

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 7, 2024

CLEARPOINT NEURO, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-34822
(Commission
File Number)

58-2394628
(I.R.S. Employer
Identification Number)

120 S. Sierra Ave., Suite 100
Solana Beach, CA 92075
(Address of principal executive offices, zip code)
(888) 287-9109
(Registrant's telephone number, including area code)

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	Nasdaq Capital 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 7, 2024, ClearPoint Neuro, Inc. (the “Company”) issued a press release announcing its financial performance for the second fiscal quarter ended June 30, 2024. A copy of the press release is furnished herewith as Exhibit 99.1.

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

Item 7.01. Regulation FD Disclosure.

On August 7, 2024, 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 7, 2024](#)

Exhibit 99.2 [Investor Presentation dated August 7, 2024](#)

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.

Date: August 7, 2024

CLEARPOINT NEURO, INC.

By: /s/ Danilo D'Alessandro

Danilo D'Alessandro
Chief Financial Officer



ClearPoint Neuro Reports Second Quarter 2024 Results

Second Quarter Revenue Growth +32%; Record Revenue Achieved

SOLANA BEACH, CA, August 7, 2024 – 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, 2024.

Second Quarter Highlights

- Reported quarterly revenue of \$7.9 million, a 32% year-over-year increase;
- Product revenue across all segments more than doubled, and grew 112% to \$4.9 million;
- Increased Biologics and Drug Delivery revenue to \$4.3 million, a 28% year-over-year increase;
- Full market release of SmartFrame OR™ platform and ClearPoint Prism® Laser Therapy System contributing to record navigation and device revenue of \$2.6 million and 34% growth versus the prior quarter;
- Activated six new global centers in the second quarter for a total of fourteen new centers so far this year;
- Partners advancing through preclinical and clinical review with seven pharmaceutical partners receiving expedited FDA review designation;
- Approval of SmartFlow® Cannula for commercial use in Taiwan by the Taiwan Food and Drug Administration;
- Operational cash burn reduced to \$2.7 million, a 47% year-over-year decrease;
- Cash and cash equivalents totaled \$32.8 million as of June 30, 2024.

“This has been the strongest quarter in our history both from a financial standpoint as well as continued execution of our four-pillar growth strategy,” commented Joe Burnett, President and CEO at ClearPoint Neuro. “In the second quarter of 2024, we were excited to achieve double-digit growth from all four pillars including Biologics and Drug Delivery, Neurosurgery Navigation, Therapy and Access Products, and achieving global scale through capital placements and customer activations. This has led to record quarterly revenue of \$7.9 million, record product revenue of \$4.9 million, gross margins rising to 63%, and an operating cash burn

reduction of 47% year over year. We expect to be well poised to continue this growth across all of our segments as we:

- Expand our biologics and drug delivery services and customers,
- Add long-term strategic agreements with pharmaceutical partners,
- Assist our biotech partners as they continue first-in-human study initiations,
- Continue our expansion into the operating room with SmartFrame OR,
- Expand our installed base of the PRISM Laser Therapy System under full market release, and
- Activate new capital customers by working through our sizable funnel of prospective customers.

As a result of our strong first half of 2024, we are raising our revenue guidance to between \$30.0 and \$33.0 million for the year 2024.”

Business Outlook

The Company is raising its full year 2024 revenue outlook to between \$30.0 and \$33.0 million.

Financial Results – Quarter Ended June 30, 2024

Total revenue was \$7.9 million for the three months ended June 30, 2024, and \$6.0 million for the three months ended June 30, 2023, which represents an increase of \$1.9 million, or 32%.

Biologics and Drug Delivery revenue, which includes sales of services and disposable products related to customer-sponsored preclinical and clinical trials utilizing our products, increased 28% to \$4.3 million for the three months ended June 30, 2024, from \$3.4 million for the same period in 2023. This increase is attributable to a \$1.3 million increase in product revenue as a result of increased demand for disposables as multiple partners progress in their trials, partially offset by a decrease of \$0.4 million in service and other revenue, during the three months ended June 30, 2024, compared to the same period in 2023.

Neurosurgery Navigation and Therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 17% to \$2.6 million for the three months ended June 30, 2024, from \$2.2 million for the same period in 2023. The increase is driven by higher product revenue of \$0.8 million as a result of increased case volume, new capital placements, and new product offerings (SmartFrame OR and Prism) during the three months ended June 30, 2024, compared to the same period in 2023. This is partially offset by a decrease of \$0.4 million in service and other revenue primarily as a result of pausing a co-development program with one of our Brain Computer Interface partners, during the three months ended June 30, 2024, compared to the same period in 2023.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, increased 148% to \$0.9 million for the three months ended June 30, 2024, from \$0.4 million for the same period in 2023 due to an increase in the placements of ClearPoint navigation capital and software and Prism laser units.

Gross margin for the three months ended June 30, 2024, was 63% compared to a gross margin of 53% for the three months ended June 30, 2023. The increase in gross margin was primarily due to lower costs for the three months ended June 30, 2024 due to the transition to the new manufacturing facility which was occurring in 2023, and higher volumes for the three months ended June 30, 2024.

Operating expenses for the second quarter of 2024 were \$9.7 million, compared to \$10.3 million for the second quarter of 2023. The decrease was mainly driven by lower product development costs and bad debt expense, partially offset by higher sales and marketing personnel expense.

At June 30, 2024, the Company had cash and cash equivalents totaling \$32.8 million as compared to \$23.1 million at December 31, 2023, with the increase resulting from the net proceeds from the public offering of

common stock of \$16.2 million in the first quarter, partially offset by the use of cash in operating activities of \$6.5 million in the six month period ending June 30, 2024.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's 2024 second quarter on Wednesday, August 7, 2024 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=u0rzWezB>. Investors and analysts who would like to participate in the conference call via telephone may do so at (888) 428-7458, or at (862) 298-0702 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 7, 2024, by calling (877) 660-6853 or (201) 612-7415 if calling from outside the U.S. or Canada, and then entering conference I.D. number 413671. An online archive of the broadcast will be available on the Company's Investor website at <https://ir.clearpointneuro.com/>.

About ClearPoint Neuro

ClearPoint Neuro is a device, cell, and gene therapy-enabling company offering precise navigation to the brain and spine. The Company uniquely provides both established clinical products as well as preclinical development services for controlled drug and device delivery. The Company's flagship product, the ClearPoint Neuro Navigation System, has FDA clearance and is CE-marked. ClearPoint Neuro is engaged with healthcare and research centers in North America, Europe, Asia, and South America. The Company is also partnered with the most innovative pharmaceutical/biotech companies, academic centers, and contract research organizations, providing solutions for direct CNS delivery of therapeutics in preclinical studies and clinical trials worldwide. To date, thousands of procedures have been performed and supported by the Company's field-based clinical specialist team, which offers support and services to our customers and partners worldwide. For more information, please visit www.clearpointneuro.com.

Forward-Looking Statements

Statements in this press release and in the teleconference referenced above concerning the Company's plans, growth and strategies may include forward-looking statements within the context of the federal securities laws. Statements regarding the Company's future events, developments and future performance, the size of total addressable markets or the market opportunity for the Company's products and services, the Company's expectation for revenues, operating expenses, the adequacy of cash and cash equivalent balances to support operations and meet future obligations, as well as management's expectations, beliefs, plans, estimates or projections relating to the future, are forward-looking statements within the meaning of these laws. These forward-looking statements are based on management's current expectations and are subject to the risks inherent in the business, which may cause the Company's actual results to differ materially from those expressed in or implied by forward-looking statements. Particular uncertainties and risks include those relating to: global and political instability, supply chain disruptions, labor shortages, and macroeconomic and inflationary conditions; 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 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. More detailed information on these and additional factors that could affect the Company's actual results are described in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2023, and the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2024, 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, 2024, which the Company intends to file with the Securities and Exchange Commission on or before August 14, 2024. The Company does not assume any obligation to update these forward-looking statements.

Contact:

Media Contact:

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info@clearpointneuro.com

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,	
	2024	2023
Revenue:		
Product revenue	\$ 4,944	\$ 2,337
Service and other revenue	2,914	3,613
Total revenue	7,858	5,950
Cost of revenue	2,870	2,824
Gross profit	4,988	3,126
Research and development costs	3,120	3,605
Sales and marketing expenses	3,834	3,474
General and administrative expenses	2,773	3,178
Operating loss	(4,739)	(7,131)
Other expense:		
Other income (expense), net	5	(2)
Interest income, net	326	81
Net loss	\$ (4,408)	\$ (7,052)
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.16)	\$ (0.29)
Weighted average shares used in computing net loss per share:		
Basic and diluted	27,468,378	24,583,712

	For The Six Months Ended June 30,	
	2024	2023
Revenue:		
Product revenue	\$ 8,579	\$ 4,967
Service and other revenue	6,918	6,416
Total revenue	15,497	11,383
Cost of revenue	5,984	5,055
Gross profit	9,513	6,328
Research and development costs	5,745	6,628
Sales and marketing expenses	7,124	6,407
General and administrative expenses	5,614	6,136
Operating loss	(8,970)	(12,843)
Other expense:		
Other expense, net	(21)	(13)
Interest income, net	437	195
Net loss	\$ (8,554)	\$ (12,661)
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.32)	\$ (0.52)
Weighted average shares used in computing net loss per share:		
Basic and diluted	26,460,237	24,583,439

CLEARPOINT NEURO, INC.
Consolidated Balance Sheets
(in thousands, except for share and per share data)

	June 30, 2024 (Unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 32,845	\$ 23,140
Accounts receivable, net	3,475	3,211
Inventory, net	8,031	7,911
Prepaid expenses and other current assets	2,205	1,910
Total current assets	46,556	36,172
Property and equipment, net	1,545	1,389
Operating lease, right-of-use assets	3,330	3,564
Software license inventory	236	386
Licensing rights	758	1,041
Other assets	149	109
Total assets	<u>\$ 52,574</u>	<u>\$ 42,661</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 822	\$ 393
Accrued compensation	2,996	2,947
Other accrued liabilities	1,302	1,053
Operating lease liabilities, current portion	516	424
Deferred product and service revenue, current portion	1,079	2,613
2020 senior secured convertible note payable, net	9,979	—
Total current liabilities	16,694	7,430
Operating lease liabilities, net of current portion	3,302	3,568
Deferred product and service revenue, net of current portion	446	541
2020 senior secured convertible note payable, net	—	9,949
Total liabilities	<u>20,442</u>	<u>21,488</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at June 30, 2024 and December 31, 2023	—	—
Common stock, \$0.01 par value; 90,000,000 shares authorized at June 30, 2024 and December 31, 2023; 27,588,812 shares issued and outstanding at June 30, 2024; and 24,652,729 issued and outstanding at December 31, 2023	276	247
Additional paid-in capital	212,866	193,382
Accumulated deficit	(181,010)	(172,456)
Total stockholders' equity	<u>32,132</u>	<u>21,173</u>
Total liabilities and stockholders' equity	<u>\$ 52,574</u>	<u>\$ 42,661</u>

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

	For The Six Months Ended June 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (8,554)	\$ (12,661)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for credit losses (recoveries)	(507)	454
Depreciation and amortization	476	285
Share-based compensation	3,300	2,952
Amortization of debt issuance costs and original issue discounts	29	28
Amortization of lease right-of-use, net of accretion in lease liabilities	461	325
Accretion of discounts on short-term investments	—	(126)
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	244	(588)
Inventory, net	(320)	94
Prepaid expenses and other current assets	(294)	(438)
Other assets	(39)	(25)
Accounts payable and accrued expenses	726	(282)
Lease liabilities	(401)	(293)
Deferred revenue	(1,629)	(480)
Net cash flows from operating activities	(6,508)	(10,755)
Cash flows from investing activities:		
Purchases of property and equipment	—	(461)
Acquisition of licensing rights	—	(167)
Proceeds from maturities of short-term investments	—	10,000
Net cash flows from investing activities	—	9,372
Cash flows from financing activities:		
Proceeds from public offering of common stock, net of offering costs	16,183	—
Proceeds from stock option exercises	21	—
Payments for taxes related to net share settlement of equity awards	(279)	(82)
Proceeds from issuance of common stock under employee stock purchase plan	288	314
Net cash flows from financing activities	16,213	232
Net change in cash and cash equivalents	9,705	(1,151)
Cash and cash equivalents, beginning of period	23,140	27,615
Cash and cash equivalents, end of period	\$ 32,845	\$ 26,464
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	\$ —	\$ —
Interest	\$ 370	\$ 369



CLEARPOINT®
NEURO

WHEN YOUR PATH IS UNCLEAR,
WE POINT THE WAY.

Nasdaq: CLPT

August 2024



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: global and political instability, supply chain disruptions, labor shortages, and macroeconomic and inflationary conditions; 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 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. More detailed information on these and additional factors that could affect the Company's actual results are described in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2023, and the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2024, 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, 2024, which the Company intends to file with the Securities and Exchange Commission on or before August 14, 2024. The Company does not assume any obligation to update these forward-looking statements.



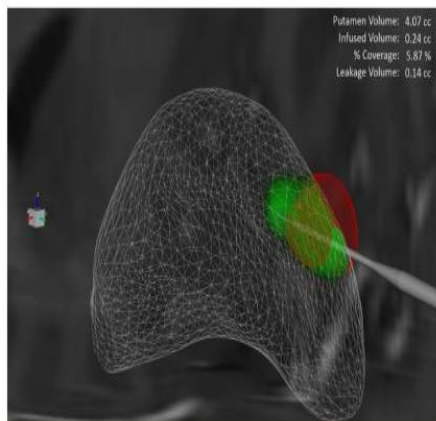
CLEARPOINT®
NEURO

Our Company

We Are a Device, Cell and Gene Therapy-
Enabling Company, Offering Precise Navigation
to the Brain and Spine

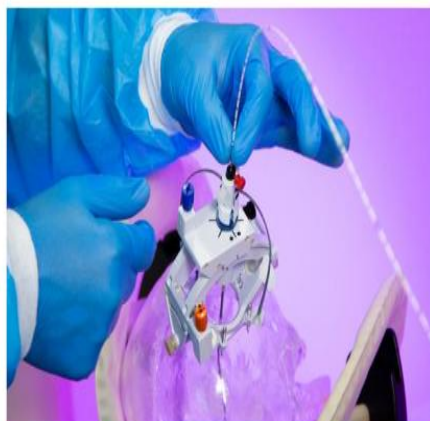
We Uniquely Provide Both Established Clinical
Products as well as Pre-Clinical Development
Services for Controlled Drug and Device Delivery

A Precision Navigation Company Supporting...



50+ Biotech & Pharma Partners:

- Drug Navigation, Combination-Infusion Devices, A.I. Monitoring Solutions
- Established Quality System and Custom Device Development
- Translational Pre-Clinical, Clinical Trial & Regulatory Services



100+ Global Neurosurgeons:

- Expanding Navigation Systems for both the MRI & Operating Room
- An FDA Cleared Second-Generation Laser Therapy System
- 20+ Global Specialists Providing On-Site Training & Quality Control



Built On a Strong Foundation:

- 20,000 sq. ft. Manufacturing, R&D Lab
- Regulatory Approvals (FDA, CE, more)
- Established, Audited Quality System
- More than 100 Issued Patents*
- 10 Years of Revenue, 7,000+ Procedures

A \$12B+ TAM Diversified Across 35+ Indications and 50+ Partners

*Including owned and licensed patents

Our Company

The ClearPoint® Neuro Navigation System

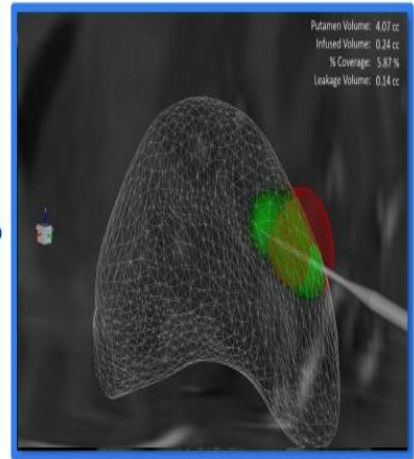
Leverage live MR Imaging to **Decide, Guide, and Confirm** with sub-millimetric accuracy



Pre-Plan Trajectory and
Decide Entry Point



Automatically **Guide** Precision
Adjustments Prior to Insertion



Confirm Quality of Delivery
Into Permanent Record

Our Company

The ClearPoint® Neuro Navigation System: *10+ Years of Experience*

Capital Hardware and Software

ClearPoint Neuro
Navigation Software
v.2.2.1
With Integrated
ClearPoint Maestro®
Brain Model



ClearPoint
Array® Software
v.1.2

ClearPoint
Maestro®
Brain Model



CLEARPOINT
NEURO



Inflexion® Head
Fixation Frame



Multi-Positional
Head Fixation
Frame



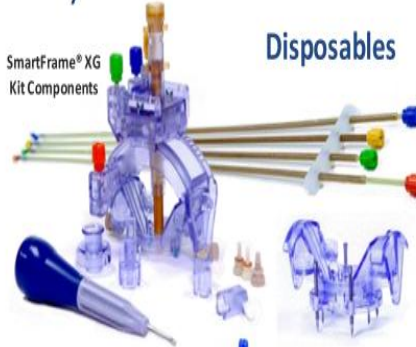
MRI Monitor



ClearPoint Prism®
Neuro Laser
Therapy System

Disposables

SmartFrame® XG
Kit Components



SmartFrame Array®
Kit Components



SmartFrame OR™

ClearPointer™



Accessory Kit
(4Fr, 5Fr, and 7Fr Available)

SmartFlow® Cannula



ClearPoint Prism®
Neuro Laser
Fibers

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6

A Strong Foundation

Key Products: **FDA** **CE** Marked Platforms

HEADQUARTERS

Solana Beach, CA

MANUFACTURING

Carlsbad, CA

2024 REVENUE GUIDANCE

\$30 m - \$33 m^(A)

CASH & CASH EQUIVALENTS

\$32.8 m^(B)

PATENTS ISSUED

100+^(C)

GROSS MARGIN

60%^(B,D)

EMPLOYEES

100+

QUALITY SYSTEM

ISO 13485

(A) Estimated and subject to revision

(B) Unaudited as of, and for the quarter ended, June 30, 2024

(C) Including owned and licensed patents

(D) For the Trailing Twelve Months (TTM)



Our Company

A Strong Foundation

- 1,500 sq. ft Class 8 Clean Room with Expansion Capability
- 1,300 sq. ft Dedicated R&D Lab Space
- ISO 13485/MDSAP/EU MDR Certified Quality System
- Successful Audit Outcomes from Global Regulatory Bodies and Pharma
- Training Facility with over 100 Surgeons and Pharma Scientist Visitors



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A Therapy Enabling Platform

85+ Global Centers

Banner Health Tucson
Baptist Medical Center Jacksonville
Baptist Memorial Hospital-Memphis
Barnes-Jewish Hospital
Barrow Neurological Institute/St. Joseph's Hospital
Benioff Children's Hospital
Beth Israel Deaconess
Boston Children's Hospital
Brigham & Women's Hospital
Carilion Clinic
Children's Hospital of Alabama
Children's Hospital of Philadelphia
Children's Mercy Hospital
Children's National Hospital
CHOA Scottish Rite
Cincinnati Children's Hospital
Cincinnati Jewish Hospital
Cook Children's Hospital
Corewell Health
Dallas Presbyterian Hospital
Dartmouth-Hitchcock
Duke University
Emory University
Froedtert Hospital
Hackensack University Medical Center
Henry Ford Health
Henry Ford West Bloomfield Hospital
Hospital of University Pennsylvania
Houston Methodist Hospital
INOVA Fairfax
JFK University Medical Center
Johns Hopkins University
Kaleida Health
Kettering Health

Loma Linda University Health
Lucile Packard Children's Hospital
Massachusetts General Hospital
Mayo Clinic in Arizona
Mayo Clinic in Florida
MD Anderson Cancer Center
MedStar Georgetown University Hospital
Memorial Sloan-Kettering Cancer Center
Methodist Hospital San Antonio
Mt. Sinai West
Nationwide Children's
Northwestern Central DuPage
Ohio State University
Oregon Health & Science University
Oschner Medical Center
Prisma Health
Riverside Methodist Hospital
Rutgers/Robert Wood Johnson

San Francisco VA
Stanford University
Tampa General Hospital
Texas Children's Hospital
University of California San Diego
University of California San Francisco
University of Alabama at Birmingham
University of Colorado
University of Kansas Medical Center
University of Maryland Medical Center
University of Michigan
University of Minnesota
University of Oklahoma Medical Center
University of Utah
University of Wisconsin
USC Keck Hospital
UT Southwestern Medical Center
Yale University

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)
Policlinico Umberto I (Rome, Italy)
Rigshospitalet (Copenhagen, Denmark)
Sahlgrenska Universitetssjukhuset (Gothenburg, Sweden)
Skånes Universitetssjukhus Lund (Lund, Sweden)
TIDU GENOV - Institut du Cerveau (Paris, France)
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)
Labcorp (Madison, Wisconsin)
Prisys Biotechnologies (Shanghai, China)

100+
Centers
Expected
by 2025

The ClearPoint Platform has been used in over 7,000 procedures

1 Biologics & Drug Delivery*



...with 50+ industry and academic partners

2 Navigation for DBS



3 Laser Therapy



ClearPoint Navigation is Compatible with all Major
Diagnostic and Intraoperative MRI Scanners



~\$12B+ Opportunity: Empowering Multiple Treatment Options for 35+ Indications[†]

ESTIMATED LAUNCH SEQUENCE	Indication	Patient Population*	Annual Incidence*	Pillar 1: Drug/Cell Delivery	Pillar 2: DBS & BCI	Pillar 3: Laser Therapy	Incremental Revenue from Annual Incidence
	Parkinson's Disease	1,000,000 ¹	60,000 ¹				\$270 M - \$1.35 B
	Drug Resistant Epilepsy	1,000,000 ²	11,000 ³				\$49.5 M - \$198 M
	Refractory Essential Tremor	3,500,000 ⁴	60,000 ⁵				\$180 M - \$1.08 B
	Brain Tumors (n=3) ⁶	35,000 ^{7,8}	13,300 ^{7,8}				\$33.3 M - \$300 M
	Severe Obsessive-Compulsive Disorder	500,000 ^{9,10}	10,000 ^{9,10}				\$45 M - \$75 M
	Dystonia	250,000 ¹¹	8,000 ¹²				\$36 M - \$60 M
	Rare Genetic/Lysosomal (n=7) ¹³	36,500 ¹⁴⁻¹⁸	3,000 ^{14,19,20}				\$13.5 M - \$67.5 M
	Paralysis / Spinal Cord (n=15) ^{21,22}	331,000 ²²⁻²⁴	17,900 ²³				\$80.6 M - \$403 M
	Huntington's Disease	30,000 ²⁵	4,000 ²⁵				\$18 M - \$90 M
	Alzheimer's Disease	6,000,000 ²⁶	500,000 ²⁶				\$1.5 B - \$11.3 B
	Severe Major Depressive Disorder	1,000,000 ¹⁰	20,000 ^{10,27}				\$90 M - \$150 M
	Stroke Rehabilitation	2,000,000 ²⁸	610,000 ²⁸				\$1.83 B - \$5.49 B
	Frontotemporal Dementia	60,000 ²⁹	12,000 ²⁹				\$54 M - \$270 M
							\$4.2 B - \$20.8 B

Commercial U.S or EU ClearPoint procedures today

Active clinical trial

Pre-clinical study/testing

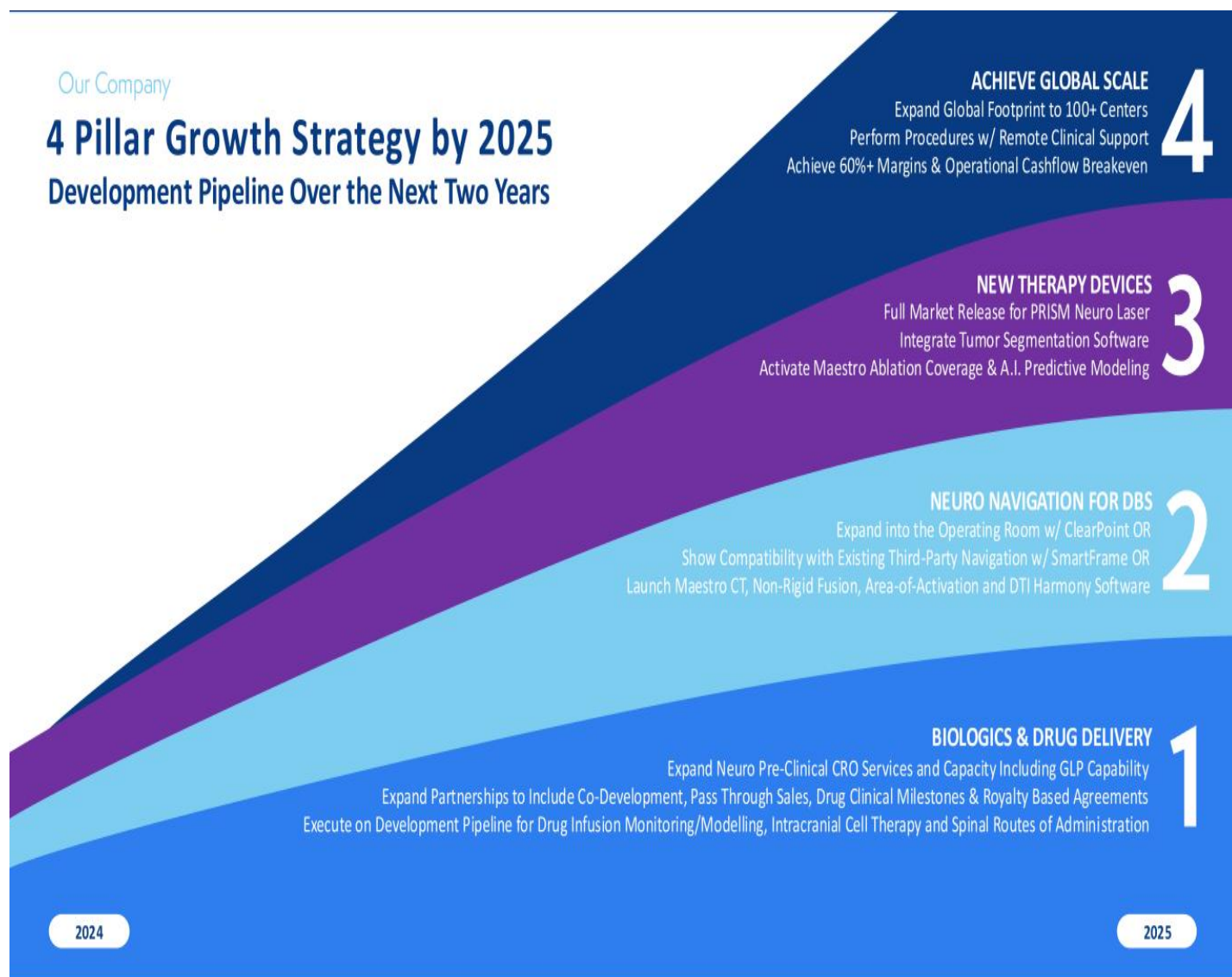
Citations & Footnotes

1. "Parkinson's Disease Statistics," Parkinson's News Today, <https://parkinsonsnewstoday.com/parkinsons-disease-statistics/#:~:text=An%20estimated%20seven%20to%2010,who%20are%2080%20and%20older>
2. Neuron Therapeutics. (2021 November 4). *Neuron Therapeutics Receives IND Clearance to Initiate Phase 1/2 Clinical Trial of Neural Cell Therapy NRTX-1001 in Chronic Focal Epilepsy Patients* [Press release] https://www.neurontherapeutics.com/wp-content/uploads/2021/11/2021_11_01_INDclearance_FINALVersion.pdf
3. Asadi-Pooya AA, Stewart GR, Abrams DJ, Sharan A. Prevalence and Incidence of Drug-Resistant Mesial Temporal Lobe Epilepsy in the United States. *World Neurosurg.* 2017;99:662-666.
4. Zesiewicz TA, Chari A, Jahan I, Miller AM, Sullivan KL. Overview of essential tremor. *Neuropsychiatr Dis Treat.* 2010;6:401-408. Published 2010 Sep 7.
5. Diaz NL, Louis ED. Survey of medication usage patterns among essential tremor patients: movement disorder specialists vs. general neurologists. *Parkinsonism Relat Disord.* 2010;16(9):604-607.
6. Includes: Glioblastoma, Diffuse Intrinsic Pontine Glioma and deep small eloquent brain tumors.
7. "Glioblastoma Multiforme," American Association of Neurological Surgeons, <https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Glioblastoma-Multiforme>
8. "About DIPG/DMG," DIPG/DMG Registry, <https://dipgregistry.org/patients-families/about-dipg-dmg/>
9. Medtronic Clinical Summary – Reclaim DBS for Chronic Extreme OCD M947128A001.
10. Mantovani A, Lisanby SH. Brain stimulation in the treatment of anxiety disorders. In: Simpson HB, Neria Y, Lewis-Fernández R, Schneier F, eds. *Anxiety Disorders: Theory, Research and Clinical Perspectives*. Cambridge: Cambridge University Press; 2010:323-335.
11. <https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Dystonia>
12. Medtronic DBS™ Therapy for Dystonia - Clinical Summary 2015.
13. Includes: AADC deficiency, Friedreich's ataxia, Angelman syndrome, multiple system atrophy, metachromatic leukodystrophy, and spinocerebellar ataxia type 3.
14. "Multiple System Atrophy," Medscape, <https://emedicine.medscape.com/article/1154583-overview#a6>
15. PTC Therapeutics November 30, 2021 Corporate Presentation, <https://ir.ptcbio.com/static-files/0fd5d54f-55b8-416b-8006-4eb4c0d82f45>
16. "Spinocerebellar ataxia type 3," Orphanet, https://www.orpha.net/consor/cgi-bin/OC_Exp.php?lng=EN&Expert=98757
17. Lysogene Corporate Presentation at 38th Annual J.P. Morgan Healthcare Conference on Jan 13, 2020, http://www.lysogene.com/wp-content/uploads/2020/01/jpm-2020-corporate-presentation_final.pdf
18. "Metachromatic Leukodystrophy," National Organization of Rare Disorders, <https://rarediseases.org/rare-diseases/metachromatic-leukodystrophy/>
19. "Aromatic L-Amino Acid Decarboxylase Deficiency," National Organization for Rare Disorders, <https://rarediseases.org/rare-diseases/aromatic-l-amino-acid-decarboxylase-deficiency/>
20. Puckett Y, Mallorga-Hernández A, Montañó AM. Epidemiology of mucopolysaccharidoses (MPS) in United States: challenges and opportunities. *Orphanet J Rare Dis.* 2021;16(1):241. Published 2021 May 29.
21. Includes: stroke, spinal cord injury, multiple sclerosis, cerebral palsy, other (traumatic brain injury, complications from surgery, amyotrophic lateral sclerosis, neurofibromatosis, Chiari malformation, syringomyelia, postpolio syndrome, spinal muscular atrophy, Friedreich's ataxia, transverse myelitis, and spina bifida).
22. Armour BS, Courtney-Long EA, Fox MH, Fredine H, Cahill A. Prevalence and Causes of Paralysis-United States, 2013. *Am J Public Health.* 2016;106(10):1855-1857.
23. Wyndaele M, Wyndaele JJ. Incidence, prevalence and epidemiology of spinal cord injury: what learns a worldwide literature survey?. *Spinal Cord.* 2006;44(9):523-529.
24. National Spinal Cord Injury Statistical Center (NSCISC): 2020 Annual Report and 2021 Facts and Figures. <https://www.nscisc.uab.edu/>
25. "Huntington's Disease," *Mov Disord.* 2019 Jun; 34(6): 858-865.
26. "Alzheimer's Disease: Facts & Figures," Brightfocus Foundation, <https://www.brightfocus.org/alzheimers/article/alzheimers-disease-facts-figures>
27. Goodman WK, Alterman RL. Deep brain stimulation for intractable psychiatric disorders. *Annu Rev Med.* 2012;63:511-524.
28. "Stroke Facts," Center for Disease Control and Prevention, <https://www.cdc.gov/stroke/facts.htm>
29. Onyike CU, Diehl-Schmid J. The epidemiology of frontotemporal dementia. *Int Rev Psychiatry.* 2013;25(2):130-137.

Our Company

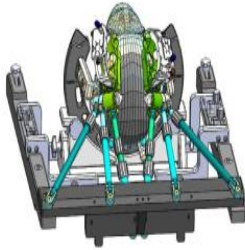
4 Pillar Growth Strategy by 2025

Development Pipeline Over the Next Two Years



New Product Growth Drivers Expected in 2024

1 Biologics & Drug Delivery



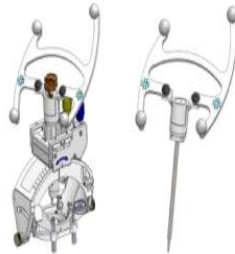
ClearPoint Orchestra™ Head Fixation Frame



Spinal Infusion
Anchoring Devices

Radially Branching Cell
therapy Devices

2 Navigation for DBS

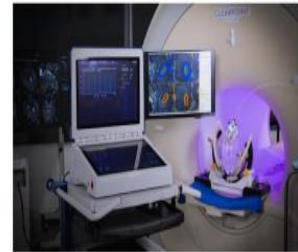


ClearPointer™ and SmartFrame OR™



ClearPoint 2.2 Software w/ Embedded
ClearPoint Maestro®

3 Laser Therapy



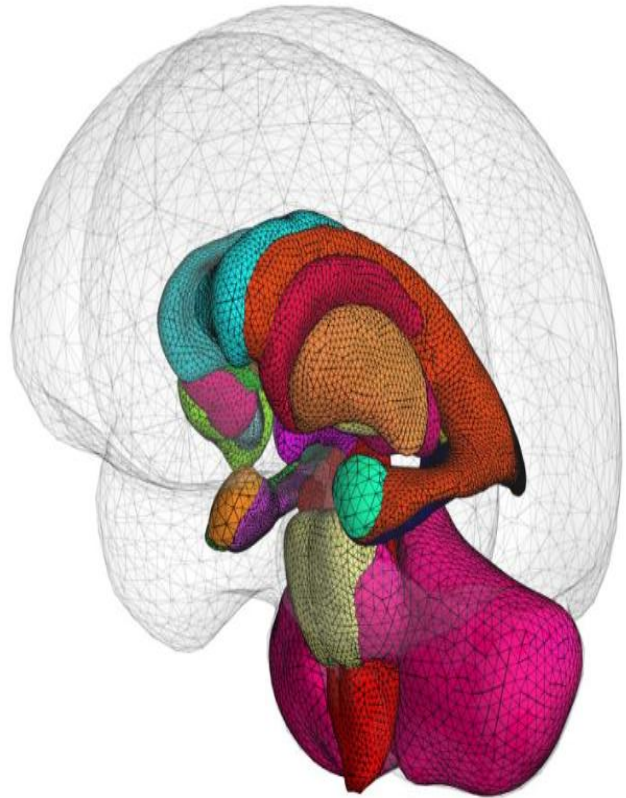
PRISM 3.0 T & 1.5 T Compatible Systems
(1.5 T Compatibility not yet FDA Cleared)



Array 1.2 Parallel Trajectory Tumor Feature

A.I. Powered 'Maestro' Brain Model

- FDA Cleared, Shape Constrained, triangular mesh model enables point-based correspondence across multiple subjects
 - Auto-Segmentation for Device Targeting
 - Direct Navigation in Clinical Trials for Drug Delivery
 - Longitudinal Comparison for Pharma Trial follow-up
- **Platform Engine** for future navigation tools for Drug Delivery, DBS, BCI, Biopsy and Laser Therapy
- Expandable to CT Guidance in the Operating Room



Executive Summary



Unique platform technology

with 10+ years of commercial experience enabling Precision MRI-Guided and OR-based Therapies to restore quality of life for some of the most debilitating disorders



Expandable Platform

through advanced A.I. and machine learning software applications and strategic partnerships



Total potential addressable market

> \$12B for our products, pipeline and partnerships



Pipeline of new revenue streams

through the expansion into the Operating Room, Launch of our own PRISM Laser Therapy, Maestro Brain Model Deployment and addition of pre-clinical services and capacity including GLP



Large, growing number of customer and partner sites

of 85+ leading Neurosurgery and research centers worldwide, on pace to be in 100+ by 2025



A growing and passionate team

of embedded scientists and specialists





CLEARPOINT®
NEURO



