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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**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 8, 2023

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**CLEARPOINT NEURO, INC.**

(Exact name of registrant as specified in its charter)

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**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)

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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.

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**Item 2.02. Results of Operations and Financial Condition.**

On August 8, 2023, ClearPoint Neuro, Inc. (the “Company”) issued a press release announcing its financial performance for the second fiscal quarter ended June 30, 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 August 8, 2023, 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	<a href="#">Press Release dated August 8, 2023</a>
Exhibit 99.2	<a href="#">Investor Presentation dated August 8, 2023</a>
Exhibit 104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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 8, 2023

**CLEARPOINT NEURO, INC.**

By: /s/ Danilo D'Alessandro  
Danilo D'Alessandro  
Chief Financial Officer



## **ClearPoint Neuro Reports Second Quarter 2023 Results**

### **Biologics & Drug Delivery growing +40%; Company Reaffirms 2023 Revenue Forecast**

SOLANA BEACH, CA, August 8, 2023 – ClearPoint Neuro, Inc. (Nasdaq: CLPT) (the “Company”), a global therapy-enabling platform company providing navigation and delivery to the brain, today announced financial results for its second quarter ended June 30, 2023.

#### **Second Quarter Highlights**

- Reported record quarterly revenue of \$6.0 million, a 14% year-over-year increase;
- Increased biologics and drug delivery revenue to \$3.4 million, a 40% year-over-year increase;
- Announced an example of a milestone-based biologics and drug delivery agreement whereby ClearPoint would earn cash compensation based on the successful progression of a drug candidate through the clinical and regulatory process;
- Installed multiple new PRISM laser therapy units and continued the limited market release in the U.S.;
- Completed construction on the manufacturing clean room at the Carlsbad, California facility;
- Cash and cash equivalents totaled \$26.5 million as of June 30, 2023.

#### **Business Outlook**

The Company reaffirms its full year 2023 revenue outlook of between \$25.0 and \$27.0 million.

“We are pleased with our result for the second quarter as we have returned to double-digit growth and delivered record revenue stemming primarily from the launch of new services in the biologics and drug delivery space which grew more than 40%,” commented Joe Burnett, President and CEO at ClearPoint Neuro. “As we look ahead to the second half of 2023, we expect to demonstrate progress toward our continued growth and scale by 1) accelerating revenue growth; 2) adding meaningful strategic and milestone-based biologics and drug delivery agreements; 3) expanding our PRISM limited market release to multiple new centers; 4) executing as many as five FDA submissions directly or through partnerships for new products; and 5) completing the qualification of our new manufacturing clean room facility in Carlsbad, California and producing sellable product. We believe these milestones will contribute to a reduction in operational cash burn compared to the first half of 2023 with continued revenue growth in biologics and drug delivery being the primary driver.”

#### **Financial Results – Quarter Ended June 30, 2023**

Total revenue was \$6.0 million for the three months ended June 30, 2023, and \$5.2 million for the three months ended June 30, 2022, which represents an increase of \$0.8 million, or 14%.

Functional neurosurgery navigation and therapy revenue, remained relatively consistent at \$2.2 million for the three months ended June 30, 2023 and 2022.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored pre-clinical and clinical trials utilizing our products, increased 40% to \$3.4 million for the

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three months ended June 30, 2023, from \$2.4 million for the same period in 2022. This increase is attributable to a \$1.8 million increase in service revenue, partially offset by \$0.9 million decrease in product revenue.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, decreased 38% to \$0.4 million for the three months ended June 30, 2023, from \$0.6 million for the same period in 2022 as a result of fewer placements of ClearPoint capital and software.

Gross margin for the three months ended June 30, 2023, was 53%, as compared to a gross margin of 63% for the three months ended June 30, 2022. The 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 product sales as we launch new services and increase our presence in this space. Increased costs related to the transition to the new manufacturing facility have also contributed to the decrease in gross margin.

Operating expenses for the second quarter of 2023 were \$10.3 million, compared to \$7.5 million for the second 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 product development costs.

At June 30, 2023, the Company had cash and cash equivalents and short-term investments totaling \$26.5 million as compared to \$37.5 million at December 31, 2022, with the decrease resulting primarily from the use of cash in operating activities of \$10.8 million.

### **Teleconference Information**

Investors and analysts are invited to listen to a live broadcast review of the Company's 2023 second quarter on Tuesday, August 8, 2023 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=n0kx7ZK0>. Investors and analysts who would like to participate in the conference call via telephone may do so at (888) 437-3179, 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, 2023, 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's mission is to improve and restore quality of life to patients and their families by enabling therapies for the most complex neurological disorders with pinpoint accuracy. Applications of the Company's current product portfolio include deep brain stimulation, laser ablation, biopsy, and delivery of drugs, biologics, and gene therapy to the brain. The ClearPoint Neuro Navigation System has FDA clearance, is CE-marked, and is installed in over 65 sites in North America, Europe, and South America. ClearPoint Neuro is partnered with more than 50 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, more than 6,000 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](http://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, 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. Uncertainties and risks may cause the Company's actual results to differ materially from those expressed in or implied by forward-looking statements. Particular uncertainties and

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risks include those relating to: the impact of the COVID-19 pandemic, global instability, supply chain disruptions, labor shortages, and macroeconomic and inflationary conditions; future revenue from sales of the Company's ClearPoint Neuro Navigation System and other new products offered by the Company; the Company's ability to market, commercialize and achieve broader market acceptance for the Company's ClearPoint Neuro Navigation System and other new products offered by the Company; the ability of our biologics and drug delivery partners to achieve commercial success, including their use of our products and services in their delivery of therapies; risks inherent in the research and development, and regulatory approval of new products; and risks in the process of developing and establishing manufacturing operations in a new facility. 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 March 31, 2023, 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, 2023, which the Company intends to file with the Securities and Exchange Commission on or before August 14, 2023.

**Contact:**

Danilo D'Alessandro, Chief Financial Officer

(949) 900-6833

[info@clearpointneuro.com](mailto:info@clearpointneuro.com)

Caroline Corner, Investor Relations

[ir@clearpointneuro.com](mailto:ir@clearpointneuro.com)

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

	For The Three Months Ended June 30,	
	2023	2022
Revenue:		
Product revenue	\$ 2,337	\$ 3,457
Service and other revenue	3,613	1,743
Total revenue	5,950	5,200
Cost of revenue	2,824	1,945
Gross profit	3,126	3,255
Research and development costs	3,605	2,411
Sales and marketing expenses	3,474	2,387
General and administrative expenses	3,178	2,661
Operating loss	(7,131)	(4,204)
Other expense:		
Other expense, net	(2)	(8)
Interest income (expense), net	81	(91)
Net loss	\$ (7,052)	\$ (4,303)
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.29)	\$ (0.18)
Weighted average shares used in computing net loss per share:		
Basic and diluted	24,583,712	23,985,577

	For The Six Months Ended June 30,	
	2023	2022
Revenue:		
Product revenue	\$ 4,967	\$ 6,620
Service and other revenue	6,416	3,611
Total revenue	11,383	10,231
Cost of revenue	5,055	3,746
Gross profit	6,328	6,485
Research and development costs	6,628	5,312
Sales and marketing expenses	6,407	4,404
General and administrative expenses	6,136	4,837
Operating loss	(12,843)	(8,068)
Other expense:		
Other (expense) income, net	(13)	3
Interest income (expense), net	195	(197)
Net loss	\$ (12,661)	\$ (8,262)
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.52)	\$ (0.35)
Weighted average shares used in computing net loss per share:		
Basic and diluted	24,583,439	23,834,847

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

	June 30, 2023 (Unaudited)	December 31, 2022
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 26,464	\$ 27,615
Short-term investments, at amortized cost	—	9,874
Accounts receivable, net	2,799	2,665
Inventory, net	9,204	9,303
Prepaid expenses and other current assets	2,244	1,723
Total current assets	40,711	51,180
Property and equipment, net	1,360	806
Operating lease, right-of-use assets	3,956	1,895
Software license inventory	407	450
Licensing rights	1,051	1,028
Other assets	156	131
Total assets	\$ 47,641	\$ 55,490
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,273	\$ 272
Accrued compensation	2,339	2,824
Other accrued liabilities	1,373	2,065
Operating lease liabilities, current portion	493	561
Deferred product and service revenue, current portion	724	1,066
Total current liabilities	6,202	6,788
Operating lease liabilities, net of current portion	3,855	1,532
Deferred product and service revenue, net of current portion	253	390
2020 senior secured convertible note payable, net	9,921	9,893
Total liabilities	20,231	18,603
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at June 30, 2023 and December 31, 2022	—	—
Common stock, \$0.01 par value; 90,000,000 shares authorized at June 30, 2023 and 200,000,000 shares authorized at December 31, 2022; 24,627,674 shares issued and outstanding at June 30, 2023; and 24,578,983 issued and outstanding at December 31, 2022	246	246
Additional paid-in capital	190,192	187,008
Accumulated deficit	(163,028)	(150,367)
Total stockholders' equity	27,410	36,887
Total liabilities and stockholders' equity	\$ 47,641	\$ 55,490



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

	<b>For The Six Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (12,661)	\$ (8,262)
<b>Adjustments to reconcile net loss to net cash flows from operating activities:</b>		
Allowance for credit losses (recoveries)	454	(10)
Depreciation and amortization	285	187
Share-based compensation	2,952	1,779
Amortization of debt issuance costs and original issue discounts	28	27
Amortization of lease right-of-use, net of accretion in lease liabilities	325	267
Accretion of discounts on short-term investments	(126)	(23)
<b>Increase (decrease) in cash resulting from changes in:</b>		
Accounts receivable	(588)	(1,001)
Inventory, net	94	(1,786)
Prepaid expenses and other current assets	(438)	(1,010)
Other assets	(25)	30
Accounts payable and accrued expenses	(282)	679
Lease liabilities	(293)	(261)
Deferred revenue	(480)	134
<b>Net cash flows from operating activities</b>	<b>(10,755)</b>	<b>(9,250)</b>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(461)	(145)
Acquisition of licensing rights	(167)	(116)
Purchase of short-term investments	—	(21,590)
Proceeds from maturities of short-term investments	10,000	—
<b>Net cash flows from investing activities</b>	<b>9,372</b>	<b>(21,851)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from stock option and warrant exercises	—	256
Payments for taxes related to net share settlement of equity awards	(82)	—
Proceeds from issuance of common stock under employee stock purchase plan	314	260
<b>Net cash flows from financing activities</b>	<b>232</b>	<b>516</b>
<b>Net change in cash and cash equivalents</b>	<b>(1,151)</b>	<b>(30,585)</b>
Cash and cash equivalents, beginning of period	27,615	54,109
Cash and cash equivalents, end of period	<u>\$ 26,464</u>	<u>\$ 23,524</u>
<b>SUPPLEMENTAL CASH FLOW INFORMATION</b>		
<b>Cash paid for:</b>		
Income taxes	\$ —	\$ —
Interest	<u>\$ 369</u>	<u>\$ 207</u>



CLEARPOINT®  
NEURO

WHEN YOUR PATH IS UNCLEAR,  
WE POINT THE WAY.™

Nasdaq: CLPT

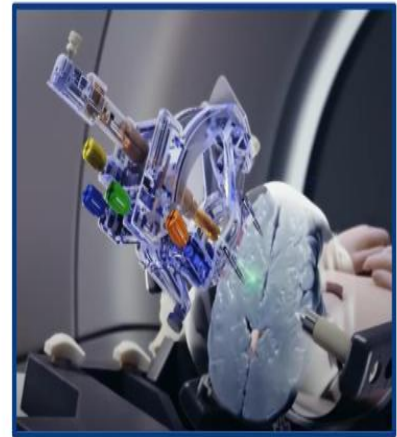
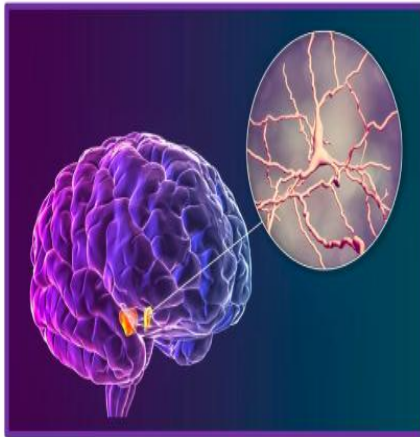
August 2023



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*Statements herein 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, 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. Uncertainties and risks 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: the impact of the COVID-19 pandemic, global instability, supply chain disruptions, labor shortages, and macroeconomic and inflationary conditions; future revenue from sales of the Company's ClearPoint Neuro Navigation System and other new products offered by the Company; the Company's ability to market, commercialize and achieve broader market acceptance for the Company's ClearPoint Neuro Navigation System and other new products offered by the Company; the ability of our biologics and drug delivery partners to achieve commercial success, including their use of our products and services in their delivery of therapies; risks inherent in the research, development, and regulatory approval of new products; and risks in the process of developing and establishing manufacturing operations in a new facility. 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 March 31, 2023, both of which the Company filed with the Securities and Exchange Commission, and the Company's Quarterly Report on Form 10-Q for the three months ended June 30, 2023, which the Company intends to file with the Securities and Exchange Commission on or before August 14, 2023.*

# ClearPoint Neuro: Two Opportunities, One Platform



←→  
A Common Installed Base Platform and  
Clinical Specialist Support team  
35 Active Indications totaling more than  
1 million patients diagnosed annually  
A \$12B+ Potential Total Addressable Market

**1 A Biologics & Drug Delivery Enabling Company with:**

- A unique portfolio of Navigation Tools, Infusion Cannulas, Pre-Clinical and Clinical Services
- More than 50 active pharma/biotech, academic and contract research organization partners

**2 A Neuro Navigation and Device Company with:**

- A growing portfolio of Navigation, Therapy and Access Devices supporting DBS, Laser Ablation, Biopsy and Brain Computer Interface implantation
- An expanding global installed base of more than 65 centers

# ClearPoint Neuro: A Proven Platform

Key Products: FDA CE Marked Platforms

HEADQUARTERS

Solana Beach, CA

MANUFACTURING

Irvine, CA

EUROPEAN HEADQUARTERS

London, UK

2023 EXPECTED REVENUE

\$25-\$27m<sup>(A)</sup>

CASH & CASH EQUIVALENTS

\$26.5m<sup>(B)</sup>

PATENTS ISSUED

100+<sup>(C)</sup>

GROSS MARGIN

62%<sup>(B,D)</sup>

EMPLOYEES

100+



(A) Estimated and subject to revision

(B) Unaudited as of, and for the quarter ended, June 30, 2023

(C) Including owned and licensed patents

(D) For the Trailing Twelve Months (TTM)

Limitations of Traditional Stereotactic Neurosurgery

## Lack of Real-Time Image Guidance

### PRIMARY CHALLENGE

For minimally invasive procedures to be successful, the surgeon needs imaging to see into the head

MRI is the best imaging tool for the brain

Large, metallic frames are not MRI compatible



*Big Iron companies like Siemens and Philips are innovating to make interoperative MRI scanners more accessible*



One Platform, Multiple Indications

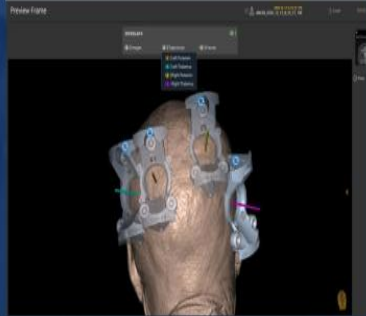
# The ClearPoint® Neuro Navigation System

## Neuromodulation

Parkinson's Disease, OCD,  
Epilepsy, Dystonia

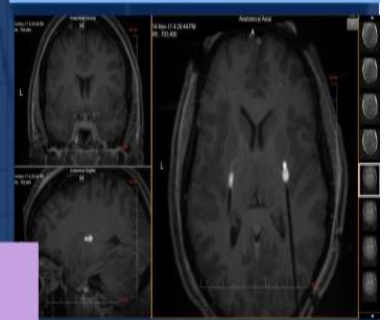


## Pre-Planning Software



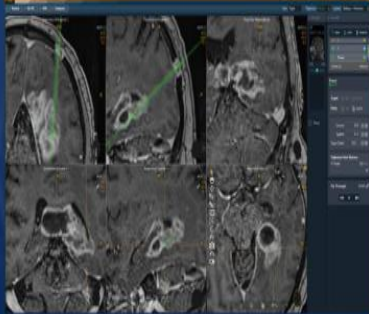
## Drug Delivery

Approved Rare Genetic Disorders +  
30 Indications in Clinical Trials



## Biopsy

Glioblastoma, Diffuse Intrinsic  
Pontine Glioma, etc.

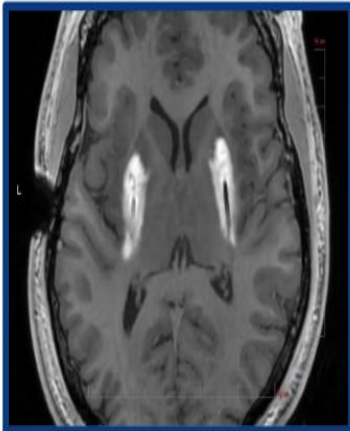
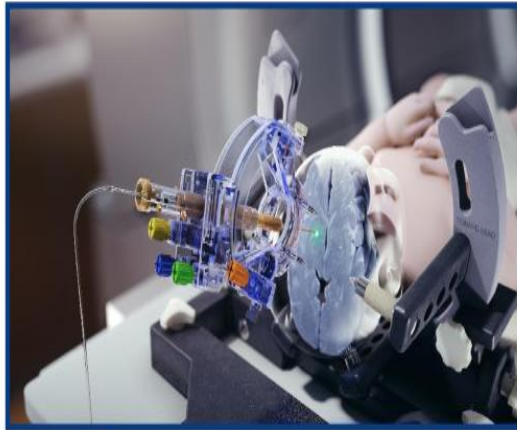


## Laser Therapy

Epilepsy, Tumors, Parkinson's,  
Essential Tremor

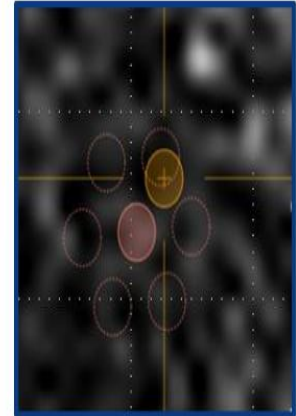
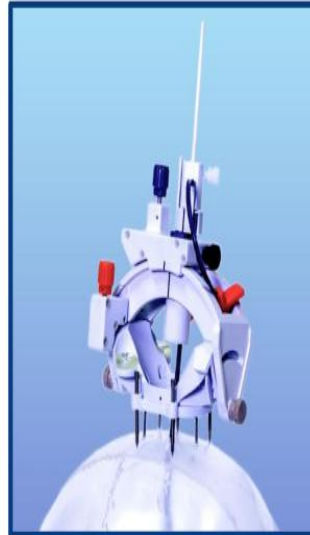


## SmartFrame® XG



SmartFrame XG Trajectory Tower  
with ClearPoint 2.1 Software

## SmartFrame Array®



SmartFrame Array Tower  
with "virtual array" Software and next generation robotic  
system with increased automation and enabling software\*

ClearPoint plans to translate more than 10 years of experience  
and over 6,000 cases performed in the complex MRI suite into  
unique and competitive products for the Operating Room

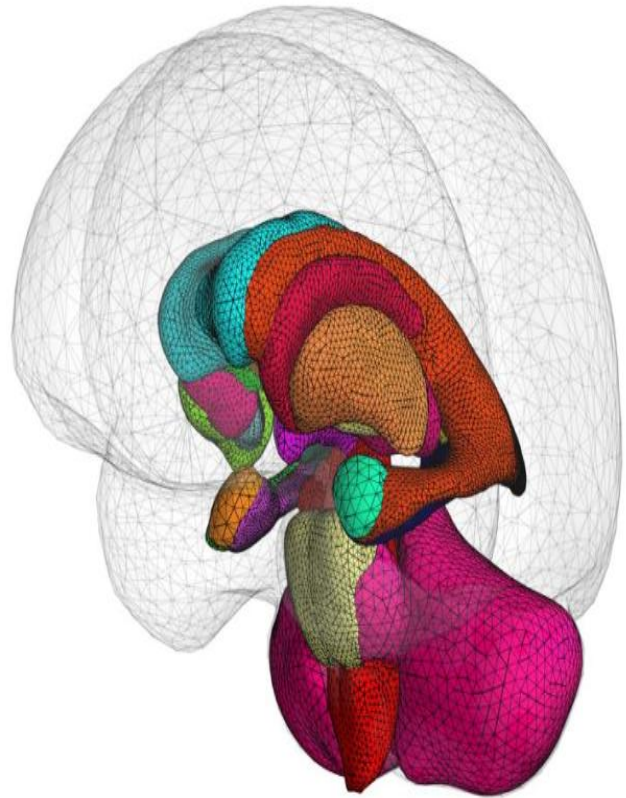


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Our Platform

## The ClearPoint 'Maestro' Brain Model\* Licensed and Jointly Developed with Philips

1. Shape Constrained, triangular mesh model enables point-based correspondence across multiple subjects.
2. Fast and capable of peri-procedural imaging without CPU acceleration.
3. Import DICOM volume bitmasks into ClearPoint software today to assist Neurosurgeons with Targeting and Pharma partners with volume dosing calculations for drug delivery trials.
4. Basis for future navigation tools, for both the MRI suite and OR, across Biologics & Drug Delivery, DBS Navigation, Brain Computer Interface, Laser Ablation and more.



Broad and Growing User Base of Leading Neurosurgery Centers

# 65+ Centers in the US, EU, Brazil and Canada... and Growing Globally

UC San Francisco  
Stanford University  
Lucile Packard Children's Hospital  
Benioff 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  
Cleveland Clinic  
UT Southwestern Medical Center

University of Wisconsin  
University of Michigan  
University of Minnesota  
Carilion Clinic  
Northwestern Central DuPage  
Nationwide Children's  
Le Bonheur  
INOVA Fairfax  
Cincinnati Children's Hospital  
Riverside Methodist Hospital  
Henry Ford Health

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

Rigshospitalet (Copenhagen, Denmark)  
Mazowiecki Szpital Bródnowski (Warsaw, Poland)  
Hôpital Fondation Rothschild (Paris, France)  
Skånes Universitetssjukhus Lund (Lund, Sweden)  
Sahlgrenska Universitetssjukhuset (Gothenburg, Sweden)  
University Hospital of Wales (United Kingdom)  
Universitätsklinikum Düsseldorf (Düsseldorf, Germany)  
Universitätsklinikum Freiburg (Freiburg, Germany)  
Policlinico Umberto I (Rome, Italy)  
Hospital Israelita Albert Einstein (São Paulo, Brazil)

Emory University  
Mt. Sinai West  
Yale University  
Weill Cornell  
Johns Hopkins University  
Boston Children's Hospital  
Massachusetts 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  
University of Virginia  
Tampa General Hospital  
Baptist Medical Center Jacksonville

100+  
Centers  
Expected  
by 2025

A Therapy-Enabling Platform

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

Deliver Biologics & Drugs\*



...with 50+ industry and academic partners

Implant Neuro Stimulation Leads



Administer Laser Therapy

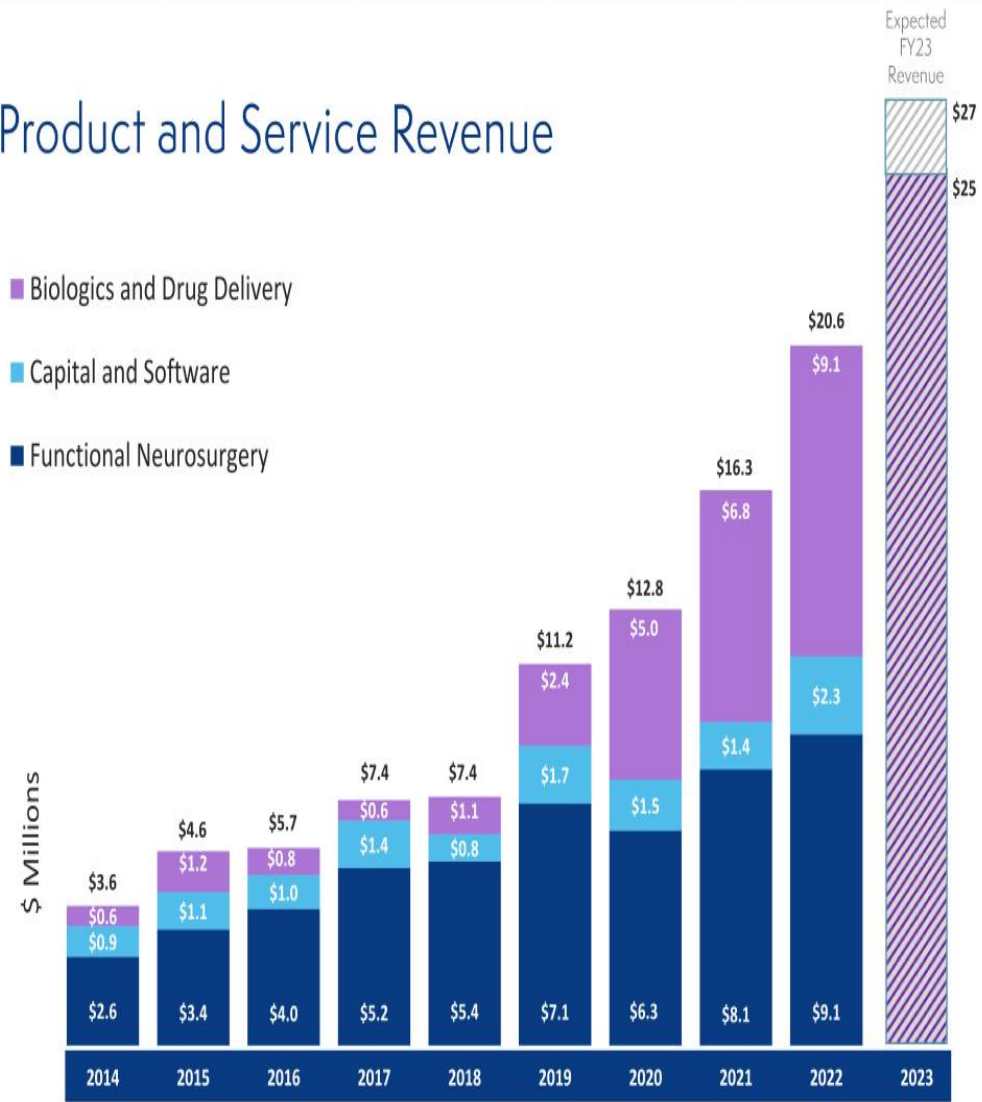


ClearPoint Navigation is Compatible with all Major Diagnostic and Intraoperative MRI Scanners



2014 - 2023

# Growth in Product and Service Revenue



~\$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	1,000,000 <sup>1</sup>	60,000 <sup>1</sup>	○ ○	●	●	\$270 M - \$1.35 B
Drug Resistant Epilepsy	1,000,000 <sup>2</sup>	11,000 <sup>3</sup>	○ ○	●	●	\$49.5 M - \$198 M
Refractory Essential Tremor	3,500,000 <sup>4</sup>	60,000 <sup>5</sup>		●	○	\$180 M - \$1.08 B
Brain Tumors (n=3) <sup>6</sup>	35,000 <sup>7,8</sup>	13,300 <sup>7,8</sup>	○ ○		●	\$33.3 M - \$300 M
Severe Obsessive-Compulsive Disorder	500,000 <sup>9,10</sup>	10,000 <sup>9,10</sup>		●		\$45 M - \$75 M
Dystonia	250,000 <sup>11</sup>	8,000 <sup>12</sup>		●		\$36 M - \$60 M
Rare Genetic/Lysosomal (n=7) <sup>13</sup>	36,500 <sup>14-18</sup>	3,000 <sup>14,19,20</sup>	○ ●			\$13.5 M - \$67.5 M
Paralysis / Spinal Cord (n=15) <sup>21,22</sup>	331,000 <sup>22-24</sup>	17,900 <sup>23</sup>	○ ○	○		\$80.6 M - \$403 M
Huntington's Disease	30,000 <sup>25</sup>	4,000 <sup>25</sup>	○ ○	○		\$18 M - \$90 M
Alzheimer's Disease	6,000,000 <sup>26</sup>	500,000 <sup>26</sup>	○ ○	○		\$1.5 B - \$11.3 B
Severe Major Depressive Disorder	1,000,000 <sup>10</sup>	20,000 <sup>10,27</sup>		○		\$90 M - \$150 M
Stroke Rehabilitation	2,000,000 <sup>28</sup>	610,000 <sup>28</sup>		○		\$1.83 B - \$5.49 B
Frontotemporal Dementia	60,000 <sup>29</sup>	12,000 <sup>29</sup>	○			\$54 M - \$270 M
						<b>\$4.2 B - \$20.8 B</b>

ESTIMATED LAUNCH SEQUENCE

- Commercial U.S or EU ClearPoint procedures today
- Active clinical trial
- Pre-clinical study/testing



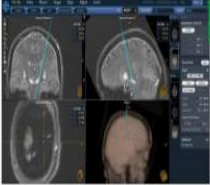
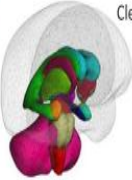


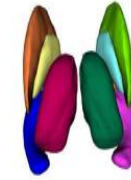

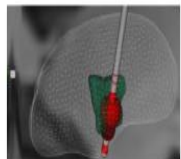
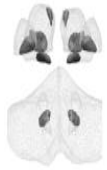


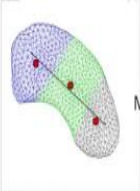
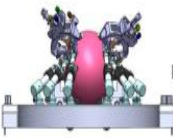

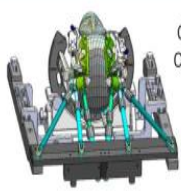
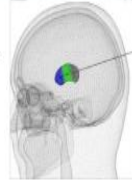



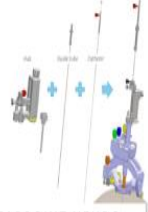
ClearPoint Neuro Navigation Capital, Robotics & Disposables  
 Cannulas, Pumps | MER Probes | Laser Cath., Biopsy  
 Access Technologies, Clinical Services, Digital Health

\*Citations & footnotes on next slide

## 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](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](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](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.

# ClearPoint Neuro is Dedicated to Innovation in the Neuro Space

	First Use in 2022	Active Development Programs*
<b>Functional Navigation &amp; Therapy</b>	 <p>ClearPoint Neuro Navigation Software v. 2.1</p>	 <p>ClearPoint Maestro® Brain Model</p>
	 <p>ClearPoint Prism™ Neuro Laser Therapy System</p>	<div style="display: flex; justify-content: space-between;"> <div style="width: 30%;">  <p>Brain Computer Interface Navigation</p> </div> <div style="width: 30%;">  <p>Maestro® Sub-Nuclei Brain Model</p> </div> <div style="width: 30%;">  <p>Revolution™ Robotic-Assisted Navigation Closed Loop Robotic-Assisted Navigation</p> </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 30%;">  <p>Maestro® Area of Activation Application</p> </div> <div style="width: 30%;">  <p>CT Based Navigation w/ Maestro® Brain Model</p> </div> <div style="width: 30%;">  <p>Z-Axis Robotics</p> </div> </div>
<b>Biologics &amp; Drug Delivery, Access Technologies</b>	 <p>Expanded Pre-Clinical Development Services for Pharma</p>	 <p>ClearPoint Maestro® Infusion Modeling App*</p>
	<div style="display: flex; justify-content: space-between;"> <div style="width: 30%;">  <p>ClearPoint Orchestra™ Pre-Clinical Head Fixation Frame</p> </div> <div style="width: 30%;">  <p>Operating Room Drill</p> </div> </div>	<div style="display: flex; justify-content: space-between;"> <div style="width: 30%;">  <p>ClearPoint Orchestra™ Head Fixation Frame</p> </div> <div style="width: 30%;">  <p>ClearPoint Maestro® Infusion Targeting App</p> </div> <div style="width: 30%;">  <p>Spinal Infusion Catheter</p> </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 30%;">  <p>MRI Suite Safe Drill</p> </div> <div style="width: 30%;">  <p>Flexible, Chronic Drug Delivery Infusion Catheters</p> </div> <div style="width: 30%;">  <p>Radially Branching Cell Therapy Devices licensed from UCSF</p> </div> </div>

New Global Showcase Site

# ClearPoint Global Training & Innovation Center – Solana Beach, CA

- Simulated training experience for surgeons and staff to perform mock procedures and provide development pipeline feedback
- Showcase new technologies to Pharmaceutical and BCI partners
- Home for Clinical Specialists to support cases remotely without travel





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New Manufacturing Facility – Coming Q4 2023

## ~20,000 Sq. Ft. Manufacturing Capability – Carlsbad, CA

- 2,500 Sq. Ft. Clean Room
- Designed for best-in-class lean manufacturing, warehouse and shipping expertise
- Will be available for Neurosurgeon and Pharmaceutical site visits in late 2023



# 4 Pillar Growth Strategy by 2025

Target Indications of > 1,000,000 Patients Diagnosed Each Year  
Potential Total Addressable Market for CLPT of \$12B+



## ACHIEVE GLOBAL SCALE

Expand Global Footprint to 100 Centers  
Achieve Product Clearance Beyond US, EU  
Open New ~20,000 sq ft Manufacturing Facility  
Launch Orchestra and Robotic Platforms

4

## NEW THERAPY DEVICES

Full Market Release for PRISM Neuro Laser  
Integrate Maestro Tools Into Navigation Software  
Launch Array Trajectory Software into Oncology Market  
Penetrate 'Access' Markets to Improve Efficiency (Drill)

3

## NEURO NAVIGATION FOR DBS & BCI

Expand into the Operating Room, Including MER Accessories  
Educate Patients on DBS Options including 'Asleep' and 'Awake' Procedures  
Participate in Trials for new DBS indications  
Launch Pre-Planning and Surgical Navigation Solution for Brain-Computer Interfaces (BCI)

2

## BIOLOGICS & DRUG DELIVERY

Continue to Expand Translational, Pre-Clinical & Clinical Services  
Accumulate Additional Global Partners Across Diverse Indications  
Execute on Development Pipeline for Intracranial Cell Therapy and Spinal Routes of Administration  
Progress Partner Programs Through Regulatory Pathways to Achieve Combination Product Clearances  
Expand Partnership Models to Include Pass Through, Milestone & Royalty Based Collaborative Agreements

1

2023

2025

# Executive Summary



### Unique platform technology

enabling Precision MRI-Guided Therapies to restore quality of life for some of the most debilitating disorders



### Pipeline of new revenue streams

from product improvements, biologic and drug delivery partnerships and services, standalone therapy products, and Brain Computer Interface Navigation



### Expandable Platform

with realizable synergies beyond the MRI and into the operating room and radiology suite



### Large, growing installed base

in 65+ of 500+ leading Neurosurgery and research centers worldwide



### Total potential addressable market

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



### A growing and passionate team

of embedded scientists and specialists





CLEARPOINT<sup>®</sup>  
NEURO



