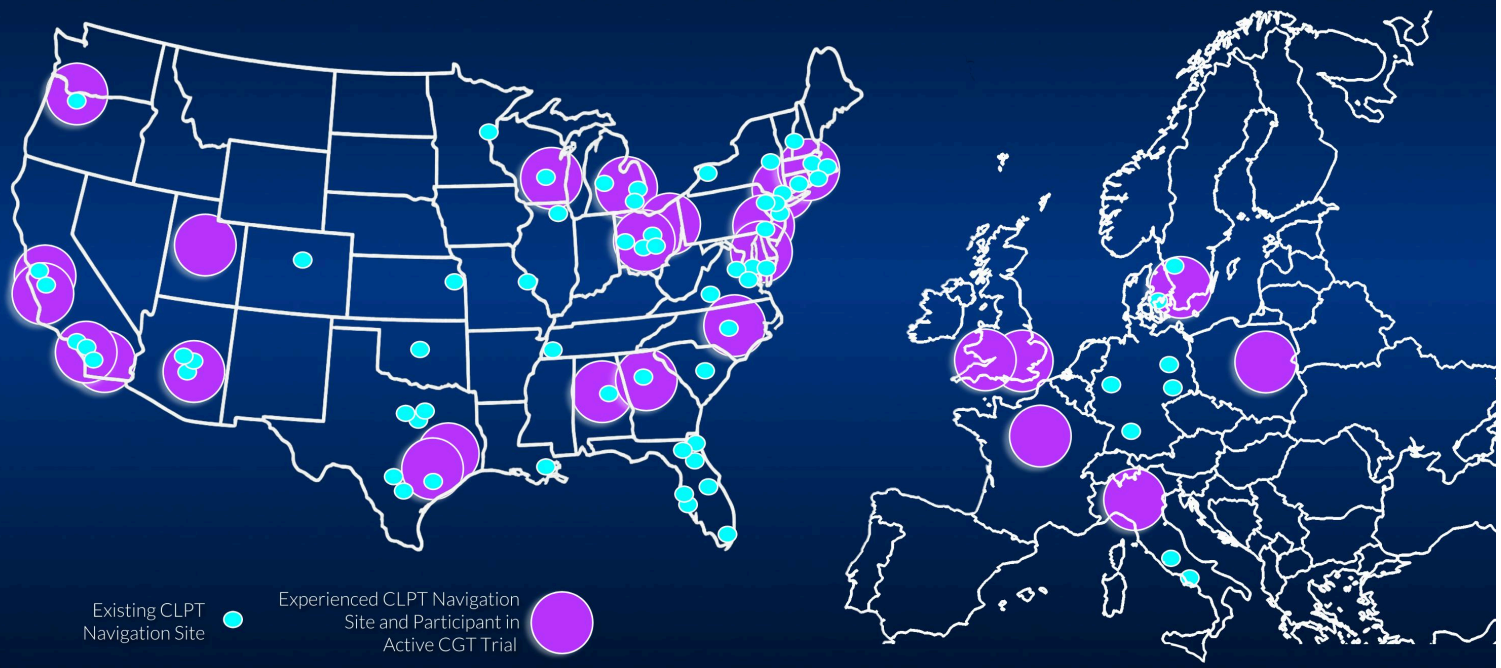
Essential. Everywhere.

10+ Programs Are Already Under FDA Expedited Review



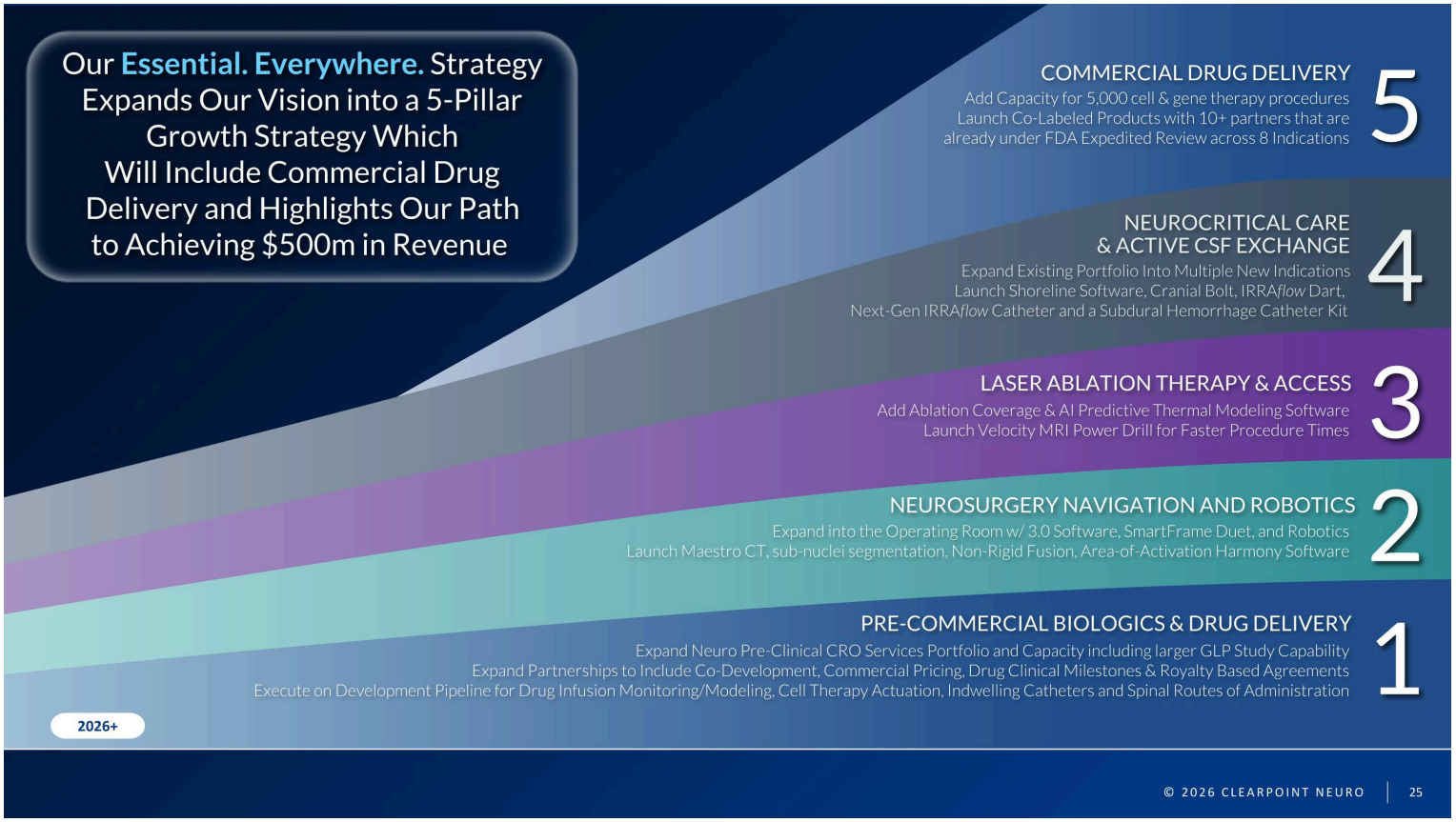
Essential. Everywhere.

Building Surgical Experience and Capacity to Prepare for Drug Commercialization



Existing CLPT Navigation Site

Experienced CLPT Navigation Site and Participant in Active CGT Trial



Our Company

Our 4-Phase Strategy Positions ClearPoint for Decades of Growth

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

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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