UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Delaware (State or other jurisdiction		001-34822 (Commission	58-2394628 (I.R.S. Employer
of incorporation)	(Addı	File Number) 120 S. Sierra Ave., Suite 100 Solana Beach, CA 92075 ress of principal executive offices, zip code	Identification Number)
	(Registr	(888) 287-9109 ant's telephone number, including area co	ode)
heck the appropriate box below if the Form 8-	K filing is intended to s	imultaneously satisfy the filing obliga	tion of the registrant under any of the following provisions:
Written communications pursuant to Rule Soliciting material pursuant to Rule 14a-1 Pre-commencement communications purs Pre-commencement communications purs	2 under the Exchange Asuant to Rule 14d-2(b) u	Act (17 CFR 240.14a-12) under the Exchange Act (17 CFR 240.	· '''
ecurities registered pursuant to Section 12(b) of	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

Item 2.02. Results of Operations and Financial Condition.

On January 8, 2024, ClearPoint Neuro, Inc. (the "Company") issued a press release announcing its preliminary, unaudited financial results for the fourth fiscal quarter 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 January 8, 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 January 8, 2024

Exhibit 99.2 <u>Investor Presentation dated January 8, 2024</u>

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: January 8, 2024 CLEARPOINT NEURO, INC.

By: /s/ Danilo D'Alessandro

Danilo D'Alessandro Chief Financial Officer



ClearPoint Neuro Reports Fourth Quarter and Full Year 2023 Preliminary Revenue Results and Guidance for Full Year 2024 Revenue

SOLANA BEACH, CA, January 8, 2024 – ClearPoint Neuro, Inc. (Nasdaq: CLPT) (the "Company"), a global therapy-enabling platform company providing navigation and delivery to the brain, today announced preliminary, unaudited financial results for its fourth quarter and full year ended December 31, 2023. These preliminary unaudited financial results are management's estimates and are subject to revision in the course of completing annual audit processes. Audited results for 2023 will be publicly reported by the Company later in the first quarter of 2024, prior to a Form 10-K filing for the year with full financial statements.

Fourth Quarter 2023 Preliminary Unaudited Financial Highlights

- Preliminary unaudited revenue of approximately \$6.8 million, a 32% year-over-year increase;
- Increased biologics and drug delivery revenue to approximately \$4.1 million, a 76% year-over-year increase; and
- Cash burn of approximately \$1.2 million in the fourth quarter. The Company had approximately \$23.1 million in cash and cash equivalents at December 31, 2023.

Full Year 2023 Preliminary Unaudited Financial Highlights

- Achieved preliminary unaudited record revenue of approximately \$24 million, a 17% year-over-year increase, versus most recent guidance of \$23 \$25 million; and
- Increased biologics and drug delivery revenue to approximately \$13.6 million, a 49% year-over-year increase.

Business Outlook and Planned Value Creating Milestones

- The Company estimates revenue in 2024 to be between \$28 million and \$32 million, representing growth between 17% and 33%;
- · Achieve FDA clearance and launch SmartFrame OR for navigation and first revenue in the operating room;
- Launch full market release of the ClearPoint PRISM® Neuro Laser Therapy System;
- Launch and deploy ClearPoint 2.2 Software with embedded ClearPoint Maestro[®] and 1.2 Array Software with parallel trajectory tumor planning
 application to the installed base;
- Win first purchase orders for GLP ready pre-clinical services;
- Prototype demonstration of next generation software application for AI predictive modeling to pharma partners;
- Continue global expansion to achieve 100 ClearPoint sites by 2025; and
- Demonstrate operating leverage with expenses increasing less than revenue growth.

"We are thrilled with our fourth quarter performance delivering record revenue of \$6.8 million, reflecting 32% growth, while meaningfully reducing our cash burn and gaining commitments for multiple new ClearPoint installations," commented Joe Burnett, President and CEO at ClearPoint Neuro.

"In 2024, we look forward to several new product introductions reflecting success with the strategic investments we have made to expand our leadership position, including the SmartFrame OR for our entrance into the operating room; the full market release of the PRISM laser therapy system; the integration of ClearPoint Maestro into our navigation software; and the expansion of our pre-clinical biologics and drug delivery services including GLP readiness. These represent four new potential revenue streams that we plan to add to our base business throughout the year."

Management will be available for meetings in San Francisco during the J.P. Morgan Healthcare Conference from January 8-11, 2024.

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

This press release contains forward-looking statements within the context of the federal securities laws, including the Company's expectation for revenues, operating expenses, 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.

Contact:

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



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 Reports on Form 10-Q for the three months ended September 30, 2023, both of which the Company 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. We do not assume any obligation to update these forward-looking statements.







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

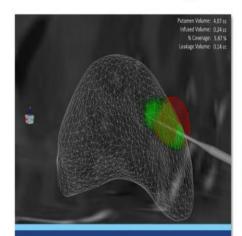
We Uniquely Provide Both Established Clinical Products as well as Pre-Clinical Development Services for Controlled Drug and Device Delivery

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CLEARPOINT'

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, 6,000+ Procedures

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

*Including owned and licensed patents

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The ClearPoint® Neuro Navigation System

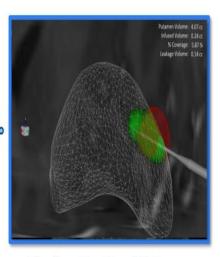
Leverage live MR Imaging to Decide, Guide, and Confirm with sub-millimetric accuracy



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



Automatically **Guide** Precision Adjustments Prior to Insertion



Confirm Quality of Delivery Into Permanent Record



© 2024 CLEARPOINT NEURO

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

Capital Hardware and Software



ClearPoint Neuro Navigation Software v.2.1



Multi-Positional **Head Fixation**

Frame

Inflexion® Head **Fixation Frame**

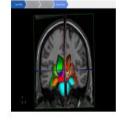








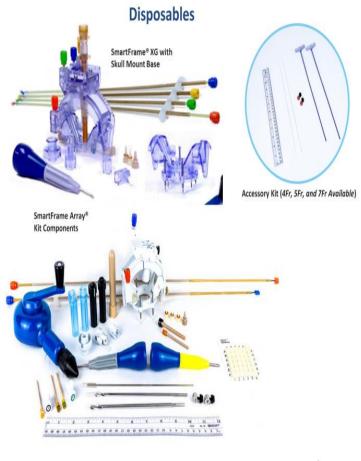
MRI Monitor



CLEARPOINT

ClearPoint Maestro® Brain Model





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A Strong Foundation

Revenue Guidance \$28.0 - \$32.0 **HEADQUARTERS** MANUFACTURING 10 Years of Continued Solana Beach, CA Carlsbad, CA **Product Sales and Revenue Growth** 2024 REVENUE GUIDANCE CASH & CASH EQUIVALENTS \$23.1 m^(B) \$28 m - \$32 m^(A) \$20.6 \$16.3 **PATENTS ISSUED GROSS MARGIN** 60% (D,E) 100+^(c) \$12.8 \$11.2 **QUALITY SYSTEM EMPLOYEES** \$7.4 \$7.4 MD-SAP 100+ \$5.7 (A) Estimated and subject to revision (B) Unaudited as of, and for the guarter ended December 31, 2023 (C) Including owned and licensed patents (D) For the Trailing Twelve Months (TTM) (E) Unaudited as of, and for the quarter ended September 30, 2023 2014 2015 2017 2020 2024 2016 2018 2019 2021 2022 2023



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





A Therapy Enabling Platform

75+ Centers in the US, EU, UK, China, Brazil, and Canada

UC San Francisco Stanford University Lucile Packard Children's Hospital Benjoff Children's Hospital San Francisco VA USC Keck Hospital UC San Diego Mayo Clinic in Arizona University of Colorado University of Utah Cook Children's Hospital Texas Children's Hospital **MD Anderson Cancer Center** Houston Methodist Hospital Univ. Kansas Medical Center Dallas Presbyterian Hospital Cincinnati Jewish Hospital Children's National Hospital Banner Health Tucson Ohio State University University of Oklahoma Medical Center Methodist Hospital San Antonio Barnes-Jewish Hospital Froedtert Hospital **UT Southwestern Medical Center** Baptist Medical Center Jacksonville Henry Ford Health

University of Wisconsin
University of Michigan
University of Minnesota
Northwestern Central DuPage
Nationwide Children's
Cincinnati Children's Hospital
Riverside Methodist Hospital
University of Virginia
INOVA Fairfax
Carilion Clinic
JFK University Medical Center

Charles River Labs – Laval
Charles River Labs – Mattawan
Children's Mercy Hospital
Hos. Univ. of Pennsylvania
University of Alabama at Birmingham
CHOA Scottish Rite
Children's Hospital of Alabama
Mayo Clinic in Florida
Oschner Medical Center
Emory University
Duke University

Rigshospitalet (Copenhagen, Denmark) Mazowiecki Szpital Bródnowski (Warsaw, Poland) Hôpital Fondation Rothschild (Paris, France) TIDU GENOV - Institut du Cerveau (Paris, France) Skånes Universitetssjukhus Lund (Lund, Sweden) Sahlgrenska Universitetssjukhuset (Gothenburg, Sweden) University Hospital of Wales (Cardiff, United Kingdom) Universitätsklinikum Düsseldorf (Düsseldorf, Germany) Universitätsklinikum Freiburg (Freiburg, Germany) Policlinico Umberto I *(Rome, Italy)* Hospital Israelita Albert Einstein (São Paulo, Brazil) Charles River Labs (Lyon, France) Prisys Biotechnologies (Shanghai, China) Kaleida Health Mt. Sinai West Yale University Weill Cornell Johns Hopkins University Boston Children's Hospital lassachusetts General Hospital Brigham & Women's National Institutes of Health Memorial Sloan-Kettering

Dartmouth-Hitchcock

Beth Israel Deaconess

Children's Hospital of Philadelphia

Hackensack Univ. Med. Center Tampa General Hospital

100+ Centers Expected by 2025

CLEARPOINT'

A Therapy-Enabling Platform

The ClearPoint Platform has been used in over 6,000 procedures







earPoint Navigation is Compatible with all Major

Diagnostic <u>and</u> Intraoperative MRI Scanners

Healthineers ClearPoint Navigation is Compatible with all Major









Pillar 4: **Global Expansion**

~2 X U.S. Revenue

ClearPoint Neuro Market Opportunity – United States

~\$12B+ Opportunity: Empowering Multiple Treatment Options for 35+ Indications*

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	1,000,0001	60,0001	00	•	•	\$270 M - \$1.35 B
Drug Resistant Epilepsy	1,000,000²	11,000³	00			\$49.5 M - \$198 M
Refractory Essential Tremor	3,500,0004	60,000 ⁵			0	\$180 M - \$1.08 B
Brain Tumors (n=3) ⁶	35,000 ^{7,8}	13,300 ^{7,8}	00			\$33.3 M - \$300 M
Severe Obsessive-Compulsive Disorder	500,000 ^{9,10}	10,0009,10				\$45 M - \$75 M
Dystonia	250,00011	8,00012				\$36 M - \$60 M
Rare Genetic/Lysosomal (n=7)13	36,50014-18	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	00	0		\$80.6 M - \$403 M
Huntington's Disease	30,000 ²⁵	4,000 ²⁵	00	0		\$18 M - \$90 M
Alzheimer's Disease	6,000,000 ²⁶	500,000 ²⁶	00	0		\$1.5 B - \$11.3 B
Severe Major Depressive Disorder	1,000,00010	20,00010,27		0		\$90 M - \$150 M
Stroke Rehabilitation	2,000,000 ²⁸	610,000 ²⁸		0		\$1.83 B - \$5.49 B
Frontotemporal Dementia	60,000 ²⁹	12,000 ²⁹	0			\$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



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*Citations & footnotes on next slide

ClearPoint Neuro Market Opportunity – United States

Citations & Footnotes

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- 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).
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ACHIEVE GLOBAL SCALE
Expand Global Footprint to 100+ Centers
Perform Procedures w/ Remote Clinical Support
Achieve 60%+ Margins & Operational Cashiflow Breakeven

NEW THERAPY DEVICES
Full Market Release for PRISM Neuro Laser
Integrate Tumor Segmentation Software
Activate Maestro Ablation Coverage & A.I. Predictive Modeling

NEURO NAVIGATION FOR DBS
Expand into the Operating Room w/ ClearPoint OR
Show Compatibility with Existing Third-Party Navigation w/ SmartFrame OR
Launch Maestro CT, Non-Rigid Fusion, Area-of-Activation and DTI Harmony Software

Expand Neuro Pre-Clinical CRO Services and Capacity Including GLP Capability
Expand Partnerships to Include Co-Development, Pass Through Sales, Drug Clinical Milestones & Royalty Based Agreements
Execute on Development Pipeline for Drug Infusion Monitoring/Modelling, Intracranial Cell Therapy and Spinal Routes of Administration



2024

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2025

New Product Growth Drivers Expected in 2024

1 Biologics & Drug Delivery



ClearPoint Orchestra™ Head Fixation Frame



Spinal Infusion Anchoring Devices

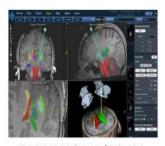


Radially Branching Cell therapy Devices

2 Navigation for DBS



ClearPointer™ and SmartFrame O.R. FDA 510(k) Pending



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





