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): February 26, 2025

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 February 26, 2025, ClearPoint Neuro, Inc. (the "Company") issued a press release announcing its financial results for the fourth fiscal quarter and full year ended December 31, 2024. 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 February 26, 2025, the Company posted an updated investor presentation to its website at http://ir.stockpr.com/clearpointneuro/investor-presentations. A copy of the investor presentation is being furnished herewith as Exhibit 99.2. The Company may use the investor presentation from time to time in conversations with analysts, investors and others.

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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith:

Exhibit 99.1	Press Release dated February 26, 2025
Exhibit 99.2	Investor Presentation dated February 26, 2025
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: February 26, 2025

By: /s/ Danilo D'Alessandro

Danilo D'Alessandro
Chief Financial Officer

Exhibit 99.1

ClearPoint Neuro Reports Fourth Quarter and Full Year 2024 Results

Achieved Record Revenue for 2024 and Growth of 31%;
Reduced 2024 Operational Cash Burn by 35%

SOLANA BEACH, CA, February 26, 2025 – 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 fourth quarter and full-year ended December 31, 2024.

2024 Full Year and Fourth Quarter Highlights

- Reported fourth quarter 2024 revenue of $7.8 million, a 14% year-over-year increase compared with the fourth quarter of 2023;
- Reported revenue of $31.4 million for the full year 2024, an increase of 31% over 2023 and representing the tenth consecutive year of growth;
- Overall product revenue, including biologics and drug delivery, grew 76% to $18.6 million for the full year as a result of the SmartFrame OR™ platform and ClearPoint Prism® Laser Therapy System and partner progression in clinical trials;
- Activated six new global centers in the fourth quarter for a total of 25 new centers in 2024, approximately three times our historic activation rate;
- Continued patient enrollment in numerous cell and gene therapy trials for partners selected in FDA expedited review programs across multiple indications;
- Full early repayment of the principal amount and interest on a $10 million convertible note leaving the Company with no outstanding debt;
- Quarterly operational cash burn of $1.2 million, bringing total 2024 operational cash burn of $9.0 million, a reduction of 35% versus 2023; and
- Reported cash and cash equivalents totaling $20.1 million as of December 31, 2024.

"2024 represented the strongest financial and strategic performance in our history including more than 30% revenue growth, and a 35% reduction in operational cash burn," commented Joe Burnett, President and CEO at ClearPoint Neuro. "Very importantly we feel that we have entered the next phase of ClearPoint as a company, a phase that we call "Fast. Forward." This new phase will be represented by three key strategic initiatives. First, we will extend our lead as the premier drug delivery partner for neuro disorders by continuing to build the leading solution in the drug delivery ecosystem including hardware, software, routes-of-administration, clinical support and preclinical drug development services. We will provide best-in-class support to our more than 60 current BioPharma partners as they progress through the global regulatory process to commercialization, including several already selected for expedited review in the United States. Second, we will expand our global footprint and regulatory clearances so that we create worldwide capacity for patients who will benefit from these new cell

and gene therapies as they become available. Third, we will accelerate the launch of new fast, simple and predictable products for both the MRI Suite and the Operating Room, increasing hospital throughput and driving sales and scale in our existing accounts. We will train sites on the use of the ClearPoint Neuro technology in both the MRI Suite and the OR to build universal familiarity with our drug delivery ecosystem in anticipation of cell and gene therapy commercialization in the coming years. Everything we do will be to help physicians and hospitals prepare for these regenerative cell and gene therapies that have the potential to transform the treatment for these severe neuro disorders and restore quality of life to countless patients and their families."

Business Outlook

The Company estimates revenue in 2025 to be between $36.0 million and $41.0 million, representing growth between 15% and 31%.

Financial Results – Year Ended December 31, 2024

Total revenue was $31.4 million and $24.0 million for the years ended December 31, 2024 and 2023, respectively.

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 27% to $17.3 million for the year ended December 31, 2024, from $13.6 million for the same period in 2023. This increase is attributable to a $3.5 million increase in product revenue resulting from higher demand for disposables as multiple partners progress in their trials, and a $0.3 million increase in service and other revenue related to new preclinical trials and service agreements entered into with our partners for the year ended December 31, 2024, compared to the same period in 2023.

Neurosurgery navigation and therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 21% to $10.3 million during the year ended December 31, 2024, from $8.5 million for the same period in 2023. Product revenue increased $2.7 million, or 36%, resulting from newly activated accounts, increased case count, and new product offerings, including SmartFrame OR and Prism Laser Therapy, compared to the same period in 2023. This was partially offset by a decrease in service and other revenue of $0.9 million primarily as a result of pausing a co-development program with one of our Brain Computer Interface partners.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software and related services, increased 107% to $3.8 million for the year ended December 31, 2024, from $1.8 million for the same period in 2023, due to an increase in the placements of ClearPoint navigation capital equipment and software and Prism laser units.

The Company achieved a gross margin of 61% on its sales for 2024, compared to a gross margin of 57% for 2023. The increase in gross margin was primarily due to lower costs for the year ended December 31, 2024 due to the transition to the new manufacturing facility, occurring in 2023, and higher volumes for the year ended December 31, 2024.

Operating expenses were $38.9 million for the full year 2024, compared with $36.1 million for 2023, an increase of 8%. The increase was mainly driven by higher personnel-related expenses, including share-based compensation, as we increased headcount to fuel the expansion of the research and development, clinical, and support organizations, partially offset by a decrease in the allowance for credit losses as a result of subsequent recoveries and lower development costs as a result of reprioritization of certain initiatives.

Financial Results – Quarter Ended December 31, 2024

Total revenue was $7.8 million for the three months ended December 31, 2024, in comparison to $6.8 million for the three months ended December 31, 2023, representing an increase of $1.0 million, or 14%.

Biologics and Drug Delivery revenue, which includes sales of services and disposable products related to customer-sponsored preclinical and clinical trials utilizing our products, increased 4% to $4.2 million for the three months ended December 31, 2024, from $4.1 million for the same period in 2023. The growth is attributable to a $0.6 million increase in product revenue resulting from higher demand for disposables as multiple partners progress in their trials, partially offset by a decrease of $0.4 million in service and other revenue due to a lower number of preclinical studies performed.

Neurosurgery Navigation and Therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 43% to $2.9 million for the three months ended December 31, 2024, from $2.0 million for the same period in 2023. The increase is driven by higher product revenue resulting from newly activated accounts, increased case count, and new product offerings, including the SmartFrame OR and Prism Laser Therapy, during the three months ended December 31, 2024, compared to the same period in 2023.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software and related services, decreased slightly to $0.6 million for the three months ended December 31, 2024, from $0.7 million for the same period in 2023.

Gross margin for the three months ended December 31, 2024, was 61% compared to a gross margin of 59% for the three months ended December 31, 2023.

Operating expenses for the fourth quarter of 2024 were $10.4 million, compared to $8.7 million for the fourth quarter of 2023. The increase was mainly driven by higher personnel costs, research and development, and regulatory fees.

At December 31, 2024, the Company had cash and cash equivalents totaling $20.1 million as compared to $23.1 million at December 31, 2023, with the decrease resulting from the full repayment of debt of $10 million and the use of cash in operating activities of $9.0 million in the year ended December 31, 2024, partially offset by the net proceeds from the public offering of common stock of $16.2 million in the first quarter of 2024 .

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's fourth quarter and full year 2024 results on Wednesday, February 26, 2025 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=2j7boq1J. 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 March 28, 2025, 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 CNS delivery of therapeutics in preclinical studies and clinical trials worldwide. To date, thousands of procedures have been performed and supported by the Company's field-based clinical specialist team, which offers support and services to our customers and partners worldwide. For more information, please visit www.clearpointneuro.com.

Forward-Looking Statements

Statements in this press release and in the teleconference referenced above concerning the Company's plans, growth and strategies may include forward-looking statements within the context of the federal securities laws. Statements regarding the Company's future events, developments and future performance, the size of total addressable markets or the market opportunity for the Company's products and services, the Company's expectation for revenues, operating expenses, the adequacy of cash and cash equivalent balances to support operations and meet future obligations, as well as management's expectations, beliefs, plans, estimates or projections relating to the future, are forward-looking statements within the meaning of these laws. These forward-looking statements are based on management's current expectations and are subject to the risks inherent in the business, which may cause the Company's actual results to differ materially from those expressed in or implied by forward-looking statements. Particular uncertainties and risks include those relating to: 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 protectionism and economic nationalism; future revenue from sales of the Company's products and services; the Company's ability to market, commercialize and achieve broader market acceptance for new products and services offered by the Company; the ability of our biologics and drug delivery partners to achieve commercial success, including their use of the Company's products and services in their delivery of therapies; the Company's ability to maintain its current relationships with biologics and drug delivery partners or enter into new relationships with such partners; the Company's expectations, projections and estimates regarding expenses, future revenue, capital requirements, and the availability of and the need for additional financing; the Company's ability to obtain additional funding to support its research and development programs; the ability of the Company to manage the growth of its business; the Company's ability to attract and retain its key employees; and risks inherent in the research, development, and regulatory approval of the Company's new products and the new products of its biologics and drug delivery partners. More detailed information on these and additional factors that could affect the Company's actual results are described in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2023, and the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2024, both of which have been filed with the Securities and Exchange Commission, and the Company's Annual Report on Form 10-K for the year ended December 31, 2024, which the Company intends to file with the Securities and Exchange Commission on or before March 31, 2025. The Company does not assume any obligation to update these forward-looking statements.

Contact:

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

CLEARPOINT NEURO, INC.

Consolidated Statements of Operations
(Dollars in thousands, except for share and per share data)

	Years Ended December 31,	
	2024	**2023**
Revenue:		
Product revenue	$ 18,626	$ 10,603
Service and other revenue	12,764	13,352
Total revenue	31,390	23,955
Cost of revenue	12,268	10,341
Gross profit	19,122	13,614
Research and development costs	12,392	11,709
Sales and marketing expenses	14,478	12,595
General and administrative expenses	11,998	11,756
Operating loss	(19,746)	(22,446)
Other income (expense):		
Other expense, net	(40)	(29)
Interest income, net	872	386
Net loss	$ (18,914)	$ (22,089)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.70)	$ (0.90)
Weighted average shares outstanding:		
Basic and diluted	27,027,692	24,605,212

CLEARPOINT NEURO, INC.

Consolidated Balance Sheets

(Dollars in thousands, except for share and per share data)

	December 31,	
	2024	**2023**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,104	$ 23,140
Accounts receivable, net	4,713	3,211
Inventory, net	6,863	7,911
Prepaid expenses and other current assets	1,683	1,910
Total current assets	33,363	36,172
Property and equipment, net	2,005	1,389
Operating lease rights of use	3,086	3,564
Software license inventory	103	386
Licensing rights	484	1,041
Other assets	148	109
Total assets	$ 39,189	$ 42,661
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,340	$ 393
Accrued compensation	4,885	2,947
Other accrued liabilities	1,450	1,053
Operating lease liabilities, current portion	557	424
Deferred product and service revenue, current portion	2,121	2,613
Total current liabilities	10,353	7,430
Operating lease liabilities, net of current portion	3,011	3,568
Deferred product and service revenue, net of current portion	436	541
2020 senior secured convertible note payable, net	—	9,949
Total liabilities	13,800	21,488
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized at December 31, 2024 and 2023; none issued and outstanding at December 31, 2024 and 2023	—	—
Common stock, $0.01 par value; 90,000,000 shares authorized at December 31, 2024 and 2023; 27,617,415 and 24,652,729 shares issued and outstanding at December 31, 2024 and 2023, respectively	276	247
Additional paid-in capital	216,483	193,382
Accumulated deficit	(191,370)	(172,456)
Total stockholders' equity	25,389	21,173
Total liabilities and stockholders' equity	$ 39,189	$ 42,661

CLEARPOINT NEURO, INC.

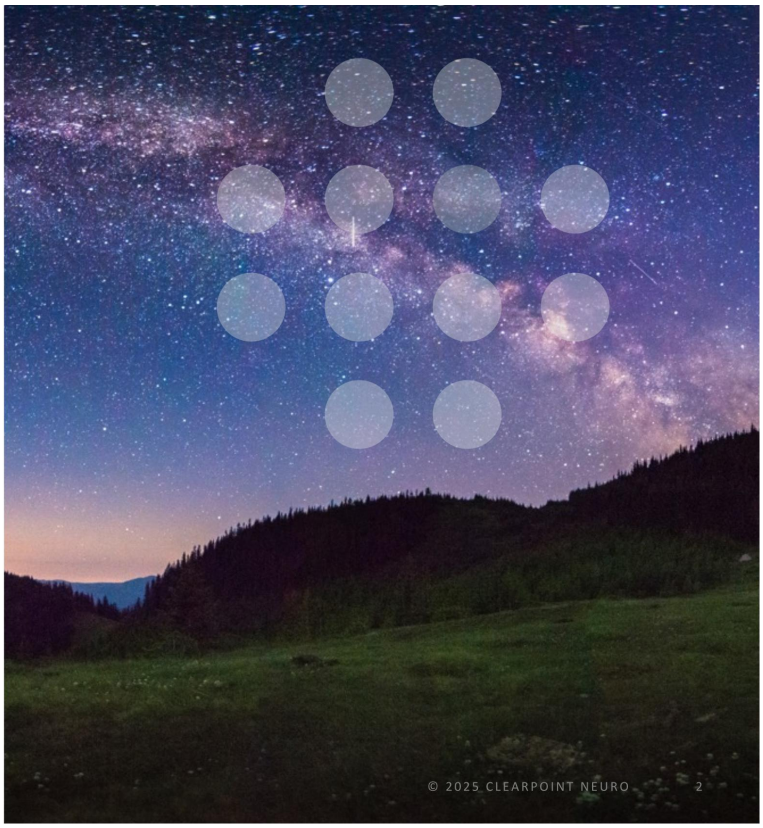
Consolidated Statements of Cash Flows
(Dollars in thousands)

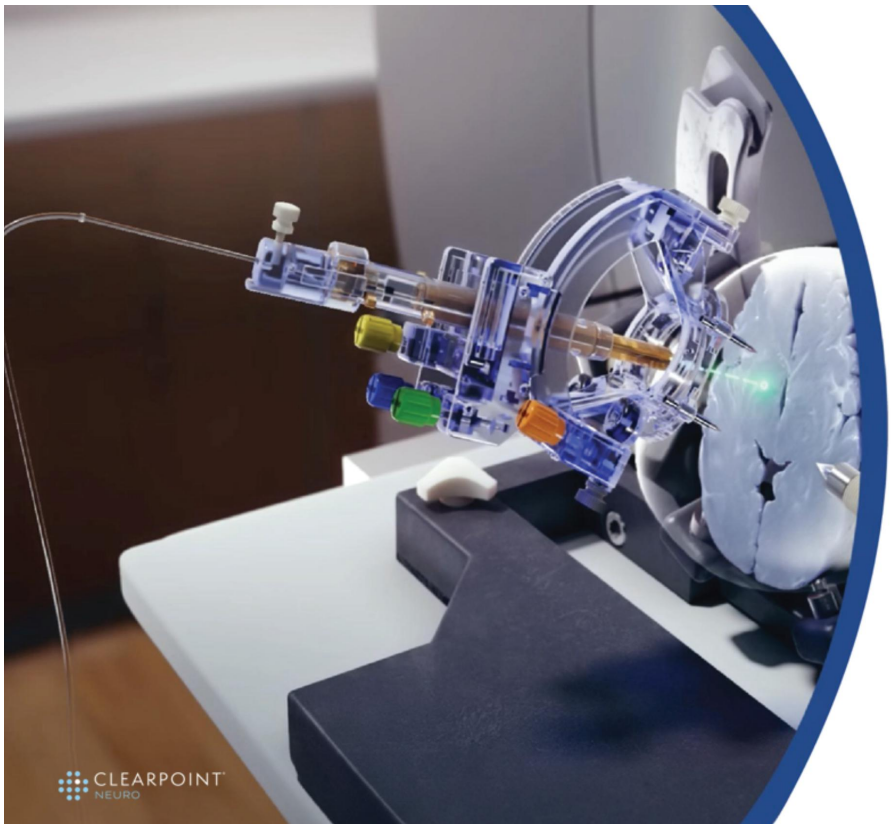
	Years Ended December 31, 2024	2023
Cash flows from operating activities:		
Net loss	$ (18,914)	$ (22,089)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for credit losses (recoveries)	(296)	1,258
Depreciation and amortization	980	626
Share-based compensation	6,907	6,079
Amortization of debt issuance costs and original issue discounts	51	57
Amortization of lease right of use assets, net of accretion in lease liabilities	923	831
Accretion of discounts on short-term investments	—	(126)
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(1,206)	(1,804)
Inventory, net	743	1,246
Prepaid expenses and other current assets	262	(113)
Other assets	(39)	22
Accounts payable and accrued expenses	3,105	(649)
Lease liabilities	(869)	(755)
Deferred revenue	(597)	1,697
Net cash flows from operating activities	(8,950)	(13,720)
Cash flows from investing activities:		
Purchases of property and equipment	(275)	(717)
Acquisition of licensing rights	—	(334)
Proceeds from maturities of short-term investments	—	10,000
Net cash flows from investing activities	(275)	8,949
Cash flows from financing activities:		
Proceeds from public offering of common stock, net of offering costs	16,149	—
Repayment of 2020 senior secured convertible note	(10,000)	—
Proceeds from stock option exercises	21	—
Proceeds from issuance of common stock under employee stock purchase plan	443	506
Payments for taxes related to net share settlement of equity awards	(424)	(210)
Net cash flows from financing activities	6,189	296
Net change in cash and cash equivalents	(3,036)	(4,475)
Cash and cash equivalents, beginning of year	23,140	27,615
Cash and cash equivalents, end of year	$ 20,104	$ 23,140
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ 62	$ —
Interest	$ 480	$ 743


CLEARPOINT
NEURO
WHEN YOUR PATH IS UNCLEAR,
WE POINT THE WAY.
Nasdaq: CLPT
February 2025

DISCLAIMER

This presentation and discussion contain forward-looking statements within the context of the federal securities laws, including the Company's expectation for revenues, gross margin, the adequacy of cash and cash equivalent balances to support operations and meet future obligations, the future market of its products and services, and other performance and results. 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: macroeconomic and inflationary conditions; the introduction of or changes in tariffs, sanctions, or trade barriers; changes in monetary policy; geopolitical trends, such as protectionism and economic nationalism; future revenue from sales of the Company's products and services; the Company's ability to market, commercialize and achieve broader market acceptance for new products and services offered by the Company; the ability of our biologics and drug delivery partners to achieve commercial success, including their use of the Company's products and services in their delivery of therapies; the Company's ability to maintain its current relationships with biologics and drug delivery partners or enter into new relationships with such partners; the Company's expectations, projections and estimates regarding expenses, future revenue, capital requirements, and the availability of and the need for additional financing; the Company's ability to obtain additional funding to support its research and development programs; the ability of the Company to manage the growth of its business; the Company's ability to attract and retain its key employees; and risks inherent in the research, development, and regulatory approval of new products and the new products of its biologics and drug delivery partners. More detailed information on these and additional factors that could affect the Company's actual results are described in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2023, and the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2024, both of which have been filed with the Securities and Exchange Commission, and the Company's Annual Report on Form 10-K for the year ended December 31, 2024, which the Company intends to file with the Securities and Exchange Commission on or before March 31, 2025. The Company does not assume any obligation to update these forward-looking statements.





CLEARPOINT®
NEURO

OUR COMPANY

We Enable Cell, Gene and Device Therapies by Offering Precise Navigation to the Brain and Spine

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

CLEARPOINT NEURO EXECUTIVE SUMMARY

A UNIQUE PLATFORM TECHNOLOGY USED FOR CELL AND GENE THERAPY DELIVERY

15+ years building a complete drug delivery ecosystem including navigation solutions, predictive modeling, delivery devices, infusion monitoring software and clinical case support

A $10B POTENTIAL MARKET DIVERSIFIED ACROSS 60+ PARTNERS, 20+ INDICATIONS*

Combination device success, proprietary technology and deep FDA experience provide our BioPharma partners with a meaningful head start, and our investors with a Portfolio-like biotech strategy

100+ ACTIVE GLOBAL CENTERS

An expanding global installed base of regional treatment centers are scaling capacity to be ready for additional cell and gene therapy patients to be treated with a unified platform

CURRENT PORTFOLIO PROVIDES ACCESS TO A ≈$500M MARKET OPPORTUNITY TODAY

Evolved beyond the MRI and into operating room CT navigation, laser ablation therapy, surgical access tools and preclinical CRO services which fuel growth via new product launches and provide path to profitability

A GROWING & PASSIONATE TEAM

Our dedicated team of engineers, scientists and clinical specialists wake up every morning focused on the future of neurosurgery and drug delivery - *This is all that we do...*

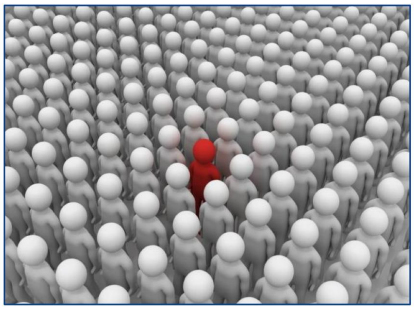
*Including indications for all cell, gene, and device therapies enabled by ClearPoint Neuro technologies

The Future of Cell and Gene Therapy is Not Coming… **It is HERE TODAY**

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

- Parkinson's Disease (≈1,000,000)
- Essential Tremor (≈7,000,000)
- Epilepsy (≈2,900,000)
- Huntington's Disease (≈41,000)
- Rare Childhood Genetic Disorders (≈25,000)
- Dementia and Alzheimer's Disease (≈6,900,000)
- Tumor and Glioblastoma (≈280,000)
- Severe OCD (≈1,000,000)
- Treatment Resistant Depression (≈2,900,000)
- ALS and Spinal Cord Injury (≈300,000)
- Stroke Rehabilitation (≈7,000,000)
- Neuropathic Pain (≈2,000,000)

Neurological diseases cost Americans nearly $800 billion annually. The only way to decrease these costs is to improve treatment.



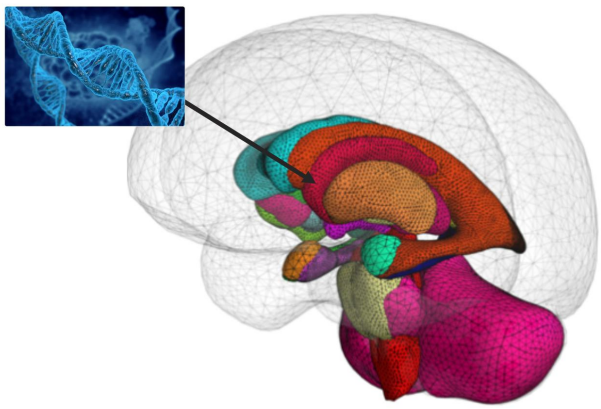
Despite some available treatments, **very few of these patients** undergo a direct surgical intervention to improve their **quality of life**…

Sources on file at ClearPoint Neuro

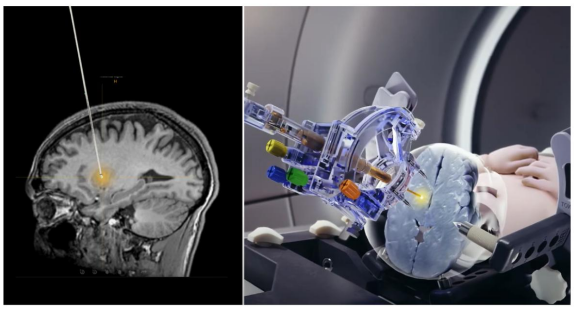
The Future of Cell and Gene Therapy is Not Coming… **It is HERE TODAY**

Our Goal is to Help More Patients by Addressing **Two Primary Barriers to Treatment**

1 **We will partner** to Develop Device, Cell and Gene Therapies that may **cure the underlying disease and restore function…**



2 **We will Enable** fast, minimally invasive, asleep procedures for **a more comfortable and predictable patient experience…**



The Future of Cell and Gene Therapy is Not Coming… **It is HERE TODAY**

1 Partner has received FDA approval for a neuro gene therapy that is co-labeled with ClearPoint

FDA NEWS RELEASE

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

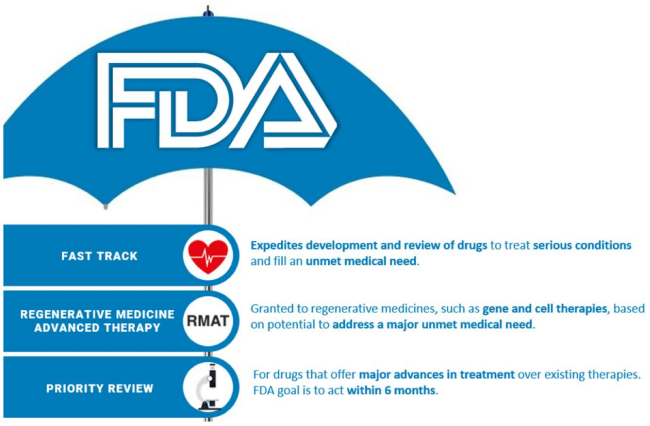
For Immediate Release:
November 14, 2024

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.

"Clinical advancements in the field of gene therapy continue to lead to the discovery and availability of innovative treatment options for rare diseases that are otherwise difficult to manage," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research (CBER). "Today's approval underscores our commitment to help make safe and effective treatments available for patients in need."

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.

7 Partners have programs selected for expedited review - the FDA recognizes the urgency



The Future of Cell and Gene Therapy is Not Coming…**it is HERE TODAY**

7 Active Clinical-Stage Partners have been selected for expedited review, including:

	Indication	RMAT	Fast Track	Clinical Status
PTC THERAPEUTICS	AADC Deficiency	-	-	**Approved**
uniQure	Huntington's Disease	✓	-	Trials in US, EU
BlueRock THERAPEUTICS	Parkinson's Disease	✓	-	Trials in NorthAm
NEURONA THERAPEUTICS	Epilepsy (MTLE)	✓	-	Trials in the US
AskBio	Parkinson's Disease	✓	✓	Trials in US, EU
Aspen NEUROSCIENCE	Parkinson's Disease	-	✓	Trials in the US
AVIADOBIO	Frontotemporal Dementia	-	✓	Trials in US, EU

In 2025 Our Journey Enters the **NEXT CHAPTER**

2010 - 2020

Discovery. Design.

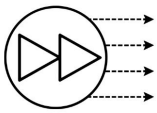
- Neurosurgeon-Led Ideation
- Unique MRI Navigation
- Initial FDA Clearance and Product Revenue
- Accumulation of Clinical Trial Experience Using SmartFlow
- Maestro A.I. Software Development
- Initial IP Generation and Licenses
- NASDAQ Listed

2021 - 2024

Funded. Foundation.

- 100+ Activated Customers
- 60+ Biopharma Partners
- 20+ Potential Disease Indications*
- Preclinical Team Creation
- Operating Room Product Launch
- Laser Therapy Product Launch
- 100+ Owned & Licensed Patents
- EU MDR Certification
- Expanded, Audit-Ready Manufacturing in California
- Leadership Team Complete

2025 - 2027



Fast. Forward.

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- Operational Cash Breakeven

2028+

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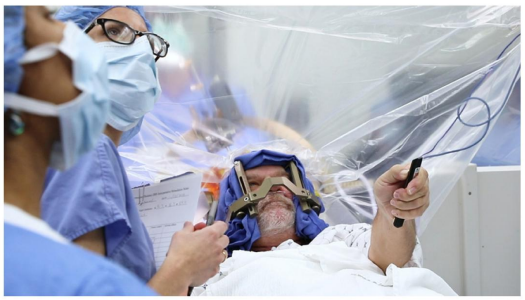
- Additional Global Regulatory Approvals Beyond the U.S. and E.U.

*Including indications for all cell, gene, and device therapies enabled by ClearPoint Neuro technologies

Discovery. Design.

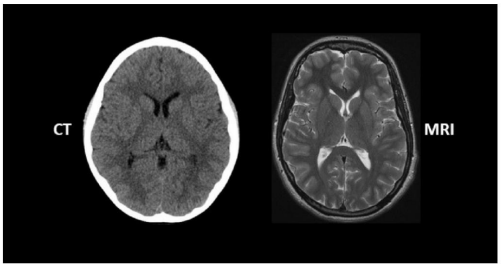
Our Start: Unique Neurosurgery Navigation Guided by Live MRI

Neurosurgery has traditionally been done via open craniotomy or by using CT guidance in the operating room



The historical limitations of CT accuracy would often require patients to remain awake for hours-long brain surgery to confirm the location and impact of technologies like DBS

ClearPoint believed that building a navigation system that could harness the power of live MRI would be accurate enough that **the patient could be comfortably asleep for this minimally invasive procedure**



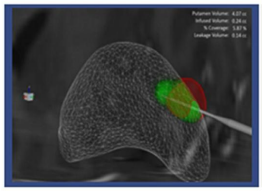
The ClearPoint SmartFrame family of products uses MR-safe materials and enables surgeons to **Decide, Guide & Confirm using live MR Imaging to achieve sub-millimetric accuracy**

Discovery. Design.

Our Start: Decide, Guide & Confirm

Pre-Plan Trajectory
and **D E C I D E**
Entry Point

Automatically **G U I D E**
Precision Adjustments
Prior to Insertion



C O N F I R M
Quality of Delivery Into
Permanent Record

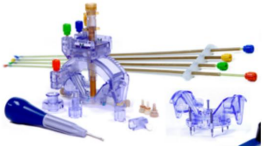
Three Primary Use Cases demonstrate the value of the ClearPoint Neuro Navigation System:

1. Functional neurosurgeons could confidently place DBS electrodes with the **patient comfortably asleep**
2. Neuro-oncologists could perform **entire tumor laser ablations in one room instead of having to transport the patient from the OR to the MRI**
3. BioPharma researchers could confirm that cell and gene therapies are not only **delivered to a precise location**, but could also **confirm proper coverage** of the target structure before closing the patient

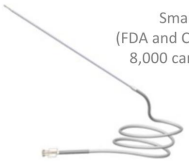
Discovery. Design.

Our Start: Assemble the Building Blocks

Leveraging our **unique platform** and **dedicated team,** we developed and acquired essential technologies necessary to complete the entire ecosystem for MR-Guided Navigation with a focus on cell and gene therapy delivery

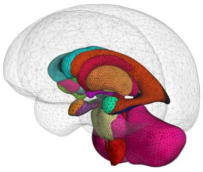


SmartFrame XG and Surgical Accessory Kit

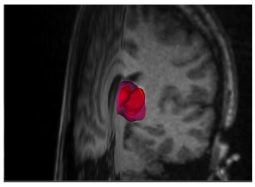


SmartFlow Cannula
(FDA and CE Marked, more than 8,000 cannulas sold to date)

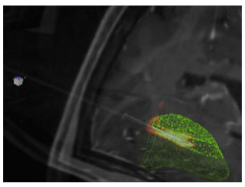
Radial Branching Cell Therapy Devices and Spinal Infusion Anchors
(Investigational Use Only)



ClearPoint Maestro Brain Model Segmentation and Image Fusion



3D Peri-procedural Infusion Monitoring Software
(Investigational Use Only)



Biophysical Modeling of patient specific drug infusions
(Investigational Use Only)

Funded. Foundation.

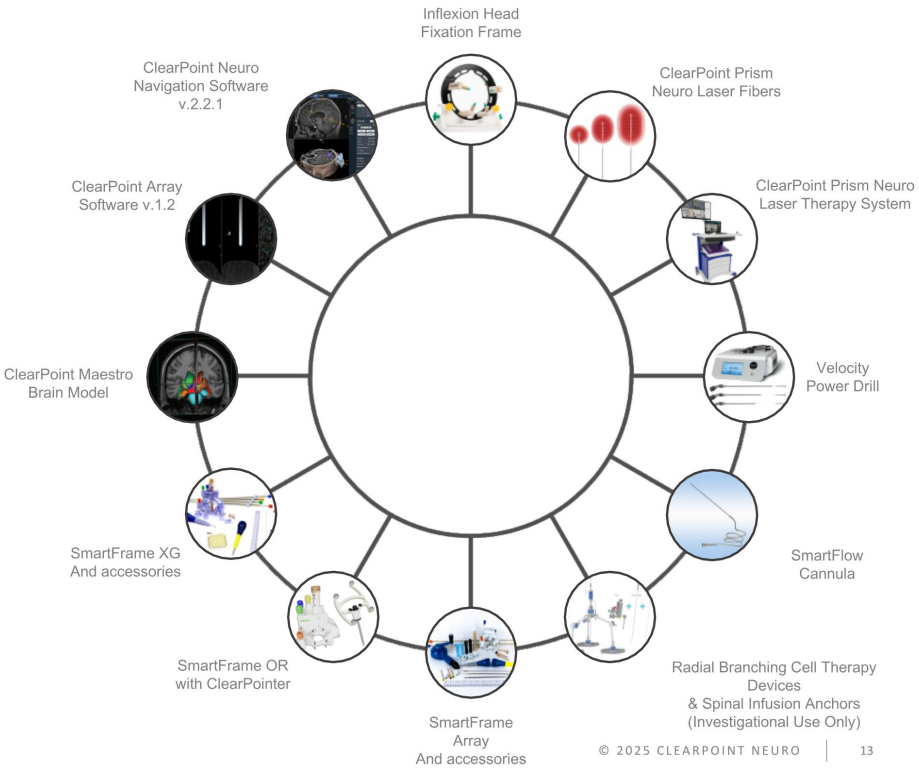
Building the Business

ClearPoint Neuro built a **complete and unique ecosystem of clinical and preclinical products and has achieved regulatory approvals in multiple geographies**

This proven technology has **more than 10 years of experience and been used in more than 7,000 procedures** to date

Demand for our platform has grown driven by the **promise of cell and gene therapies, new DBS indications, and the expansion of laser therapy**

ClearPoint Neuro **activated a record 25 new Global Customers in 2024**



Building the Business: Our Four-Pillar Growth Strategy Remains **Our Foundation**

1 BIOLOGICS & DRUG DELIVERY

PTC Therapeutics · uniQure · Spark Therapeutics · Aspen Neuroscience · UCB · Neurona Therapeutics · BlueRock Therapeutics · AskBio · AviadoBio · charles river · envol Biomedical

60+ INDUSTRY & ACADEMIC PARTNERS

2 NEURSURGERY NAVIGATION

Abbott · Boston Scientific · Medtronic · NeuroPace

3 LASER THERAPY & ACCESS

ClearPoint PRISM Neuro Laser Therapy System · Monteris Medical · Medtronic Visualase · adeor Medical

4 GLOBAL SCALE

100+ GLOBAL CENTERS

Siemens Healthineers · IMRIS · GE · Philips · Medtronic

CLEARPOINT NAVIGATION IS COMPATIBLE WITH MAJOR DIAGNOSTIC AND INTRAOPERATIVE MRI AND CT SCANNERS


CLEARPOINT NEURO
United States Centers
International Centers
Preclinical Centers
Banner Health Tucson
Baptist Medical Center Jacksonville
Baptist Memorial Hospital-Memphis
Barnes-Jewish Hospital
Barrow Neurological Institute/St. Joseph's Hospital
Benioff Children's Hospital
Beth Israel Deaconess
Boston Children's Hospital
Brigham & Women's Hospital
Carilion Clinic
Children's Hospital of Alabama
Children's Mercy Hospital
Children's National Hospital
CHOA Scottish Rite
Cincinnati Children's Hospital
Cincinnati Jewish Hospital
Cleveland Clinic Hospital
Cook Children's Hospital
Corewell Health
Dallas Presbyterian Hospital
Dartmouth-Hitchcock
Duke University
Emory University
Froedtert Hospital
Hackensack University Medical Center
Henry Ford Health
Henry Ford West Bloomfield Hospital
Hospital of University Pennsylvania
Houston Methodist Hospital
INOVA Fairfax
JFK University Medical Center
Johns Hopkins University
Kaleida Health
Kettering Health
Loma Linda University Health
Lucile Packard Children's Hospital
Massachusetts General Hospital
Mayo Clinic in Arizona
Mayo Clinic in Florida
MD Anderson Cancer Center
MedStar Georgetown University Hospital
Memorial Sloan-Kettering Cancer Center
Methodist Hospital San Antonio
Mt. Sinai West
Nationwide Children's
Northwestern Central DuPage
Ohio State University
Oregon Health & Science University
Orlando Health Arnold Palmer Hospital for Children
Oschner Medical Center
Prisma Health
Riverside Methodist Hospital
Rutgers/Robert Wood Johnson
San Francisco VA Health Care System
Southern Arizona VA Health Care System
Stanford University
Sunnyside Kaiser Permanente
Tampa General Hospital
Texas Children's Hospital
University of California Los Angeles
University of California San Diego
University of California San Francisco
University of Alabama at Birmingham
University of Colorado
University of Kansas Medical Center
University of Maryland Medical Center
University of Michigan
University of Minnesota
University of North Carolina (UNC) Health
University of Oklahoma Medical Center
University of Utah
University of Wisconsin
USC Keck Hospital
UT Southwestern Medical Center
Yale University
Charité – Universitätsmedizin Berlin (Berlin, Germany)
Fondazione I.R.C.C.S. Istituto Neurologico Carlo Besta (Milan, Italy)
Great Ormond Street Hospital (London, UK)
Hôpital Fondation Rothschild (Paris, France)
Hospital Israelita Albert Einstein (São Paulo, Brazil)
Hospital Santa Joana (Recife, Brazil)
Mazowiecki Szpital Bródnowski (Warsaw, Poland)
Meyer Children's Hospital (Florence, Italy)
Policlinico Umberto I (Rome, Italy)
Rigshospitalet (Copenhagen, Denmark)
Sahlgrenska Universitetssjukhuset (Gothenburg, Sweden)
Skånes Universitetssjukhus Lund (Lund, Sweden)
Santobono Pausilipon – purchased, not yet installed (Naples, Italy)
Universitätsklinikum Tübingen (Tübingen, Germany)
Universitätsklinikum Düsseldorf (Düsseldorf, Germany)
Universitätsklinikum Freiburg (Freiburg, Germany)
University Hospital of Wales (Cardiff, UK)
100+
GLOBAL CENTERS NOW ACTIVATED
Amplify Bio (Ohio)
Charles River Labs (Laval, Canada)
Charles River Labs (Lyon, France)
Charles River Labs (Mattawan, Michigan)
Children's Hospital of Philadelphia
Envol Biomedical (Florida)
Labcorp (Madison, Wisconsin)
Prisys Biotechnologies (Shanghai, China)
TIDU GENOV - Institut du Cerveau (Paris, France)
University of Pennsylvania Gene Therapy
© 2025 CLEARPOINT NEURO
15

Funded. Foundation.

Building the Business

We have invested in the Development, Quality and Supply infrastructure to build confidence for both hospitals and BioPharma partners

We are not a start-up company but an **experienced and sophisticated medical device extension** for any cell and gene therapy company

ClearPoint Neuro assets available to our partners:

- HQ & Training Facility in Solana Beach, California
- Research Laboratory in San Diego, California
- Manufacturing Facility in Carlsbad, California
- ISO 13485 / MDSAP / EU MDR Certified QMS
- Significant and positive experience with BioPharma Audits, FDA and Global Notified Body inspections

Building the Business

Key Products: FDA CE Marked Platforms

HEADQUARTERS
Solana Beach, CA

MANUFACTURING
Carlsbad, CA

2024 REVENUE
$31.4M[A]

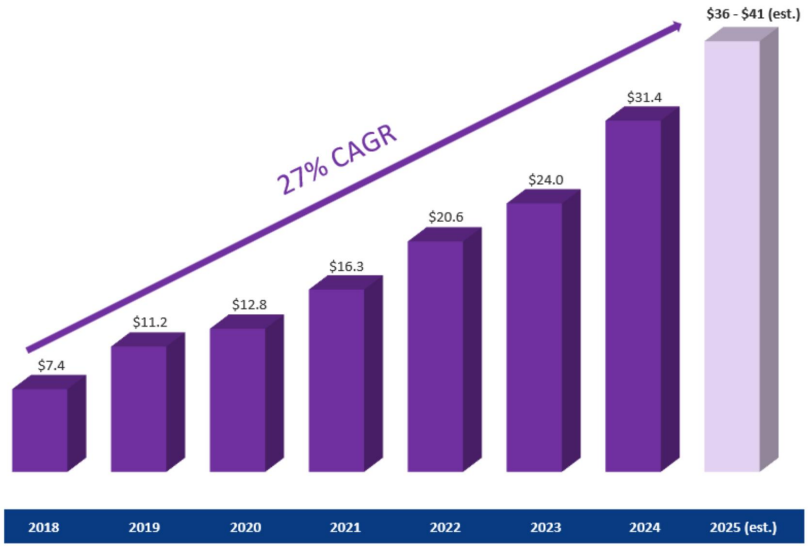
CASH & CASH EQUIVALENTS
$20.1M[A]

PATENTS ISSUED
100+[B]

GROSS MARGIN
61%[C]

EMPLOYEES
100+

2024 Operational Cash Burn
($9.0M)[A]



(A) For the year ended December 31, 2024
(B) Including owned and licensed patents
(C) For the Trailing Twelve Months (TTM)

Building the Business

EXECUTIVE LEADERSHIP TEAM

Experienced leadership team with decades of leadership in medical devices, pharmaceuticals, 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

Ellisa Cholapranee
General
Counsel

Megan Faulkenberry
Vice President
of Quality

Lyubomir Zagorchev, PhD
Vice President of Clinical
Science & Applications

Mary McNamara-Cullinane
Vice President
of Regulatory Affairs

Ernesto Salegio, PhD
Vice President of Translational
& Preclinical Research

Rob Korn
Vice President
U.S. Commercial Sales

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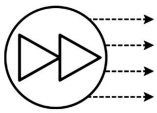
2025 - 2027



Fast. Forward.

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*Including indications for all cell, gene, and device therapies enabled by ClearPoint Neuro technologies

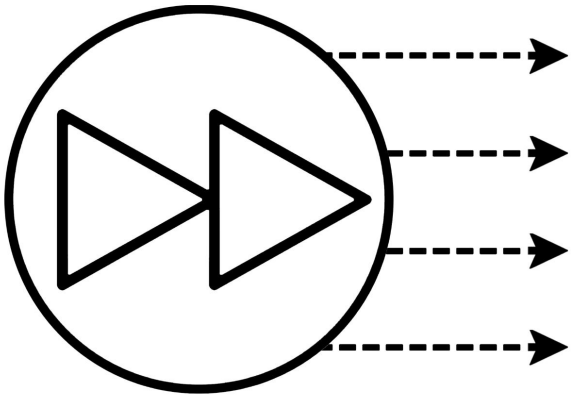
We are Pointing the Way for a Cell and Gene Therapy Future: **Fast. Forward.**

Our commitment to hospitals & BioPharma partners is to help prepare for tens-of-thousands of anticipated new patients who will be seeking these restorative therapies

1. **Extend Our Lead** in Neuro Drug Delivery by leveraging our complete and unique ecosystem of both products and drug development services

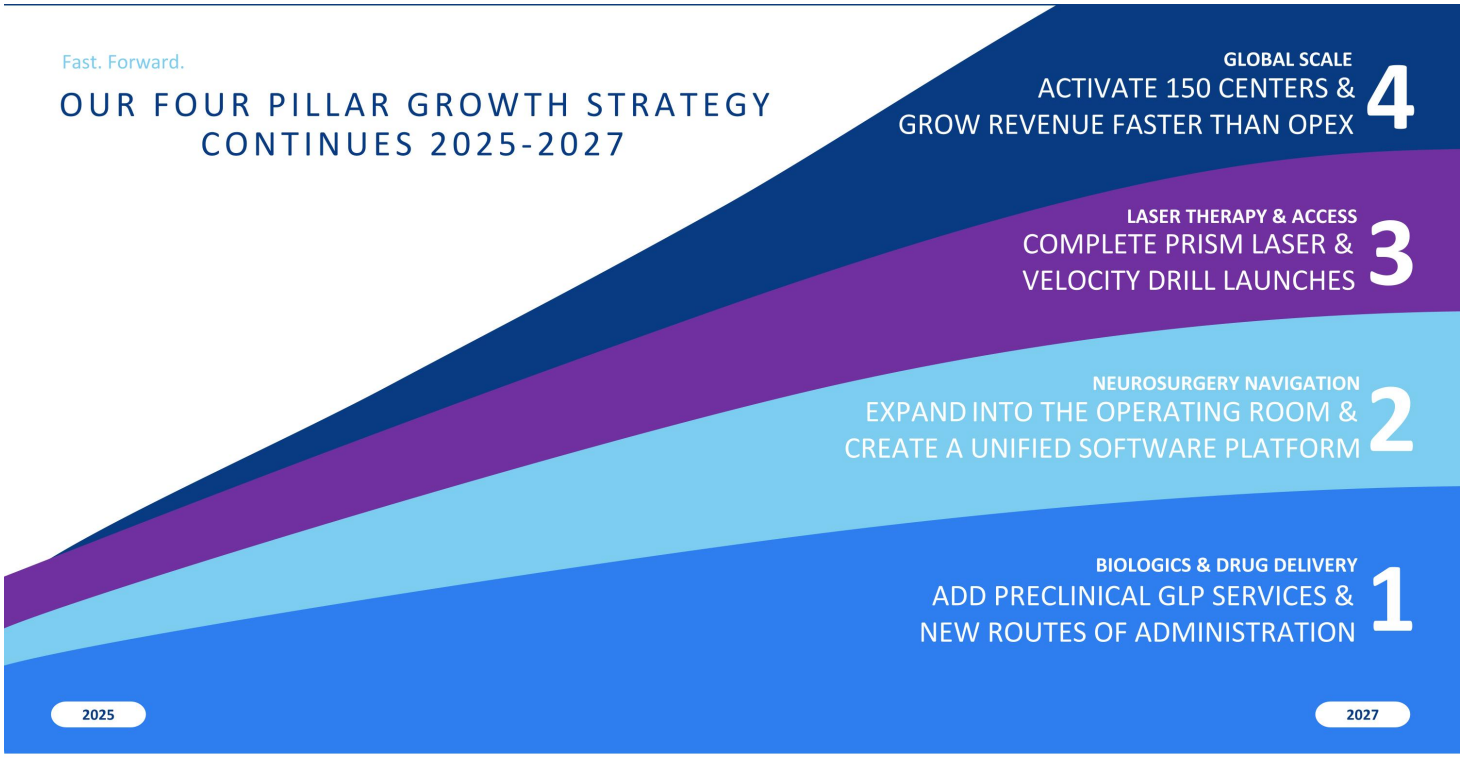
2. **Evolve our Portfolio** to focus on fast, simple, predictable procedures in both the MRI and Operating Room to increase hospital throughput

3. **Expand our Base** of global activated centers to increase capacity and ensure access of these novel cell and gene therapies



Fast. Forward.

OUR FOUR PILLAR GROWTH STRATEGY CONTINUES 2025-2027



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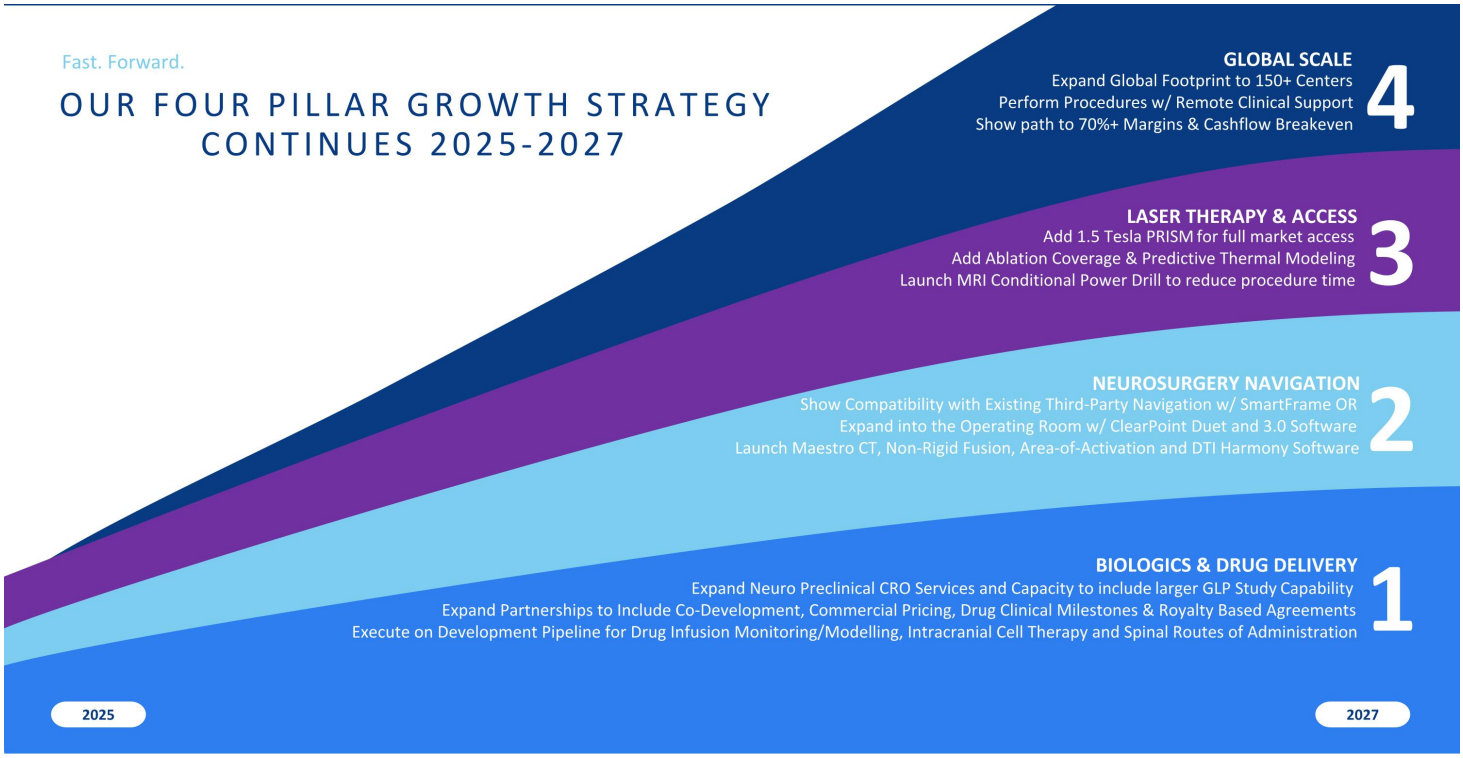
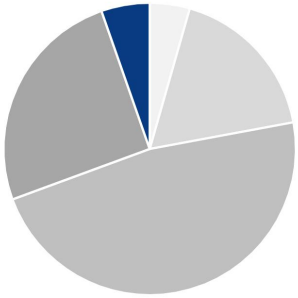


GLP Services & New Routes of Administration

2025 Estimated Preclinical & Clinical TrialMarket (≈$300M)



- Consulting, Bench Testing and Co-Development Services
- Pilot Pre-Clinical Testing (non-GLP)
- FDA Submission Preclinical Testing (GLP)
- Clinical Trial Products & Support Services
- Current CLPT Share

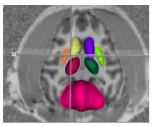
Estimated Market Size, Growth Drivers, and Share Drivers are based on internal estimates and assumptions, market trends, and customer insights. Assumptions may not reflect actual future performance.

Market Growth Drivers:

- Improved BioPharma funding environment
- Additional cell and gene therapies entering the 'funnel'
- Partner progression into larger spend GLP studies and clinical trials
- Successful implementation of FDA 'Expedited Review' pathways including RMAT offering faster clinical trials and less capital required

Market Share Drivers:

- Addition of GLP capability and increased study capacity
- Expansion to ClearPoint Advanced Laboratories ('CAL')
- Product portfolio expansion including new routes of administration
- More custom-development and strategic partnerships w/ BioPharma



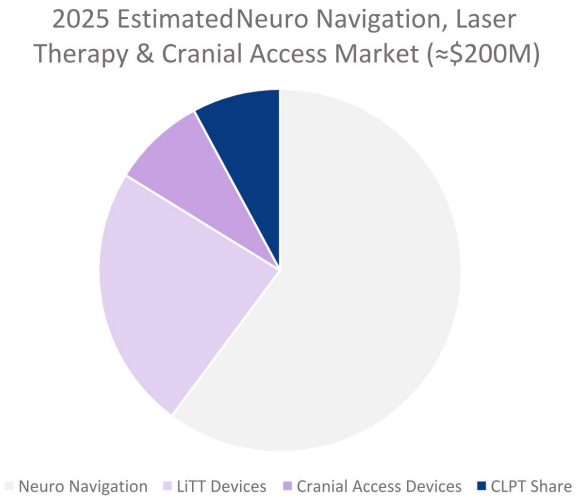
GLP Preclinical Services and Image Analysis Lab (Expected 2H 2025)

New Routes of Administration (Investigational Use Only)

Coverage Estimation and Biophysical modeling (Investigational Use Only)

Assumptions:
150 active cell and gene therapy programs globally
7.5 years average program duration
200 patients studied clinically on average as part of trials

Neuro Navigation, Therapy and Access Product Growth



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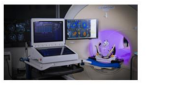
Market Growth Drivers:

- Asleep DBS FDA Clearance and Patient Awareness
- New DBS Indications including Epilepsy, OCD, Depression, BCI
- Increased hospital throughput of laser therapy compared to open surgery
- Improved laser insurance decisions and awareness
- Additional global approvals

Market Share Drivers:

- 3.0 Software for proficient, mirrored CLPT workflow in the MRI and OR
- Asleep, simultaneous workflows for fast procedures, low radiation
- 1.5 Tesla PRISM Laser approval for full market access
- Velocity Alpha MR Drill for faster cranial access times

SmartFrame OR and ClearPointer™



1.5 Tesla PRISM (Expected 2H 2025)

ClearPoint 3.0 Software w/ CT Functionality (FDA Cleared January 2025)

Adeor Velocity MRI Conditional Power Drill (Pending FDA Clearance)

SmartFrame DUET w/ flexible MRI & CT workflows (Expected 2026)

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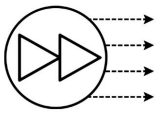

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The FDA & Global Notified Bodies **Recognize the Urgency**

1 Partner has received FDA approval for a neuro gene therapy that is co-labeled with ClearPoint

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.

"Clinical advancements in the field of gene therapy continue to lead to the discovery and availability of innovative treatment options for rare diseases that are otherwise difficult to manage," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research (CBER). "Today's approval underscores our commitment to help make safe and effective treatments available for patients in need."

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.

7 Partners have programs selected for expediated review - the FDA recognizes the urgency

Essential. Everywhere.

ClearPoint has **60+ Active BioPharma Programs across 20+ indications including DBS, LiTT**

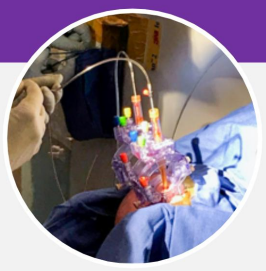
BENCHTOP TESTING

- Device Compatibility Testing
- Infusion Pump Testing
- Custom Device Development
- Performance Assessment
- Device Comparisons / Bridging

PRECLINICAL STUDIES

- Running Preclinical Studies
- Surgical Planning & Guidance
- Writing IACUC / Study Protocols
- Dosing and Surgical Support
- Post-Infusion Reporting

CLINICAL TRIALS



- Surgical Guidance
- Procedure Pre-Planning
- On-Site Clinical Support
- Inventory Management
- Data / Infusion Reporting

Sophisticated Partnerships are Enabled by the **ClearPoint Ecosystem of Products & Services**

We provide the creative flexibility to structure agreements as an **essential and long-term supplier**

ClearPoint May Provide to BioPharma:	**ClearPoint May Secure from BioPharma:**
• Assurance of Supply	• Demand Planning
• Access to FDA Device Dossier	• Purchasing Commitments
• Redundant Global Manufacturing	• Minimum Device Purchases
• Contracted Commercial Pricing	• Co-Development Design Fees
• Licenses to Key Intellectual Property	• Strategic Retainer Agreements
• Custom Device Development	• Clinical Milestone Payments
• Clinical Specialist Procedural Support	• Premium Commercial Pricing
• Dedicated Inventory Locations	• Royalties on Drug Revenue
• Extensive Audit Access & Experience	• Preclinical Service Purchases
• Supply Continuity and Reliability	• Multiple Program Collaborations

CLPT is like a **Portfolio of BioPharma without drug development costs or binary outcomes**

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

- Parkinson's Disease (≈1,000,000)
- Essential Tremor (≈7,000,000)
- Epilepsy (≈2,900,000)
- Huntington's Disease (≈41,000)
- Rare Childhood Genetic Disorders (≈25,000)
- Dementia and Alzheimer's Disease (≈6,900,000)
- Tumor and Glioblastoma (≈280,000)
- Severe OCD (≈1,000,000)
- Treatment Resistant Depression (≈2,900,000)
- ALS and Spinal Cord Injury (≈300,000)
- Stroke Rehabilitation (≈7,000,000)
- Neuropathic Pain (≈2,000,000)

ClearPoint Neuro is Diversified Across:

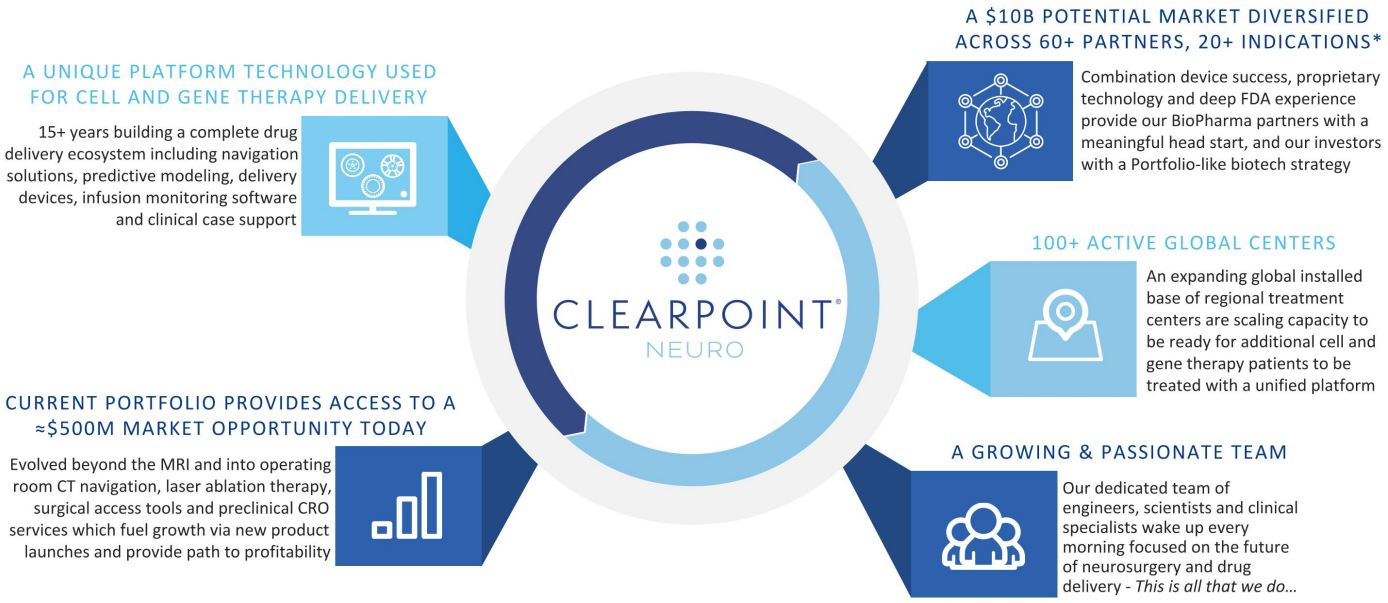
- 60+ BioPharma Partners
- 20+ Indications including device, cell and gene therapies
- Redundant Partners for multiple indications
- Many Partners with multiple programs
- Additional device treatments including DBS, Laser, BCI

Many shots on goal with a path to operational cash breakeven:

	Indication	RMAT	Fast Track	Clinical Status
PTC THERAPEUTICS	AADC Deficiency	-	-	**Approved**
uniQure	Huntington's Disease	✓	-	Trials in US, EU
BlueRock	Parkinson's Disease	✓	-	Trials in NorthAm
NEURONA THERAPEUTICS	Epilepsy (MTLE)	✓	-	Trials in the US
AskBio	Parkinson's Disease	✓	✓	Trials in US, EU
Aspen NEUROSCIENCE	Parkinson's Disease	-	✓	Trials in the US
AVIADOBIO	Frontotemporal Dementia	-	✓	Trials in US, EU

If just 1% of patients with diseases under expedited review are treated each year, at current ASPs that would yield more than $250M in additional CLPT revenue

CLEARPOINT NEURO EXECUTIVE SUMMARY



*Including indications for all cell, gene, and device therapies enabled by ClearPoint Neuro technologies

Sources

Sources

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