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): October 28, 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 October 28, 2026, ClearPoint Neuro, Inc. (the "Company") issued a press release announcing its financial results for the third fiscal quarter ended September 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 October 28, 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 exhibits are furnished herewith:

Exhibit 99.1	Press Release dated October 28, 2026
Exhibit 99.2	Investor Presentation dated October 28, 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: October 28, 2026

By: /s/ Danilo D'Alessandro

Danilo D'Alessandro
Chief Financial Officer

Exhibit 99.1

ClearPoint Neuro Reports Third Quarter 2026 Results

Neurosurgery Navigation & Therapy Grew 59% to $5.4 Million

SOLANA BEACH, CA, October 28, 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 third quarter ended September 30, 2026.

Third Quarter 2026 Highlights

- Reported third quarter revenue of $12.1 million, representing 36% overall growth, including the recently acquired IRRA*flow* Portfolio;
- Neurosurgery navigation and therapy, which includes navigation, laser, drill and IRRA*flow* products, increased 59% to $5.4 million in the quarter;
- Achieved record capital equipment and software revenue of $1.7 million, representing 68% growth in the quarter, including the recently acquired IRRA*flow* equipment;
- Increased biologics and drug delivery revenue to $4.9 million, an 11% year-over-year increase;
- First formal BLA was submitted by one partner for the treatment of Huntington's Disease;
- ClearPoint is an industry partner in a five-year, $2.98 million competitively awarded NCI R01, led by Dartmouth Health to advance MR-guided laser therapy for spinal metastases.[1] The program runs from benchtop through large subject validation to a clinical trial, using the ClearPoint Prism system. ClearPoint contributes technical, software development, and procedural expertise. This is early-stage research that supports our spine LITT roadmap;
- Received net proceeds of $22.0 million from the at-the-market equity offering program; and
- Reported cash and cash equivalents of $46.2 million as of September 30, 2026.

"Throughout 2026 we have continued to make substantial strategic progress in building our comprehensive drug delivery ecosystem, adding new biopharma partners, and assisting existing partners progress through the regulatory process globally," commented Joe Burnett, President and CEO at ClearPoint Neuro. "The acceleration of our financial performance in the third quarter was driven by our core organic clinical product revenue, as well as our biologics and drug delivery revenue both returning to double-digit growth. The 36% revenue growth outpaced operating expense growth of 23% in the third quarter, as the completion of the IRRA*flow* product integration has enabled improved operating leverage. Our current cash balance of $46.2 million provides us with additional confidence to fund our product pipeline which now includes AI Derived Planning and Simulation, Neuro Navigation in the MRI and Operating Room, Laser Therapy and Access, IRRA*flow* CSF management, Robotic Surgery, Focused Ultrasound, as well as our comprehensive drug delivery ecosystem including pre-clinical and clinical services. This unmatched portfolio and partnership advantage will make us the premier therapy enabling company in the cranial neurosurgery space for many years to come."

Business Outlook

The Company now estimates revenue in 2026 to be between $48.0 million and $50.0 million.

Financial Results – Quarter Ended September 30, 2026

Total revenue was $12.1 million for the three months ended September 30, 2026, and $8.9 million for the three months ended September 30, 2025, which represents an increase of $3.2 million, or 36%.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored preclinical and clinical trials utilizing our products, increased 11% to $4.9 million for the three months ended September 30, 2026 from $4.4 million for the three months ended September 30, 2025. This increase is primarily attributable to higher revenue from services performed at ClearPoint Advanced Laboratories.

Neurosurgery navigation and therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint and IRRA*flow* systems, increased 59% to $5.4 million for the three months ended September 30, 2026, from $3.4 million for the same period in 2025. The increase is driven primarily by additional revenues due to sales of the IRRA*flow* product, which the Company acquired in connection with its acquisition of IRRAS in the fourth quarter of 2025.

Capital equipment and software revenue, consisting of sales of ClearPoint and IRRA*flow* reusable hardware and software and related services, increased 68% to $1.7 million for the three months ended September 30, 2026, from $1.0 million for the same period in 2025 primarily 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 58% on its sales for the three months ended September 30, 2026, and a gross margin of 63% in the same period in 2025. The decrease in gross margin is primarily due to overhead costs at the new ClearPoint Advanced Laboratories facility and additional amortization expense of acquired intangible assets, partially offset by a decrease in other cost of revenue, for the three months ended September 30, 2026, as compared to the same period in 2025.

Operating expenses were $13.4 million for the three months ended September 30, 2026, compared with $10.9 million for the same period in 2025, an increase of 23%. 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 September 30, 2026, the Company had cash and cash equivalents totaling $46.2 million as compared to $45.9 million at December 31, 2025, with the increase resulting from the net proceeds of $22.0 million from the at-the-market equity offering program, partially offset by the use of $20.1 million in cash for operating activities.

[1] Research reported in this press release is supported by the National Cancer Institute of the National Institutes of Health under award number R01CA307001. A total of $633,819, or 100 percent of the first-year project budget, is financed with federal funds. No non-governmental funds are included in the approved budget. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's third quarter 2026 results on Wednesday, October 28, 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=cPBDKSsR. 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 November 27, 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, including the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and are intended to be covered by the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, among others, statements regarding: the Company's 2026 revenue guidance and other expectations regarding future financial performance, liquidity and capital resources; the expected adoption and growth of the Company's neurosurgery navigation and therapy products, including IRRA*flow* and laser therapy, and its capital equipment and software placements; the growth of the Company's biologics and drug delivery business, including preclinical services at ClearPoint Advanced Laboratories; the regulatory progress of the Company's biologics and drug delivery partners; the expansion of the Company's laser therapy program into spine; the development of the Company's product pipeline; and other statements of management's expectations, beliefs, plans, estimates or projections relating to the future. Words such as "anticipate," "believe," "estimate," "expect," "intend," "plan," "potential," "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.

Factors that could cause actual results to differ materially include, among others: the Company's ability to achieve broader market adoption of its products and services; the timing and outcome of its biologics and drug delivery partners' clinical trials and regulatory submissions; the Company's ability to maintain and expand its partner relationships; the risk that ClearPoint Advanced Laboratories may not achieve or maintain GLP compliance or generate revenue on anticipated timelines; the integration of acquired businesses, including IRRAS; changes in

government regulation, reimbursement and funding; competition; supply chain disruptions; the Company's ability to fund its operations and service its indebtedness; and general economic, market and geopolitical 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, including the "Risk Factors" sections therein. 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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue:				
Product revenue	$ 7,891	$ 5,361	$ 24,069	$ 16,649
Service and other revenue	4,184	3,500	11,014	9,912
Total revenue	12,075	8,861	35,083	26,561
Cost of revenue	5,016	3,261	13,558	10,273
Gross profit	7,059	5,600	21,525	16,288
Research and development costs	4,018	3,452	13,172	10,660
Sales and marketing expenses	5,532	3,838	19,015	11,691
General and administrative expenses	3,841	3,586	14,392	11,056
Operating loss	(6,332)	(5,276)	(25,054)	(17,119)
Other income (expense):				
Other income (expense), net	22	(64)	(20)	(112)
Interest income	292	396	932	832
Interest expense	(1,446)	(939)	(4,241)	(1,304)
Net loss before income taxes	(7,464)	(5,883)	(28,383)	(17,703)
Income tax (benefit) expense	(4)	8	(34)	51
Net loss	$ (7,460)	$ (5,891)	$ (28,349)	$ (17,754)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.24)	$ (0.21)	$ (0.94)	$ (0.63)
Weighted average shares outstanding:				
Basic and diluted	30,983,193	28,427,574	30,237,502	28,137,528

CLEARPOINT NEURO, INC.

Consolidated Balance Sheets

(in thousands, except for par value and share data)

	September 30, 2026 (Unaudited)	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 46,184	$ 45,923
Accounts receivable, net	8,017	6,549
Inventory, net	9,772	8,359
Prepaid expenses and other current assets	2,741	2,769
Total current assets	66,714	63,600
Property and equipment, net	3,122	2,621
Operating lease right-of-use assets	21,195	8,430
Goodwill	7,472	7,472
Intangible assets, net	12,412	13,922
Other assets	1,813	1,702
Total assets	$ 112,728	$ 97,747
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,060	$ 1,256
Accrued compensation	4,559	4,360
Other accrued liabilities	2,502	2,786
Operating lease liabilities, current portion	198	694
Contract liabilities, current portion	1,550	1,669
Total current liabilities	9,869	10,765
Operating lease liabilities, net of current portion	22,661	8,461
Contract liabilities, net of current portion	428	581
Long-term notes payable, net	50,840	49,077
Accrued interest payable	1,358	489
Deferred tax liabilities, net	305	354
Total liabilities	85,461	69,727
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized; none issued and outstanding at September 30, 2026 and December 31, 2025	—	—
Common stock, $0.01 par value; 90,000,000 shares authorized at September 30, 2026 and December 31, 2025; 32,051,494 and 29,368,760 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	320	294
Additional paid-in capital	269,639	238,995
Shares to be issued	2,567	5,641
Accumulated deficit	(245,259)	(216,910)
Total stockholders' equity	27,267	28,020
Total liabilities and stockholders' equity	$ 112,728	$ 97,747

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

	Nine Months Ended September 30,	
	2026	2025
Cash flows from operating activities:		
Net loss	$ (28,349)	$ (17,754)
Adjustments to reconcile net loss to net cash used in operating activities:		
(Recovery of) provision for bad debt expense	(657)	217
Depreciation and amortization	339	565
Amortization of intangible assets	1,510	—
Share-based compensation	6,369	6,199
Payment-in-kind interest	1,609	490
Amortization of debt issuance costs and original issue discounts	154	60
Amortization of lease right-of-use assets, net of accretion in lease liabilities	2,260	821
Deferred income taxes	(49)	—
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(811)	497
Inventory, net	(1,202)	(16)
Prepaid expenses and other current assets	(40)	(696)
Other assets	(235)	(192)
Accounts payable and accrued expenses	(268)	(1,515)
Lease liabilities	(1,321)	(716)
Contract liabilities	(272)	(69)
Accrued interest payable	869	264
Net cash used in operating activities	(20,094)	(11,845)
Cash flows from investing activities:		
Purchases of property and equipment	(996)	(473)
Net cash used in investing activities	(996)	(473)
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	654	49
Payments for taxes related to net share settlement of equity awards	(1,993)	(1,661)
Proceeds from issuance of common stock under at-the-market equity offering program, net of issuance costs of $0.5 million	22,020	—
Proceeds from issuance of common stock under employee stock purchase plan	546	311
Net cash provided by financing activities	21,227	30,615
Net change in cash, cash equivalents and restricted cash	137	18,297
Cash, cash equivalents and restricted cash, beginning of period	46,973	20,104
Cash, cash equivalents and restricted cash, end of period	$ 47,110	$ 38,401
Cash and cash equivalents	46,184	38,221
Restricted cash included in other current assets and other assets, non-current	926	180
Total cash, cash equivalents and restricted cash	$ 47,110	$ 38,401
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ 34	$ 69
Interest	$ 1,609	$ 490
Non-cash investing and financing transactions:		
Property and equipment included in accounts payable and other accrued liabilities	$ 329	$ —
Net transfers of reusable components between property and equipment and inventory	$ 307	$ 262
Right-of-use assets obtained in exchange for operating lease liabilities	$ 13,882	$ 3,309


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

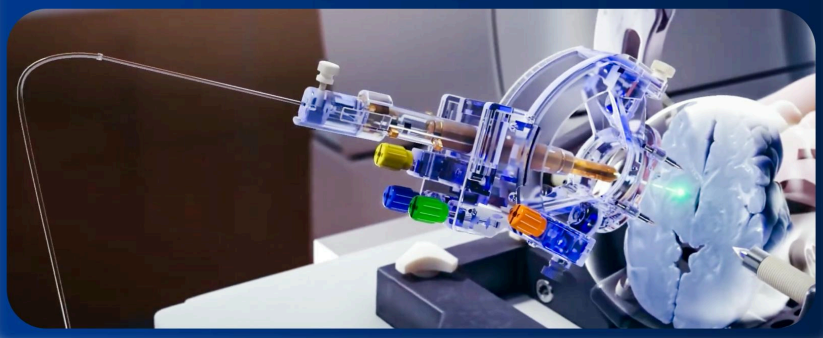
This presentation contains information concerning the Company's biotech Partners and their product candidates and clinical and regulatory programs, as well as market, industry, prevalence, cost and ranking data attributed to third parties. That information is derived from the Partners' own public disclosures 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.

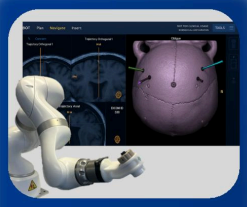
PRODUCT STATUS

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.

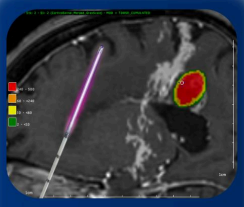
For a detailed description of the Company's risks and uncertainties, you are encouraged to review its documents filed with the SEC including the Company's recent filings on Form 8-K, Form 10-K and Form 10-Q. You are cautioned not to place undue reliance on forward-looking statements, which speak only 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. Most cell and gene therapies referenced are investigational and have not been approved by FDA or other regulatory authorities.

CLEARPOINT® NEURO

OUR COMPANY

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

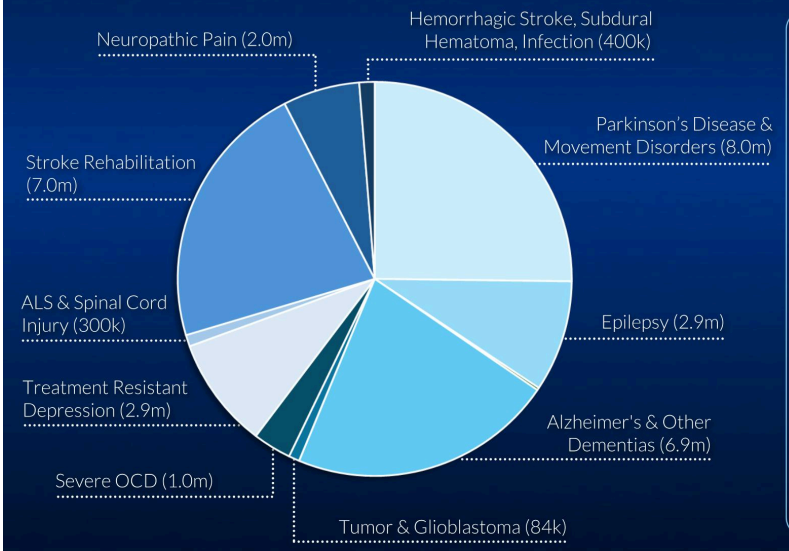
Our Unique Platform Includes Proven Clinical Products Used by Hospitals and Neurosurgeons, and Drug Development Services Used by BioPharma Partners

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.

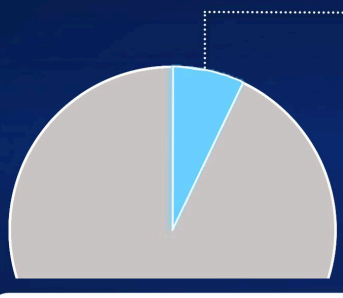
Prevalence estimates are based on publicly available sources. Categories shown are representative and may not be mutually exclusive.

© 2026 CLEARPOINT NEURO

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.



- Parkinson's Disease (1.0m)
- Drug Resistant Epilepsy (1.0m)
- Frontotemporal Dementia (60k)
- Huntington's Disease (41k)
- Glioblastoma (22k)
- Friedreich's Ataxia (5k)
- AADC Deficiency (rare)

AskBio · Aspen Neuroscience · AVIADOBIO · BlueRock Therapeutics · kenai therapeutics · NEURONA THERAPEUTICS · PTC Therapeutics · 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

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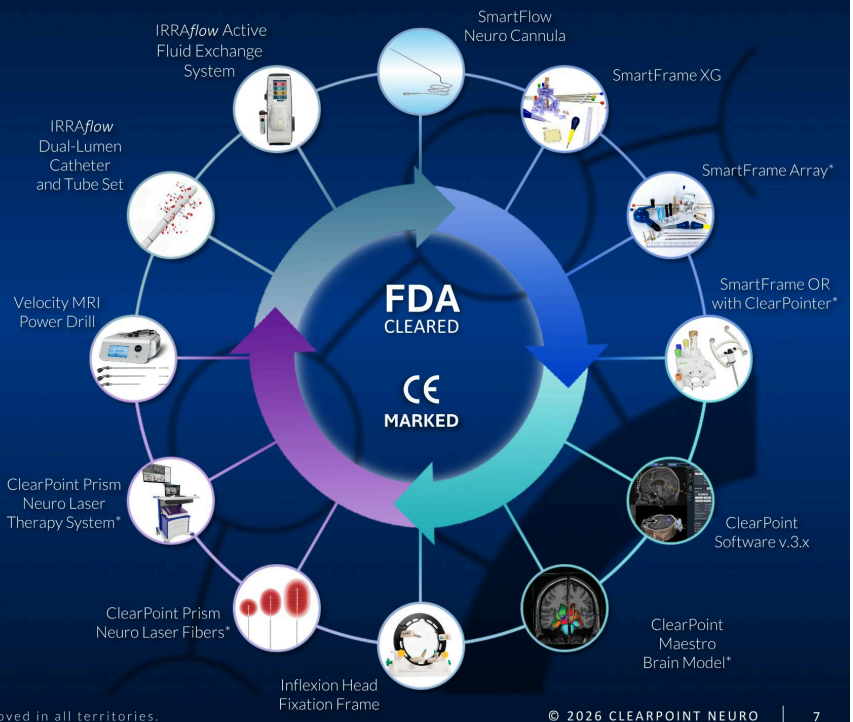
Design. Discovery.

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

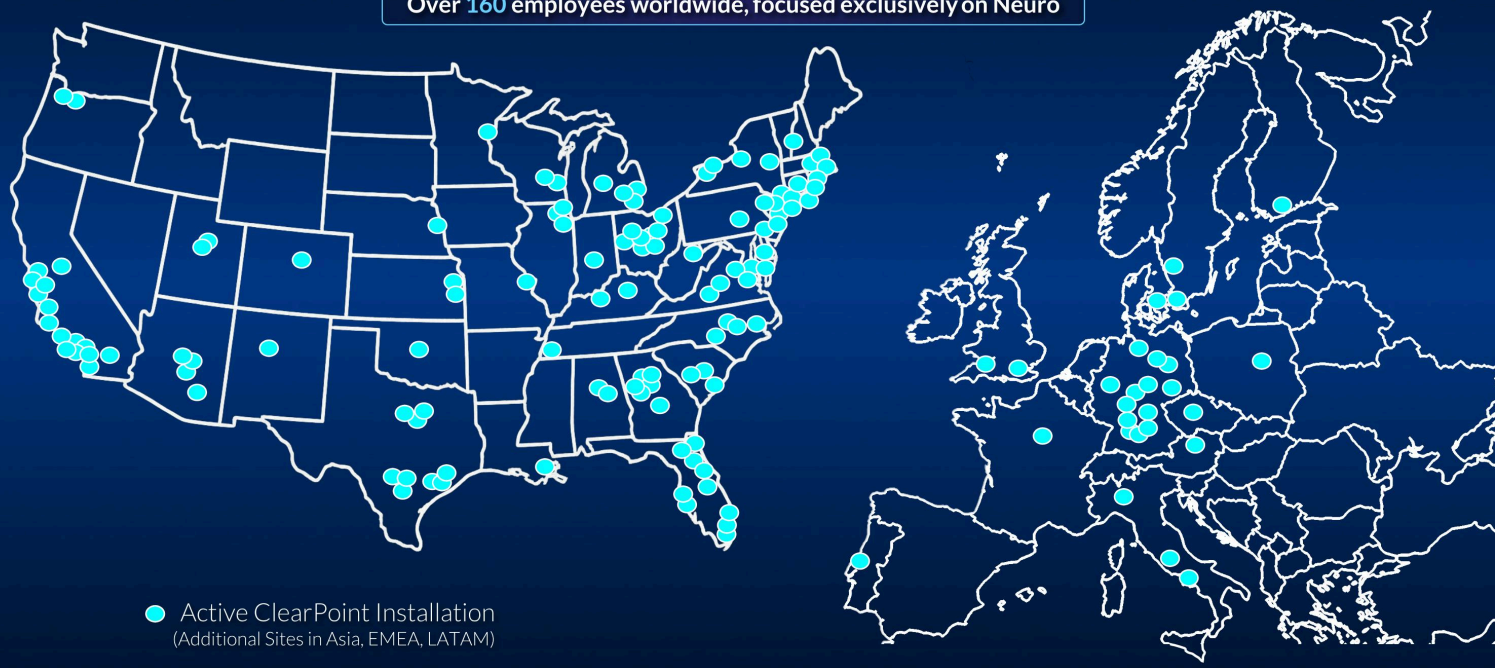
*Not all products cleared or approved in all territories.

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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)

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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).

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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



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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

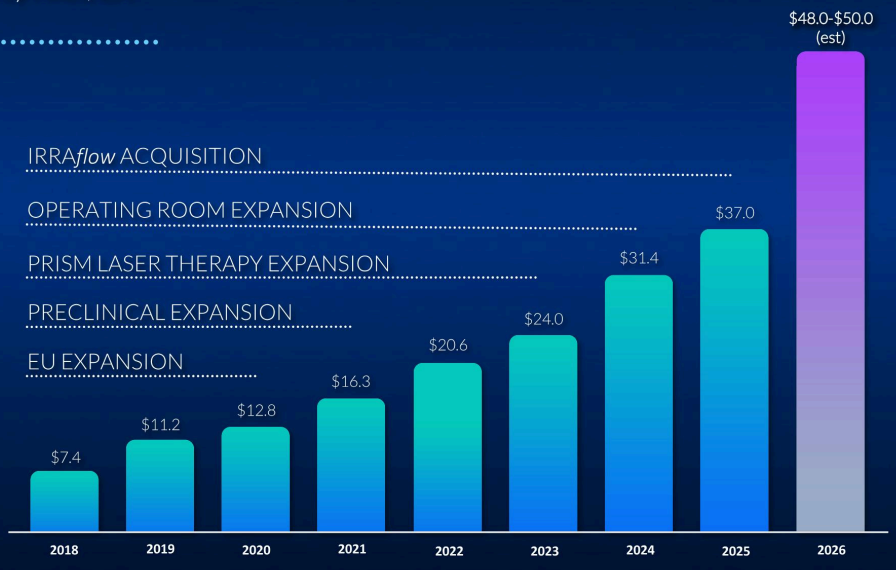
2025 REVENUE
$37.0m[A]

GROSS MARGIN
61%[B]

PATENTS ISSUED
130+[C]

CASH & CASH EQUIVALENTS
$46.2m[D]

EMPLOYEES
160+



*All Annual Totals in Millions

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

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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



Megan Faulkenberry
Senior Vice President of Quality



Mary McNamara-Cullinane
Senior Vice President of Regulatory Affairs

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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.

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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.

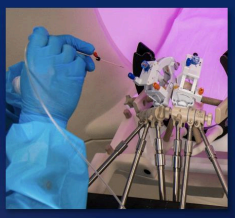
Combining Services & Technology

Benchtop Testing



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

Preclinical Studies



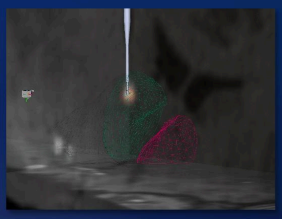
- Running preclinical studies
- Surgical planning & strategy
- Dosing & surgical expertise
- Post-procedure analysis

Hardware



Leverage Both Commercial and In-Development Delivery and Navigation Tools

Software



SmartFlow Software & Biophysical Modeling in Collaboration with NE Scientific

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Fast. Forward.

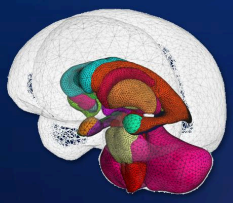
Pillar 2: Neuro Navigation & Robotics

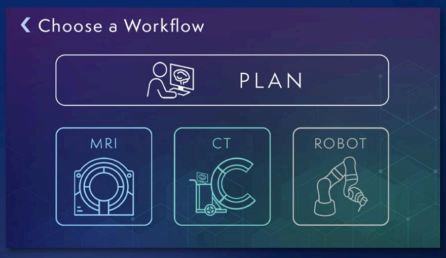
CLEARPOINT NAVIGATION SYSTEM
Neurosurgery Navigation & Robotics

$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.

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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

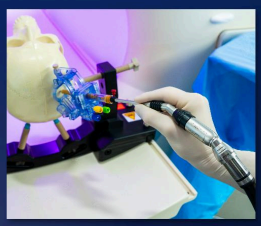

One Team

Velocity^{ALPHA} MRI Conditional Power Drill

A Versatile Power Solution for SmartFrame in the MRI and OR



adeor MEDICAL



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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 ✓ Publication of iCT Real-World Data • Global Installed Base with iCT Upgrade	• 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

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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**

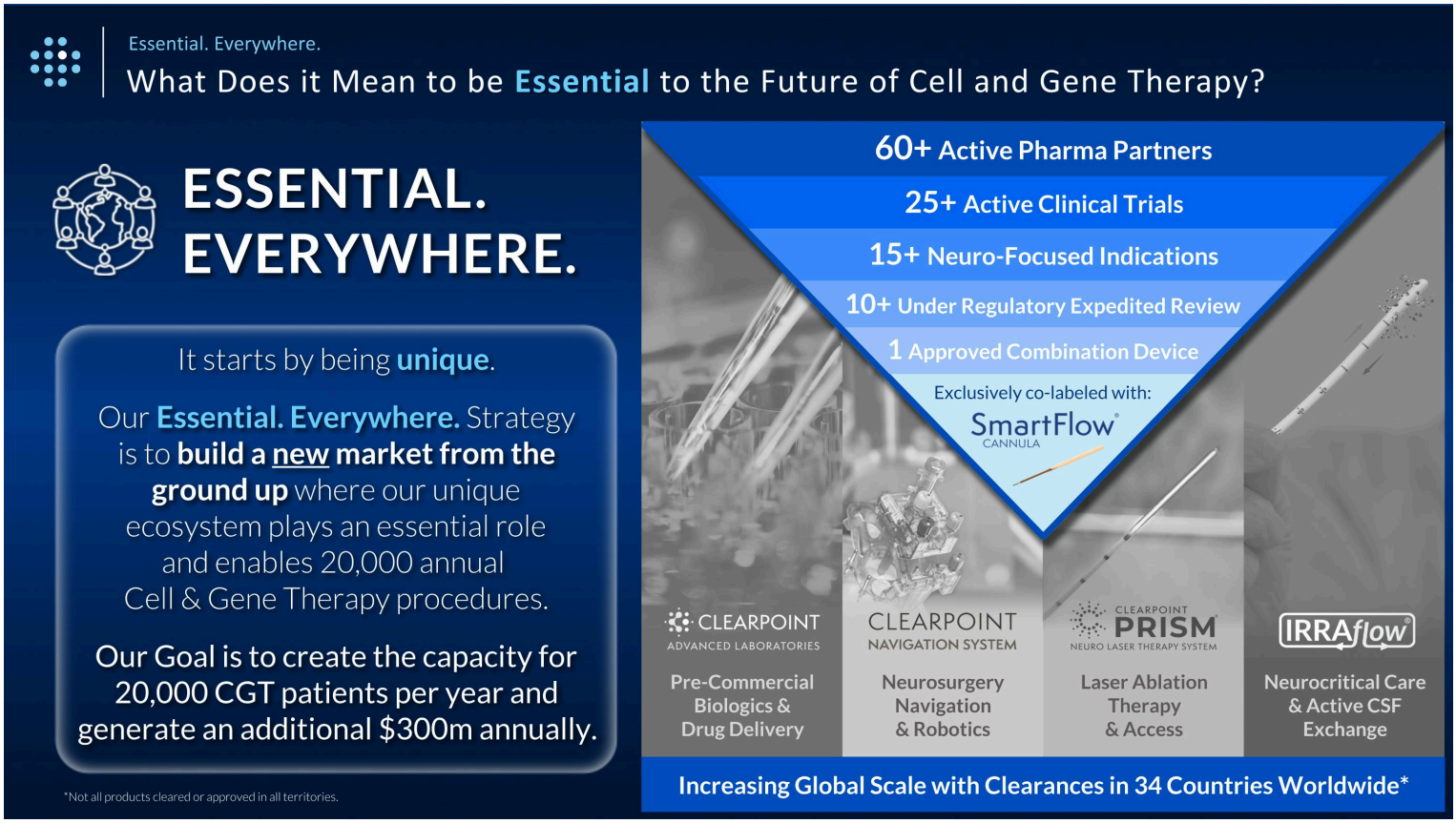
4 NEUROCRITICAL CARE & ACTIVE CSF EXCHANGE
Expand Existing Portfolio Into Multiple New Indications
Launch Shoreline Software, Cranial Bolt, IRRA*flow* Dart, Next-Gen IRRA*flow* Catheter and a Subdural Hemorrhage Catheter Kit

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

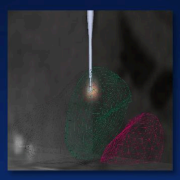
1 PRE-COMMERCIAL BIOLOGICS & DRUG DELIVERY
Expand Neuro Pre-Clinical CRO Services Portfolio and Capacity including GLP Study Capability
Expand Partnerships to Include Co-Development, Commercial Pricing, Drug Clinical Milestones & Royalty Based Agreements
Execute on Development Pipeline for Drug Infusion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

2027+


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*

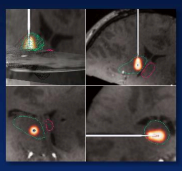
Essential. Everywhere.

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

+



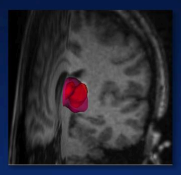
Flexible Options for Surgeon Selected Navigation Including Frames, Robotics

+



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

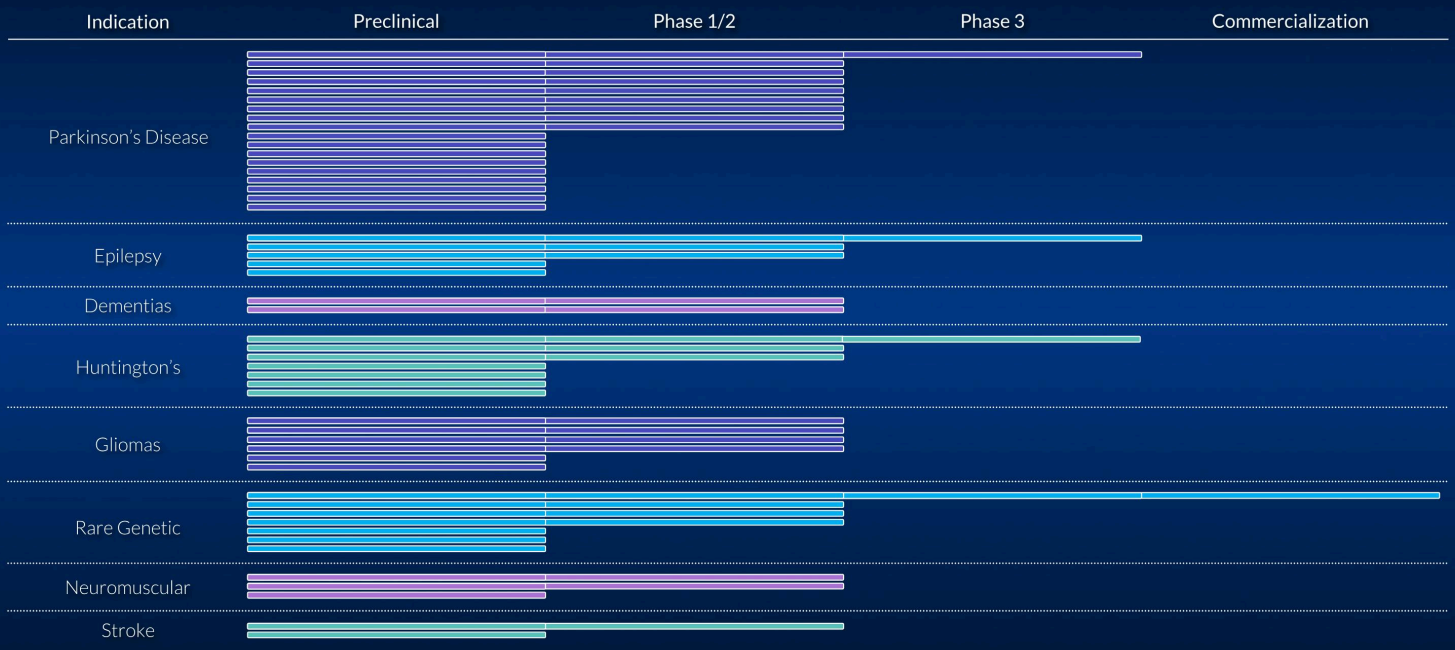


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Essential. Everywhere.

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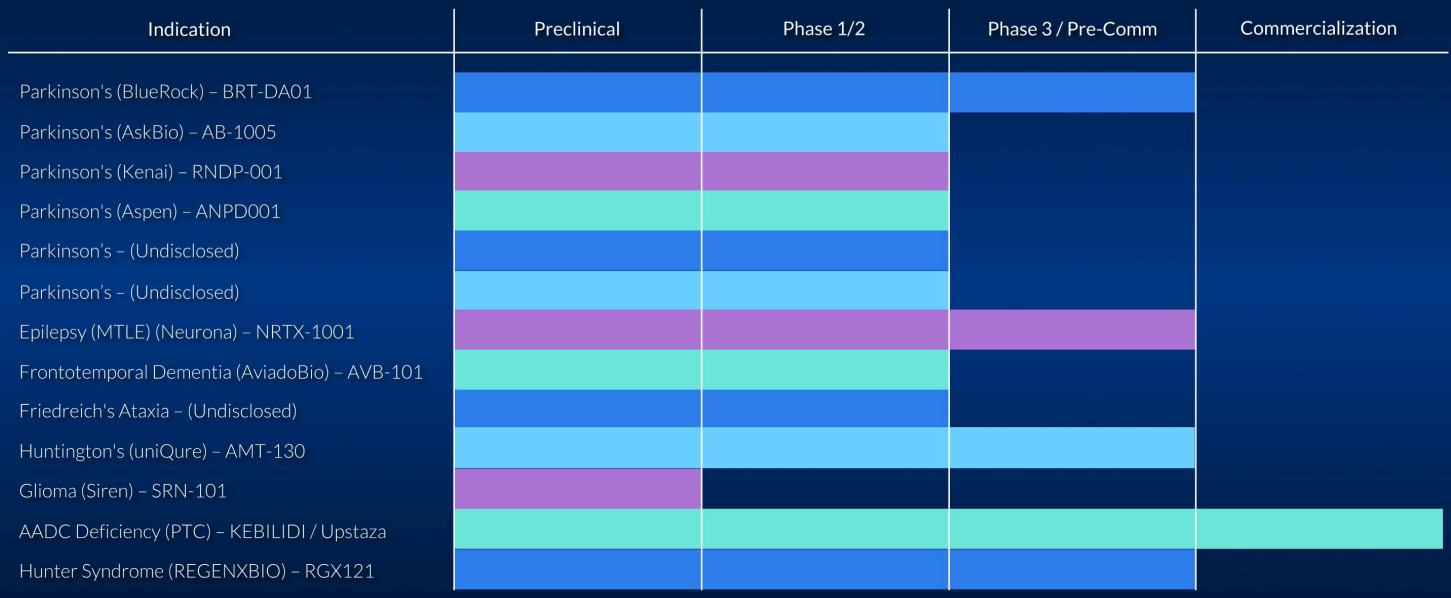


…and more than 15 additional programs that are undisclosed and in preclinical development.

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Essential. Everywhere.

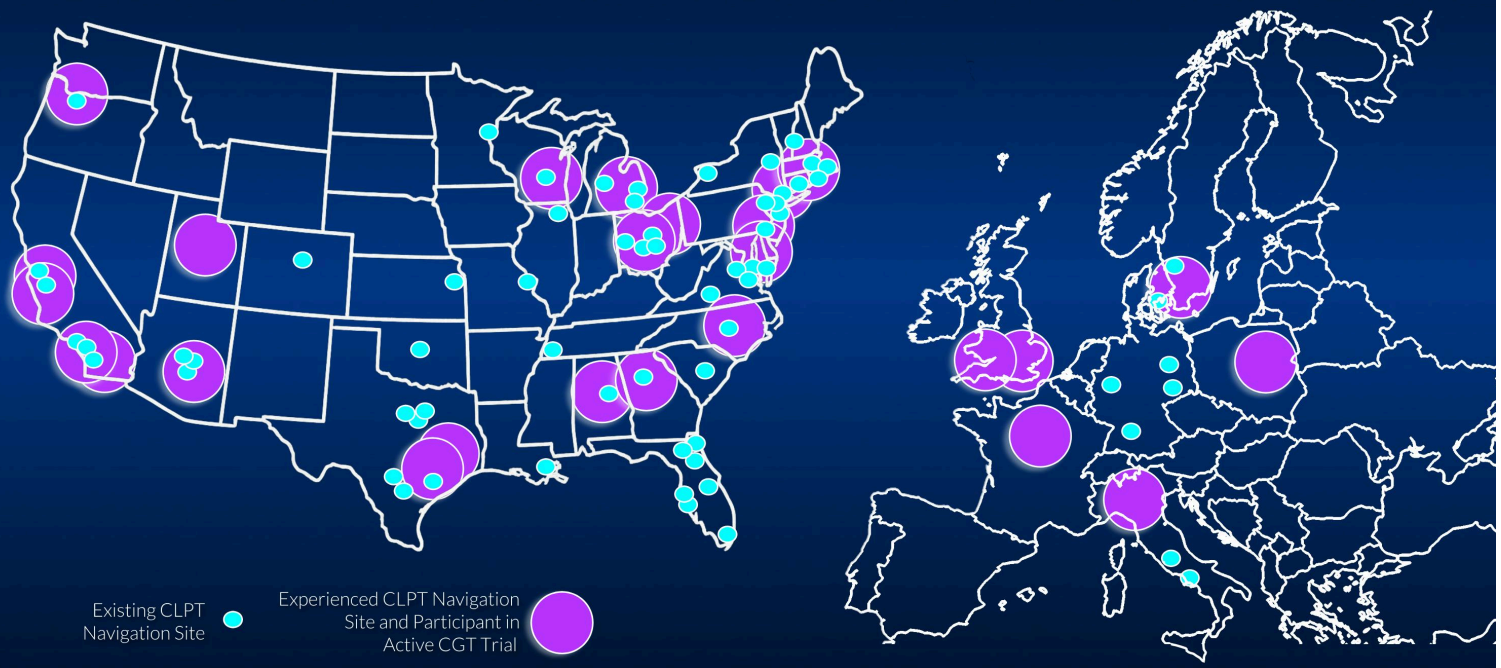
10+ Programs Are Already Under FDA Expedited Review



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Essential. Everywhere.

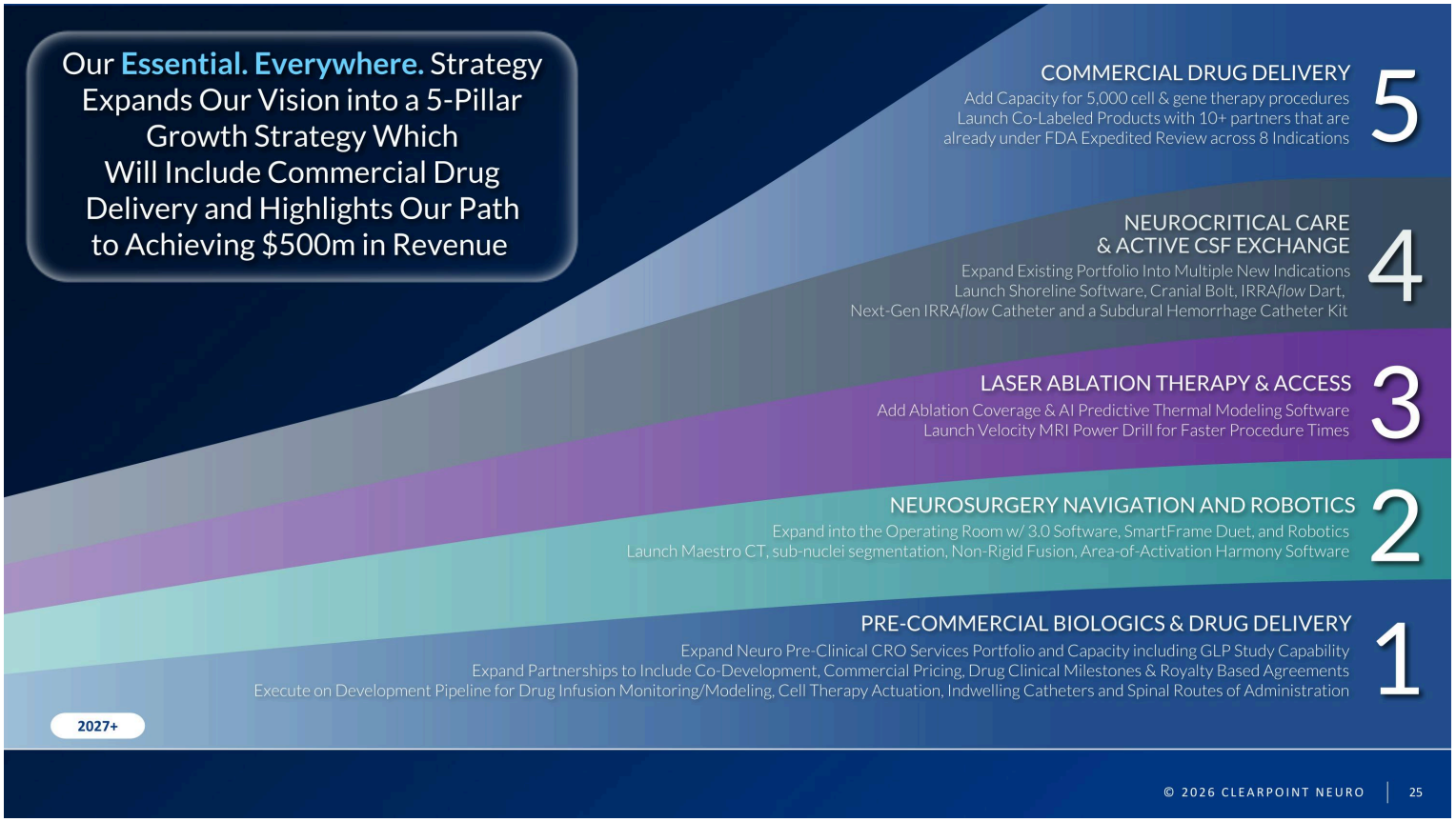
Building Surgical Experience and Capacity to Prepare for Drug Commercialization



Existing CLPT Navigation Site

Experienced CLPT Navigation Site and Participant in Active CGT Trial

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Our Company

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