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

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): May 13, 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** **(Address of Principal Executive Offices)**	**92075** **(Zip Code)**

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

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

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

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

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

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

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

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

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

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

Emerging growth company ☐

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

Item 2.02 Results of Operations and Financial Condition.

On May 13, 2025, ClearPoint Neuro, Inc. (the "Company") issued a press release announcing its financial results for the first fiscal quarter ended March 31, 2025. A copy of the press release is furnished herewith as Exhibit 99.1.

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

Item 7.01 Regulation FD Disclosure.

On May 13, 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 May 13, 2025
Exhibit 99.2	Investor Presentation dated May 13, 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: May 13, 2025

By: /s/ Danilo D'Alessandro

Danilo D'Alessandro
Chief Financial Officer

Exhibit 99.1

ClearPoint Neuro Reports First Quarter 2025 Results

Record Revenue Highlighted by 70% Growth in Single-Use Navigation and Therapy Products

SOLANA BEACH, CA, May 13, 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 first quarter ended March 31, 2025.

First Quarter Highlights

- Reported record quarterly revenue of $8.5 million, an 11% year-over-year increase compared with the first quarter of 2024;
- Grew total consumable product revenue by $2.6 million year-over-year, or 104%, including biologics and drug delivery cannulas, SmartFrame® Family Navigation devices, and ClearPoint PRISM® Laser Therapy Applicators;
- Received FDA Clearance for the ClearPoint 3.0 Software which includes both operating room navigation capability and enhanced laser therapy features. This software is now in Full Market Release and is contributing to meaningful revenue and case volume growth; and
- Reported cash and cash equivalents totaling $12.4 million as of March 31, 2025 (balance does not include credit facility proceeds).

"Our 2025 fiscal year is off to a strong start as we enter the Fast Forward phase of the company, starting with a record revenue quarter and fueled by multiple new product launches that are delivering on our promise of fast, simple and predictable procedures," commented Joe Burnett, President and CEO at ClearPoint Neuro. "The foundational investments that we have made over the past few years to grow our global biopharma partnerships, expand navigation into the operating room, and enter the laser therapy market are now paying off and are underlined by 104% growth in these single-use devices. It is especially exciting to see all three of these product lines contributing meaningfully to this growth."

"In addition, despite recent volatility in the capital markets, we have now secured a long-term credit facility and an equity investment that gives us flexibility on our balance sheet to ensure we can achieve ClearPoint Neuro's strategic objectives. We are excited to see the confidence that Oberland Capital has in our future, as both a lender and a shareholder, and we look forward to this new partnership."

Business Outlook

The Company reaffirms its full year 2025 revenue outlook between $36.0 million and $41.0 million.

Financial Results – Quarter Ended March 31, 2025

Total revenue was $8.5 million and $7.6 million for the three months ended March 31, 2025 and 2024, respectively, representing an increase of 11%.

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 9% to $4.7 million for the three months ended March 31, 2025, from $4.3 million for the same period in 2024. This increase is attributable to a year-over-year increase of $1.2 million, or 222%, in product revenue resulting from higher demand for disposables as multiple partners progress in their trials, partially offset by a $0.8 million decrease in service and other revenue, due to less work performed in preclinical trials and consulting during the three months ended March 31, 2025, compared to the same period in 2024.

Neurosurgery navigation and therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 70% to $3.3 million during the three months ended March 31, 2025, from $1.9 million for the same period in 2024. The increase is driven by higher sales for new product offerings as well as an increased customer base, during the three months ended March 31, 2025, compared to the same period in 2024.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software and related services, decreased 63% to $0.5 million for the three months ended March 31, 2025, from $1.4 million for the same period in 2024, due to a decrease in the placements of ClearPoint navigation capital equipment and software and Prism laser units, primarily driven by installation timing.

The Company achieved a gross margin of 60% on its sales for three months ended March 31, 2025, compared to a gross margin of 59% for the same period in 2024. The increase in gross margin was primarily due to lower excess and obsolete inventory for the three months ended March 31, 2025, as compared to the same period in 2024.

Operating expenses were $11.3 million for the three months ended March 31, 2025, compared with $8.7 million for same period in 2024, an increase of 29%. 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, higher product development costs, an increase in the allowance for credit losses, and higher professional and regulatory fees.

At March 31, 2025, the Company had cash and cash equivalents totaling $12.4 million as compared to $20.1 million at December 31, 2024, with the decrease resulting from the use of $6.2 million in cash for operating activities, primarily driven by the payment of the employee annual incentive and $1.3 million for tax payments made related to the net share settlement of equity awards. The net share settlement of equity awards upon vesting results in the Company withholding from the shares issuable at vest a number of shares having a value equal to the employees' tax obligations and remitting a cash payment to the appropriate taxing authority.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's 2025 first quarter results on Tuesday, May 13, 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=ZS0iBbgx. Investors and analysts who would like to participate in the conference call via telephone may do so at (877) 407-9034, or at (201) 493-6737 if calling from outside the U.S. or Canada.

For those who cannot access the live broadcast, a replay will be available shortly after the completion of the call until June 12, 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 central nervous system delivery of therapeutics in preclinical studies and clinical trials worldwide. To date, thousands of procedures have been performed and supported by the Company's field-based clinical specialist team, which offers support and services to our customers and partners worldwide. For more information, please visit www.clearpointneuro.com.

Forward-Looking Statements

Statements in this press release and in the teleconference referenced above concerning the Company's plans, growth and strategies may include forward-looking statements within the context of the federal securities laws. Statements regarding the Company's future events, developments and future performance, the 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, 2024, which has been filed with the Securities and Exchange Commission, and the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2025, which the Company intends to file with the Securities and Exchange Commission on or before May 15, 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

(Unaudited)

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

	For the Three Months Ended March 31,	
	2025	**2024**
Revenue:		
Product revenue	$ 5,291	$ 3,635
Service and other revenue	3,194	4,004
Total revenue	8,485	7,639
Cost of revenue	3,353	3,114
Gross profit	5,132	4,525
Research and development costs	3,379	2,625
Sales and marketing expenses	3,834	3,290
General and administrative expenses	4,082	2,826
Operating loss	(6,163)	(4,216)
Other income (expense):		
Other income (expense), net	4	(26)
Interest income, net	151	111
Net loss before income taxes	(6,008)	(4,131)
Income tax expense	(18)	(15)
Net loss	$ (6,026)	$ (4,146)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.22)	$ (0.16)
Weighted average shares outstanding:		
Basic and diluted	27,718,918	25,452,096

CLEARPOINT NEURO, INC.

Consolidated Balance Sheets
(in thousands, except for share and per share data)

	March 31, 2025 (Unaudited)	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,387	$ 20,104
Accounts receivable, net	3,651	4,713
Inventory, net	6,582	6,863
Prepaid expenses and other current assets	1,594	1,683
Total current assets	24,214	33,363
Property and equipment, net	2,183	2,005
Operating lease, right-of-use assets	2,960	3,086
Software license inventory	107	103
Licensing rights	458	484
Other assets	148	148
Total assets	$ 30,070	$ 39,189
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,216	$ 1,340
Accrued compensation	1,944	4,885
Other accrued liabilities	1,510	1,450
Operating lease liabilities, current portion	578	557
Contract liabilities, current portion	1,618	2,121
Total current liabilities	6,866	10,353
Operating lease liabilities, net of current portion	2,860	3,011
Contract liabilities, net of current portion	357	436
Total liabilities	10,083	13,800
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized; none issued and outstanding at March 31, 2025 and December 31, 2024	—	—
Common stock, $0.01 par value; 90,000,000 shares authorized at March 31, 2025 and December 31, 2024; 27,980,184 and 27,617,415 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	280	276
Additional paid-in capital	217,103	216,483
Accumulated deficit	(197,396)	(191,370)
Total stockholders' equity	19,987	25,389
Total liabilities and stockholders' equity	$ 30,070	$ 39,189

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

	For the Three Months Ended March 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (6,026)	$ (4,146)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for credit losses (recoveries)	217	(146)
Depreciation and amortization	103	243
Share-based compensation	1,908	1,504
Amortization of debt issuance costs and original issue discounts	—	15
Amortization of lease right of use assets, net of accretion in lease liabilities	231	231
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	846	846
Inventory, net	78	53
Prepaid expenses and other current assets	168	165
Other assets	—	(39)
Accounts payable and accrued expenses	(2,882)	(931)
Lease liabilities	(234)	(171)
Contract liabilities	(581)	(1,464)
Net cash flows from operating activities	(6,172)	(3,840)
Cash flows from investing activities:		
Purchases of property and equipment	(183)	—
Net cash flows from investing activities	(183)	—
Cash flows from financing activities:		
Proceeds from public offering of common stock, net of offering costs	—	16,183
Payment of At-The-Market offering costs	(78)	—
Proceeds from stock option exercises	21	21
Payments for taxes related to net share settlement of equity awards	(1,305)	(151)
Net cash flows from financing activities	(1,362)	16,053
Net change in cash and cash equivalents	(7,717)	12,213
Cash and cash equivalents, beginning of period	20,104	23,140
Cash and cash equivalents, end of period	$ 12,387	$ 35,353
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ —	$ —
Interest	$ —	$ 185


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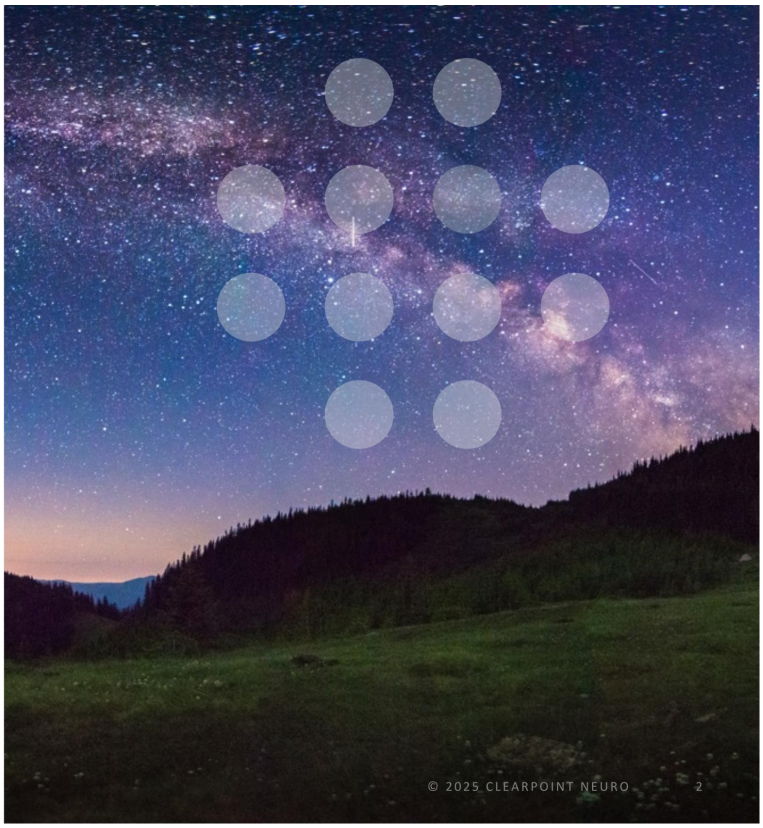
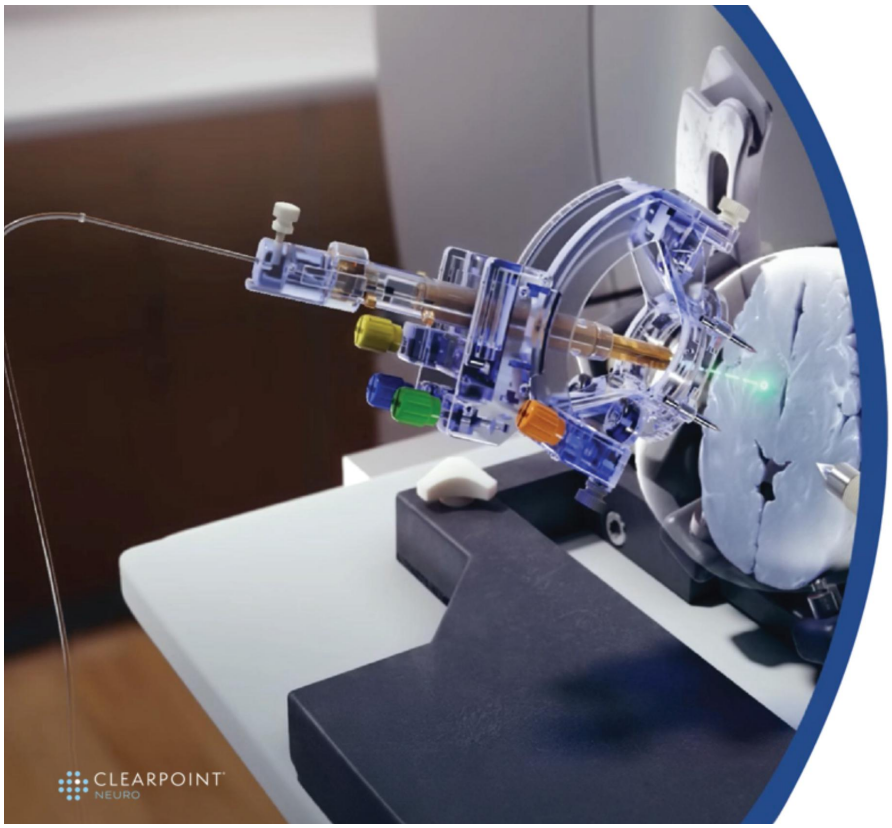
DISCLAIMER

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; regulatory and policy uncertainty due to presidential administration change; 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, 2024,which has been filed with the Securities and Exchange Commission, and the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2025, which the company intends to file with the Securities and Exchange Commission on or before May 15, 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

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 pre-clinical CRO services which fuel growth via new product launches and provide path to profitability

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

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...*

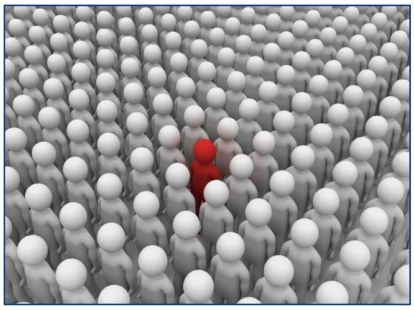
*Including indications for all cell, gene, and device therapies enabled by ClearPoint Neuro technologies

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.



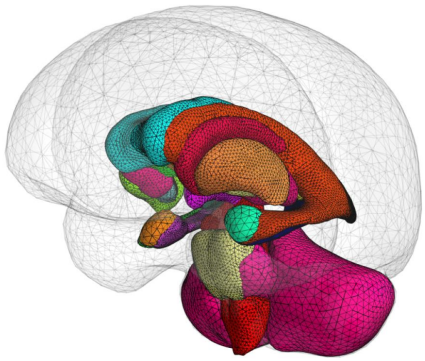
Despite some available treatments, **very few of these patients** undergo a direct surgical intervention to improve their **quality of life**…

Sources on file at ClearPoint Neuro

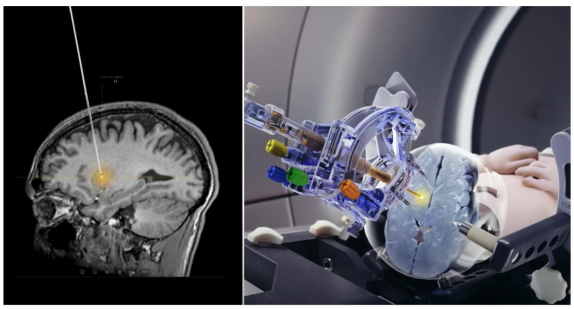
The Future of Cell and Gene Therapy is Not Coming… **It is HERE TODAY**

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

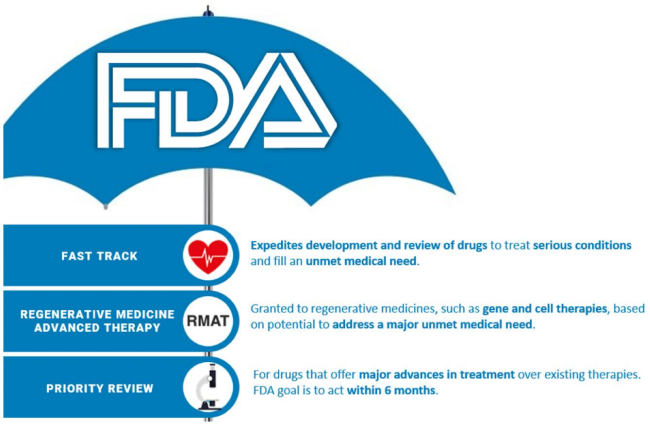
For Immediate Release:
November 14, 2024

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 Designation	Clinical Strategy
PTC THERAPEUTICS	AADC Deficiency	-	-	Approved
uniQure	Huntington's' Disease	June 2024	-	Confirmed
BlueRock THERAPEUTICS	Parkinson's Disease	May 2024	-	Confirmed
NEURONA THERAPEUTICS	Epilepsy (MTLE)	June 2024	-	Confirmed
AskBio	Parkinson's Disease	February 2025	-	TBD
Aspen NEUROSCIENCE	Parkinson's Disease	-	June 2024	TBD
AVIADOBIO	Frontotemporal Dementia	-	November 2023	TBD

Source: Lake Street Capital Markets analyst coverage of uniQure, Bluerock, Neurona, AskBio, Aspen Neuroscience, and AviadoBio

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

2010 - 2020

Discovery. Design.

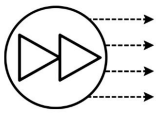
- Neurosurgeon Led Ideation
- Unique MRI Navigation
- Initial FDA Clearance and Product Revenue
- Accumulation of Clinical Trial Experience Using SmartFlow®
- Maestro A.I. Software Development
- Initial IP Generation and Licenses
- NASDAQ Listed

2021 - 2024

Funded. Foundation.

- ≈ 100 Activated Customers
- 60+ Biopharma Partners
- 20+ Potential Disease Indications*
- Pre-Clinical 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.

- Grow into an estimated, existing $500m Market Opportunity
- 150 Activated Customers
- First Commercial CGT Launched
- GLP Pre-Clinical Capability
- Operating Room Nav Growth
- Laser Therapy Growth
- MR Drill and Access Growth
- ‘Harmony’ Software Launch
- New Routes of Administration
- Operational Cash Breakeven

2028+

Essential. Everywhere.

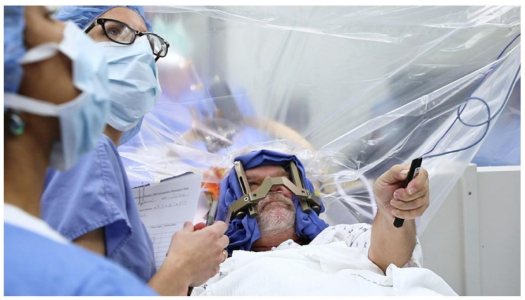
- $10b Potential Revenue Opportunity
- ‘Combination Product’ Regulatory Designation for multiple cell and gene therapy indications
- Meaningful Revenue from Sophisticated BioPharma Deal Structures beyond product sales including royalty and milestone payments, co-development
- One Unified Platform with both MRI and Operating Room Capability and Workflows
- 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.

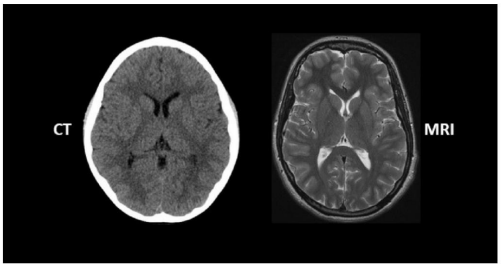
Our Start: Unique Neurosurgery Navigation Guided by Live MRI

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**



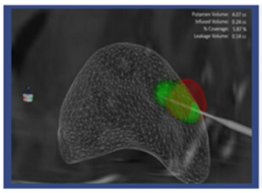
The ClearPoint SmartFrame® family of products use MRI-safe materials and enable surgeons to **Decide, Guide & Confirm using live MR Imaging to achieve sub-millimetric accuracy**

Discovery. Design.

Our Start: Decide, Guide & Confirm

Pre-Plan Trajectory and **DECIDE** Entry Point

Automatically **GUIDE** Precision Adjustments Prior to Insertion



CONFIRM Quality of Delivery Into Permanent Record

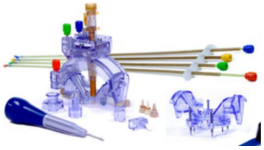
Three Primary Use Cases demonstrated the value of the ClearPoint MRI Navigation System:

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

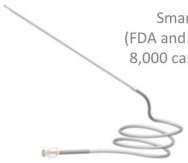
Discovery. Design.

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 MRI Guided Navigation, and with a focus on cell and gene therapy delivery

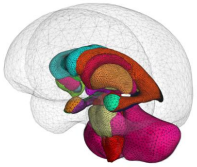


SmartFrame® XG and
Surgical Accessory Kit

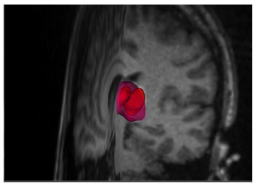


SmartFlow® Cannula
(FDA and CE Mark, more than
8,000 cannulas sold to date)

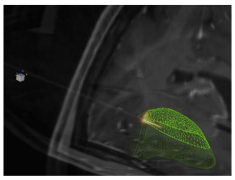
Radial Branching Cell Therapy Devices
and Spinal Infusion Anchors
(Investigational Use Only)



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.

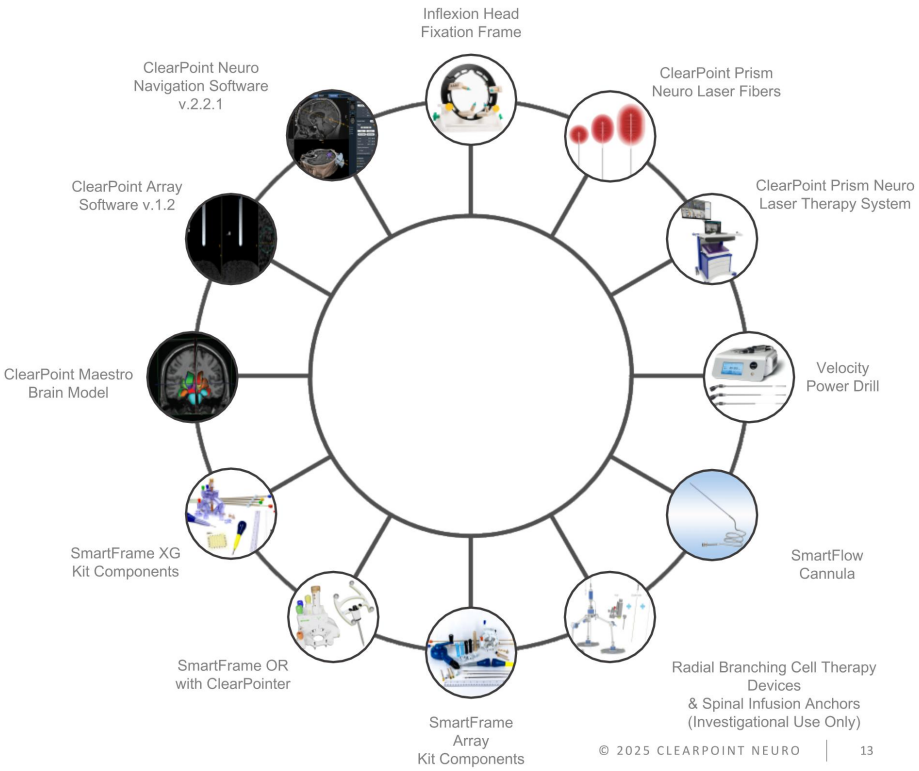
Building the Business

ClearPoint built a **complete and unique ecosystem of clinical and pre-clinical 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 expansion of laser therapy**

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



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 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
Brown University / Rhode Island 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
Ochsner Medical Center
Ohio State University
Oregon Health & Science University
Orlando Health Arnold Palmer Hospital for Children
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 Alabama at Birmingham
University of California Los Angeles
University of California San Diego
University of California San Francisco
University of Colorado
University of Florida Jacksonville
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
Wolfson Children's Hospital
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 Children's Hospital (Naples, Italy)
Universitätsklinikum Tübingen (Tübingen, Germany)
Universitätsklinikum Düsseldorf (Düsseldorf, Germany)
Universitätsklinikum Freiburg (Freiburg, Germany)
University Hospital of Wales (Cardiff, UK)

Charles River Labs (Laval, Canada)
Charles River Labs (Lyon, France)
Charles River Labs (Mattawan, Michigan)
Children's Hospital of Philadelphia
Envoi Biomedical (Florida)
Labcorp (Madison, Wisconsin)
Prisys Biotechnologies (Shanghai, China)
PDU GENOV - Institut du Cerveau (Paris, France)
University of Pennsylvania Gene Therapy

100+
GLOBAL CENTERS NOW ACTIVATED

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 assets available to our partners;

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

Funded. Foundation.

Building the Business

Key Products: FDA CE Marked Platforms

HEADQUARTERS
Solana Beach, CA

MANUFACTURING
Carlsbad, CA

2024 REVENUE
$31.4m (A)

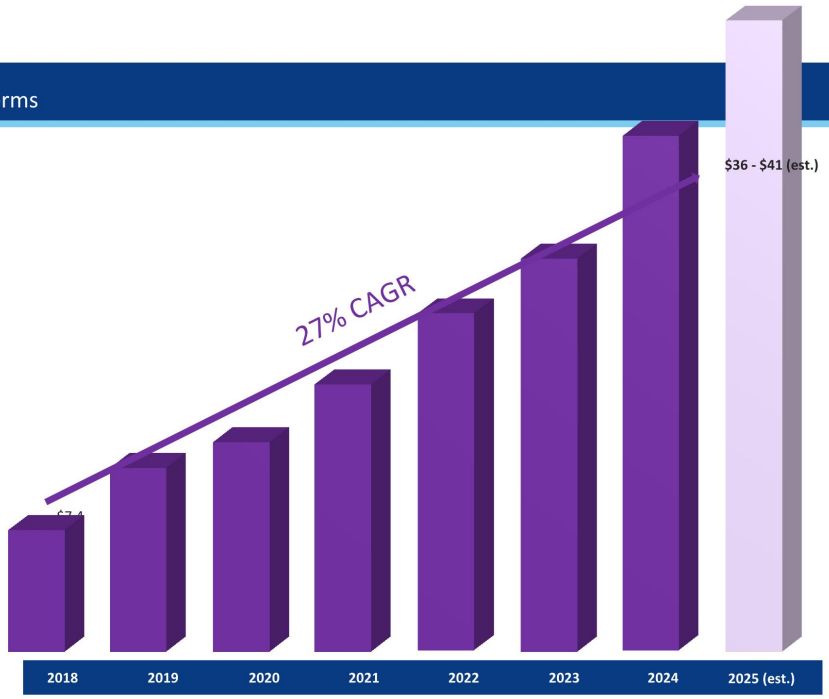
CASH & CASH EQUIVALENTS
$12.1 m (B,C)

PATENTS ISSUED
100+ (D)

GROSS MARGIN
61% (B,E)

EMPLOYEES
100+

2024 Operational Cash Burn
($9.0m) (A)



(A) For the year ended December 31, 2024
(B) Unaudited, as of, and for the quarter ended March 31, 2025
(C) Excludes Gross Proceeds of $33.5m received on May 12, 2025
(D) Including owned and licensed patents
(E) 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
& Pre-Clinical Research

Rob Korn
Vice President
U.S. Commercial Sales

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

2010 - 2020

Discovery. Design.

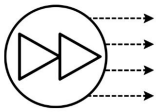
- Neurosurgeon Led Ideation
- Unique MRI Navigation
- Initial FDA Clearance and Product Revenue
- Accumulation of Clinical Trial Experience Using SmartFlow®
- Maestro A.I. Software Development
- Initial IP Generation and Licenses
- NASDAQ Listed

2021 - 2024

Funded. Foundation.

- ≈ 100 Activated Customers
- 60+ Biopharma Partners
- 20+ Potential Disease Indications*
- Pre-Clinical 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.

- Grow into an Estimated, Existing $500m Market Opportunity
- 150 Activated Customers
- First Commercial CGT Launched
- GLP Pre-Clinical Capability
- Operating Room Nav Growth
- Laser Therapy Growth
- MR Drill and Access Growth
- 'Harmony' Software Launch
- New Routes of Administration
- Operational Cash Breakeven

2028+

Essential. Everywhere.

- $10b Potential Revenue Opportunity
- 'Combination Product' Regulatory Designation for multiple cell and gene therapy indications
- Meaningful Revenue from Sophisticated BioPharma Deal Structures beyond product sales including royalty and milestone payments, co-development
- One Unified Platform with both MRI and Operating Room Capability and Workflows
- Global Regulatory Approvals Beyond the U.S. and E.U.

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

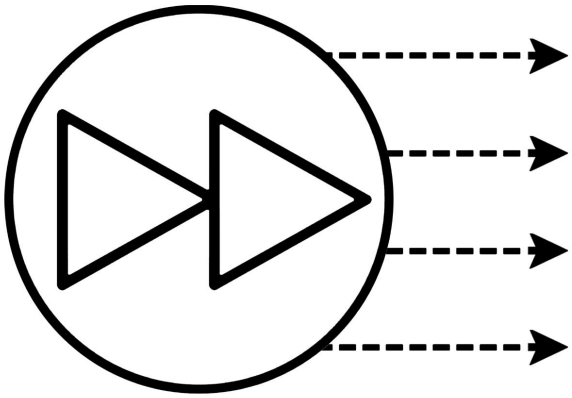
We are Pointing the Way for a Cell and Gene Therapy Future: **Fast. Forward.**

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 new-to-world cell and gene therapies

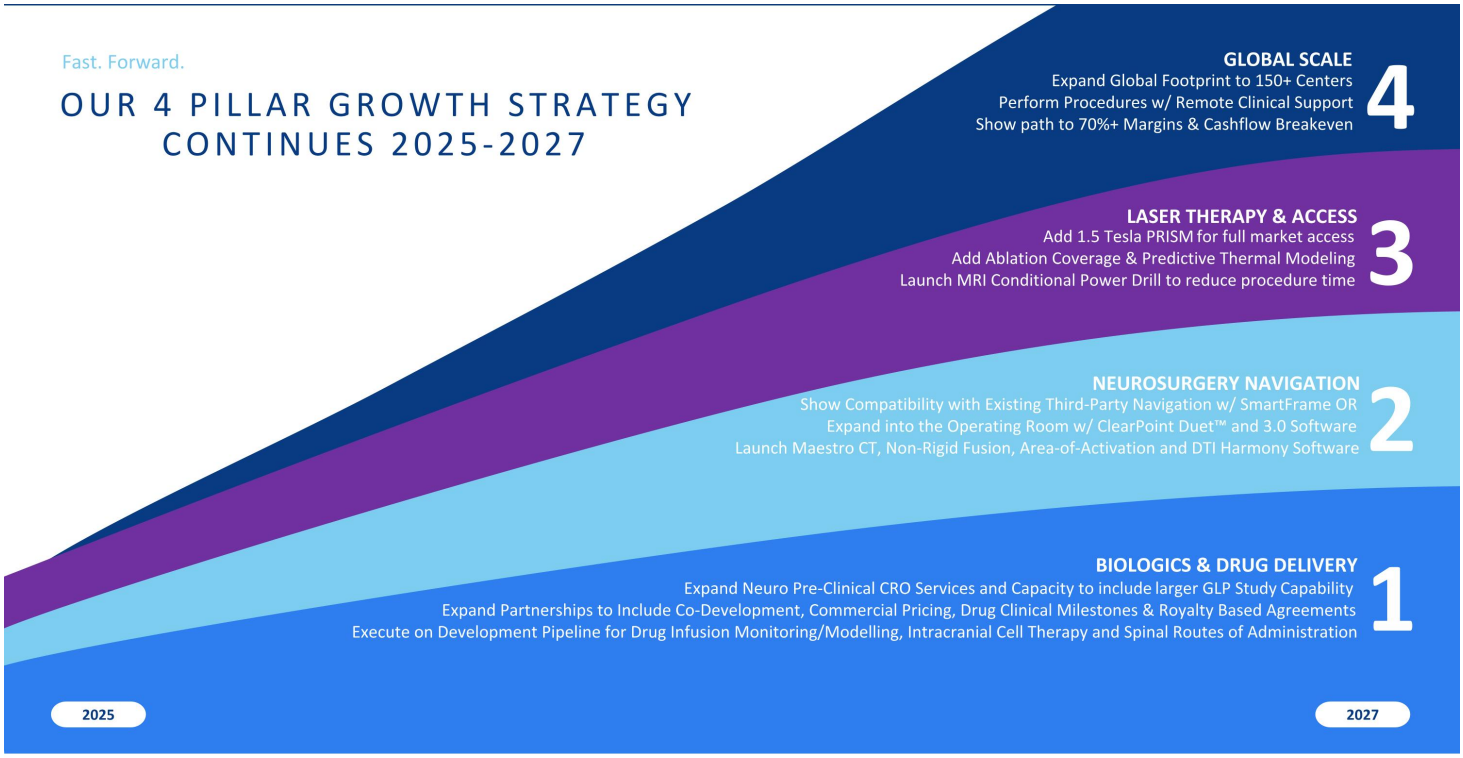


Fast. Forward.

OUR 4 PILLAR GROWTH STRATEGY CONTINUES 2025-2027

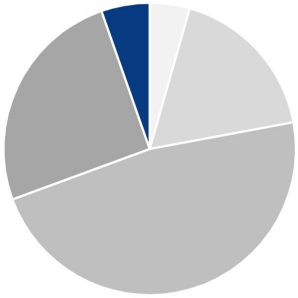
Fast. Forward.

OUR 4 PILLAR GROWTH STRATEGY CONTINUES 2025-2027



GLP Services & New Routes of Administration

2025 Estimated Pre-Clinical & Clinical Trial Market (≈$300m)



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

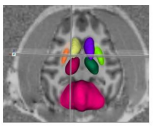
Estimated Market Size, Growth Drivers, and Share Drivers are based on internal estimates and assumptions, market trends, and customer insights. Assumptions may not reflect actual future performance.

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

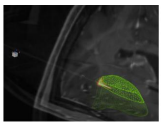
Market Share Drivers:

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



GLP Pre-Clinical Services and Image Analysis Lab (Expected 2H 2025)

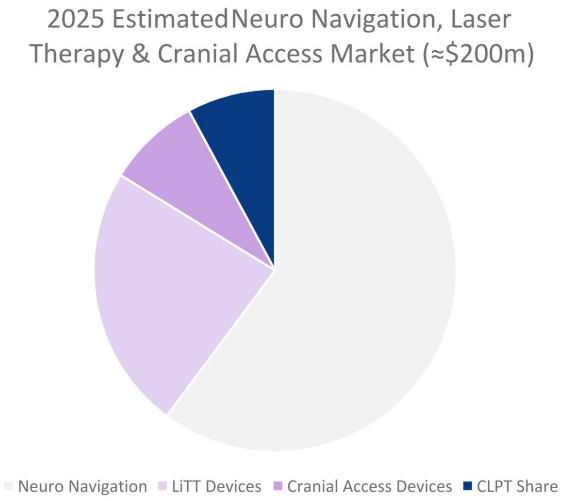
New Routes of Administration (Investigational Use Only)



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



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:

- 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 in EU and APAC

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™

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

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

1.5 Tesla PRISM (Expected 2H 2025)

Adeor Velocity® MRI Conditional Power Drill

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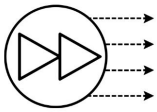
2025 - 2027



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

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**

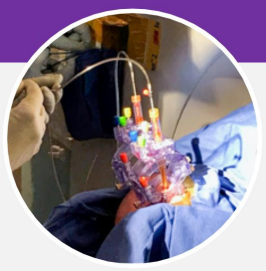
BENCHTOP TESTING

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

PRECLINICAL STUDIES

- Running Pre-Clinical studies
- Surgical Planning & Guidance
- Writing IACUC / Study Protocols
- Dosing and Surgical Support
- Post-Infusion Reporting

CLINICAL TRIALS



- Surgical Guidance + Site Intros
- 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	⟷	• Pre-Clinical 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. alone suffer from **severe and debilitating neurological disorders**;

- Parkinson's Disease (1.0m)
- Essential Tremor (7.0m)
- Epilepsy (2.9m)
- Huntington's Disease (41k)
- Rare Childhood Genetic Disorders (25k)
- Dementia and Alzheimer's Disease (6.9m)
- Tumor and Glioblastoma (280k)
- Severe OCD (1.0m)
- Treatment Resistant Depression (2.8m)
- ALS and Spinal Cord Injury (300k)
- Stroke Rehabilitation (7.0m)
- Neuropathic Pain (2.0m)

ClearPoint is Diversified Across;

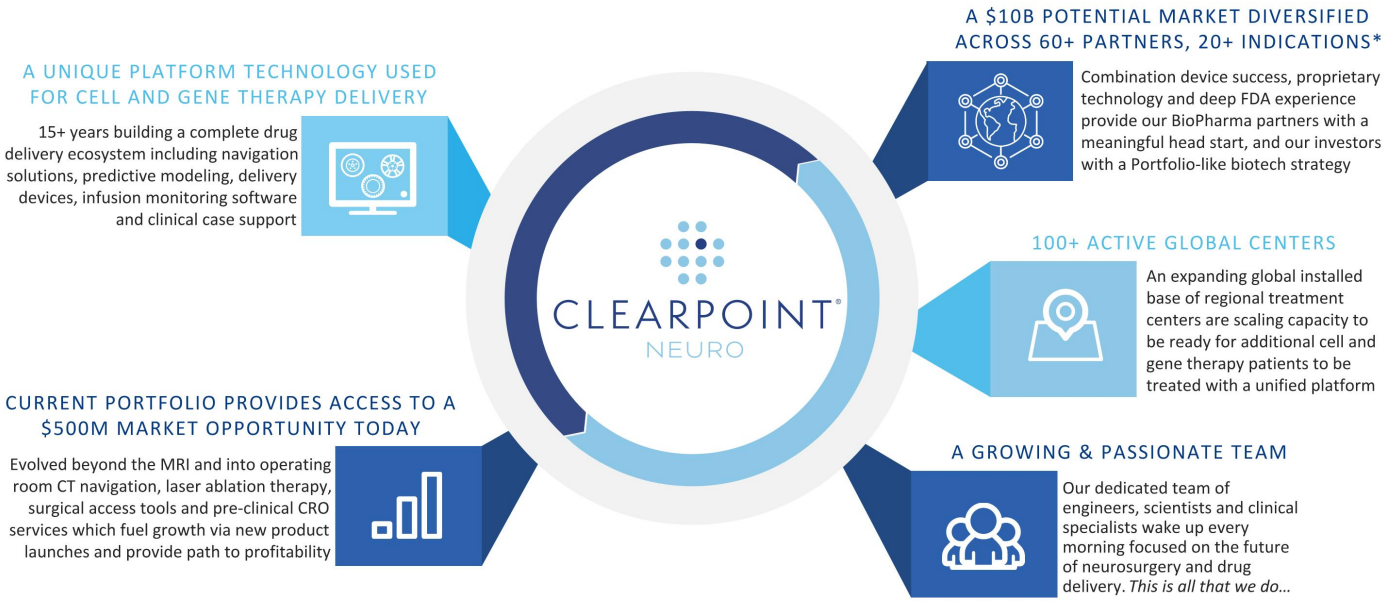
- 60+ BioPharma Partners
- 20+ Indications including device, cell and gene therapies
- Redundant Partners for multiple indications
- Many Partners with multiple programs
- Additional Device treatments including DBS, Laser, BCI

Many 'Shots on Goal' with a path to operational cash breakeven;

	Indication	RMAT	Fast Track Designation	Clinical Strategy
PTC Therapeutics	AADC Deficiency	-	-	Approved
uniQure	Huntington's' Disease	June 2024	-	Confirmed
BlueRock	Parkinson's Disease	May 2024	-	Confirmed
NEURONA THERAPEUTICS	Epilepsy (MTLE)	June 2024	-	Confirmed
AskBio	Parkinson's Disease	February 2025	-	TBD
Aspen Neuroscience	Parkinson's Disease	-	June 2024	TBD
AVIADOBIO	Frontotemporal Dementia	-	November 2023	TBD

If just 1% of patients with diseases under expedited review are treated each year, at current ASP's 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

Alzheimer's Association 2024 Alzheimer's Disease Facts and Figures
How Many People in the USA Have Essential Tremor? Deriving a Population Estimate Based on Epidemiological Data - PMC
Parkinson's Disease: Challenges, Progress, and Promise | National Institute of Neurological Disorders and Stroke
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