

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):
March 12, 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 March 12, 2024, ClearPoint Neuro, Inc. (the “Company”) issued a press release announcing its financial results for the fourth fiscal quarter and full year ended December 31, 2023. 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 March 12, 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 March 12, 2024](#)

Exhibit 99.2 [Investor Presentation dated March 12, 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: March 12, 2024

CLEARPOINT NEURO, INC.

By: /s/ Danilo D'Alessandro

Danilo D'Alessandro

Chief Financial Officer



ClearPoint Neuro Reports Fourth Quarter and Full-Year 2023 Results

Release Includes Commentary on Early 2024 Progress

SOLANA BEACH, CA, March 12, 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 fourth quarter and full-year ended December 31, 2023.

2023 Full Year and Fourth Quarter Highlights

- Reported fourth quarter 2023 revenue of \$6.8 million, a 32% year-over-year increase compared with the fourth quarter of 2022;
- Reported revenue of \$24.0 million for the full year 2023, an increase of 17% over 2022 and representing the ninth consecutive year of growth;
- Increased biologics and drug delivery revenue to \$13.6 million for the full year 2023, a 49% increase over 2022;
- Completed Certification of Carlsbad development and manufacturing facility and shut down of Irvine manufacturing facility; and
- Cash burn of \$1.2 million in the fourth quarter, bringing cash and cash equivalents to \$23.1 million as of December 31, 2023.

2024 Operational Highlights

- Six new hospital customers already added since the beginning of the year;
- Received 510(k) clearance for Smartframe OR™ Stereotactic System;
- First-in-Human cases performed using ClearPoint 2.2 Software and ClearPoint Array 1.2 Parallel Trajectory Software;
- First product approved under European MDR and products shipped to Europe from new Carlsbad development and manufacturing facility;
- Validation Papers for ClearPoint Maestro and ClearPoint PRISM products published in peer-reviewed journals;
- Completed a public offering of common stock, resulting in gross proceeds of approximately \$15 million; and
- Reaffirming 2024 revenue guidance to be between \$28.0 million and \$32.0 million.

Business Outlook

“We are pleased to confirm our fourth quarter 2023 performance which included record revenue of \$6.8 million, over 30% topline growth, and a reduction in our quarterly cash burn to only \$1.2 million, our lowest since 2020,” commented Joe Burnett, President and CEO at ClearPoint Neuro. “In just the first two months of 2024 we have already achieved some key strategic milestones including multiple FDA clearances and first-in-human procedures, first shipments to EU countries from our new Carlsbad facility and under EU-MDR certification,

publication of key validation papers in peer-reviewed journals supporting both our navigation software and laser therapy system, and activation of more new clinical customers in the first quarter than in all of 2023.

“As a result,” continued Burnett, “we have been able to complete an important equity offering of approximately \$15 million which solidifies our balance sheet for our pharma partners and will allow us to retire our entire outstanding debt in the next 12 months. It was very encouraging to perform this capital raise alongside many other biotech companies in the past few weeks, highlighting renewed investment into this important and exciting gene and cell therapy space. We continue to look with confidence at 2024 and reaffirm our 2024 revenue guidance to be in the range of \$28.0 million - \$32.0 million.”

Financial Results - Year Ended December 31, 2023

Total revenue was \$24.0 million and \$20.6 million for the years ended December 31, 2023 and 2022, respectively.

Biologics and drug delivery revenue, which include sales of disposable products and services related to customer-sponsored preclinical and clinical trials utilizing our products, increased 49% to \$13.6 million for the year ended December 31, 2023, from \$9.1 million for the same period in 2022. This increase is attributable to a \$6.0 million increase in service revenue related to new preclinical studies and services entered into with our partners for the year ended December 31, 2023, compared to the same period in 2022, partially offset by a \$1.5 million decrease in product revenue.

Functional neurosurgery navigation and therapy revenue which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, decreased 7% to \$8.5 million during the year ended December 31, 2023, from \$9.1 million for the same period in 2022. The decrease is driven by lower service revenue of \$0.6 million as a result of pausing a co-development program with one of our Brain Computer Interface partners for the year ended December 31, 2023, compared to the same period in 2022.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, decreased 21% to \$1.8 million for the year ended December 31, 2023, from \$2.3 million for the same period in 2022, due primarily to a decrease in the placements of ClearPoint capital and software.

The Company achieved a gross margin of 57% on its sales for 2023, compared to a gross margin of 66% for 2022. This decrease in gross margin was primarily due to an increase in biologics and drug delivery preclinical services, which, to date, have had a lower margin than in prior years, as we launch new services and increase our presence in this space. Increased costs related to the transition to the new manufacturing facility also contributed to the decrease in gross margin compared to the prior year.

Operating expenses were \$36.1 million for the full year 2023, compared with \$29.9 million for 2022. The increase was mainly driven by an increase in personnel-related expenses, including share-based compensation, as we increased headcount to fund the expansion of the research and development, clinical, and support organizations, as well as an increase in the allowance for credit losses.

Financial Results – Quarter Ended December 31, 2023

Total revenue was \$6.8 million for the three months ended December 31, 2023, and \$5.2 million for the three months ended December 31, 2022, which represents an increase of \$1.6 million, or 32%.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored preclinical and clinical trials utilizing our products, increased 76% to \$4.1 million for the three months ended December 31, 2023, from \$2.3 million for the same period in 2022. This increase is attributable to a \$1.8 million increase in service revenue, partially offset by a slight decrease in product revenue.

Functional neurosurgery navigation and therapy revenue decreased 11% to \$2.0 million for the three months ended December 31, 2023, from \$2.3 million for the same period in 2022. The decrease was driven by lower service revenue.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, increased 23% to \$0.7 million for the three months ended December 31, 2023, from \$0.6 million for the same period in 2022.

Gross margin for the three months ended December 31, 2023, was 59%, as compared to a gross margin of 64% for the three months ended December 31, 2022. The decrease in gross margin was due primarily to an increase in biologics and drug delivery preclinical services, which, to date, have had a lower margin than in prior years, as we launch new services and increase our presence in this space.

Operating expenses for the fourth quarter of 2023 were \$8.7 million, compared to \$7.8 million for the fourth quarter of 2022. The increase was mainly driven by the increase in headcount across the organization and share-based compensation as well as an increase in the allowance for credit losses.

At December 31, 2023, the Company had cash and cash equivalents and short-term investments totaling \$23.1 million compared to \$37.5 million at December 31, 2022, with the decrease resulting primarily from the use of cash in operating activities of \$13.7 million.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's fourth quarter and full year 2023 on Tuesday, March 12, 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=198rn5GM>. 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 April 12, 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 Relations 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 pre-clinical 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 pre-clinical 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, 2022, and the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2023, both of which have been filed with the Securities and Exchange Commission, and the Company's Annual Report on Form 10-K for the year ended December 31, 2023, which the Company intends to file with the Securities and Exchange Commission on or before March 31, 2024. The Company does not assume any obligation to update these forward-looking statements.

Contact:

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

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

	Years Ended December 31,	
	2023	2022
Revenue:		
Product revenue	\$ 10,603	\$ 12,789
Service and other revenue	13,352	7,762
Total revenue	23,955	20,551
Cost of revenue	10,341	7,020
Gross profit	13,614	13,531
Research and development costs	11,709	10,894
Sales and marketing expenses	12,595	9,358
General and administrative expenses	11,756	9,611
Operating loss	(22,446)	(16,332)
Other income (expense):		
Other expense, net	(29)	(22)
Interest income (expense), net	386	(81)
Net loss	\$ (22,089)	\$ (16,435)
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.90)	\$ (0.68)
Weighted average shares outstanding:		
Basic and diluted	24,605,212	24,181,854

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

	December 31,	
	2023	2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 23,140	\$ 27,615
Short-term investments	—	9,874
Accounts receivable, net	3,211	2,665
Inventory, net	7,911	9,303
Prepaid expenses and other current assets	1,910	1,723
Total current assets	36,172	51,180
Property and equipment, net	1,389	806
Operating lease rights of use	3,564	1,895
Software license inventory	386	450
Licensing rights	1,041	1,028
Other assets	109	131
Total assets	\$ 42,661	\$ 55,490
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 393	\$ 272
Accrued compensation	2,947	2,824
Other accrued liabilities	1,053	2,065
Operating lease liabilities, current portion	424	561
Deferred product and service revenue, current portion	2,613	1,066
Total current liabilities	7,430	6,788
Operating lease liabilities, net of current portion	3,568	1,532
Deferred product and service revenue, net of current portion	541	390
2020 senior secured convertible note payable, net	9,949	9,893
Total liabilities	21,488	18,603
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized at December 31, 2023 and 2022; none issued and outstanding at December 31, 2023 and 2022	—	—
Common stock, \$0.01 par value; 90,000,000 shares authorized at December 31, 2023 and 200,000,000 shares authorized at December 31, 2022; 24,652,729 and 24,578,983 shares issued and outstanding at December 31, 2023 and 2022, respectively	247	246
Additional paid-in capital	193,382	187,008
Accumulated deficit	(172,456)	(150,367)
Total stockholders' equity	21,173	36,887
Total liabilities and stockholders' equity	\$ 42,661	\$ 55,490

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

	Years Ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (22,089)	\$ (16,435)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for credit losses (recoveries)	1,258	(117)
Depreciation and amortization	626	244
Share-based compensation	6,079	4,126
Amortization of debt issuance costs and original issue discounts	57	55
Amortization of lease right of use assets, net of accretion in lease liabilities	831	533
Accretion of discounts on short-term investments	(126)	(284)
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(1,804)	(211)
Inventory, net	1,246	(4,421)
Prepaid expenses and other current assets	(113)	(1,216)
Other assets	22	(6)
Accounts payable and accrued expenses	(649)	1,591
Lease liability	(755)	(541)
Deferred revenue	1,697	515
Net cash flows from operating activities	(13,720)	(16,167)
Cash flows from investing activities:		
Purchases of property and equipment	(717)	(253)
Acquisition of licensing rights	(334)	(893)
Purchase of short-term investments	—	(21,590)
Proceeds from maturities of short-term investments	10,000	12,000
Net cash flows from investing activities	8,949	(10,736)
Cash flows from financing activities:		
Proceeds from stock option and warrant exercises	—	268
Proceeds from issuance of common stock under employee stock purchase plan	506	477
Payments for taxes related to net share settlement of equity awards	(210)	(336)
Net cash flows from financing activities	296	409
Net change in cash and cash equivalents	(4,475)	(26,494)
Cash and cash equivalents, beginning of year	27,615	54,109
Cash and cash equivalents, end of year	<u>\$ 23,140</u>	<u>\$ 27,615</u>

SUPPLEMENTAL CASH FLOW INFORMATION

Cash paid for:

Income taxes	<u>\$ —</u>	<u>\$ —</u>
Interest	<u>\$ 743</u>	<u>\$ 523</u>



CLEARPOINT[®]
NEURO

WHEN YOUR PATH IS UNCLEAR,
WE POINT THE WAY.

Nasdaq: CLPT

March 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, 2022, and the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2023, both of which have been filed with the Securities and Exchange Commission, and the Company's Annual Report on Form 10-K for the year ended December 31, 2023, which the Company intends to file with the Securities and Exchange Commission on or before March 31, 2024. The Company does not assume any obligation to update these forward-looking statements.



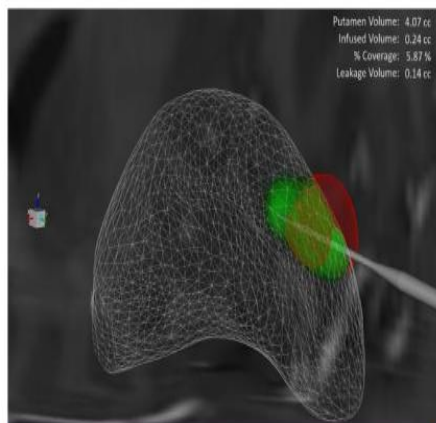
CLEARPOINT®
NEURO

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

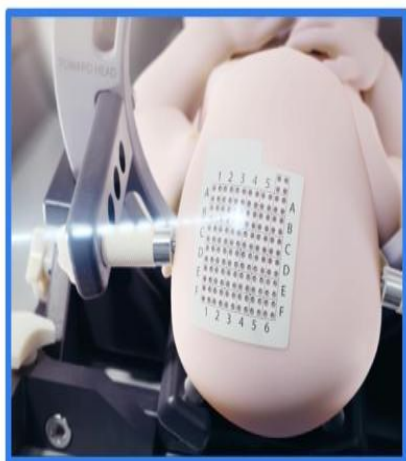
A \$12B+ TAM Diversified Across 35+ Indications and 50+ Partners

*Including owned and licensed patents

Our Company

The ClearPoint® Neuro Navigation System

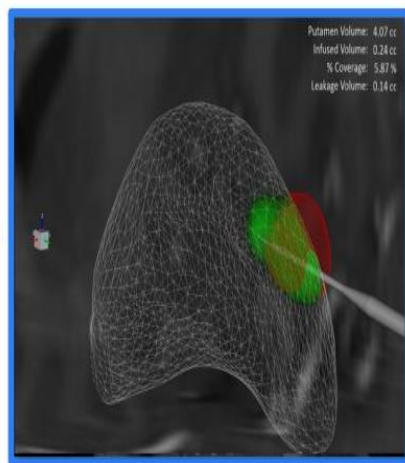
Leverage live MR Imaging to Decide, Guide, and Confirm with sub-millimetric accuracy



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



ClearPoint
Array® Software
v.1.2

ClearPoint
Maestro®
Brain Model



Inflexion® Head
Fixation Frame



Multi-Positional
Head Fixation
Frame

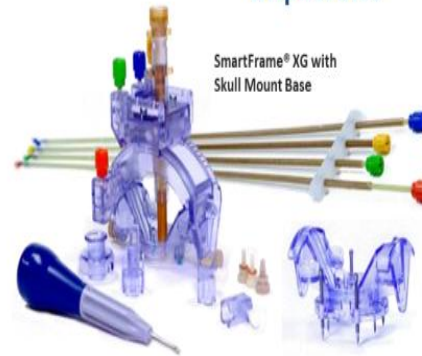


MRI Monitor



ClearPoint Prism®
Neuro Laser
Therapy System

Disposables



SmartFrame® XG with
Skull Mount Base



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



SmartFrame Array®
Kit Components



SmartFlow Cannula



ClearPoint Prism®
Neuro Laser
Fibers

A Strong Foundation

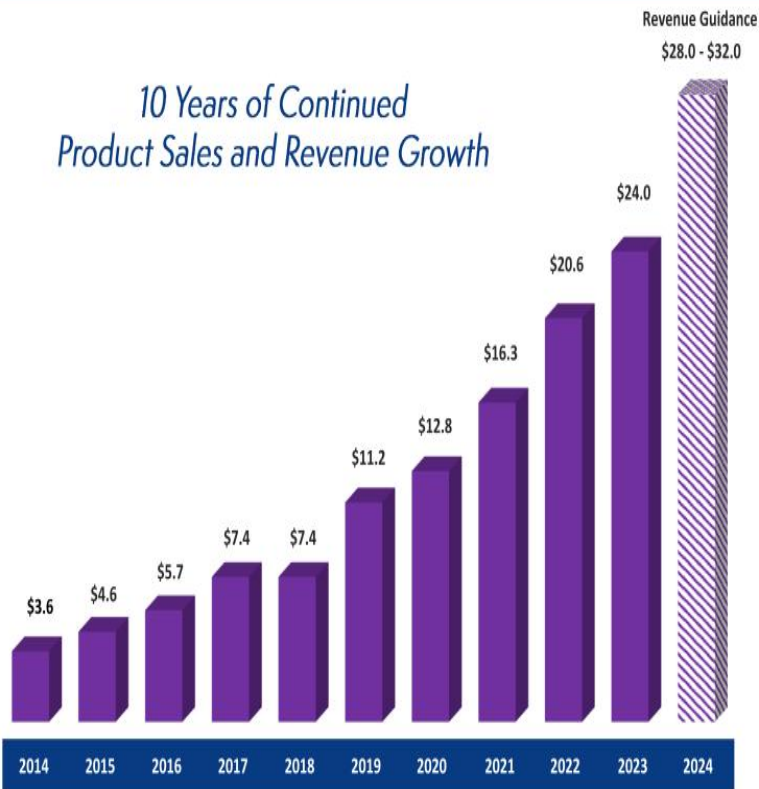
Key Products: **FDA** **CE** Marked Platforms

HEADQUARTERS	MANUFACTURING
Solana Beach, CA	Carlsbad, CA
2024 REVENUE GUIDANCE	CASH & CASH EQUIVALENTS
\$28 m - \$32 m ^(A)	\$23.1 m ^(B)
PATENTS ISSUED	GROSS MARGIN
100+ ^(C)	57% ^(D)
EMPLOYEES	QUALITY SYSTEM
100+	MD-SAP

(A) Estimated and subject to revision
(B) For the quarter ended December 31, 2023
(C) Including owned and licensed patents
(D) For the Trailing Twelve Months (TTM)



10 Years of Continued
Product Sales and Revenue Growth



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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75+ Global Centers

Banner Health Tucson
Baptist Medical Center Jacksonville
Barnes-Jewish 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
Dallas Presbyterian Hospital
Dartmouth-Hitchcock
Duke University
Emory University
Froedtert Hospital
Hackensack University Medical Center
Henry Ford Health
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
Oschner Medical Center
Ohio State University
Riverside Methodist Hospital
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 Michigan
University of Minnesota
University of Oklahoma Medical Center
University of Utah
University of Virginia
University of Wisconsin
USC Keck Hospital
UT Southwestern Medical Center
Weill Cornell Medicine
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, Canada)
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

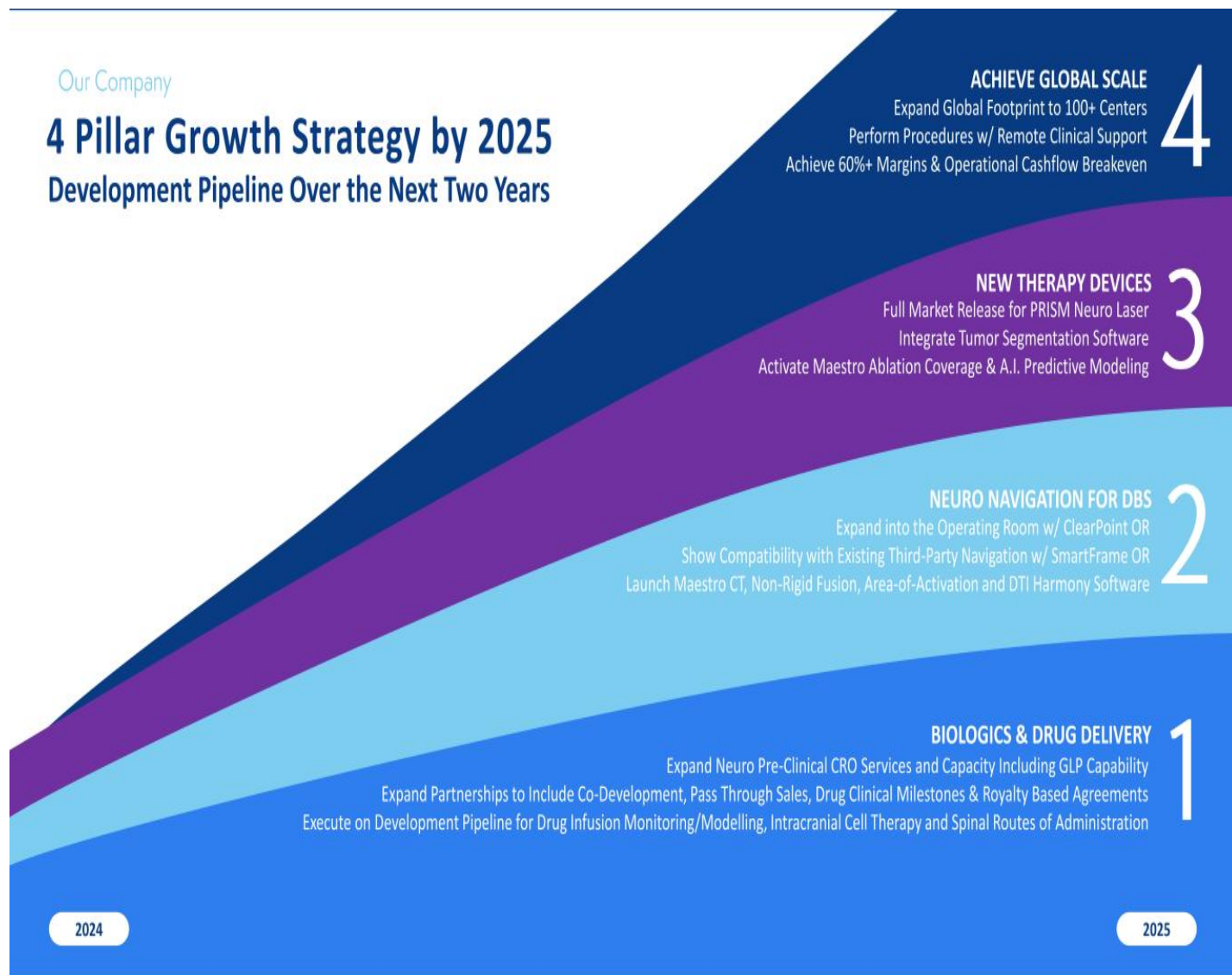
Citations & Footnotes

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). *Neurona 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

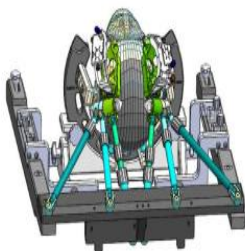
4 Pillar Growth Strategy by 2025

Development Pipeline Over the Next Two Years



New Product Growth Drivers Expected in 2024

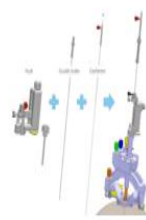
1 Biologics & Drug Delivery



ClearPoint Orchestra™ Head Fixation Frame

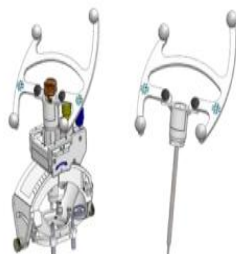


Spinal Infusion Anchoring Devices



Radially Branching Cell therapy Devices

2 Navigation for DBS



ClearPointer™ and SmartFrame OR™



ClearPoint 2.2 Software w/ Embedded ClearPoint Maestro®

3 Laser Therapy



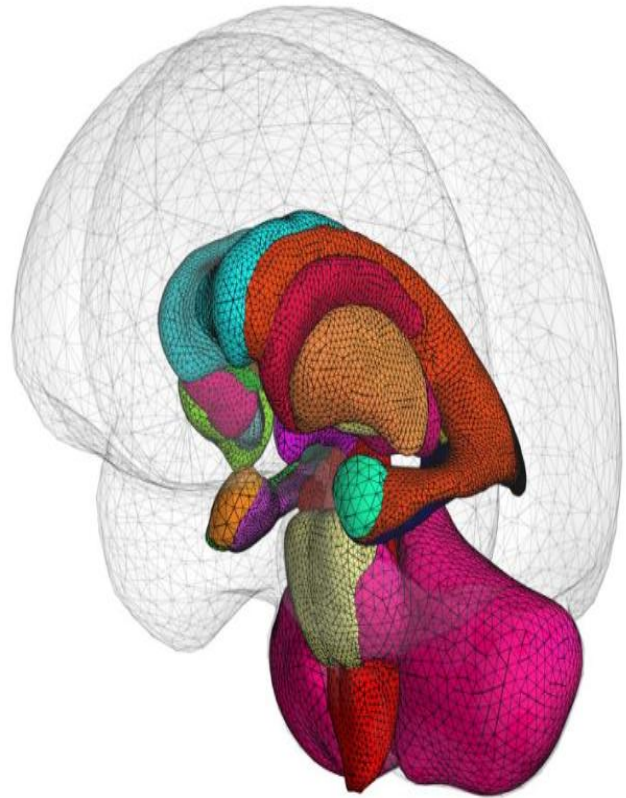
PRISM 3.0 T & 1.5 T Compatible Systems
(1.5 T Compatibility not yet FDA Cleared)



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 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 75+ 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



