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

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): August 12, 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 August 12, 2025, ClearPoint Neuro, Inc. (the "Company") issued a press release announcing its financial results for the second fiscal quarter ended June 30, 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 August 12, 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 August 12, 2025
Exhibit 99.2	Investor Presentation dated August 12, 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: August 12, 2025

By: /s/ Danilo D'Alessandro

Danilo D'Alessandro
Chief Financial Officer

ClearPoint Neuro Reports Second Quarter 2025 Results

Record Revenue and Substantial Cash Infusion Highlight the Company's 'Fast. Forward.' Strategy

SOLANA BEACH, CA, August 12, 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 second quarter ended June 30, 2025.

Second Quarter Highlights

- Reported record quarterly revenue of $9.2 million, a 17% year-over-year increase compared with the second quarter of 2024;
- Neurosurgery navigation and therapy revenue grew 33% to $3.4 million year-over-year fueled by SmartFrame® Family Navigation devices and ClearPoint PRISM® Laser Therapy Applicators;
- Entered into a note financing arrangement with Oberland Capital Management of up to $105.0 million, with $30.0 million of gross proceeds funded at closing;
- Entered into a stock purchase agreement with Oberland Capital Management for the purchase of shares of the Company's common stock for an additional $3.5 million of gross proceeds; and
- Reported cash and cash equivalents totaling $41.5 million as of June 30, 2025.

"The team has continued to deliver strong results here in the second quarter, both financially and strategically," commented Joe Burnett, President and CEO at ClearPoint Neuro. "From a financial perspective we achieved record revenue, benefiting from sales contributions across all four of our growth pillars. Strategically, we were able to achieve key milestones that give us confidence that we will see continued growth across our entire portfolio. This is an exciting phase for the company, which we call the 'Fast. Forward.' phase as we now have multiple growth vectors taking shape at the same time including: 1) the expansion into the operating room, 2) the expansion into laser therapy and access, 3) the expansion of regulatory approvals into new geographies, 4) the addition of multiple new BioPharma Partners, 5) the addition of new products and services to offer BioPharma, 6) the expansion of our site capacity for larger preclinical studies, and 7) the progression of Biopharma partners into larger phase III clinical trials and eventual commercialization of these new-to-the-world cell and gene therapies. All of this is taking place against the backdrop of our strongest cash position in years and the confidence to use that capital to move all of these growth vectors forward…. Fast. Forward."

Business Outlook

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

Financial Results – Quarter Ended June 30, 2025

Total revenue was $9.2 million for the three months ended June 30, 2025, and $7.9 million for the three months ended June 30, 2024, which represents an increase of $1.4 million, or 17%.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored preclinical and clinical trials, increased 10% to $4.7 million for the three months ended June 30, 2025, from $4.3 million for the same period in 2024. This increase is attributable to $0.2 million of higher product revenue resulting from greater demand for disposables as multiple partners progress in their trials, and $0.2 million increase in service revenue and other revenue.

Neurosurgery navigation and therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 33% to $3.4 million for the three months ended June 30, 2025, from $2.6 million for the same period in 2024. The increase is driven by higher sales for new offerings of SmartFrame OR, Prism Laser Therapy, and introduction of our 3.0 operating room navigation software, during the three months ended June 30, 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, increased 11% to $1.0 million for the three months ended June 30, 2025, from $0.9 million for the same period in 2024 due to an increase in service revenue.

The Company achieved a gross margin of 60% on its sales for the three months ended June 30, 2025, as compared to 63% in the same period in 2024. The decrease in gross margin was primarily due to higher excess and obsolete inventory reserves for the three months ended June 30, 2025, as compared to the same period in 2024.

Operating expenses were $11.2 million for the three months ended June 30, 2025, compared with $9.7 million for same period in 2024, an increase of 16%. The increase was mainly driven by higher product and software development costs, an increase in the allowance for credit losses, and personnel-related expenses, including share-based compensation, as we increased headcount to fuel the expansion of the research and development, clinical, and support organizations.

At June 30, 2025, the Company had cash and cash equivalents totaling $41.5 million as compared to $20.1 million at December 31, 2024, with the increase resulting from the net proceeds of the note payable and stock offering of $32.0 million, partially offset by the use of $8.7 million in cash for operating activities.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's 2025 second quarter results on Tuesday, August 12, 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=3mqLeBhl. Investors and analysts who would like to participate in the conference call via telephone may do so at (877) 407-9034, or at (201) 493-6737 if calling from outside the U.S. or Canada.

For those who cannot access the live broadcast, a replay will be available shortly after the completion of the call until September 11, 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 future development, regulatory approval and the market for cell and gene therapies, the anticipated adoption of the Company's products and services for use in the delivery of gene and cell therapies, 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, and the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2025, both of which have been filed with the Securities and Exchange Commission, and the Company's Quarterly Report on Form 10-Q for the three months ended June 30, 2025, which the Company intends to file with the

Securities and Exchange Commission on or before August 14, 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 June 30,	
	2025	**2024**
Revenue:		
Product revenue	$ 5,997	$ 4,944
Service and other revenue	3,218	2,914
Total revenue	9,215	7,858
Cost of revenue	3,659	2,870
Gross profit	5,556	4,988
Research and development costs	3,829	3,120
Sales and marketing expenses	4,019	3,834
General and administrative expenses	3,388	2,758
Operating loss	(5,680)	(4,724)
Other income (expense):		
Other income (expense), net	(52)	5
Interest income (expense), net	(80)	326
Net loss before income taxes	(5,812)	(4,393)
Income tax expense	(25)	(15)
Net loss	$ (5,837)	$ (4,408)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.21)	$ (0.16)
Weighted average shares outstanding:		
Basic and diluted	28,258,305	27,468,378

	For the Six Months Ended June 30,	
	2025	**2024**
Revenue:		
Product revenue	$ 11,288	$ 8,579
Service and other revenue	6,412	6,918
Total revenue	17,700	15,497
Cost of revenue	7,012	5,984
Gross profit	10,688	9,513
Research and development costs	7,208	5,745
Sales and marketing expenses	7,853	7,124
General and administrative expenses	7,470	5,585
Operating loss	(11,843)	(8,941)
Other income (expense):		
Other expense, net	(48)	(21)
Interest income, net	71	437
Net loss before income taxes	(11,820)	(8,525)
Income tax expense	(43)	(29)
Net loss	$ (11,863)	$ (8,554)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.42)	$ (0.32)
Weighted average shares outstanding:		
Basic and diluted	27,990,102	26,460,237

CLEARPOINT NEURO, INC.

Consolidated Balance Sheets

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

	June 30, 2025 (Unaudited)	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 41,541	$ 20,104
Accounts receivable, net	4,260	4,713
Inventory, net	6,293	6,863
Prepaid expenses and other current assets	1,897	1,683
Total current assets	53,991	33,363
Property and equipment, net	2,019	2,005
Operating lease, right-of-use assets	6,139	3,086
Other assets	720	735
Total assets	$ 62,869	$ 39,189
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,531	$ 1,340
Accrued compensation	2,949	4,885
Other accrued liabilities	1,210	1,450
Operating lease liabilities, current portion	331	557
Contract liabilities, current portion	1,377	2,121
Total current liabilities	7,398	10,353
Operating lease liabilities, net of current portion	6,280	3,011
Contract liabilities, net of current portion	603	436
Long-term note payable, net	28,845	—
Total liabilities	43,126	13,800
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized; none issued and outstanding at June 30, 2025 and December 31, 2024	—	—
Common stock, $0.01 par value; 90,000,000 shares authorized at June 30, 2025 and December 31, 2024; 28,423,611 and 27,617,415 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively	284	276
Additional paid-in capital	222,692	216,483
Accumulated deficit	(203,233)	(191,370)
Total stockholders' equity	19,743	25,389
Total liabilities and stockholders' equity	$ 62,869	$ 39,189

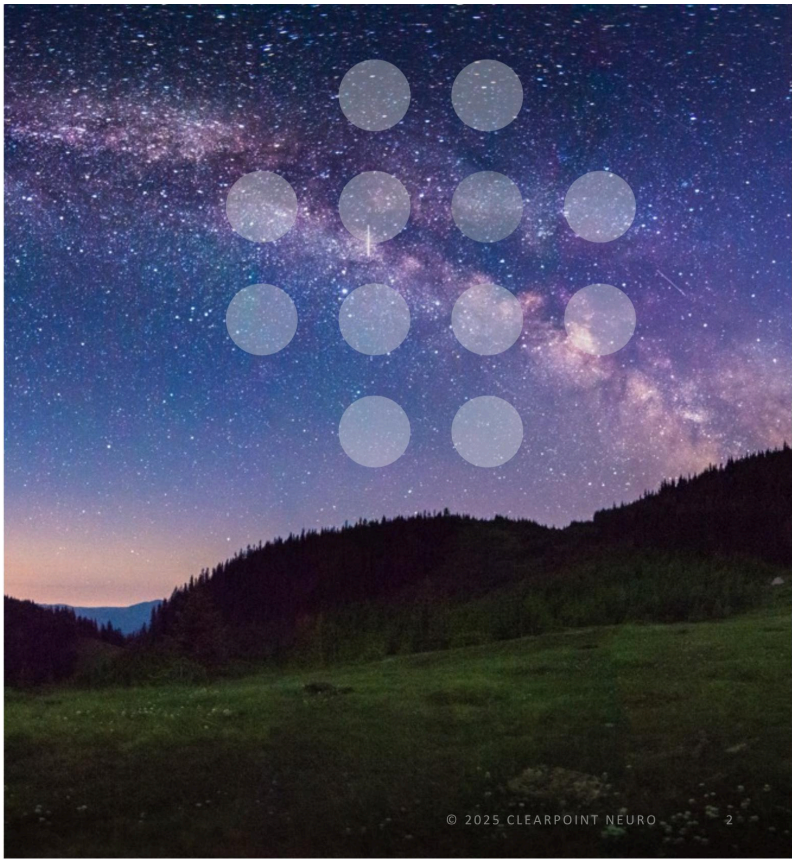
CLEARPOINT NEURO, INC.
Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

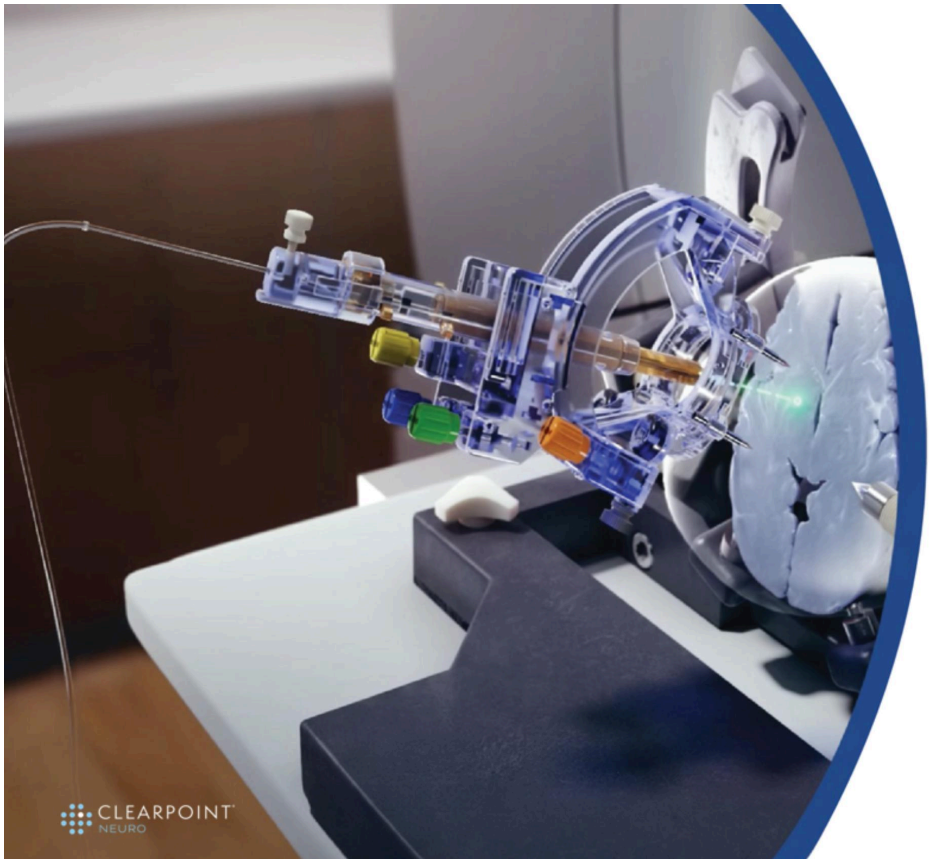
	For the Six Months Ended June 30,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (11,863)	$ (8,554)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for credit losses (recoveries)	217	(507)
Depreciation and amortization	499	476
Share-based compensation	4,177	3,300
Payment-in-kind interest	172	—
Amortization of debt issuance costs and original issue discounts	21	29
Amortization of lease right of use assets, net of accretion in lease liabilities	461	461
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	237	244
Inventory, net	482	(320)
Prepaid expenses and other current assets	(136)	(294)
Other assets	—	(39)
Accounts payable and accrued expenses	(1,944)	726
Lease liabilities	(471)	(401)
Contract liabilities	(576)	(1,629)
Net cash flows from operating activities	(8,724)	(6,508)
Cash flows from investing activities:		
Purchases of property and equipment	(274)	—
Net cash flows from investing activities	(274)	—
Cash flows from financing activities:		
Proceeds from offerings of common stock, net of offering costs	3,263	16,183
Proceeds from issuance of note payable, net of financing costs and discount	28,653	—
Proceeds from stock option exercises	49	21
Payments for taxes related to net share settlement of equity awards	(1,661)	(279)
Proceeds from issuance of common stock under employee stock purchase plan	311	288
Net cash flows from financing activities	30,615	16,213
Net change in cash, cash equivalents and restricted cash	21,617	9,705
Cash, cash equivalents and restricted cash, beginning of period	20,104	23,140
Cash, cash equivalents and restricted cash, end of period	$ 41,721	$ 32,845
Cash and cash equivalents	41,541	32,845
Restricted cash included in other assets, non-current	180	—
Total cash, cash equivalents and restricted cash	$ 41,721	$ 32,845
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ 12	$ 41
Interest	$ 172	$ 370


CLEARPOINT
NEURO
WHEN YOUR PATH IS UNCLEAR,
WE POINT THE WAY.
Nasdaq: CLPT
August 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, 2024, and the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2025, both of which have been filed with the Securities and Exchange Commission, and the Company's Quarterly Report on Form 10-Q for the three months ended June 30, 2025, which the company intends to file with the Securities and Exchange Commission on or before August 14, 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...*

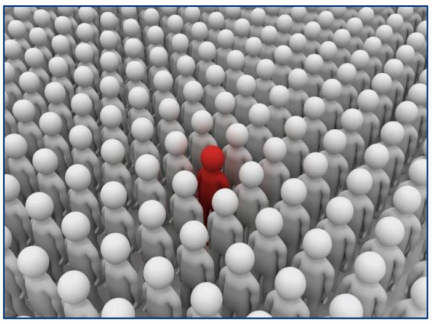
*Including indications for all cell, gene, and device therapies enabled by ClearPoint Neuro technologies

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.



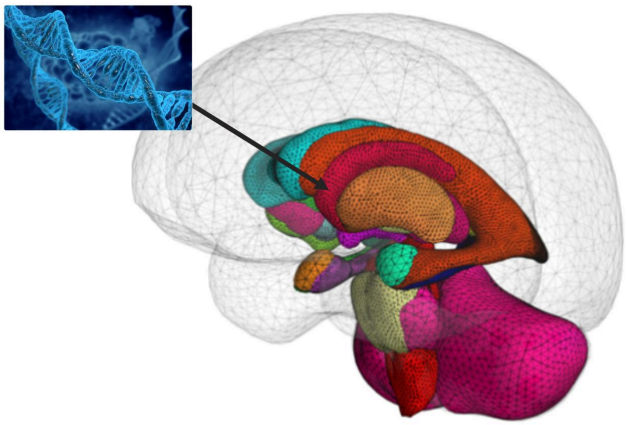
Despite some available treatments, **very few of these patients** undergo a direct surgical intervention to improve their **quality of life**…

Sources on file at ClearPoint Neuro

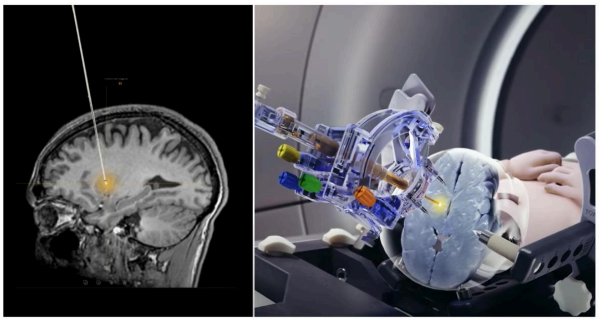
The Future of Cell and Gene Therapy is Not Coming… **It is HERE TODAY**

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

FAST TRACK
Expedites development and review of drugs to treat **serious conditions** and fill an **unmet medical need**.

REGENERATIVE MEDICINE ADVANCED THERAPY RMAT
Granted to regenerative medicines, such as **gene and cell therapies**, based on potential to **address a major unmet medical need**.

PRIORITY REVIEW
For drugs that offer **major advances in treatment** over existing therapies. FDA goal is to act **within 6 months**.

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.

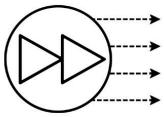
- Neurosurgeon-Led Ideation
- Unique MRI Navigation
- Initial FDA Clearance and Product Revenue
- Accumulation of Clinical Trial Experience Using SmartFlow
- Maestro A.I. Software Development
- Initial IP Generation and Licenses
- NASDAQ Listed

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.

- Grow into an estimated, existing $500M Market Opportunity
- 150 Activated Customers
- First Commercial CGT Launched
- GLP Preclinical 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
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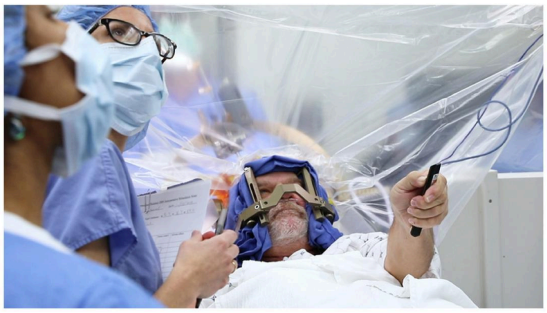
- Meaningful Revenue from Sophisticated BioPharma Deal Structures beyond product sales including royalty and milestone payments, co-development
- One Unified Platform with both MR and Operating Room Capability and Workflows
- Additional Global Regulatory Approvals Beyond the U.S. and E.U.

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

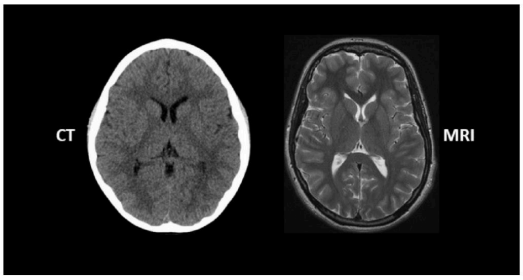
Our Start: Unique Neurosurgery Navigation Guided by Live MRI

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**



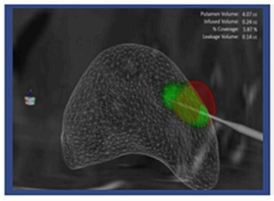
The ClearPoint SmartFrame family of products uses MR-safe materials and enables surgeons to **Decide, Guide & Confirm using live MR Imaging to achieve sub-millimetric accuracy**

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**

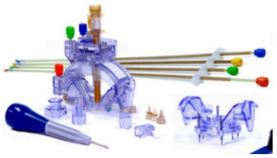
2. Neuro-oncologists could perform **entire tumor laser ablations in one room instead of having to transport the patient from the OR to the MRI**

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.

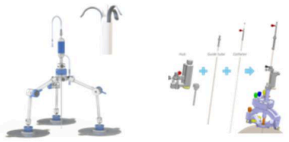
Our Start: Assemble the Building Blocks

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

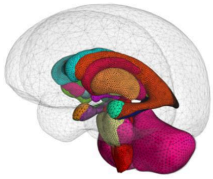


SmartFrame XG and Surgical Accessory Kit

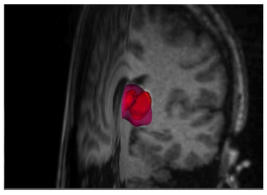
SmartFlow Cannula
(FDA and CE Marked, more than 8,000 cannulas sold to date)



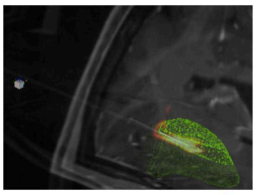
Radial Branching Cell Therapy Devices and Spinal Infusion Anchors
(Investigational Use Only)



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.

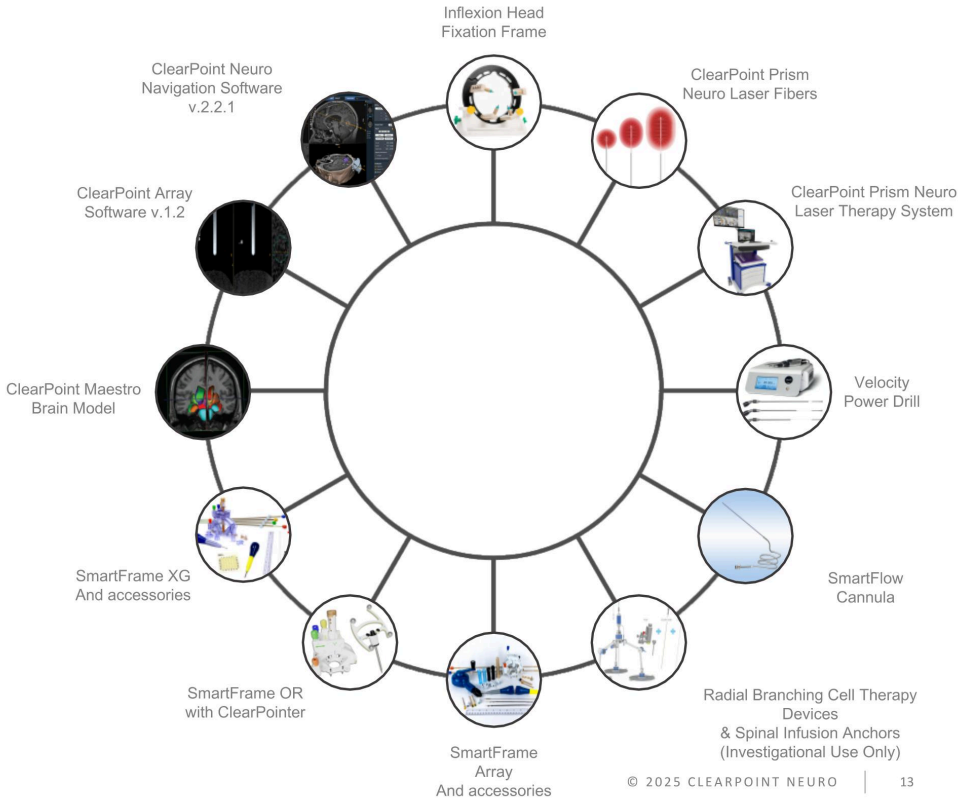
Building the Business

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**



Funded. Foundation.

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 NEUROSURGERY 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 Hospital of Miami
Baptist Memorial Hospital-Memphis
Barnes-Jewish Hospital
Barrow Neurological Institute/St. Joseph's Hospital
BayCare Health System
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
Cooperman Barnabas Medical Center
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
Envol Biomedical (Florida)
Labcorp (Madison, Wisconsin)
Pinys Biotechnologies (Shanghai, China)
IHU-GENOV's Institut du Cerveau (Paris, France)
University of Pennsylvania Gene Therapy
100+
GLOBAL
CENTERS NOW
ACTIVATED
© 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

Funded. Foundation.

Building the Business

Key Products: FDA CE Marked Platforms

HEADQUARTERS
Solana Beach, CA

MANUFACTURING
Carlsbad, CA

2024 REVENUE
$31.4M[A]

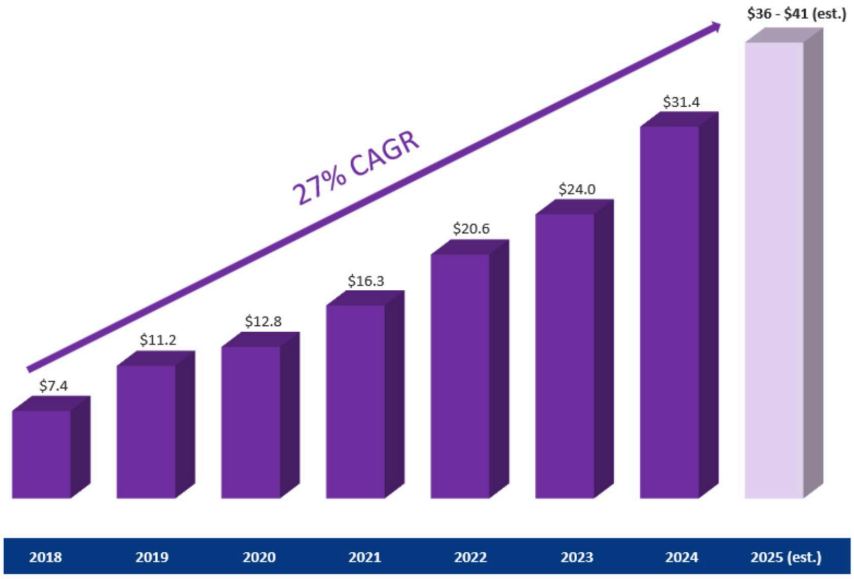
CASH & CASH EQUIVALENTS
$41.5M[B]

PATENTS ISSUED
100+[C]

GROSS MARGIN
60%[B,D]

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, June 30, 2025
(C) Including owned and licensed patents
(D) 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

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

2010 - 2020

Discovery. Design.

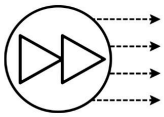
- Neurosurgeon-Led Ideation
- Unique MRI Navigation
- Initial FDA Clearance and Product Revenue
- Accumulation of Clinical Trial Experience Using SmartFlow
- Maestro A.I. Software Development
- Initial IP Generation and Licenses
- NASDAQ Listed

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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2028+

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

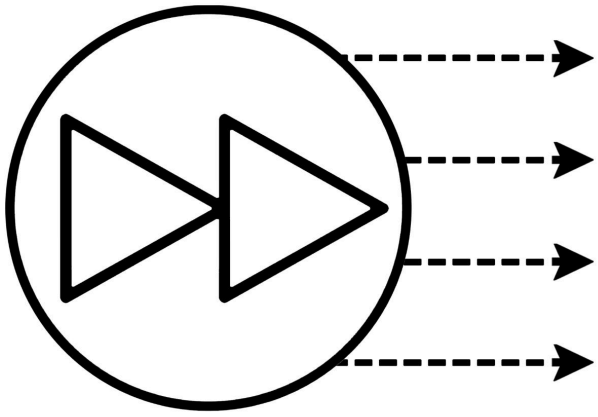
We are Pointing the Way for a Cell and Gene Therapy Future: **Fast. Forward.**

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

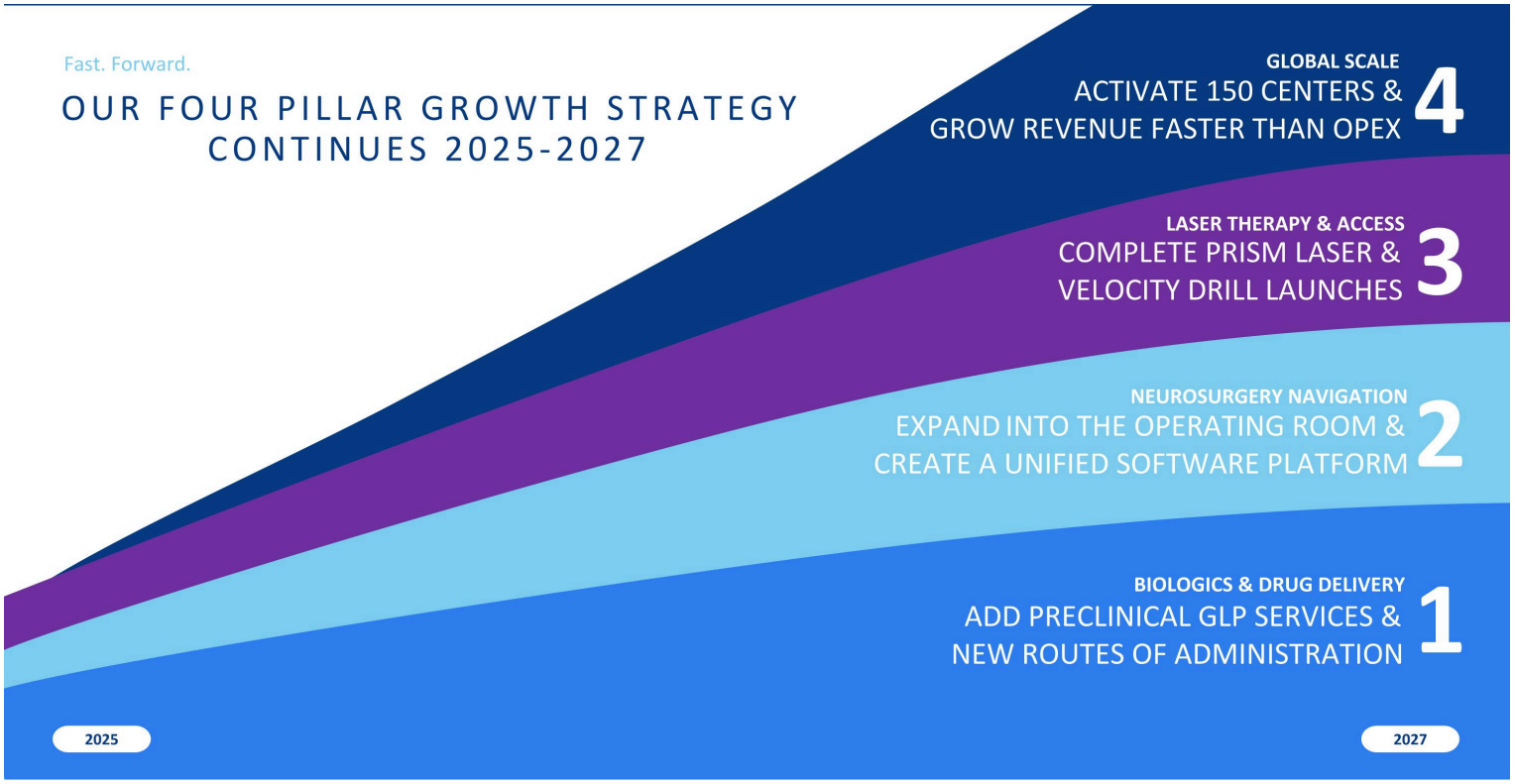
2. **Evolve our Portfolio** to focus on fast, simple, predictable procedures in both the MRI and Operating Room to increase hospital throughput

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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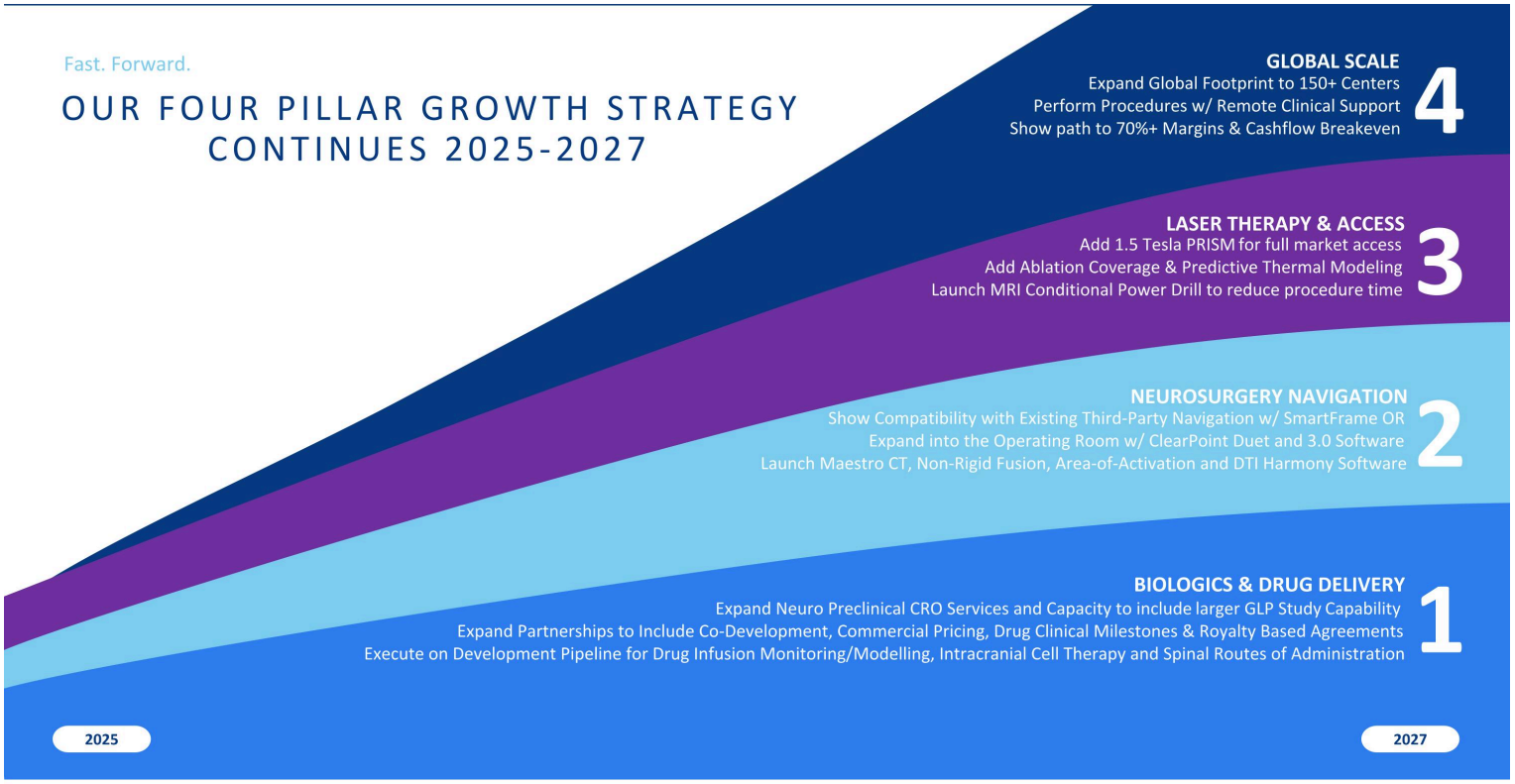
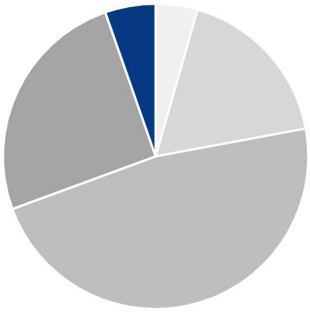


CLEARPOINT NEURO

GLP Services & New Routes of Administration

2025 Estimated Preclinical & Clinical Trial Market (≈$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

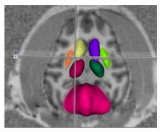
Estimated Market Size, Growth Drivers, and Share Drivers are based on internal estimates and assumptions, market trends, and customer insights. Assumptions may not reflect actual future performance.

Market Growth Drivers:

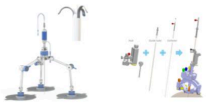
- Improved BioPharma funding environment
- Additional cell and gene therapies entering the 'funnel'
- Partner progression into larger spend GLP studies and clinical trials
- Successful implementation of FDA 'Expedited Review' pathways including RMAT offering faster clinical trials and less capital required

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)



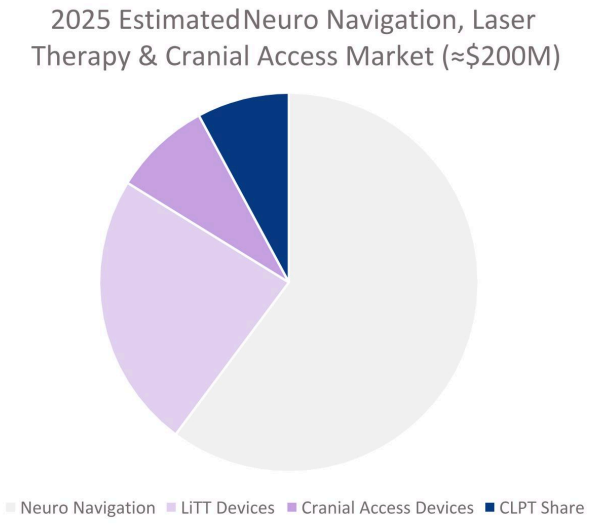
New Routes of Administration (Investigational Use Only)

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

Fast. Forward.

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™

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

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

1.5 Tesla PRISM (Expected 2H 2025)

Adeor Velocity MRI Conditional Power Drill (Pending FDA Clearance)

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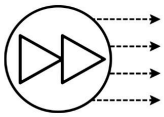

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*Including indications for all cell, gene, and device therapies enabled by ClearPoint Neuro technologies

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

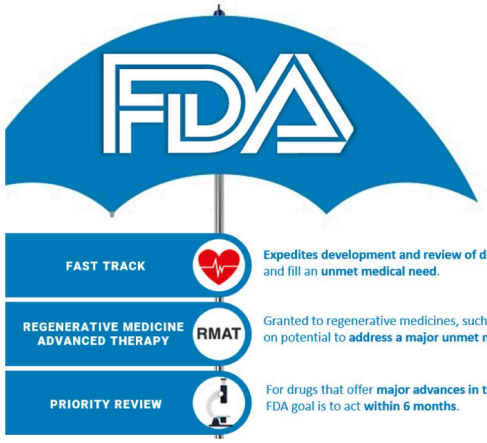
For Immediate Release:
November 14, 2024

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**

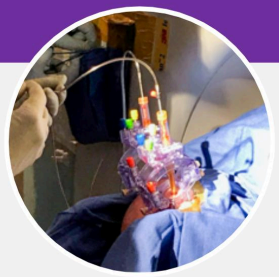
BENCHTOP TESTING

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

PRECLINICAL STUDIES

- Running 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

Essential. Everywhere.

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

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

Sources

Sources

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