

**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):
February 15, 2022

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, California 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 February 15, 2022, ClearPoint Neuro, Inc. (the "Company") issued a press release announcing its preliminary, unaudited financial results for the fourth fiscal quarter and year ended December 31, 2021. 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 February 15, 2022, 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 February 15, 2022](#)

Exhibit 99.2 [Investor Presentation dated February 2022](#)

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: February 15, 2022

CLEARPOINT NEURO, INC.

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



ClearPoint Neuro Reports Fourth Quarter and Full Year 2021 Preliminary Revenue Results and Guidance for Full Year 2022 Revenue

Company to Hold Earnings Call on March 1, 2022

SOLANA BEACH, CA, February 15, 2022 – 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, 2021. The Company also announced that its earnings call will take place on Tuesday, March 1, 2022, after the market close.

Fourth Quarter 2021 Revenue Highlights

- Reported revenue of \$4.3 million, a 15% year-over-year increase;
- Increased functional neurosurgery products and services to \$2.1 million, a 37% year-over-year increase;
- Increased biologics and drug delivery revenue to \$1.7 million, a 10% year-over-year increase;
- Clinical team supported 239 cases despite a regional impact of the Omicron variant on elective procedures, a 37% year-over-year increase.

Full Year 2021 Revenue Highlights

- Achieved record revenue of \$16.3 million, a 27% year-over-year increase and within the initial 2021 forecast of \$16.0 - \$17.5 million despite the impact of both Delta and Omicron variants throughout the year on elective procedures and supply chain;
- Achieved record case volume of 929 cases, a 36% year-over-year increase and within initial 2021 forecast of 900 – 1,000 cases supported by our clinical specialist team;
- The Company had approximately \$54.1 million in cash and cash equivalents at December 31, 2021.

Business Outlook

- The Company estimates revenue in 2022 to be between \$20.0 and \$22.0 million, representing growth between 23% and 35%;
- The single largest risk factor for 2022 revenue is expected to remain the impact of COVID, including the resumption of elective procedures post-Omicron and the risk of new emerging variants as seen in 2021.

“As we close the books on 2021, we reflect on a tremendous year for the Company as we have continued to execute and make progress across our four-pillar growth strategy,” commented Joe Burnett, President and CEO of ClearPoint Neuro. “Overall, we achieved record revenue and case volume across all of our segments including functional neurosurgery, biologics and drug delivery and capital and service. We also met our initial guidance for both revenue and case volume despite multiple disruptions to elective procedures caused by the Delta and Omicron variants.”

“We continue to manage the business appropriately during these uncertain times caused by the pandemic and will use our existing capital to balance growth with thoughtful spending. Our current cash position entering 2022 is \$54.1 million and we do not at present feel the need for additional capital at any time in 2022. We have a unique product offering at a special time and will continue to invest and innovate in the neurosurgical space. If you add up all the different patient indications where we plan to participate using our platform supporting Biologics, Deep Brain Stimulation, Brain-Computer-Interfaces, and laser ablation, the total amounts to 35 different patient populations. In the United States alone, this represents approximately one million new patients diagnosed each year across these various indications who could one day benefit from treatments utilizing the ClearPoint platform.”

Investors and analysts are invited to listen to a live broadcast review of the Company's fourth quarter and full year 2021 financial results on Tuesday, March 1, 2022 at 4:30 p.m. Eastern time (1:30 p.m. Pacific time) which may be accessed online here: <https://themediiframe.com/mediiframe/webcast.html?webcastid=ZSukJDu1>. 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 Thursday, March 31, 2022 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 website at www.clearpointneuro.com, on the “Investor Relations” page.

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, neuro-aspiration, 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 approximately 60 active sites in the United States, Canada, and Europe. ClearPoint Neuro is partnered with approximately 40 biologics/pharmaceutical companies and academic centers, providing solutions for direct CNS delivery of therapeutics in pre-clinical studies and clinical trials worldwide. To date, more than 5,000 cases have been performed and supported by the Company's field-based clinical specialist team, which offers support and services to our customers and partners. For more information, please visit www.clearpointneuro.com.

Forward-Looking Statements

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, 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 and the measures adopted to contain its spread; future revenue from sales of the Company's ClearPoint Neuro Navigation System products; the Company's ability to market, commercialize and achieve broader market acceptance for the Company's ClearPoint Neuro Navigation System products; and risks inherent in the research and development 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, 2020, and the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2021, 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, 2021, which the Company intends to file with the Securities and Exchange Commission on or before March 31, 2022.

Contact:

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info@clearpointneuro.com

Caroline Corner, Investor Relations
ir@clearpointneuro.com



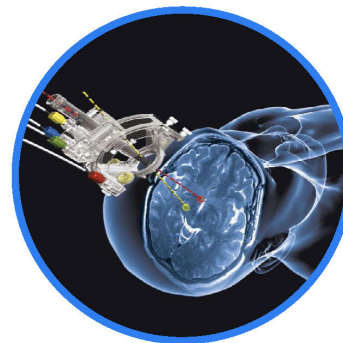
WHEN YOUR PATH IS UNCLEAR, WE POINT THE WAY.™

Nasdaq: CLPT

February 2022

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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
- Approximately 40 active Pharma and Academic 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 60 centers

ClearPoint Neuro: A Proven Platform

Key Products: **FDA CE** Marked Platforms

HEADQUARTERS

Solana Beach, CA

MANUFACTURING

Irvine, CA

EUROPEAN HEADQUARTERS

London, UK

2021 REVENUE

\$16.3m^(A)

CASH

\$54.1m^(A)

U.S. PATENTS ISSUED

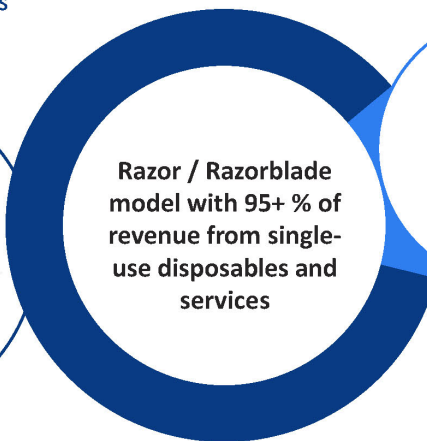
75^(B)

2021 GROSS MARGIN

69%^(A)

EMPLOYEES

75+



(A) Estimated, Unaudited as of, and for the quarter ended, December 31, 2021
(B) Including owned and licensed patents

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

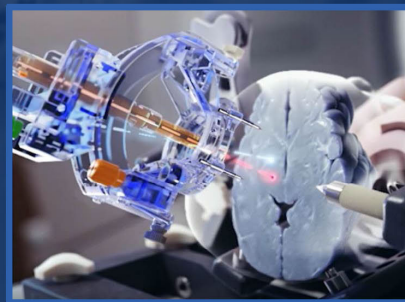


Big Iron companies like Siemens and Philips are innovating to make interoperative MRI scanners more accessible



Our Platform – Procedure Overview

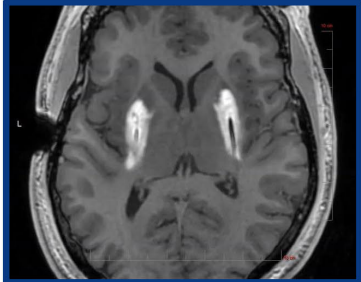
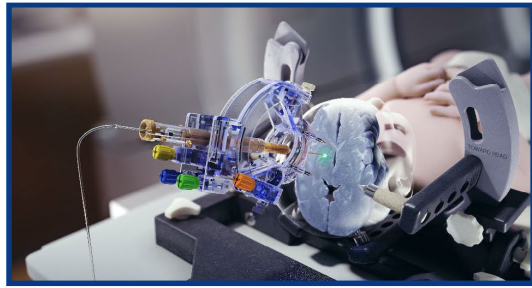
The ClearPoint® Neuro Navigation System



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

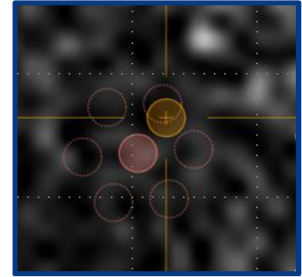
Our Platform

SmartFrame® XG



SmartFrame XG Trajectory Tower with ClearPoint 2.0 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 5,000 cases performed in the complex MRI suite into unique and competitive products for the Operating Room

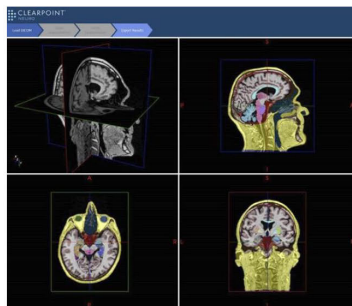
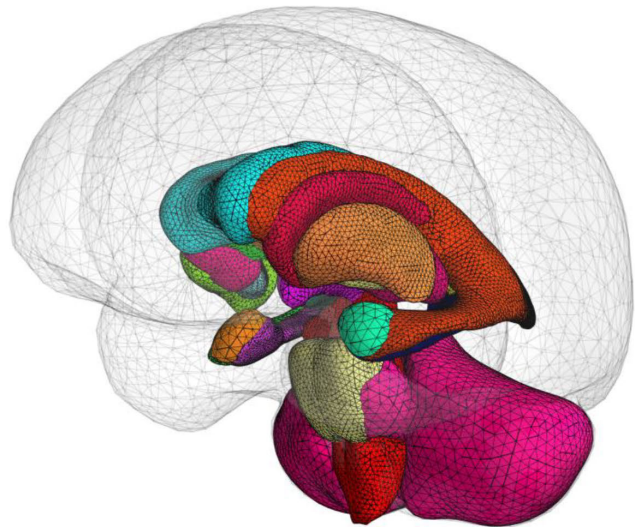


*Software and Robotic System are currently under development.

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. This model is the basis for future navigation tools across Biologics & Drug Delivery, DBS Navigation, Brain Computer Interface, Laser Ablation and more.



*The ClearPoint Maestro™ Brain Model is currently under development.

Broad and Growing User Base of Leading Neurosurgery Centers

60+ Centers in the US, Canada and EU... and Growing Globally

UC San Francisco
Stanford University
Stanford Children's Hospital
UCSF Benioff Children's
San Francisco VA
USC Keck Hospital
UC San Diego
Mayo Clinic Phoenix
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
Children's National
Banner Health Tucson
Ohio State University
University of Oklahoma Medical Center
Methodist Hospital San Antonio
Barnes-Jewish Hospital

University of Wisconsin
University of Michigan
University of Minnesota
Cincinnati Children's Hospital
Cleveland Clinic
Northwestern Central DuPage
Nationwide Children's
UPMC

Charles River Labs – Laval
Charles River Labs – Mattawan
Children's Mercy Hospital
CHOA Scottish Rite
Le Bonheur
INOVA Fairfax
Carilion Clinic
Hos. Univ. of Pennsylvania

Rigshospitalet (Copenhagen, Denmark)
Mazowiecki Szpital Bródnowski (Warsaw, Poland)
Hôpital Fondation Rothschild (Paris, France)
Skåne University Hospital (Lund, Sweden)
Cardiff University (United Kingdom)
Mt. Sinai West
Yale University
Weill Cornell

Johns Hopkins University
Boston Children's Hospital
Brigham & Women's
Massachusetts General Hospital
National Institutes of Health
Memorial Sloan-Kettering
Dartmouth-Hitchcock
Beth Israel Deaconess
Children's Hospital of Philadelphia
Hackensack Univ. Med. Center
University of Virginia
Children's Hospital of Alabama
Duke University
Tampa General Hospital
Mayo Clinic in Florida
Emory University

100+
Centers
Expected
by 2025



Our MRI-guided therapy platform
is currently being used to...

CLPT PLATFORM RUNS
ON ALL MAJOR SCANNERS

DELIVER BIOLOGICS
AND DRUGS

IMPLANT NEURO
STIMULATION LEADS

PLACE LASER
ABLATION PROBES

SIEMENS



PHILIPS



LYSOGENE

uniQure

charles river

Medtronic



Boston
Scientific



Medtronic
VISUALASE

MONTERIS[®]
MEDICAL

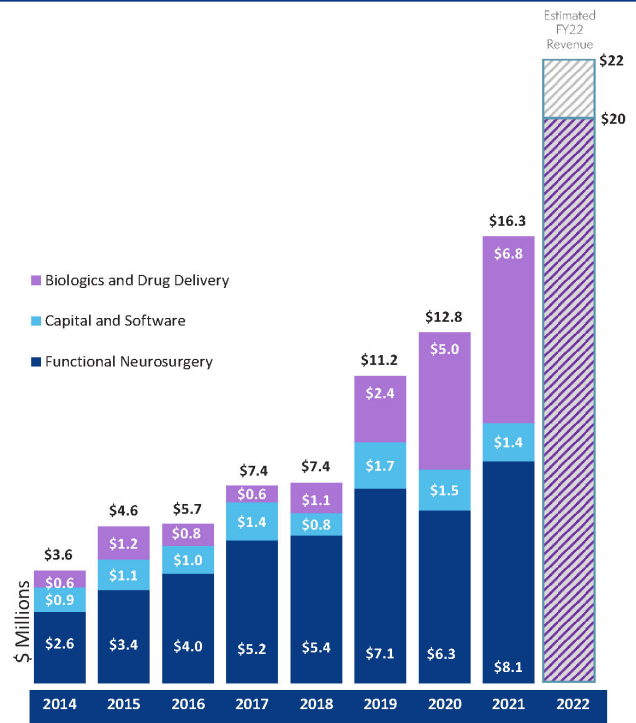
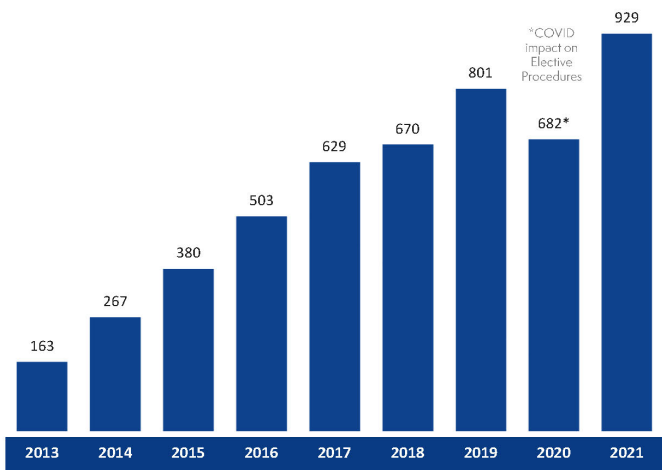


*Expected First Clinical Case in 2022



... Approximately 40 total commercial
and academic partners

2013 - 2022 Growth in Case Volume and Revenue



ClearPoint Neuro Market Opportunity – United States

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

Pillar 4: Global Expansion
~2 X U.S. Revenue

Indication	Patient Population	Annual Incidence	Pillar 1: Drug/Cell Delivery			Pillar 2: DBS & BCI		Pillar 3: Laser Ablation		Incremental Revenue from Annual Incidence
			Pre-clinical	Clinical	Commercial	Pre-clinical	Clinical	Commercial		
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	
Auditory Nerve Implant	1,867,000 ^{26,27}	7,000 ^{26,27}	○	○	●	○	○	○	\$31.5 M - \$63 M	
Alzheimer's Disease	6,000,000 ²⁸	500,000 ²⁸	○	○	●	○	○	○	\$1.5 B - \$11.3 B	
Severe Major Depressive Disorder	1,000,000 ¹⁰	20,000 ^{10,29}	○	○	●	○	○	○	\$90 M - \$150 M	
Stroke Rehabilitation	2,000,000 ³⁰	610,000 ³⁰	○	○	●	○	○	○	\$1.83 B - \$5.49 B	
Frontotemporal Dementia	60,000 ³¹	12,000 ³¹	○	○	●	○	○	○	\$54 M - \$270 M	

\$4.2 B - \$20.8 B

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

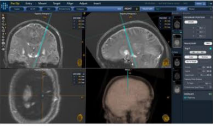

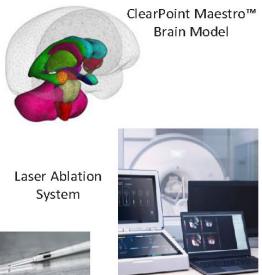

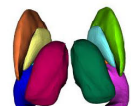
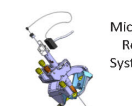
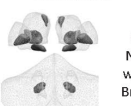
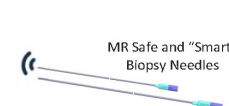

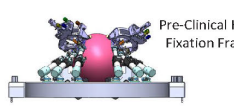

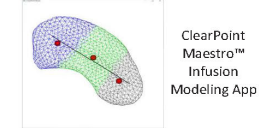
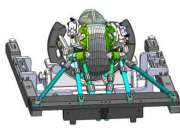
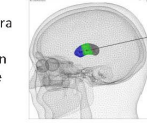




ClearPoint Neuro Navigation Capital, Robotics & Disposables
Cannulas, Pumps | MER Probes | Laser Cath., Biopsy
Access Technologies, Clinical Services, Digital Health

*Citations and footnotes on next slide

ClearPoint Neuro Market Opportunity – United States 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_IND_Clearance_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/>
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Innovation Pipeline ClearPoint Neuro is Dedicated to Innovation in the Neuro Space

	Expected 2022 First-Clinical Use*	Expected First-Clinical Use by 2025*
Functional Navigation & Therapy	 <p>ClearPoint Neuro Navigation Software v. 2.1</p>  <p>ClearPoint® Array Pre-Planning Software & SmartFrame Array™</p>  <p>ClearPoint Maestro™ Brain Model</p> <p>Laser Ablation System</p>	 <p>Brain Computer Interface Navigation</p>  <p>Maestro Sub-Nuclei Brain Model</p>  <p>Micro-Electric Recording System (MER)</p>  <p>CT Based Navigation w/ Maestro Brain Model</p>  <p>MR Safe and "Smart" Biopsy Needles</p>
	 <p>Expanded Pre-Clinical Development Services for Pharma</p>  <p>Pre-Clinical Head Fixation Frame</p>  <p>Operating Room Drill</p>  <p>ClearPoint Maestro™ Infusion Modeling App</p>	 <p>Orchestra Head Fixation Frame</p>  <p>ClearPoint Maestro™ Infusion Targeting App</p>  <p>MRI Suite Safe Drill</p>  <p>Flexible, Chronic Drug Delivery Infusion Catheters</p>  <p>Spinal Infusion Catheter</p>  <p>Digital Health Patient Connection Platform</p>

New Global Showcase Site ClearPoint Global Training & Innovation Center – Solana Beach, CA

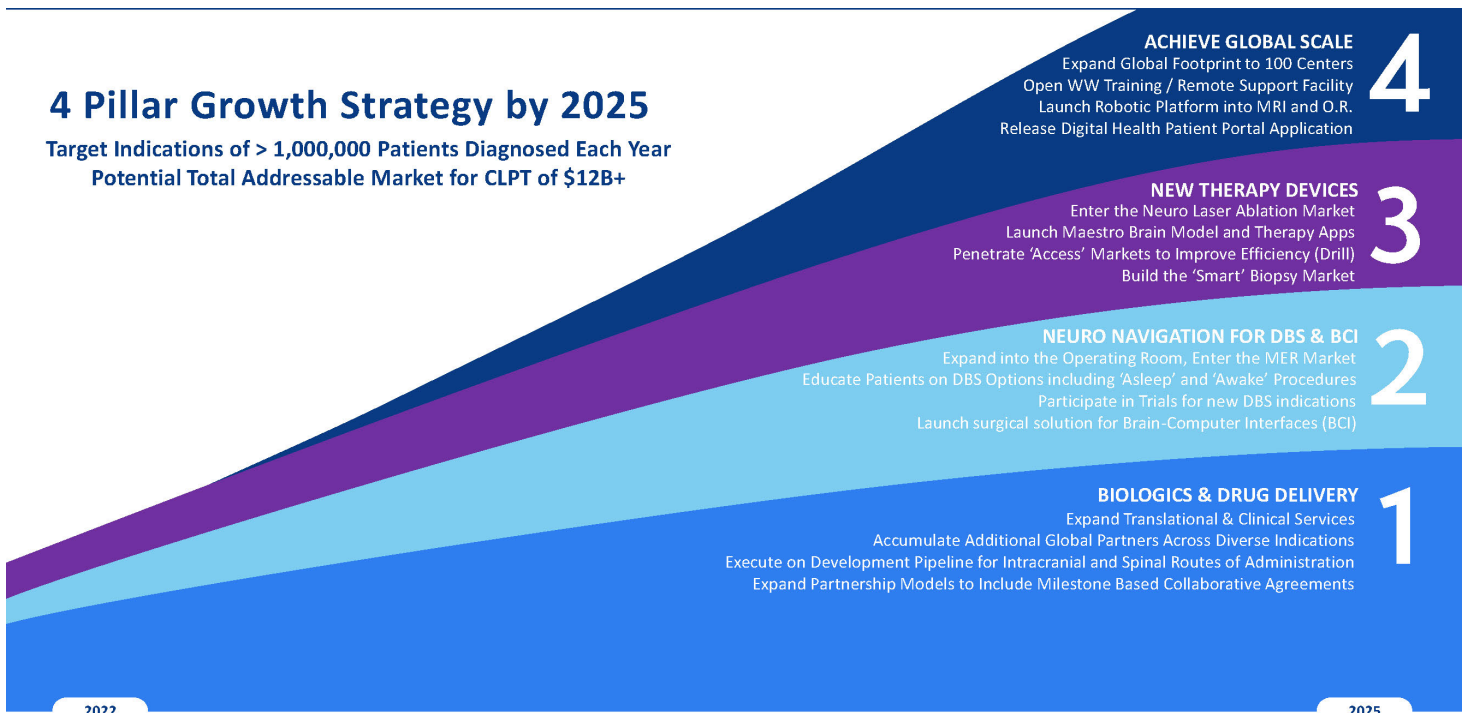


- Simulated training experience for surgeons and staff to perform mock procedures and provide development pipeline feedback
- Showcase new technologies to Pharmaceutical and BCI partners
- Home for Clinical Specialists to support cases remotely without travel



4 Pillar Growth Strategy by 2025

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



CLPT Capabilities Executive Summary



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



Large, growing installed base in 60+ of 500+ leading Neurosurgery and research centers Worldwide



Pipeline of new revenue streams from product improvements, biologic and drug delivery partnerships and services, standalone therapy products, and Brain Computer Interface Navigation



Total potential addressable market > \$12B for our products, pipeline and partnerships



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



A growing and passionate team of embedded scientists and specialists





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