

**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):
November 9, 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, CA 92075
(Address of principal executive offices, zip code)

(888) 287-9109
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|--|-------------------|---|
| Common Stock, \$0.01 par value per share | CLPT | Nasdaq Capital Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On November 9, 2021, ClearPoint Neuro, Inc. (the "Company") issued a press release announcing its financial performance for the third fiscal quarter ended September 30, 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 November 9, 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 99.2. 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 November 9, 2021](#)
- Exhibit 99.2 [Investor Presentation dated November 2021](#)
- 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: November 9, 2021

CLEARPOINT NEURO, INC.

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



ClearPoint Neuro Reports Third Quarter 2021 Results Record Revenue Achieved; Company Reaffirms 2021 Revenue Forecast

SOLANA BEACH, CA, November 9, 2021 – 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 third quarter ended September 30, 2021.

Third Quarter Highlights

- Reported record revenue of \$4.6 million, a 30% year-over-year increase;
- Increased biologics and drug delivery revenue to \$2.1 million, a 39% year-over-year increase;
- Achieved additional biologics and drug delivery relationships, bringing current count of active partners to approximately 40;
- Initiated development program for a navigation and delivery system for Brain-Computer Interfaces;
- Supported 227 cases despite the impact of the Delta variant on elective procedures, a 14% year-over-year increase; and
- Launched Patient Education Program to increase awareness around DBS options, including awake MER-guided procedures and MRI-guided procedures under general anesthesia.

Business Outlook

- The Company continues to estimate total case volume support to be in the range of 900 – 1000 for 2021; and
- The Company continues to estimate revenue to be between \$16.0 and \$17.5 million for 2021.

“The ClearPoint Neuro Team continued to execute against our four-pillar growth strategy in the third quarter and celebrated a number of successes along the way”, commented Joe Burnett, President and CEO. “First, we achieved record revenue in both Functional Neurosurgery Navigation and Biologics & Drug Delivery, yielding total revenue of \$4.6 M which represents year-over-year growth of 30% growth. These results are in spite of the postponement of numerous elective procedures due to the rise of the Delta Variant which adversely impacted case volume in August and September. The majority of our impacted centers have again scheduled cases starting in October. Our Biologics and Drug Delivery Team, driven by the expansion of pre-clinical services and placements in Europe have added additional pharma partners to our ‘active’ list, bringing the total number of active relationships to approximately 40. We have started development of our navigation system for Brain Computer Interface placements, leveraging the ClearPoint platform and expect to have functional prototypes for pre-clinical testing in the second half of 2022. We also made progress across all of our previously announced development programs, with timeline estimates remaining intact. Very importantly, we utilized a portion of the capital we raised last February to invest in innovation and expand our market presence by hiring 18 talented engineers, programmers, researchers, and clinical specialists. Our ability to attract talent I believe demonstrates the excitement our team generates, and the recognition of the important work that we are doing.”

Financial Results – Quarter Ended September 30, 2021

Total revenue was \$4.6 million for the three months ended September 30, 2021, and \$3.5 million for the three months ended September 30, 2020, which represents an increase of \$1.1 million, or 30%.

Functional neurosurgery navigation revenue, which consists of disposable product commercial sales and services related to cases utilizing the ClearPoint system, increased 17% to \$2.2 million for the three months ended September 30, 2021, from \$1.8 million for the same period in 2020.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored clinical trials utilizing our products, increased 39% to \$2.1 million for the three months ended September 30, 2021, from \$1.5 million for the same period in 2020. This increase was due to (a) a higher number of biologic and drug delivery partners and (b) the resumption of investments in pre-clinical research and clinical trials by our biologics and drug delivery customers.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, increased 78% to \$0.4 million for the three months ended September 30, 2021, from \$0.2 million for the same period in 2020.

Gross margin for the three months ended September 30, 2021, was 68%, as compared with gross margin of 74% for the same period in 2020. This decrease in gross margin was due primarily to increases in the reserve for excess and obsolete inventory and in overhead costs allocated to cost of sales during the three months ended September 30, 2021 as compared to the same period in 2020.

Research and development costs were \$2.6 million for the three months ended September 30, 2021, compared to \$1.1 million for the same period in 2020, an increase of \$1.5 million, or 130%. This increase was due primarily to increases in personnel costs due to growth in headcount, and product and

software development costs, both resulting from our efforts to expand the applications of our technological platforms. Sales and marketing expenses were \$1.8 million for the three months ended September 30, 2021, compared to \$1.5 million for the same period in 2020, an increase of \$0.3 million, or 22%. This increase was due primarily to increases in personnel costs resulting from increases in headcount, travel expenses, and marketing activities. General and administrative expenses were \$2.4 million for the three months ended September 30, 2021, compared to \$1.3 million for the same period in 2020, an increase of \$1.2 million, or 95%. This increase was due primarily to increases in personnel costs, share-based compensation and various professional and consulting fees.

At September 30, 2021, the Company had cash and cash equivalents totaling \$57.7 million as compared to \$20.1 million at December 31, 2020, with the increase resulting primarily from the completion of a public offering of the Company's common stock in February 2021.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's 2021 third quarter on Tuesday, November 9, 2021 at 4:30 p.m. Eastern time (1:30 p.m. Pacific time) which may be accessed [online here](#). Investors and analysts who would like to participate in the conference call via telephone may do so at (888) 428-7458, 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 December 9, 2021, 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 over 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 worldwide. For more information, please visit www.clearpointneuro.com.

Forward-Looking Statements

Statements in this press release and in the teleconference referenced above concerning the Company's plans, growth and strategies may include forward-looking statements within the context of the federal securities laws. Statements regarding the Company's future events, developments and future performance, 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 June 30, 2021, 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 September 30, 2021, which the Company intends to file with the Securities and Exchange Commission on or before November 15, 2021.

Contact:

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info@clearpointneuro.com

Caroline Corner, Investor Relations
ir@clearpointneuro.com

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

| For The Three Months Ended September 30, | |
|---|-------------|
| 2021 | 2020 |

| | | |
|---|------------|------------|
| Revenue: | | |
| Product revenue | \$ 3,338 | \$ 2,371 |
| Service and other revenue | 1,236 | 1,148 |
| Total revenue | 4,574 | 3,519 |
| Cost of revenue | 1,486 | 903 |
| Gross profit | 3,088 | 2,616 |
| Research and development costs | 2,630 | 1,143 |
| Sales and marketing expenses | 1,826 | 1,493 |
| General and administrative expenses | 2,436 | 1,252 |
| Operating loss | (3,804) | (1,272) |
| Other expense: | | |
| Other income (expense), net | 62 | (11) |
| Interest expense, net | (238) | (201) |
| Net loss | \$ (3,980) | \$ (1,484) |
| Net loss per share attributable to common stockholders: | | |
| Basic and diluted | \$ (0.18) | \$ (0.09) |
| Weighted average shares used in computing net loss per share: | | |
| Basic and diluted | 22,522,460 | 15,724,401 |

| | For The Nine Months Ended September 30, | |
|---|--|------------|
| | 2021 | 2020 |
| Revenues: | | |
| Product revenues | \$ 8,863 | \$ 6,186 |
| Service and other revenues | 3,154 | 2,927 |
| Total revenues | 12,017 | 9,113 |
| Cost of revenues | 4,015 | 2,636 |
| Gross profit | 8,002 | 6,477 |
| Research and development costs | 6,251 | 2,774 |
| Sales and marketing expenses | 5,081 | 3,916 |
| General and administrative expenses | 6,062 | 3,742 |
| Operating loss | (9,392) | (3,955) |
| Other income (expense): | | |
| Other (expense), net | (60) | (5) |
| Interest expense, net | (809) | (1,240) |
| Net loss | \$ (10,261) | \$ (5,200) |
| Net loss per share attributable to common stockholders: | | |
| Basic and diluted | \$ (0.50) | \$ (0.33) |
| Weighted average shares used in computing net loss per share: | | |
| Basic and diluted | 20,545,080 | 15,556,231 |

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

| | September 30, 2021 (Unaudited) | December 31, 2020 |
|---|--------------------------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 57,651 | \$ 20,099 |
| Accounts receivable, net | 2,559 | 1,881 |
| Inventory, net | 3,943 | 3,238 |
| Prepaid expenses and other current assets | 842 | 244 |
| Total current assets | 64,995 | 25,462 |
| Property and equipment, net | 450 | 319 |
| Operating lease rights of use | 2,365 | 2,736 |
| Software license inventory | 519 | 589 |
| Licensing rights | 287 | 353 |
| Other assets | 86 | 59 |
| Total assets | \$ 68,702 | \$ 29,518 |

| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
|--|--------|--------|
| Current liabilities: | | |
| Accounts payable | \$ 777 | \$ 300 |
| Accrued compensation | 1,804 | 1,595 |
| Other accrued liabilities | 1,081 | 349 |
| Operating lease liabilities, current portion | 486 | 394 |
| Deferred product and service revenue | 440 | 562 |
| Total current liabilities | 4,588 | 3,200 |
| Operating lease liabilities, net of current portion | 2,071 | 2,446 |
| Deferred product and service revenue, net of current portion | 310 | 215 |
| 2020 senior secured convertible notes payable, net | 17,613 | 21,280 |
| Total liabilities | 24,582 | 27,141 |

| | | |
|---|-----------|-----------|
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at September 30, 2021 and December 31, 2020 | — | — |
| Common stock, \$0.01 par value; 200,000,000 shares authorized; 22,855,187 shares issued and outstanding at September 30, 2021; and 17,047,584 issued and outstanding at December 31, 2020 | 229 | 170 |
| Additional paid-in capital | 173,674 | 121,729 |
| Accumulated deficit | (129,783) | (119,522) |
| Total stockholders' equity | 44,120 | 2,377 |
| Total liabilities and stockholders' equity | \$ 68,702 | \$ 29,518 |

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

| | For The Nine Months Ended September 30, | |
|--|--|------------------|
| | 2021 | 2020 |
| Cash flows from operating activities: | | |
| Net loss | \$ (10,261) | \$ (5,200) |
| Adjustments to reconcile net loss to net cash flows from operating activities: | | |
| Allowance for doubtful accounts | 170 | 13 |
| Depreciation and amortization | 113 | 170 |
| Share-based compensation | 1,153 | 762 |
| Payment-in-kind interest | 285 | — |
| Amortization of debt issuance costs and original issue discounts | 73 | 856 |
| Amortization of lease rights of use, net of accretion in lease liabilities | 400 | 75 |
| Increase (decrease) in cash resulting from changes in: | | |
| Accounts receivable | (848) | (373) |
| Inventory, net | (682) | (323) |
| Prepaid expenses and other current assets | (599) | (136) |
| Other assets | (28) | 59 |
| Accounts payable and accrued expenses | 1,418 | 60 |
| Accrued interest | — | (960) |
| Lease liabilities | (312) | (71) |
| Deferred revenue | (27) | (338) |
| Net cash flows from operating activities | <u>(9,145)</u> | <u>(5,406)</u> |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | (130) | — |
| Acquisition of licensing rights | — | (441) |
| Net cash flows from investing activities | <u>(130)</u> | <u>(441)</u> |
| Cash flows from financing activities: | | |
| Proceeds from issuance of 2020 senior secured convertible notes, net of financing costs and discount | — | 16,758 |
| Proceeds from issuance of Paycheck Protection Program loan | — | 896 |
| Proceeds from public offering of common stock, net of offering costs | 46,785 | — |
| Proceeds from stock option and warrant exercises | 584 | — |
| Payments for taxes related to net share settlement of equity awards | (542) | — |
| Repayment of notes payable | — | (2,838) |
| Net cash flows from financing activities | <u>46,827</u> | <u>14,816</u> |
| Net change in cash and cash equivalents | 37,552 | 8,969 |
| Cash and cash equivalents, beginning of period | 20,099 | 5,696 |
| Cash and cash equivalents, end of period | <u>\$ 57,651</u> | <u>\$ 14,665</u> |

SUPPLEMENTAL CASH FLOW INFORMATION

| | | |
|----------------|---------------|-----------------|
| Cash paid for: | | |
| Income taxes | \$ — | \$ — |
| Interest | <u>\$ 495</u> | <u>\$ 1,399</u> |



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

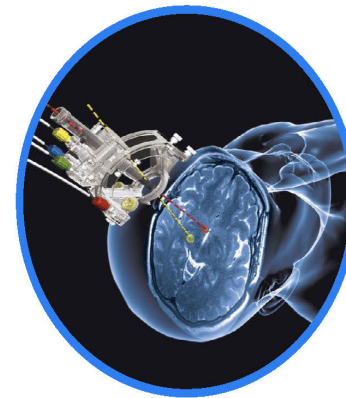
Nasdaq: CLPT

November 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 COVID-19 and the measures adopted to contain its spread; future revenues 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 in 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 June 30, 2021, 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 September 30, 2021, which the Company intends to file with the Securities and Exchange Commission on or before November 15, 2021.

ClearPoint Neuro: Two Opportunities, One Platform



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

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

A Neuro Navigation Platform Company with an Innovative and Expanding Portfolio Supported by an Established On-Site Clinical Channel

- 5+ New Products Expected in next 2 Years
- \$1B+ Potential Market, first BCI indication expected in 2022

ClearPoint Neuro: A Proven Platform

Key Products: **FDA CE** Marked Platforms

HEADQUARTERS
Solana Beach, CA

MANUFACTURING
Irvine, CA

EUROPEAN HEADQUARTERS
Manchester, UK

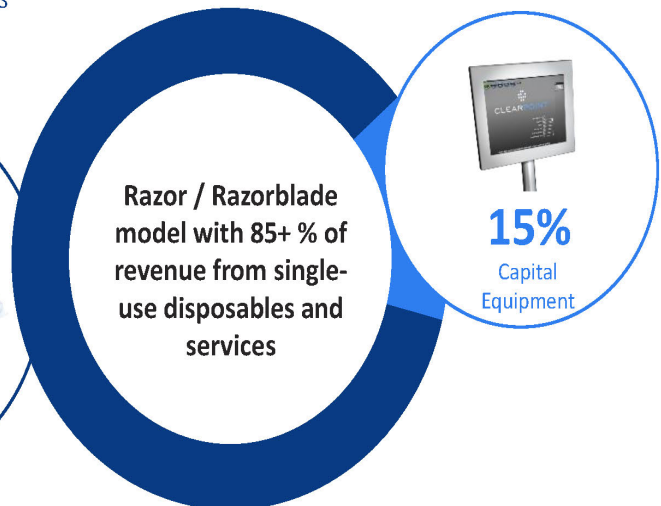
2020 REVENUE
\$12.8m

CASH
\$ 57.7m^(A)

U.S. PATENTS ISSUED
65

GROSS MARGIN
68%^(A)

EMPLOYEES
70+
30+ field
40+ production & development



[A] As of, and for the quarter ended, September 30, 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



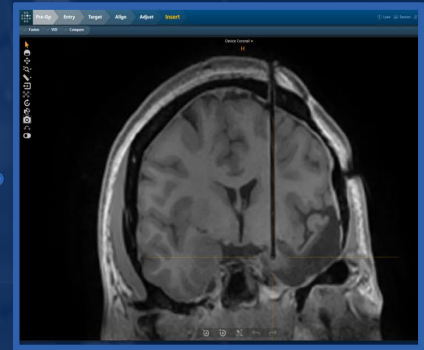
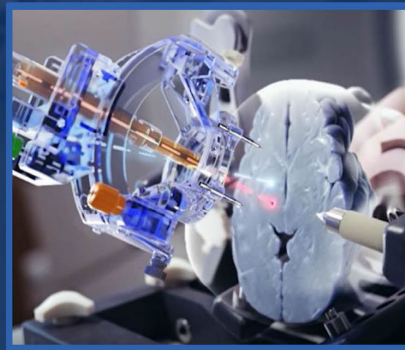
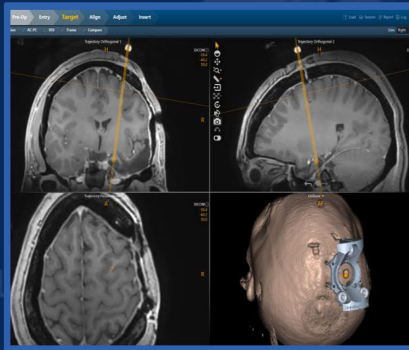
Video source: <https://www.youtube.com/watch?v=PsL9B7fbG4>

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Our Platform – Procedure Overview

The ClearPoint® Neuro Navigation System



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

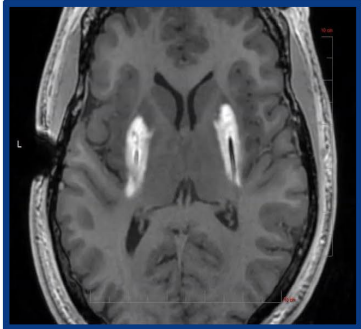
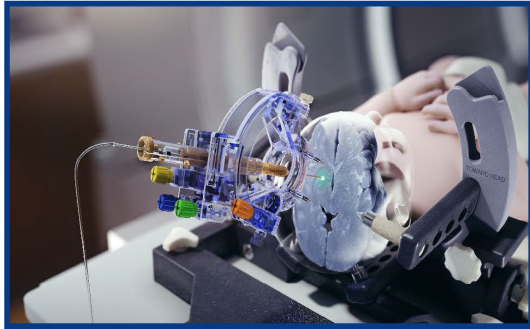


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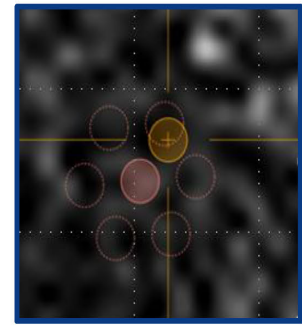
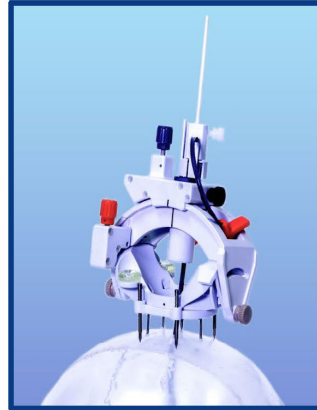
Our Platform

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

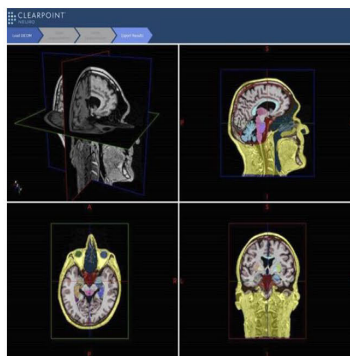
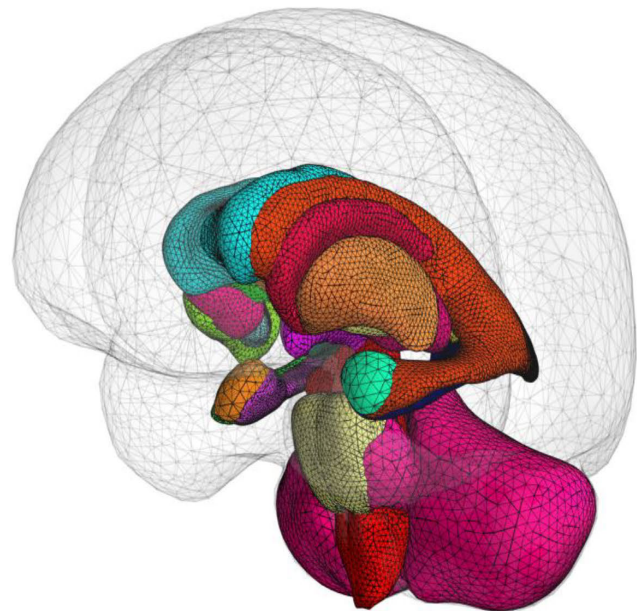


*The SmartFrame Array Tower, Software and Robotic System are currently under development.

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



Medtronic



Medtronic
VISUALASE

MONTERIS
MEDICAL



...with ~40 total commercial and academic partners

© 2021 CLEARPOINT NEURO

9

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
Willis-Knighton
University of Oklahoma Medical Center
Cincinnati Jewish
Children's National
Banner Health Tucson

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

Charles River Labs (Laval, Canada)
Children's Mercy Hospital
CHOA Scottish Rite
Le Bonheur
INOVA Fairfax
Carilion Clinic
Hos. Univ. of Pennsylvania
UPMC

Rigshospitalet (Copenhagen, Denmark)
Mazowiecki Szpital Bródnowski (Warsaw, Poland)
Hôpital Fondation Rothschild (Paris, France)
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
Hackensack Univ. Med. Center
University of Virginia
Children's of Alabama
Duke University
Tampa General Hospital
Mayo Clinic in Florida
Emory University

100+
Centers
Expected
by 2025



10

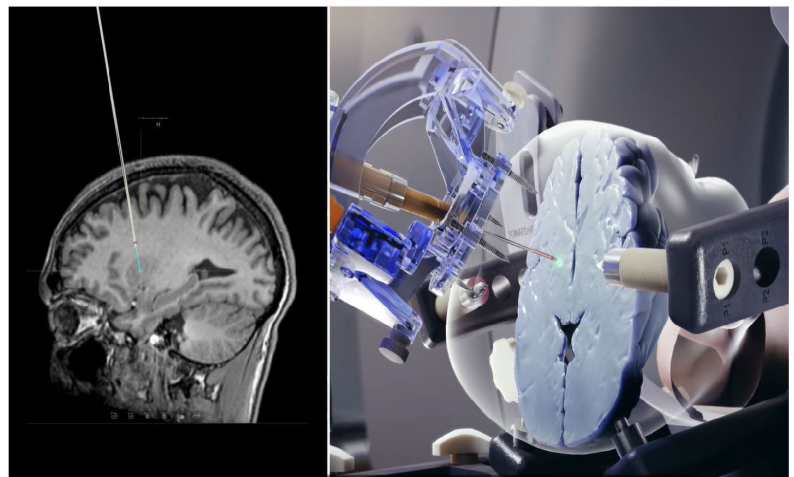
Biologics & Drug Delivery

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

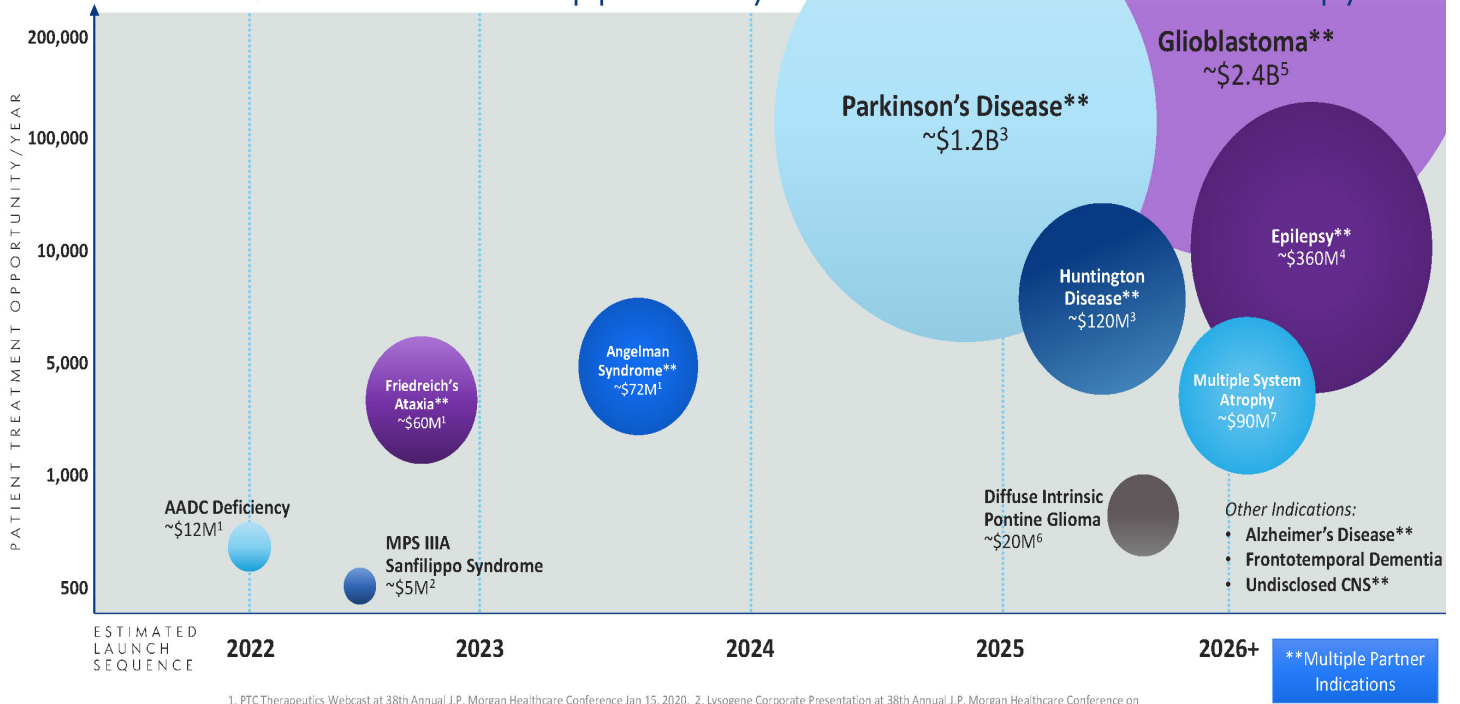
***Every Clinical Trial Patient is Crucial.
Why Take Any Chances?***



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

1. Biologics & Drug Delivery

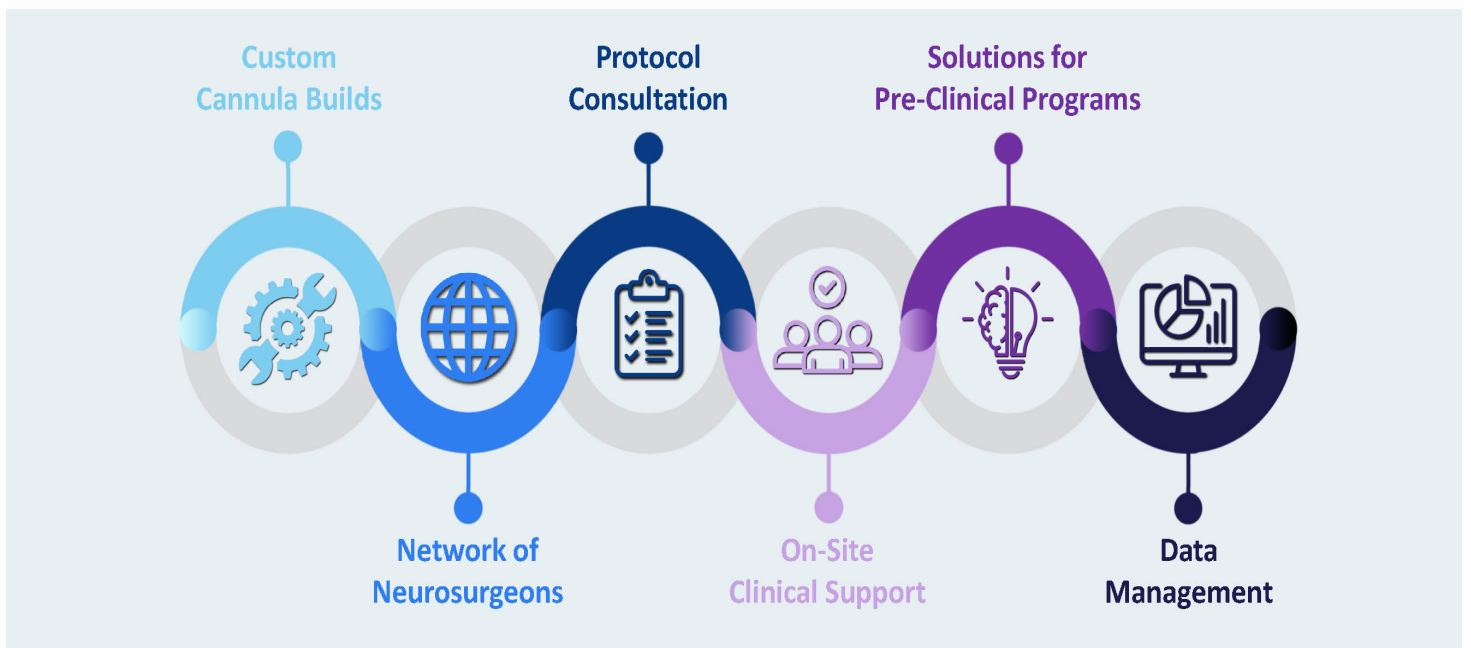
Estimated \$1.5B* Market Opportunity As Platform for Gene Therapy



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. <https://parkinsonsnewstoday.com/parkinsons-disease-statistics/#text=An%20estimated%20seven%20to%2010%20are%2080%20and%20older>
 4. <https://www.who.int/news-room/fact-sheets/detail/epilepsy> 5. <https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Glioblastoma-Multiforme>
 6. <https://dipregistry.org/patients-families/about-dipg/> 7. <https://emedicine.medscape.com/article/1154583-overview#a6>
 * Addressable market based on potential case volume for near-term programs slated to launch before 2025. Does not include long-term opportunities for Glioblastoma and Epilepsy.

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

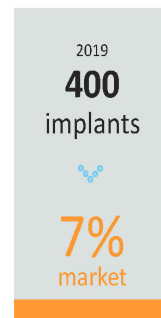
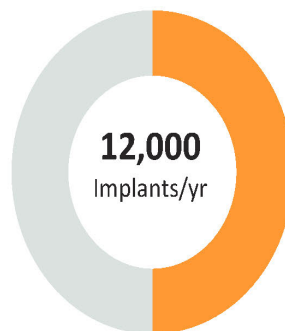
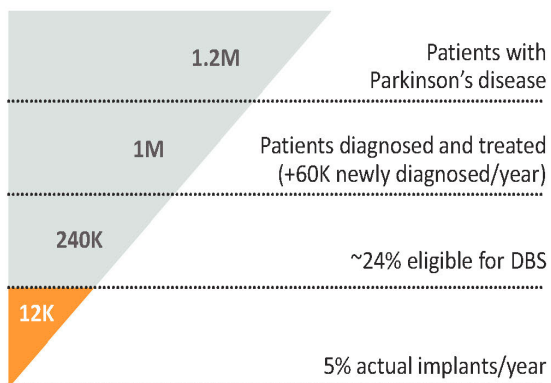
Boston
Scientific

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

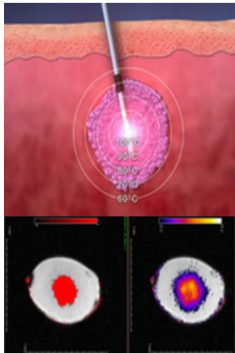
1. <https://www.cdc.gov/epilepsy/about/fast-facts.htm>; 2. <https://adaa.org/about-adaa/press-room/facts-statistics>; 3. <https://dshs.texas.gov/alzheimers/default.aspx>; 4. <https://adaa.org/about-adaa/press-room/facts-statistics>; 5. <https://parkinsonsnewstoday.com/parkinsons-disease-statistics/>; 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.

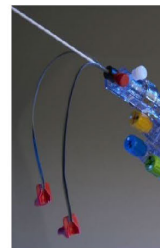


INFLEXION™ Head Fixation Frame

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.



ClearPoint Compatibility Kits

3. New Therapy Devices

ClearPoint Neuro Laser Therapy* – Capturing the Entire Procedure

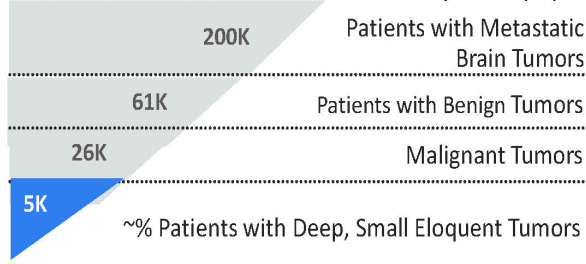
Significant Addressable Neuro Market in Epilepsy and Tumor



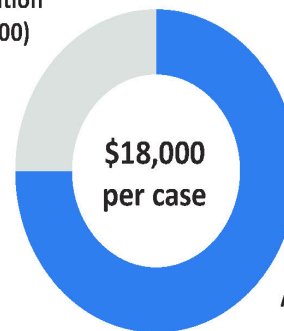
LiTT for Epilepsy - Total Addressable Patient Population (US)



LiTT for Tumors - Total Addressable Patient Population (US)



Navigation
(\$6,000)



Laser Applicators
(\$12,000)

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

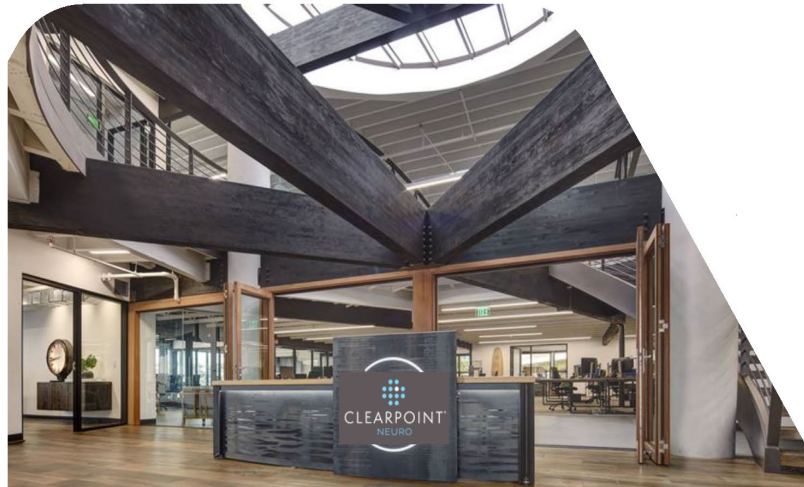
Total Current Addressable Market
20,000 x \$18,000 / case = \$360M
(Navigation & Laser Applicators)

Growing 20+%



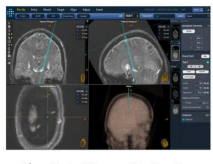
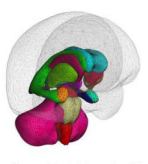
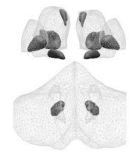
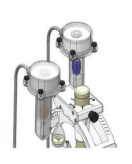

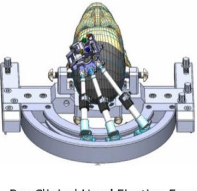
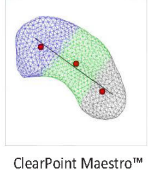
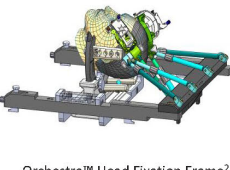
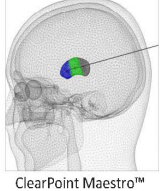


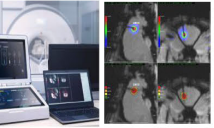



New Global Showcase Site ClearPoint Global Training & Innovation Center – Solana Beach, CA



- 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

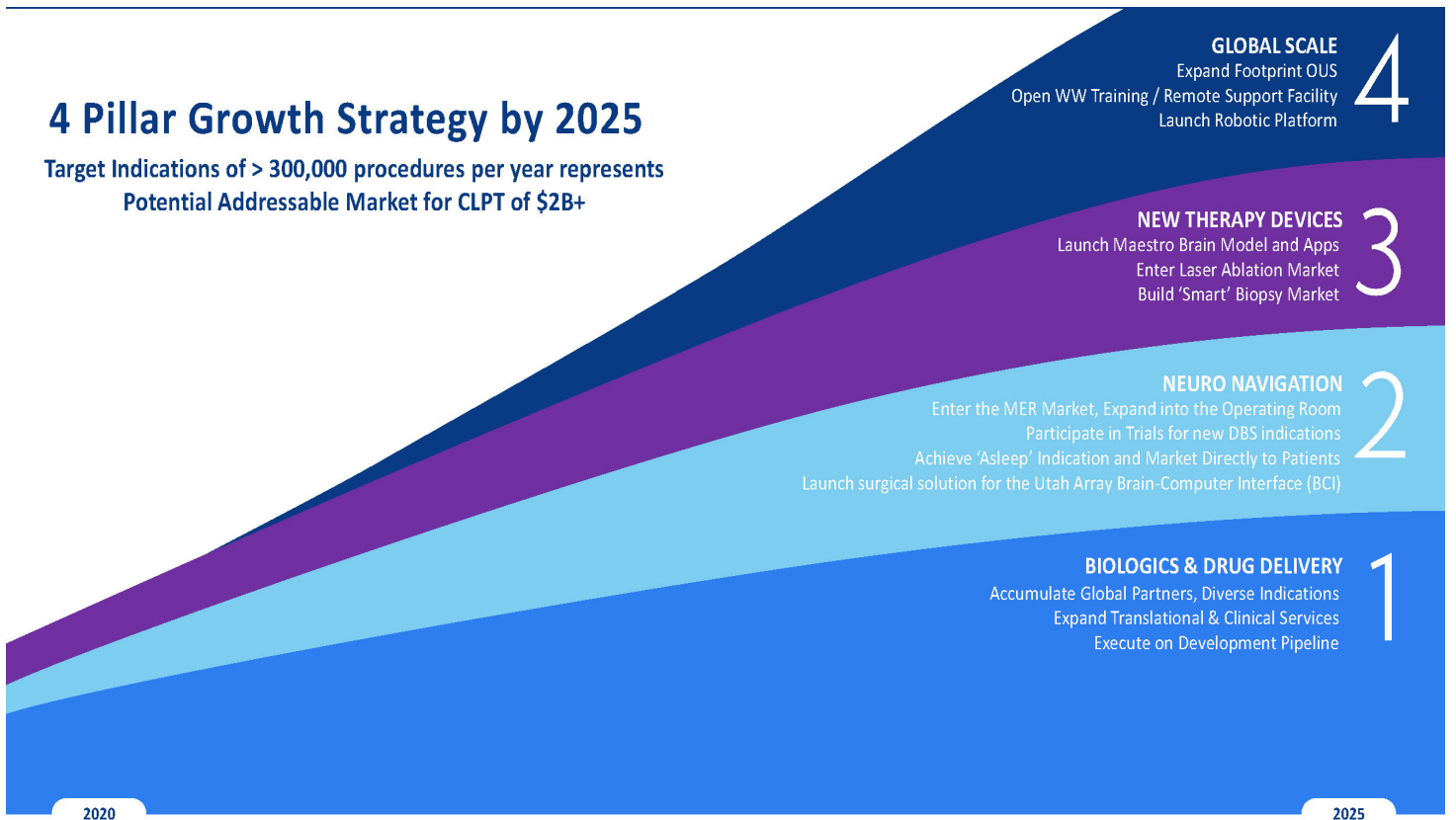


Innovation Accelerated Product Pipeline and Target First Clinical Use

| | 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 |  SF and 7F Peel-Away Sheath Kits  Bladed Lancet |  Laser Ablation System w/ ThermoGuide ²  Biopsy Needle ² |  Micro-Electric Recording System (MER) ²  Adeor MR-Conditional Drill ² |

4 Pillar Growth Strategy by 2025

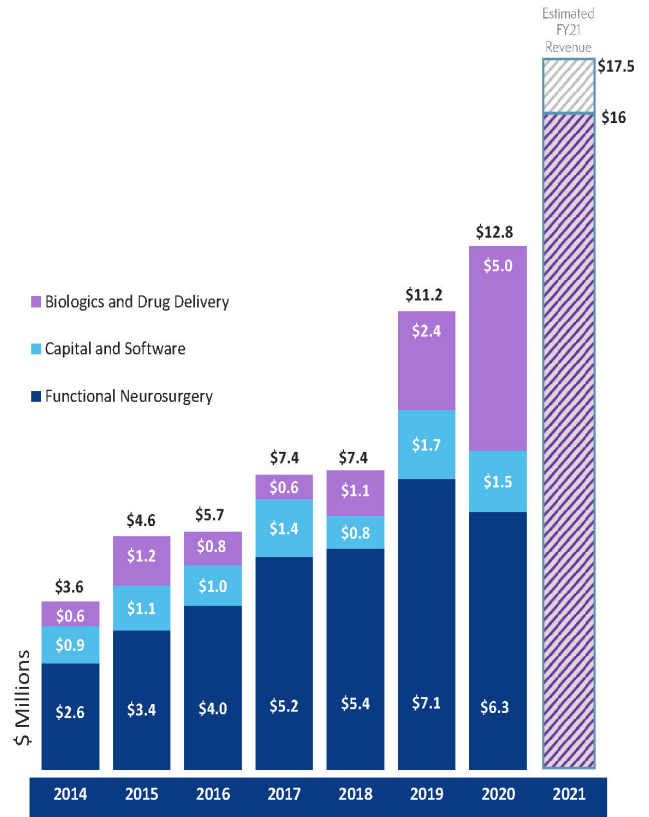
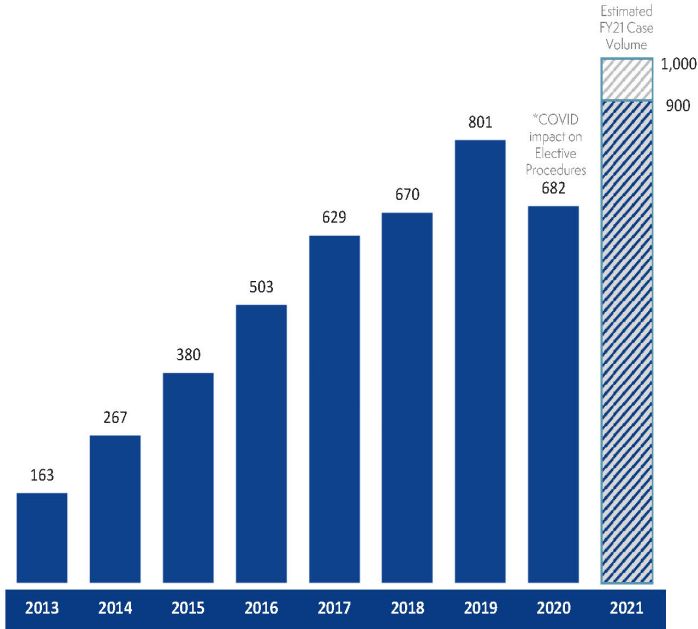
Target Indications of > 300,000 procedures per year represents
Potential Addressable Market for CLPT of \$2B+



Financials

2013 - 2021

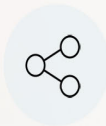
Growth in Case Volume and Revenue



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 > \$2B 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

