

**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):
May 25, 2021

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)

(949) 900-6833
(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 7.01. Regulation FD Disclosure.

On May 25, 2021, 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 99.1. 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 99.1 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 [Investor Presentation dated May 2021](#)

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: May 25, 2021

CLEARPOINT NEURO, INC.

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



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

Nasdaq: CLPT

May 2021

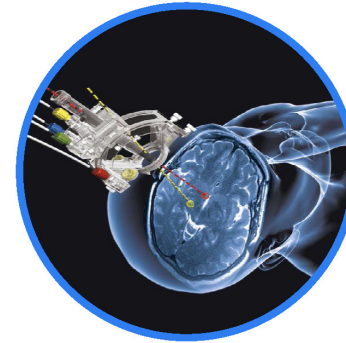
FORWARD LOOKING STATEMENTS

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; and the Company's ability to market, commercialize and achieve broader market acceptance for the Company's ClearPoint Neuro Navigation System 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 March 31, 2021, both of which have been filed with the Securities and Exchange Commission.

ClearPoint Neuro: Two Opportunities, One Platform



←————→
Leveraging a Common Navigation Engine, Installed Base and Clinical Support Channel



A Biologics & Drug Delivery Company with a Broad Portfolio of Pharma Partners and Indications with Potentially Explosive Growth

- \$1B+ Potential Market, first indication expected in 2022
- 2020 Growth of 109% during COVID

A Medical Device Company with an Innovative and Expanding Portfolio Supported by an Established On-Site Clinical Channel

- \$500M+ in Existing Market Opportunity
- 5+ New Products Expected in next 2 Years

ClearPoint Neuro: A Proven Platform

Key Products: **FDA CE** Marked Platforms

HEADQUARTERS
Solana Beach, CA

MANUFACTURING
Irvine, CA

EUROPEAN HEADQUARTERS
Manchester, UK

2020 REVENUE
\$12.8m

CASH
\$64.9m^(A)

U.S. PATENTS ISSUED
65

GROSS MARGIN
65%^(A)

EMPLOYEES
65+
28+ field
37+ production & development



**Razor / Razorblade
model with 85+ % of
revenue from single-
use disposables and
services**



15%
Capital
Equipment

[A] As of, and for the quarter ended, March 31, 2021

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

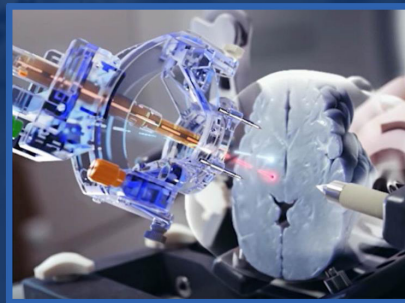
Large, metallic frames are not MRI compatible



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



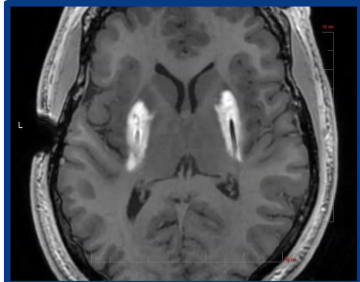
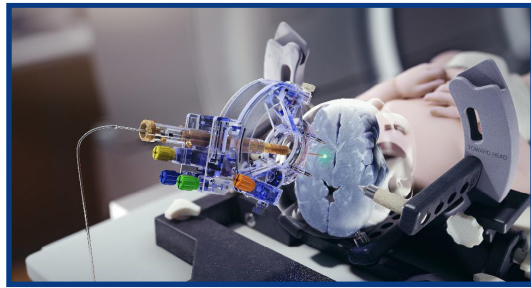
Our Platform – Procedure Overview The ClearPoint® Neuro Navigation System



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

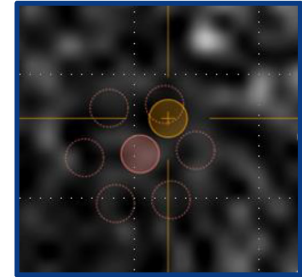
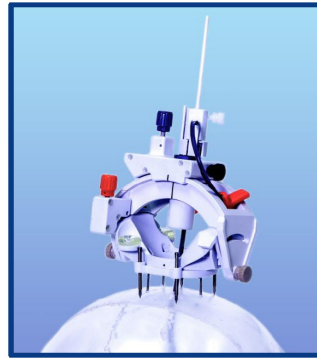
Our Platform

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

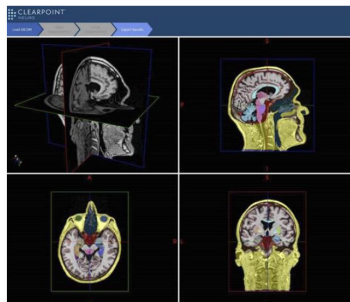
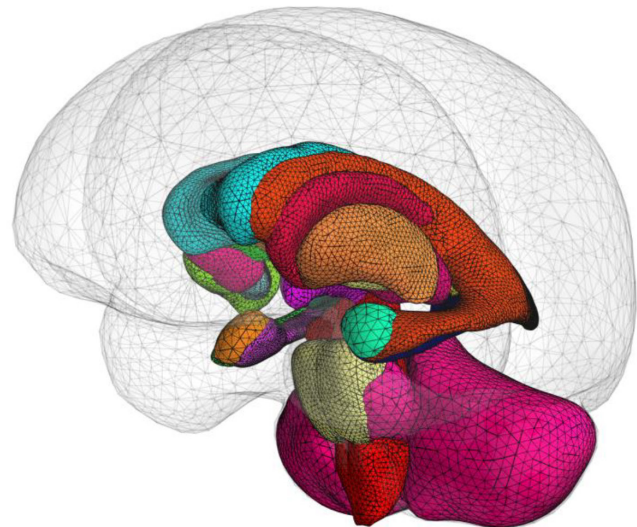


*The SmartFrame Array Tower, Software and Robotic System are currently under development.

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, Laser Ablation and more.



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

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



...with 30 total commercial and academic partners

Medtronic



Medtronic VISUALASE

MONTERIS MEDICAL



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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
University of Arizona
Banner Health Tucson
Cook Children's Hospital
Texas Children's Hospital
MD Anderson Cancer Center
Houston Methodist Hospital
Univ. Kansas Medical Center
Dallas Presbyterian Hospital
Willis-Knighton
Oklahoma State University
Cincinnati Jewish
Children's National

University of Wisconsin
University of Michigan
University of Minnesota
Cincinnati Children's Hospital
Ohio State University
Cleveland Clinic
Northwestern Central DuPage

Charles River Labs (Laval, Canada)
Nationwide Children's
Children's Mercy Hospital
CHOA Scottish Rite
Le Bonheur
INOVA Fairfax
Carilion Clinic

Rigshospitalet (Copenhagen, Denmark)
Johns Hopkins University
Yale University
Boston Children's Hospital
Weill Cornell
Brigham & Women's
Massachusetts General Hospital
National Institutes of Health
Memorial Sloan-Kettering
Dartmouth-Hitchcock
Mt. Sinai West
Beth Israel Deaconess
Children's of Philadelphia
UPMC
Hos. Univ. of Pennsylvania
Hackensack Univ. Med. Center
University of Virginia
Children's of Alabama
Duke University
Tampa General Hospital
Mayo Clinic Jacksonville
Emory University

100+
Centers
Expected
by 2025



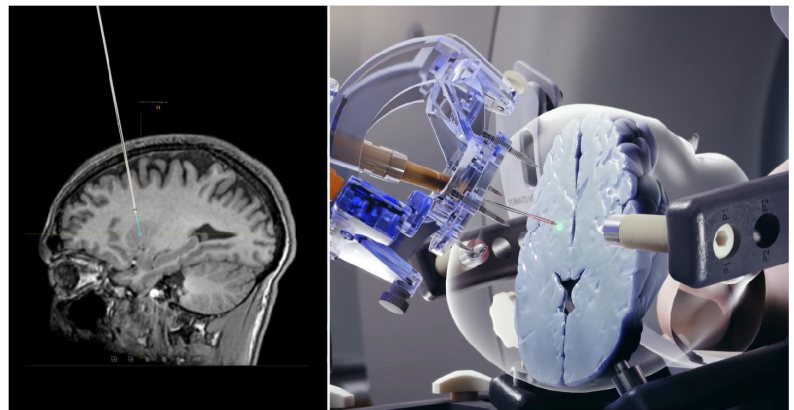
Biologics & Drug Delivery

1. Biologics & Drug Delivery Why ClearPoint?

Benefits of ClearPoint

1. Select and confirm the most accurate trajectory before insertion using live MRI Guidance
2. Identify peri-procedural safety issues live instead of after the patient is closed (i.e., hemorrhage)
3. Confirm proper target coverage with drug before closing the patient

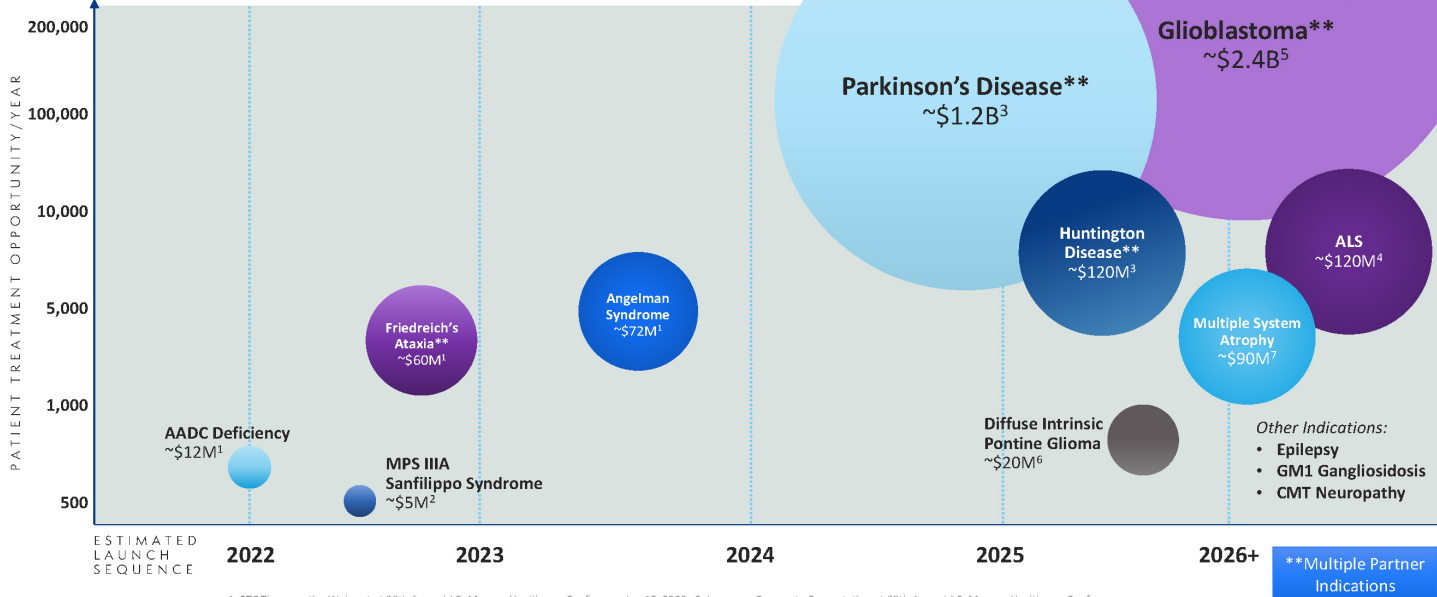
***Every Clinical Trial Patient is Crucial.
Why Take Any Chances?***



Only ClearPoint combines real-time direct imaging software and hardware to allow intra-procedural adjustment by the Neurosurgeon

1. Biologics & Drug Delivery

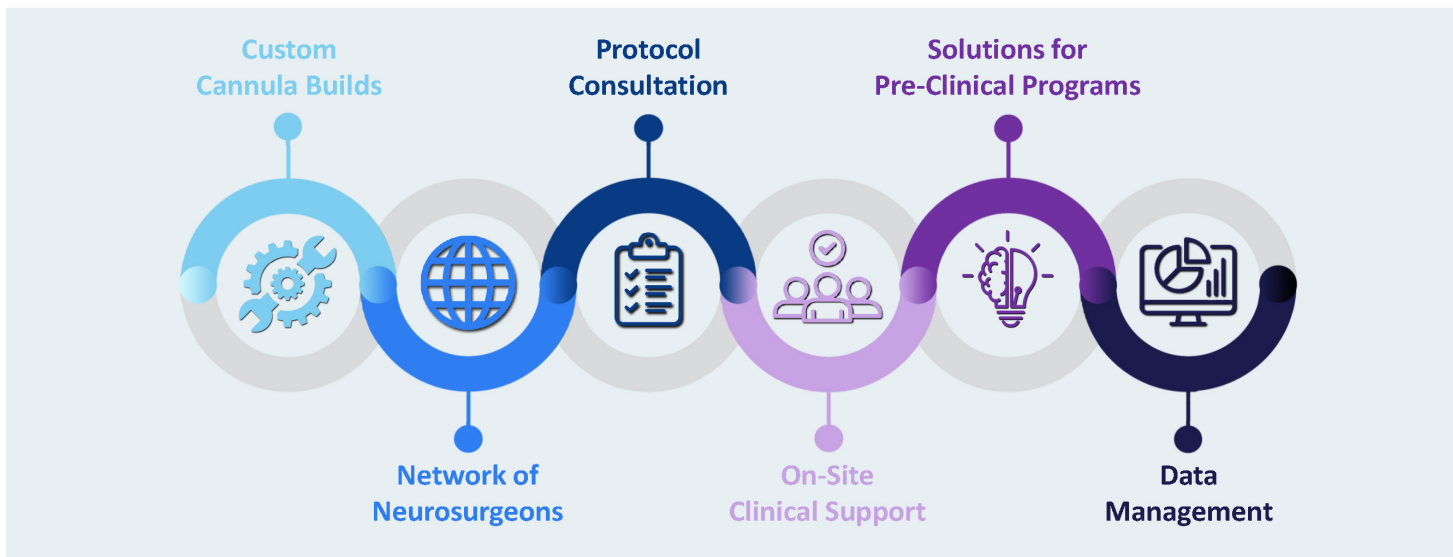
Estimated \$1.5B* Market Opportunity As Platform for Gene Therapy



1. PTC Therapeutics Webcast at 38th Annual J.P. Morgan Healthcare Conference Jan 15, 2020. 2. Lysogene Corporate Presentation at 38th Annual J.P. Morgan Healthcare Conference on Jan 13, 2020 3. Voyager Therapeutics January 2020 Corporate Presentation. 4. Arthur KG, et al. Projected increase in amyotrophic lateral sclerosis from 2015 to 2040. Nat Commun. 2016; 7:12408. 5. <https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Glioblastoma-Multiforme>. 6. <https://diagnosis.org/patients-families/about-dimg/>. 7. <https://emedicine.medscape.com/article/1154583-overview#a6>

1. Biologics & Drug Delivery

Specialized Consultation for Pharmaceutical Customers



Navigation Device & Therapy

2. Neuro Navigation (DBS) Deep Brain Stimulation

Deep brain stimulation (DBS) uses a surgically implanted medical device, similar to a cardiac pacemaker, and leads to deliver controlled electrical stimulation to precise targeted areas in the brain.



The ClearPoint® Neuro Navigation Platform is used to accurately place leads in the appropriate targeted structure. The leads are connected in a separate procedure to a neurostimulator implanted near the collarbone.

2. Neuro Navigation (DBS) Deep Brain Stimulation

Gaining Share in a Growing Market

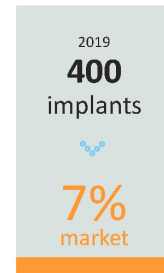
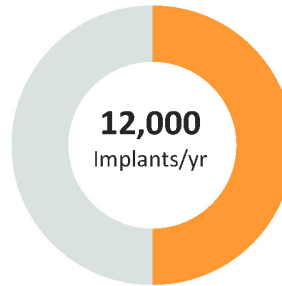
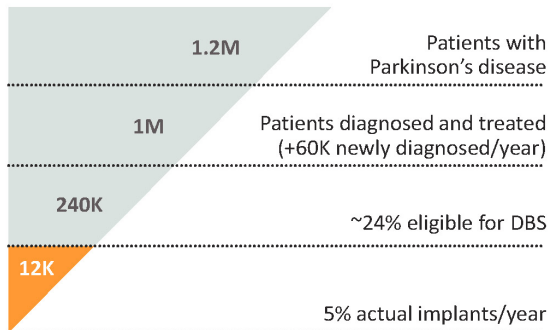
Boston
Scientific

Medtronic

Abbott

NEUROPACE

Parkinson's Patient Population (US)



Total Current Addressable U.S. Market

6,000 x \$12,000 / case = \$72M
(Navigation & MER)

Growing 10%

CLEARPOINT
NEURO

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2. Neuro Navigation (DBS)

Improved Navigation & Technology, New Indications Drive DBS Market Growth of 10%+ CAGR 2020-2025

New Indications in Trials	Treatment Populations	Neurosurgical Targets	Pilot	Phase I/II	Phase III	Commercial
Epilepsy ¹	2 million+	Multiple				
Obsessive Compulsive Disorder (OCD) ²	10 million+	Ventral internal capsule/ ventral striatum (VCVS)				
Alzheimer's Disease ³	6 million+	Fornix				
Severe Depression ⁴	10 million+	Multiple				
Early Parkinson's ⁵	2 million+	Multiple				
Stroke Rehabilitation ⁶	2 million+	Dentate nucleus				
Insomnia ⁷	1 million+	External and internal segments of the globus pallidus (GPe/Gpi)				

CLEARPOINT
NEURO

1. <https://www.cdc.gov/epilepsy/about/fast-facts.htm>; 2. <https://adaa.org/about-adaa/press-room/facts-statistics>; 3. <https://dshs.texas.gov/alzheimers/default.aspx>; 4. <https://adaa.org/about-adaa/press-room/facts-statistics>; 5. <https://parkinsonsnewstoday.com/parkinsons-disease-statistics/>; 6. <https://www.cdc.gov/stroke/facts.htm>; 7. <https://www.mayoclinicproceedings.org/action/showPdf?pii=S0025-6196%2819%2931034-1>

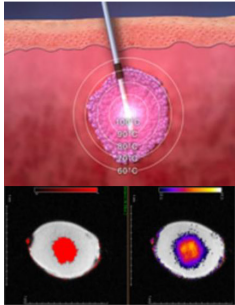
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3. New Therapy Devices

ClearPoint Neuro Laser Therapy – Capturing the Entire Procedure

LITT uses laser energy to destroy unwanted cells

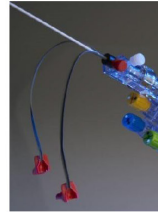


- Today MRI is required during LITT procedures to precisely monitor and control the temperature and thermal dose from that laser.
- ClearPoint is chosen by Neurosurgeons for the most difficult Neuro LITT cases today.
- One clinical support team and a simplified iMRI workflow will accelerate growth.
- ClearPoint has partnered with CLS and IGT to develop an optimized laser and thermometry system to capture the entire procedure.

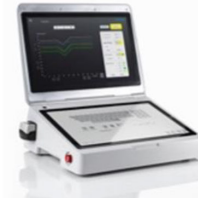


INFLEXION™ Head Fixation Frame

ClearPoint Compatibility Kits



TRANBERG® Laser

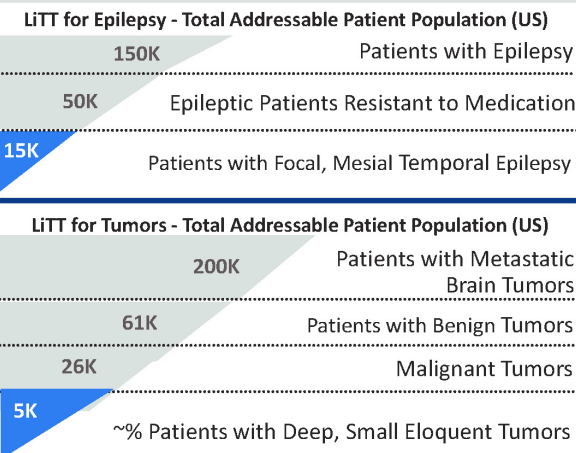


Innovative laser fiber technology designed to optimize heat distribution, eliminate external cooling, and help reduce procedure times. FDA cleared, CE Marked for non-neuro applications.

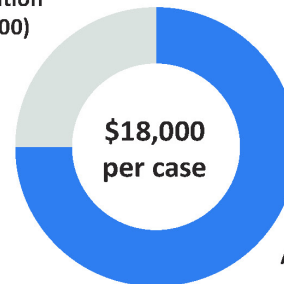
3. New Therapy Devices

ClearPoint Neuro Laser Therapy* – Capturing the Entire Procedure

Significant Addressable Neuro Market in Epilepsy and Tumor



Navigation (\$6,000)



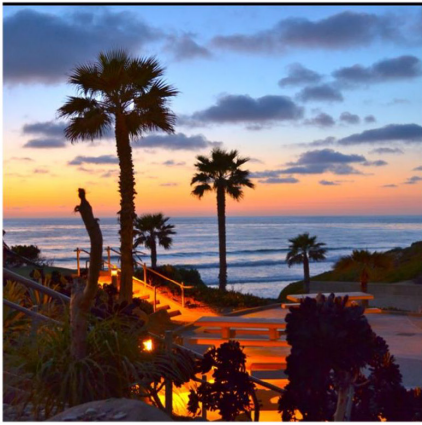
Laser Applicators (\$12,000)

Total Current Addressable Market
 $20,000 \times \$18,000 / \text{case} = \360M
 (Navigation & Laser Applicators)

2020
1,200
 Actual LiTT Procedures Today (est)
 ClearPoint used in 30%

Growing 20+%

ClearPoint Cove Training and Innovation Center – Solana Beach, CA




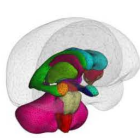
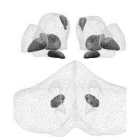


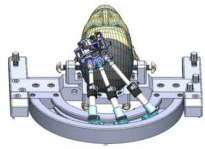
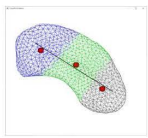
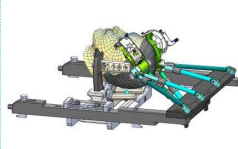
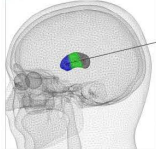


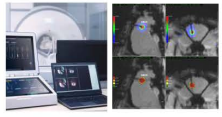





- Intimate training experience for surgeons and staff to perform mock procedures and provide pipeline feedback
- Showcase new technology for Pharmaceutical Drug Delivery partners
- Home for remote support specialists to reduce travel for simpler procedures



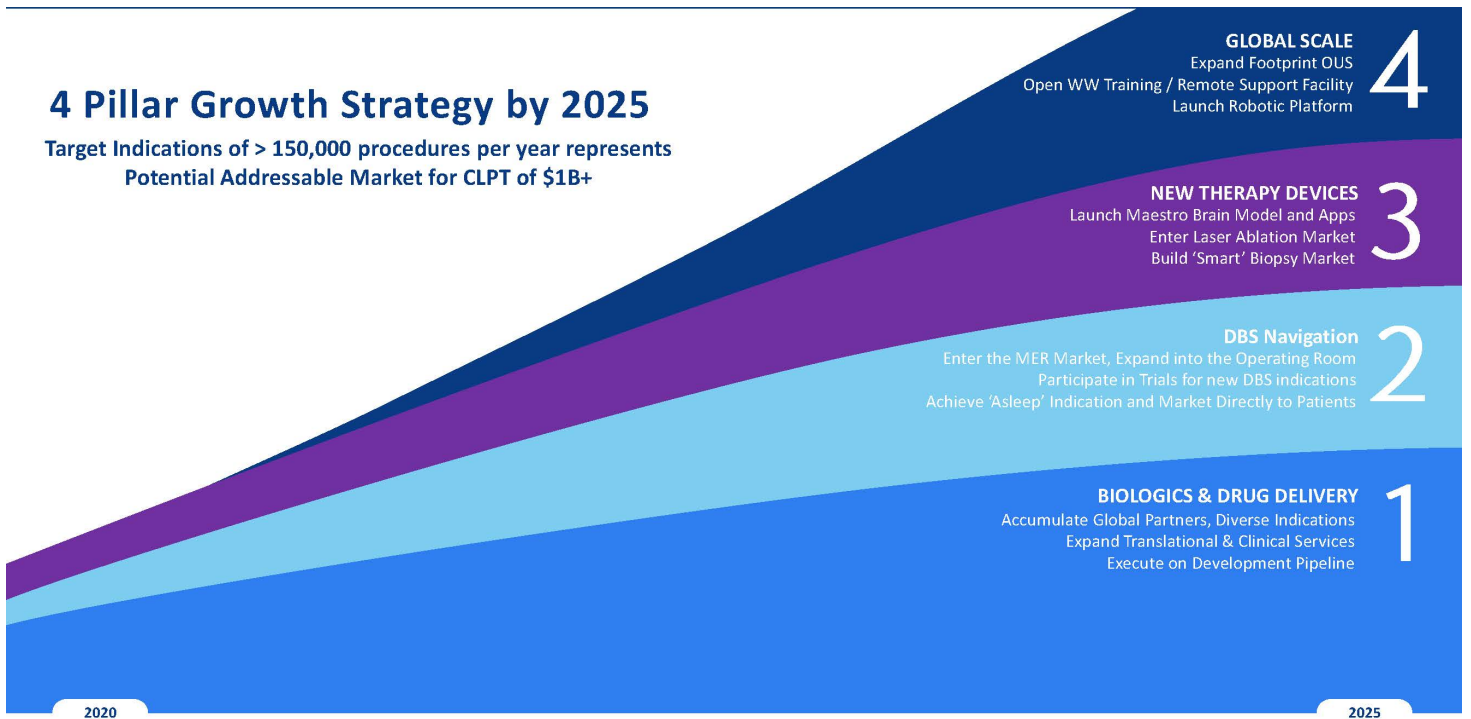
Innovation

Accelerated Product Pipeline and Target First Clinical Use

	2020-21	2022	2023
Navigation & Robotics	 Inflexion™ Head Fixation Frame  SmartFrame Array™ ¹	 ClearPoint Neuro Navigation Software v. 2.1. ²  ClearPoint Maestro™ Brain Model ²	 ClearPoint Maestro™ Sub Nuclei App ²  Robotic-Assisted Navigation ²
Biologics & Drug Delivery	 Pre-Clinical & Clinical Support Services	 Pre-Clinical Head Fixation Frame ²  ClearPoint Maestro™ Infusion Modeling App ²	 Orchestra™ Head Fixation Frame ²  ClearPoint Maestro™ Infusion Targeting App ²
Therapy and Enabling Technology	 5F and 7F Peel-Away Sheath Kits  Bladed Lancet	 Laser Ablation System w/ ThermoGuide ²  Biopsy Needle ²	 Micro-Electric Recording System (MER) ²  "Smart" Biopsy Needle ²

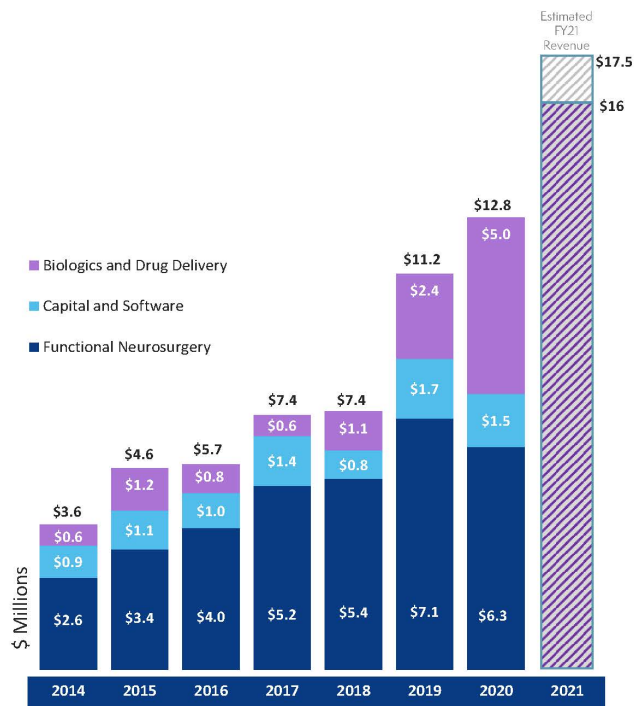
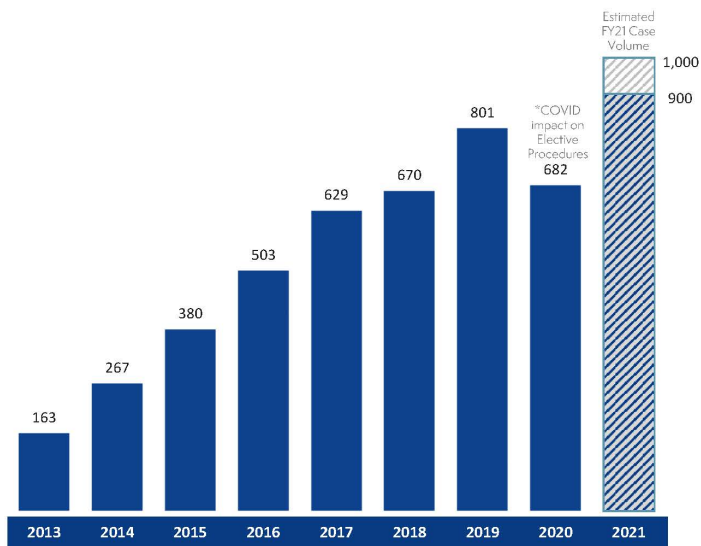
4 Pillar Growth Strategy by 2025

Target Indications of > 150,000 procedures per year represents
Potential Addressable Market for CLPT of \$1B+



Financials

2013 - 2021 Growth in Case Volume and Revenue



CLPT CAPABILITIES 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 standalone therapy products



Procedure volume has grown
33%+ CAGR from 2013-2019



Total potential addressable market
> \$1B for our products and pipeline



Large, Growing installed base
in 60+ of 250+ leading Neurology clinical and research centers in U.S., Canada and Europe



A passionate team
of embedded scientists and specialists

