

**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):  
August 12, 2020

**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)

**5 Musick**  
**Irvine, Ca. 92618**  
(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 2.02. Results of Operations and Financial Condition.**

On August 12, 2020, ClearPoint Neuro, Inc. (the “Company”) issued a press release announcing its financial performance for the second fiscal quarter and six months ended June 30, 2020. 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 12, 2020, the Company posted an updated investor presentation to its website at <http://ir.stockpr.com/clearpointneuro/investor-presentation>. 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 August 12, 2020](#)

Exhibit 99.2 [Investor Presentation dated August 2020.](#)

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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 12, 2020

**CLEARPOINT NEURO, INC.**

By: /s/ Harold A. Hurwitz  
Harold A. Hurwitz  
Chief Financial Officer



## ClearPoint Neuro Reports Second Quarter 2020 Results

*Revenue Reaches \$2.5 million Amid COVID-19 Pandemic*

IRVINE, CA, August 12, 2020 – ClearPoint Neuro, Inc. (Nasdaq: CLPT) today announced financial results for its second fiscal quarter and six months ended June 30, 2020.

### **Financial Results – Three Months Ended June 30, 2020**

Total revenues for the quarter were approximately \$2.5 million and \$2.6 million for the three months ended June 30, 2020 and 2019, respectively, a decrease of 5%.

Functional neurosurgery revenue, which consists of disposable product commercial sales related to cases utilizing the ClearPoint system, decreased 38% to \$1.0 million for the three months ended June 30, 2020, from \$1.7 million for the same period in 2019. This decrease was due to the effects of the COVID-19 pandemic, in which elective surgical procedures, historically representing more than 80% of the Company's ClearPoint system case volume, were temporarily suspended commencing in the second half of March 2020 and which have not yet returned to pre-pandemic levels.

Biologics and drug delivery revenues, which include sales of disposable products and services related to customer-sponsored clinical trials utilizing the ClearPoint system, increased 183% to \$1.2 million for the three months ended June 30, 2020, from \$413,000 for the same period in 2019. This increase in biologics and drug delivery service revenues is attributable to the establishment of additional relationships with biologic and drug delivery companies that included period-based retainers for clinical services in support of such companies' respective clinical trials.

Capital equipment revenue, consisting of sales of ClearPoint reusable hardware and software, as well as service contracts related to capital equipment, decreased 51% to \$240,000 for the three months ended June 30, 2020, from \$485,000 for the same period in 2019. While revenues from this product line historically have varied from quarter to quarter, the Company believes that many hospitals have postponed capital equipment acquisition activities, which continued postponement the Company believes will be contingent upon the prevalence and duration of the COVID-19 pandemic.

Gross margin for the three months ended June 30, 2020 was 74%, as compared to 60% for the same period in 2019. This increase was driven primarily by the greater contribution of services to total revenue during the three months ended June 30, 2020, as compared to the same period in 2019.

Operating expenses for the three months ended June 30, 2020 were \$3.3 million, a 15% increase from operating expenses of \$2.9 million for the same period in 2019. This increase was comprised of: (a) research and development costs, which increased 18% resulting primarily from increases in personnel costs; and (b) general and administrative expenses, which increased 33% resulting primarily from an increase in professional fees and a decrease in the allocation of shared departmental resources to production due to reduced manufacturing activity during the 2020 second quarter. These increases were partially offset by a decrease of 2% in sales and marketing expenses, resulting primarily from a decrease in items attributable to the effects of the COVID-19 pandemic, such as incentive-based compensation and travel, which was partially offset by headcount increases in the Company's clinical and marketing teams.

Operating loss for the three months ended June 30, 2020 was \$1.5 million, as compared with \$1.3 million for the same period in 2019.

Cash and cash equivalent balances at June 30, 2020 were \$16.0 million.

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“The second quarter of 2020 was significantly affected by the COVID-19 pandemic, which adversely impacted sales across all of our business lines,” commented Joe Burnett, President and Chief Executive Officer of ClearPoint Neuro. “More than 80% of our procedures are deemed ‘elective,’ which generally resulted in the postponement or cancellation of such procedures to give our hospital customers the capacity for treating critical COVID-19 patients, which resulted in the completion of only 11 ClearPoint cases in April. As elective procedures resumed in certain cities, May case volume increased to 44 cases and June volume followed at 71 cases, representing approximately 90% of our pre-pandemic volume. Similarly, new capital placements and evaluations were effectively put on hold in the 2020 second quarter as hospitals dealt with the influx of COVID-19 patients. This said, I am immeasurably proud of our clinical support team who stood shoulder-to-shoulder with our hospital customers and ensured that cases in which the use of our ClearPoint System was integral in patient treatment were supported during the pandemic.

“On a more positive note, our biologics and drug delivery business increased 183% to \$1.2 million, which we believe demonstrates that our strategy in this space continues to drive new business and to provide diversification in our revenue stream. While our customer-sponsored clinical trials cases were postponed as a result of the pandemic, our pre-clinical planning and clinical services continued to progress where possible.”

“The pervasiveness of the pandemic continues to result in uncertainty as to the timing of the resumption to pre-pandemic levels of elective procedures, capital placements and customer-sponsored clinical trials. Accordingly, we are not yet providing a forecast for the balance of 2020. While we do not expect elective procedures to decline to the level seen in April, we anticipate, and have observed, that hospitals in cities struggling with COVID-19 cases will suspend elective procedures to ensure ventilator access and bed capacity. Furthermore, it should be noted that patients flow through a diagnostic and treatment process before they are referred to surgery. Accordingly, it follows that diagnostic work-ups delayed in March and April will cause the resulting surgeries to be similarly delayed.”

“While we view the current situation as a temporary setback, our team continues to work tirelessly to execute on our four-pillar growth strategy, staying true to our course.”

#### **Teleconference Information**

Investors and analysts are invited to listen to a live broadcast review of the Company's 2020 second quarter and six months financial results today at 4:30 p.m. Eastern time (1:30 p.m. Pacific time) that may be accessed by visiting the Company's website at [www.clearpointneuro.com](http://www.clearpointneuro.com) and selecting “Investors” / “News” / “IR Calendar.”

Investors and analysts who would like to participate in the conference call may do so via telephone 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 August 26, 2020 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](http://www.clearpointneuro.com), on the “Investor Relations” page.

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## **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<sup>®</sup> Neuro Navigation System has FDA clearance, is CE-marked, and is installed in 60 active clinical sites in the United States. The Company's SmartFlow<sup>®</sup> cannula is being used in partnership or evaluation with more than 20 individual biologics and drug delivery companies in various stages from preclinical research to late stage regulatory trials. To date, more than 3,500 cases have been performed and supported by the Company's field-based clinical specialist team which offers support and services for our partners. For more information, please visit [www.clearpointneuro.com](http://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 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 estimates regarding the sufficiency of the Company's cash resources. 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, 2019, and the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2020, 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, 2020, which the Company intends to file with the Securities and Exchange Commission on or before August 14, 2020.

### **Contact:**

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

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**CLEARPOINT NEURO, INC.**  
Condensed Consolidated Balance Sheets

	June 30, 2020 (Unaudited)	December 31, 2019
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 16,032,082	\$ 5,695,722
Accounts receivable, net	1,163,663	1,089,917
Inventory, net	3,598,980	3,240,218
Prepaid expenses and other current assets	537,940	357,227
Total current assets	<u>21,332,665</u>	<u>10,383,084</u>
Property and equipment, net	342,584	447,162
Operating lease rights of use	321,155	374,218
Software license inventory	506,800	504,400
Licensing rights	517,207	135,000
Other assets	12,438	82,573
Total assets	<u>\$ 23,032,849</u>	<u>\$ 11,926,437</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,491,377	\$ 965,783
Accrued compensation	969,877	1,408,292
Other accrued liabilities	334,627	328,460
Operating lease liabilities, current portion	110,914	113,520
Deferred product and service revenue	620,126	1,016,892
Paycheck Protection Program loan payable, current portion	296,677	—
Total current liabilities	<u>3,823,598</u>	<u>3,832,947</u>
Accrued interest	—	959,659
Operating lease liabilities, net of current portion	227,714	276,669
Deferred product and service revenue, net of current portion	228,286	197,862
2020 senior secured convertible notes payable, net	16,814,099	—
2010 junior secured notes payable, net	—	2,072,583
Paycheck Protection Program loan payable, net of current portion	599,323	—
Total liabilities	<u>21,693,020</u>	<u>7,339,720</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at June 30, 2020 and December 31, 2019	—	—
Common stock, \$0.01 par value; 200,000,000 shares authorized; 15,512,687 shares issued and outstanding at June 30, 2020; and 15,235,308 issued and outstanding at December 31, 2019	155,127	152,353
Additional paid-in capital	117,640,195	117,173,984
Accumulated deficit	(116,455,493)	(112,739,620)
Total stockholders' equity	<u>1,339,829</u>	<u>4,586,717</u>
Total liabilities and stockholders' equity	<u>\$ 23,032,849</u>	<u>\$ 11,926,437</u>

**CLEARPOINT NEURO, INC.**  
**Condensed Consolidated Statements of Operations**  
**(Unaudited)**

	<b>For The Three Months Ended</b>	
	<b>June 30,</b>	
	<b>2020</b>	<b>2019</b>
Revenues:		
Product revenues	\$ 1,593,070	\$ 2,194,194
Service and other revenues	884,712	412,204
Total revenues	<u>2,477,782</u>	<u>2,606,398</u>
Cost of revenues	640,805	1,030,316
Research and development costs	822,301	697,803
Sales and marketing expenses	1,124,378	1,143,056
General and administrative expenses	<u>1,365,084</u>	<u>1,028,291</u>
Operating loss	(1,474,786)	(1,293,068)
Other income (expense):		
Other income, net	10,851	1,693
Interest expense, net	<u>(197,113)</u>	<u>(259,020)</u>
Net loss	<u>\$ (1,661,048)</u>	<u>\$ (1,550,395)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	<u>\$ (0.11)</u>	<u>\$ (0.13)</u>
Weighted average shares outstanding:		
Basic and diluted	<u>15,504,169</u>	<u>12,302,667</u>

	<b>For The Six Months Ended</b>	
	<b>June 30,</b>	
	<b>2020</b>	<b>2019</b>
Revenues:		
Product revenues	\$ 3,696,455	\$ 4,358,148
Service and other revenues	1,896,921	720,767
Total revenues	<u>5,593,376</u>	<u>5,078,915</u>
Cost of revenues	1,558,141	1,916,798
Research and development costs	1,651,829	1,282,343
Sales and marketing expenses	2,422,972	2,183,769
General and administrative expenses	<u>2,643,592</u>	<u>1,961,322</u>
Operating loss	(2,683,158)	(2,265,317)
Other income (expense):		
Other income, net	6,131	7,322
Interest expense, net	<u>(1,038,846)</u>	<u>(513,125)</u>
Net loss	<u>\$ (3,715,873)</u>	<u>\$ (2,771,120)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	<u>\$ (0.24)</u>	<u>\$ (0.24)</u>
Weighted average shares outstanding:		
Basic and diluted	<u>15,471,222</u>	<u>11,676,872</u>



**CLEARPOINT NEURO, INC.**  
**Condensed Consolidated Statements of Cash Flows**  
**(Unaudited)**

	<b>For The Six Months Ended</b>	
	<b>June 30,</b>	
	<b>2020</b>	<b>2019</b>
Cash flows from operating activities:		
Net loss	\$ (3,715,873)	\$ (2,771,120)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	116,026	69,600
Share-based compensation	468,985	356,580
Amortization of debt issuance costs and original issue discounts	821,301	363,465
Amortization of lease rights of use, net of accretion in lease liabilities	49,782	51,255
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(73,746)	(137,931)
Inventory, net	(313,476)	(201,503)
Prepaid expenses and other current assets	(180,712)	(216,953)
Other assets	70,134	11,899
Accounts payable and accrued expenses	93,347	716,222
Accrued interest	(959,661)	—
Lease liabilities	(48,280)	(50,285)
Deferred revenue	(366,341)	389,201
Net cash flows from operating activities	<u>(4,038,514)</u>	<u>(1,419,570)</u>
Cash flows from investing activities:		
Acquisition of licensing rights	(441,341)	(150,000)
Net cash flows from investing activities	<u>(441,341)</u>	<u>(150,000)</u>
Cash flows from financing activities:		
Proceeds from issuance of 2020 senior secured convertible notes, net of financing costs and discount	16,757,871	—
Proceeds from issuance of Paycheck Protection Program loan	896,000	—
Proceeds from private placement of common stock	—	7,522,010
Proceeds from stock option warrant exercises	—	383,075
Repayment of notes payable	(2,837,656)	(1,975,000)
Net cash flows from financing activities	<u>14,816,215</u>	<u>5,930,085</u>
Net change in cash and cash equivalents	10,336,360	4,360,515
Cash and cash equivalents, beginning of period	5,695,722	3,101,133
Cash and cash equivalents, end of period	<u>\$ 16,032,082</u>	<u>\$ 7,461,648</u>
<b>SUPPLEMENTAL CASH FLOW INFORMATION</b>		
Cash paid for:		
Income taxes	\$ —	\$ —
Interest	<u>\$ 1,043,371</u>	<u>\$ 164,157</u>



CLEARPOINT®  
NEURO

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

August 2020



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## FORWARD LOOKING STATEMENTS

Statements herein concerning ClearPoint Neuro, Inc. (the “Company”) 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: future revenues from sales of the Company's ClearPoint® Neuro Navigation Platform products; the Company's ability to market, commercialize and achieve broader market acceptance for the Company's ClearPoint Neuro Navigation Platform products; COVID-19 pandemic and measures taken or that may be taken to combat the spread of the disease; and estimates regarding the sufficiency of the Company's cash resources. 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, 2019, and the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2020, 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, 2020, which the Company intends to file with the Securities and Exchange Commission on or before August 14, 2020.

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# Severe Neurological Disorders Impact Millions of Patients and Families Each Year



Epilepsy



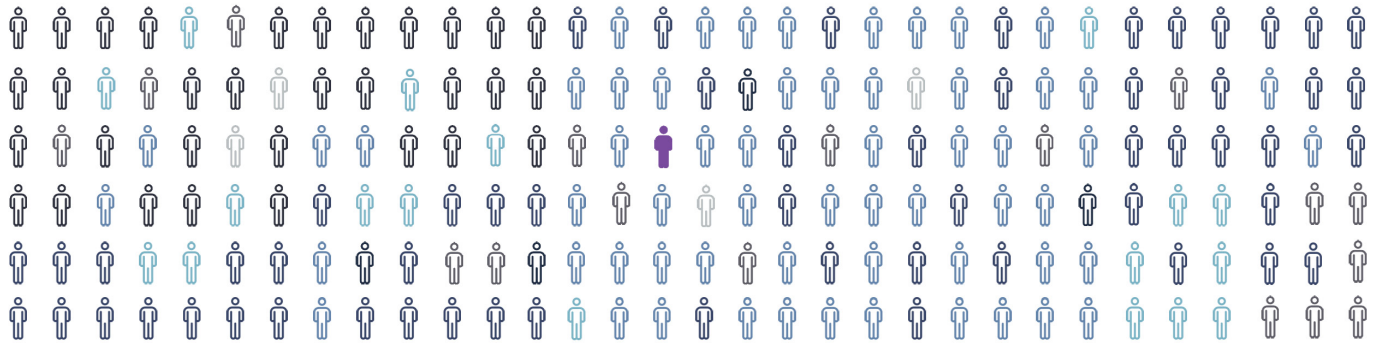
Parkinson's Disease



AADC Deficiency

# Only a fraction of patients with debilitating neurological disorders are being treated surgically today

## Prevalence of Neurological Disorders



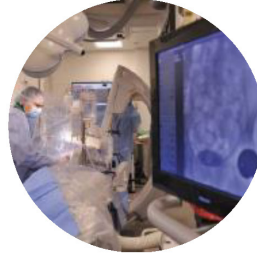
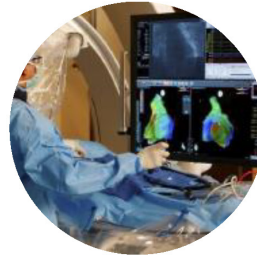
● Epilepsy ● Parkinson's and Essential Tremor ● Tumor ● ICH ● Huntington's Disease ● ALS ● Surgical Procedures

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# The Movement to Minimally Invasive Procedures has Happened Everywhere Else in the Body

This transition has always had two things in common

- More patients being treated
- Procedures **enabled by live image guidance**



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# Traditional Stereotactic Neurosurgery is Limited

## PRIMARY CHALLENGE

### The Skull is not 'See Through'

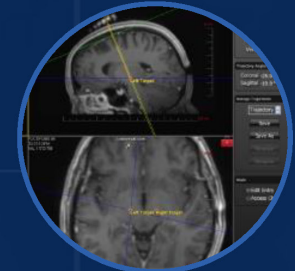
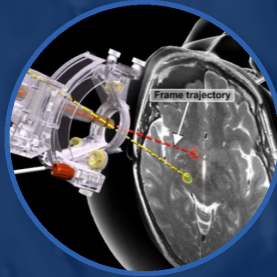
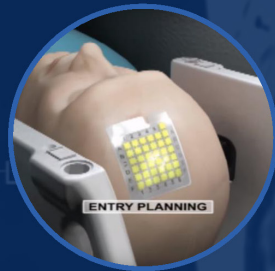
- X-Ray and CT do not show structures of the brain
- Large, Metallic Navigation Frames are not compatible inside an MRI Magnet
- Surgical Image Guidance in the Operating Room is not live but rather 'Co-Registered' to the MRI
- Each Co-Registration calculation introduces error and reduces accuracy



Our Solution – Procedure Overview

# ClearPoint® Neuro Navigation System Platform

An MRI Compatible Navigation System Delivering Live MRI Guidance to the Procedure



Decide, Guide, Treat & Confirm with Sub-millimetric Accuracy



Our Company  
ClearPoint Neuro: A Proven Platform

Key Products: **FDA CE** Marked Platforms

HEADQUARTERS  
Irvine, CA

EMPLOYEES  
50+  
26+ field | 24+ production & development

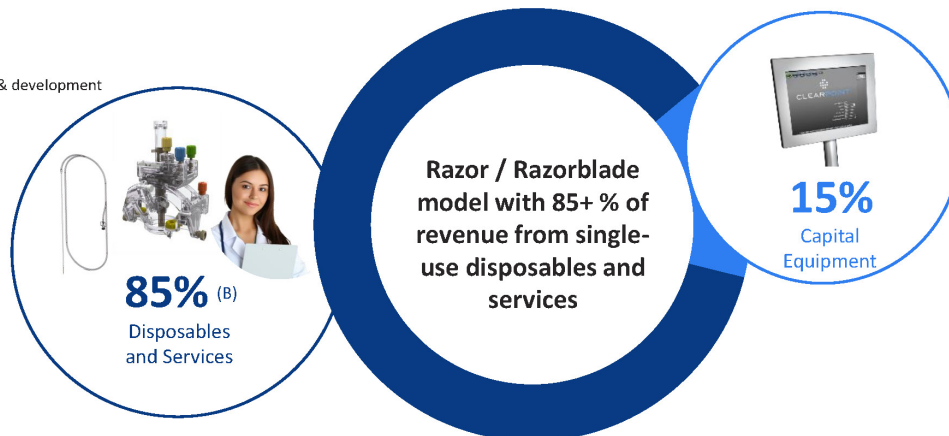
2019 REVENUE\*  
\$11.2m

CASH  
\$16.0m<sup>(A)</sup>

MARKET CAP  
\$55m<sup>(A)</sup>

GROSS MARGIN  
66%<sup>(B)</sup>

U.S. PATENTS ISSUED  
79  
+29 pending

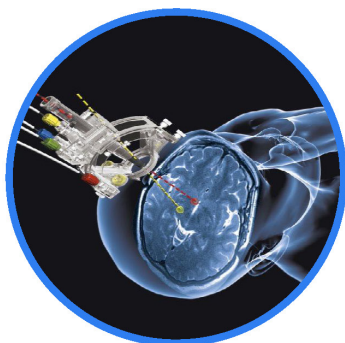


(A) As of June 30, 2020 (B) For the year ended December 31, 2019



\*Due to the unknown duration and extent of COVID-19's impact and uncertainty about how this pandemic will affect our operations, we have withdrawn 2020 guidance and will update our outlook at such time as the effects of the virus on our business become clearer.

# ClearPoint Neuro: Two Companies in One



## A Medical Device Company

- \$100M+ Existing Market, growing > 10%
- Platform Navigation, Therapy, Confirmation
- Predictable, Growing Installed Base
- Stable 15%+ Growth

## A Biologics & Drug Delivery Company

- \$1B+ Potential Market, first indication in 2021
- Platform Navigation, Delivery, Quality Control
- Diversified across partners, indications
- Potentially Explosive, Step-function Growth

Broad and Growing User Base of Leading Neurosurgeons

# Installed in 60 Top US Hospitals...and Expanding into the EU

Our Expert  
Clinical Specialist  
Team is  
Dedicated to  
Supporting Cases

UC San Francisco  
Stanford Children's  
Stanford University  
UCSF Benioff Children's  
San Francisco VA  
USC Keck  
UC San Diego  
Mayo Phoenix  
University of Colorado  
University of Utah  
University of Arizona  
Cook Children's

Texas Children's Hospital  
Cleveland Clinic  
Children's Mercy  
Univ of Kansas Med Center  
MD Anderson  
Houston Methodist Hospital  
Dallas Presbyterian  
Cincinnati Children's  
Nationwide Children's  
OhioHealth Riverside  
Spectrum Health  
Ohio State University

Boston Children's Hospital  
Mass General Hospital  
Brigham & Women's  
Yale University  
UPMC  
University of Wisconsin  
University of Michigan  
Univ of Minnesota Med Ctr  
Mt Sinai West  
Memorial Sloan Kettering  
Henry Ford Health System  
Cincinnati Jewish

Johns Hopkins  
Weill Cornell  
Children's Hosp of Philadelphia  
University of Pennsylvania HUP  
Northwestern Central DuPage  
Dartmouth Hitchcock  
National Institutes of Health  
University of Virginia  
Children's of Alabama  
CHOA Scottish Rite  
Hackensack Univ Med Center  
Beth Israel Deaconess

Duke University  
Children's National  
Le Bonheur  
Emory University  
Mayo Clinic Jacksonville  
INOVA Fairfax  
Tampa General  
Willis Knighton  
Carilion Clinic

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

IMPLANT NEURO STIMULATION LEADS

**Medtronic**

 ST. JUDE MEDICAL

**Boston Scientific**

  
NEUROPACE

 CLEARPOINT  
NEURO

PLACE LASER ABLATION PROBES

**Medtronic**  
VISUALASE

**MONTERIS**  
MEDICAL

DELIVER BIOLOGICS AND DRUGS

  
PTC  
THERAPEUTICS

  
Voyager  
THERAPEUTICS

  
Neurocrine  
BIOSCIENCES

**axovant**  
GENE THERAPIES

 BlueRock  
Therapeutics

**LYSOGENE**

 INTERNATIONAL  
**STEM CELL**  
CORPORATION

CLPT PLATFORM RUNS ON ALL MAJOR SCANNERS

**SIEMENS**

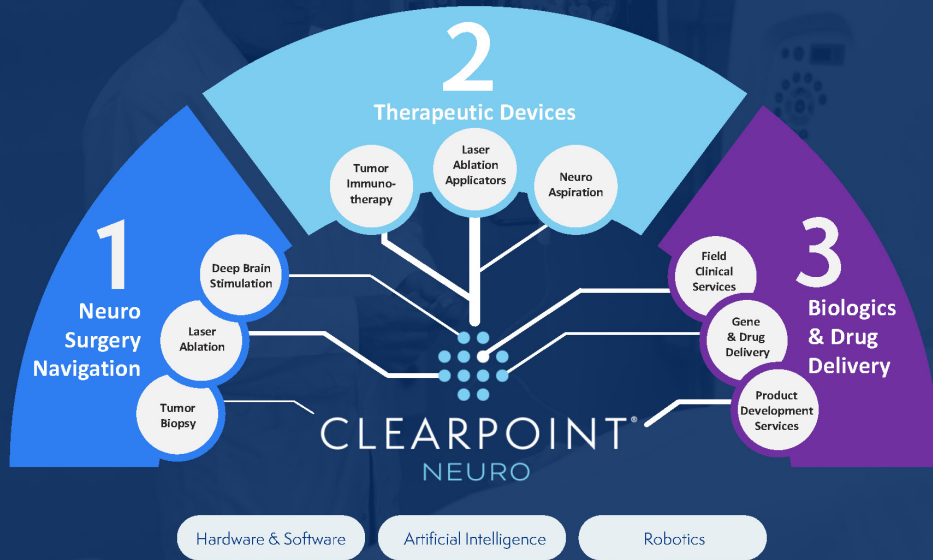


**PHILIPS**

**IMRIS** 

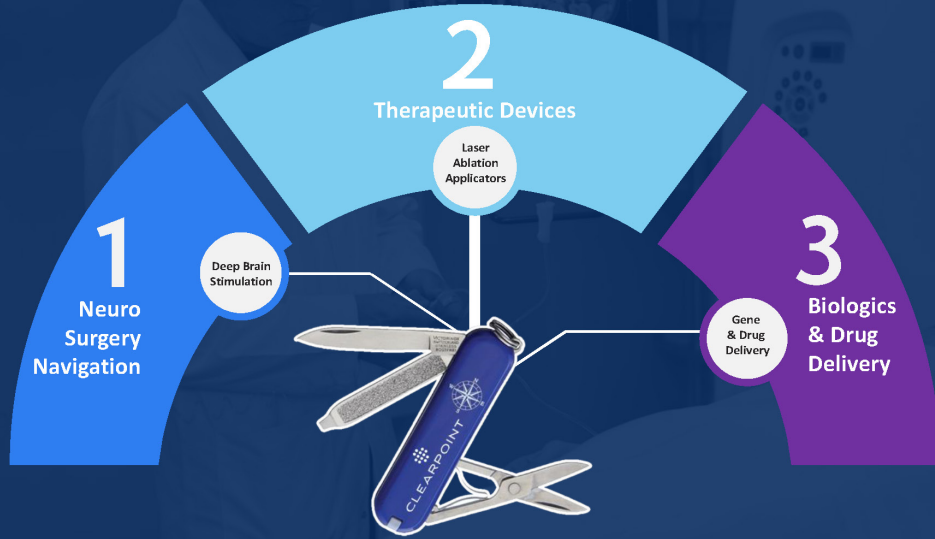
CAPABILITIES

Our platform enables choice of precision-guided therapies and services



# Example: The Parkinson's Disease Patient

Enabling Surgeons to choose the right tool for the right patient



MARKET POTENTIAL FOR PROCEDURES

Included Below Strategic & Focused Expansion to new geographies either direct or through partners  
Leverage existing sales channel for other distribution opportunities (i.e. non-neuro CLS Laser Distribution)

GLOBAL SCALE  
Expansion and Leverage

4

50,000+ 20+ Current non-hospital partners  
7+ phase I & II Clinical Trials

BIOLOGICS & DRUG DELIVERY  
Growth from New Markets

3

50,000+ Laser Therapy (LITT) for Neurosurgery existing \$25+ M Market  
Neuro Aspiration Market potential > \$100 M

THERAPY  
Growth from Existing Markets

2

12,500+ Tumor Biopsy & Ablation  
28,000+ LITT and NeuroPace for Epilepsy  
15,000+ Deep Brain Stimulation (DBS) for Parkinson's

NEURO NAVIGATION  
2019 Base Revenue

1

# Growth Strategy

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

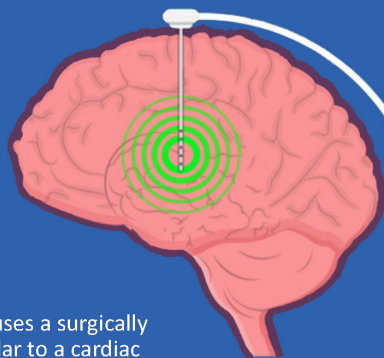
2020

2025

# Market Opportunity



## 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.

ClearPoint® 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.



# 1. Neuro Navigation Deep Brain Stimulation

## CLEARPOINT MUST FACTOR INDUSTRY CHANGES

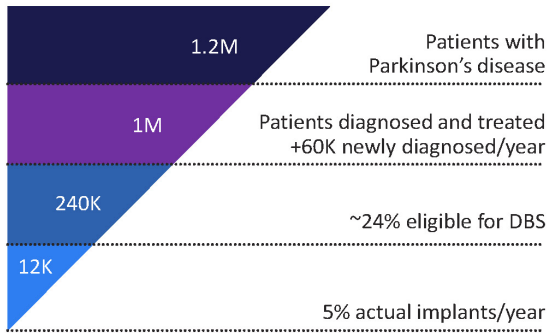
Boston  
Scientific

Medtronic

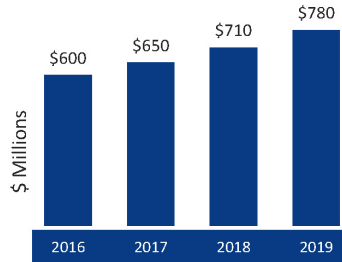
Abbott

NEUROPACE

### Parkinson's Patient Population (US)



### Movement Disorders Neuromodulation (Global): Currently 10% Annual Growth\*



### DBS Procedure Volumes

- 12,500 implantations per year (US)
- 50% are replacement device procedures (battery, etc.)
- As implantations grow 10%/y, replacement procedures will decrease



\*Due to the unknown duration and extent of COVID-19's impact and uncertainty about how this pandemic will affect our operations, we have withdrawn 2020 guidance and will update our outlook at such time as the effects on the virus of our business become clearer.

# 1. Neuro Navigation Deep Brain Stimulation

## CLEARPOINT MUST FACTOR INDUSTRY CHANGES

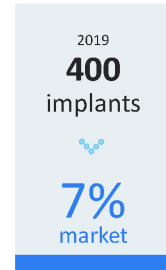
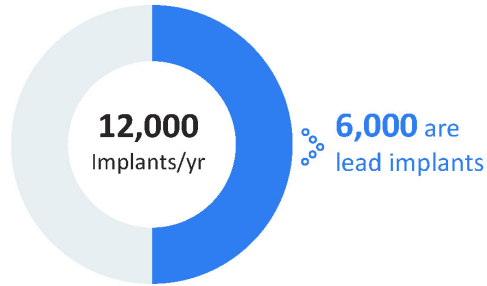
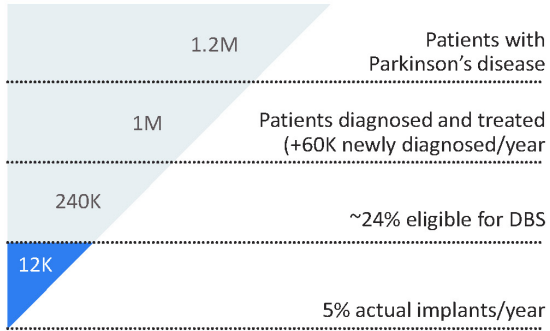
Boston  
Scientific

Medtronic

Abbott

NEUROPACE

### Parkinson's Patient Population (US)



Current addressable U.S. market

**6,000 x \$12,000 / case = \$72M**

**Growing 10%**

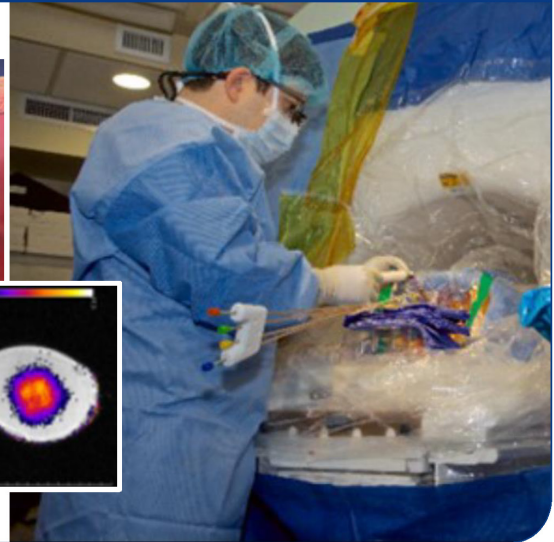
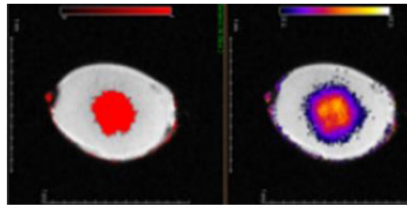
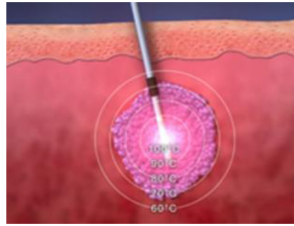
## 2. Therapy

# ClearPoint Neuro Laser Therapy

LITT uses laser energy to destroy unwanted cells

**Laser Interstitial Thermal Therapy (LITT)** is a minimally invasive surgical technique. A laser fiber is inserted through a tiny hole in the skull and then the laser applies energy to the targeted lesion, killing unwanted cells.

MR-guided LITT includes a thermometry software system, integrated with the MRI, that precisely monitors and controls the temperature and thermal dose from that laser.



## 2. Therapy

# ClearPoint Neuro Laser Therapy

### ClearPoint Neuro's Right to Win in MRgLITT

- ClearPoint Neuro chosen by Neurosurgeons for the most difficult Neuro LITT cases today.
- One clinical support team and a simplified workflow will accelerate growth.
- ClearPoint Neuro continues to invest in R&D pipeline.

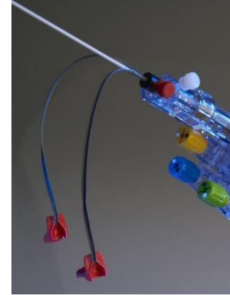
INFLEXION™ Head Fixation Frame



TRANBERG® Laser



ClearPoint® Compatibility Kits

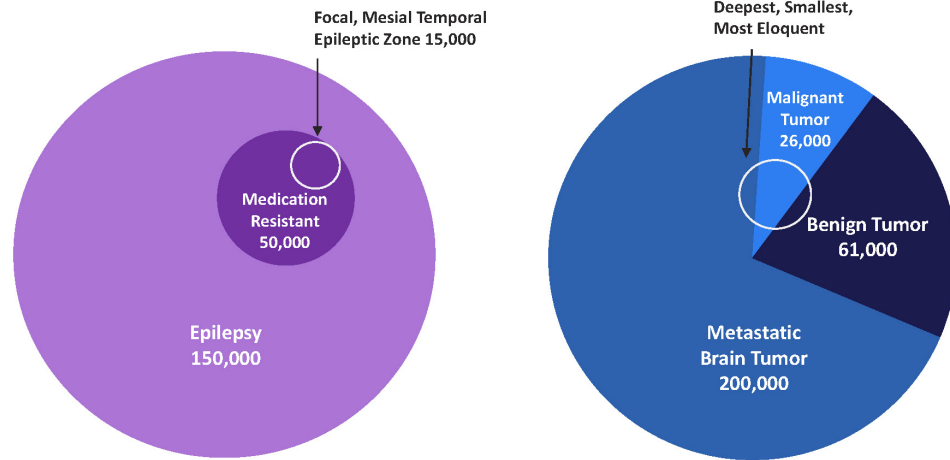


## 2. Therapy

# ClearPoint Neuro Laser Therapy

### Significant Addressable Neuro Market in Epilepsy and Tumor

- Initial beachhead market -> focal, MTLE cases and the most difficult brain tumor cases.
- Then expand to multi-focal, other zones, and larger, more surface lesions.
- Ultimately extend into non-neuro applications like spine, prostate.

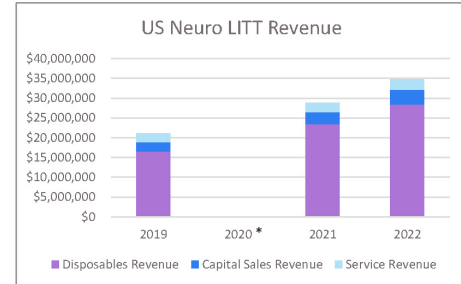
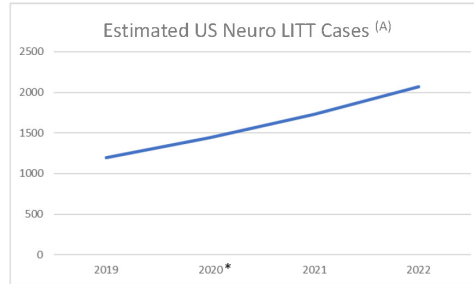


## 2. Therapy

# ClearPoint Neuro Laser Therapy

The Current US MRgLITT Market is Small, but Strong Growth Drivers Are in Place

- Patients will continue to shift from open craniotomy to minimally invasive methods.
- Clinical evidence and payer support for LITT is growing.
- Growing acceptance from referring neurologists and neuro-oncologists.
- More providers investing in surgical MRIs.







(A) Forecasted forward-looking case and revenue estimates



\*Due to the unknown duration and extent of COVID-19's impact and uncertainty about how this pandemic will affect our operations, we have withdrawn 2020 guidance and will update our outlook at such time as the effects of the virus on our business become clearer.

### 3. Biologics & Drug Delivery

## Pediatric Indications




Disorder	Description	Non-Clinical	Phase I/II Trial	Pivotal Trial	Commercial
 <p><b>AADC Deficiency</b></p>	Rare (<1/1,000,000) autosomal recessive disorder caused by mutations in the DDC gene leading to significant deficiencies in dopamine and other neurotransmitters. This causes severe motor dysfunction in infants and children. <sup>1</sup>	[Progress bar: Non-Clinical, Phase I/II Trial, Pivotal Trial, Commercial]			
 <p><b>Diffuse Intrinsic Pontine Glioma (DIPG)</b></p>	A more common (3.3/100,000) highly aggressive and difficult to treat brain tumor located in the brain stem. Peak incidence at 6-9 years old, symptoms can include weakness in the arms and legs, problems with gait and coordination, and problems controlling eye movement, speech, and chewing. <sup>2</sup>	[Progress bar: Non-Clinical, Phase I/II Trial]			
 <p><b>Friedreich's Ataxia</b></p>	A genetic, progressive, neurodegenerative movement disorder, with a typical age of onset between 10 and 15 years with a prevalence of 1/40,000 people. Initial symptoms may include unsteady posture, frequent falling, and difficulty in walking due to impaired ability to coordinate voluntary movements. <sup>3</sup>	[Progress bar: Non-Clinical, Phase I/II Trial]			
 <p><b>Angelman Syndrome</b></p>	A complex genetic disorder with a prevalence of 1/12,000-20,000 that primarily affects the nervous system. Characteristic features include delayed development, intellectual disability, severe speech impairment, and problems with movement and balance. <sup>4</sup>	[Progress bar: Non-Clinical, Phase I/II Trial]			

References: 1. Brun L, et al. Neurology, 2010;75:64-71. 2. Dana Farber <http://www.danafarberbostonchildrens.org/conditions/brain-tumor/diffuse-pontine-glioma.aspx>  
3. <https://rarediseases.org/rare-diseases/friedreichs-ataxia> 4. <https://ghr.nlm.nih.gov/condition/angelman-syndrome>



### 3. Biologics & Drug Delivery





## Pediatric Indications

	Disorder	Description	Non-Clinical	Phase I/II Trial	Pivotal Trial	Commercial
	Sanfilippo A (MPS IIIA)	Autosomal recessive, neurodegenerative lysosomal storage disorder affecting 1/1000,00 births. The primary disease characteristic is CNS degeneration which results in hyperactivity and mental retardation. <sup>1</sup>	█	█		
	Tay-Sachs (GM2 gangliosidosis)	A rare (1/201,000) autosomal recessive disorder that results in neurodegeneration in the brain and spinal cord and is classified as a lysosomal storage disorder. Symptoms can include developmental regression, exaggerated startle reaction, seizures and intellectual disability. <sup>2</sup>	█	█		
	GM1 gangliosidosis	Inherited genetic disorder that causes progressive neurodegeneration in the brain and spinal cord with a prevalence of 1/100,000-200,000. Onset varies from early infantile to juvenile Symptoms can include developmental regression, enlarged organs (liver/spleen), skeletal abnormalities, seizures and intellectual disability. <sup>3</sup>	█	█		

References: 1. Fedele AO. Sanfilippo syndrome: causes, consequences, and treatments. Appl Clin Genet. 2015;8:269–281. 2. Boston Children’s Hospital <http://www.childrenshospital.org/conditions-and-treatments/conditions/g/gm2-gangliosidosis>  
3. <https://ghr.nlm.nih.gov/condition/gm1-gangliosidosis>

### 3. Biologics & Drug Delivery

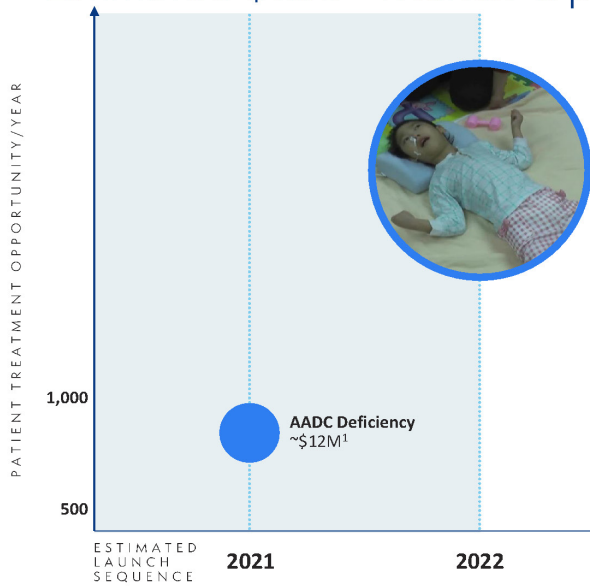
## Adult Indications

	Disorder	Description	Non-Clinical	Phase I/II Trial	Pivotal Trial	Commercial
	Glioblastoma	One of the most common and highly invasive brain neoplasms with an incidence of 2-3 new cases per 100,000. Symptoms can vary but include worsening headache, nausea, vomiting, and seizures. Treatment is difficult (and often impossible) due to the nature of the cancer type. <sup>1,2</sup>	▶	▶		
	Parkinson's Disease	Progressive nervous system disorder affecting movement impacting 10 million people worldwide. Symptoms start gradually, with a barely noticeable tremor in just one hand. Tremors are common, but the disorder also commonly causes stiffness or slowing of movement. <sup>3</sup>	▶	▶		
	Huntington's Disease	Inherited genetic disorder that causes the progressive degeneration of nerve cells in the brain with a prevalence of 1/10,000-30,000. Symptoms have a broad impact on functional abilities and results in cognitive, movement, and psychiatric disorders. <sup>4</sup>	▶	▶		
	Amyotrophic Lateral Sclerosis (ALS)	A progressive neurodegenerative disease that affects nerve cells in the brain and spinal cord with an estimated prevalence of 5 per 100,000 in the United States with a total worldwide number of cases of 222,801 in 2015. <sup>5</sup>	▶	▶		

References: 1. Mayo Clinic <https://www.mayoclinic.org/diseases-conditions/glioblastoma/cdc-20350148> 2. Xu H, et al. Front Aging Neurosci. 2017;9:352 3. Mayo Clinic <https://www.mayoclinic.org/diseases-conditions/parkinsons-disease/symptoms-causes/syc-20376055> 4. Mayo Clinic <https://www.mayoclinic.org/diseases-conditions/huntingtons-disease/symptoms-causes/syc-20356117> 5. Arthur KC, et al. Projected increase in amyotrophic lateral sclerosis from 2015 to 2040

### 3. Biologics & Drug Delivery

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



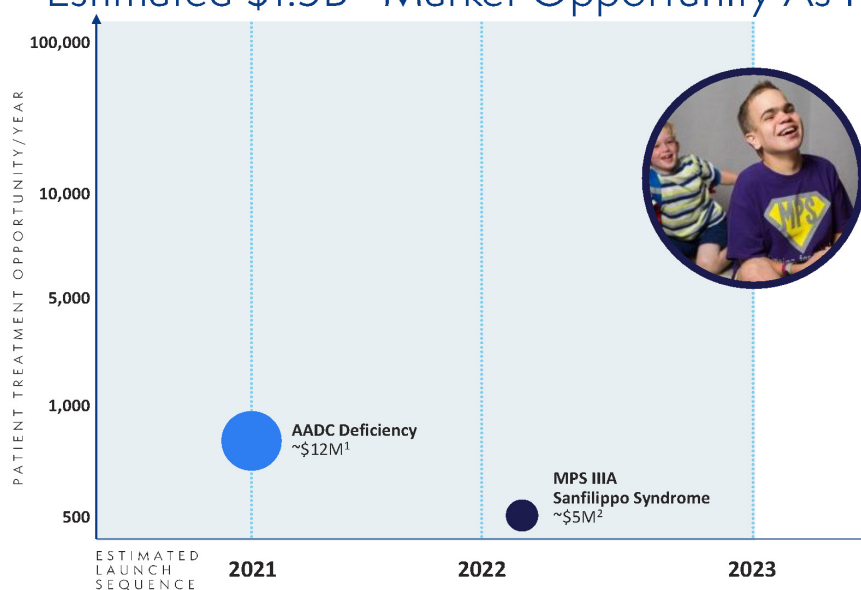
**AADC Deficiency syndrome:** Rare autosomal recessive disorder caused by mutations in the DDC gene leading to significant deficiencies in dopamine and other neurotransmitters. This causes severe motor dysfunction in infants and children.<sup>2</sup>

Estimated WW prevalence	5,000 – 10,000
Estimated new cases / year	500 – 1,000
Potential Revenue / case	2 x SmartFrames + 2 x SmartFlows = \$12,000 / case
Potential Revenue from new cases each year	\$12.0M



### 3. Biologics & Drug Delivery

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

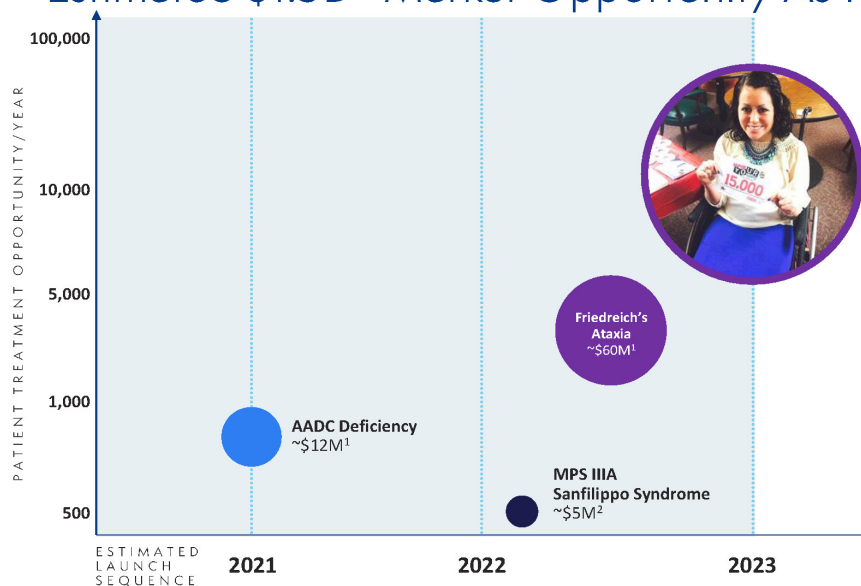


**Sanfilippo Syndrome:** Autosomal recessive, neurodegenerative lysosomal storage disorder affecting 1/100,000 births. The primary disease characteristic is CNS degeneration which results in hyperactivity and mental retardation.<sup>1</sup>

Estimated WW prevalence	2,500-3,000
Estimated new cases / year	500
Potential Revenue / case	Multiple SmartFlow Cannulas Approx. \$10,000 / case
Potential Revenue from new cases each year	\$5.0M

### 3. Biologics & Drug Delivery

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

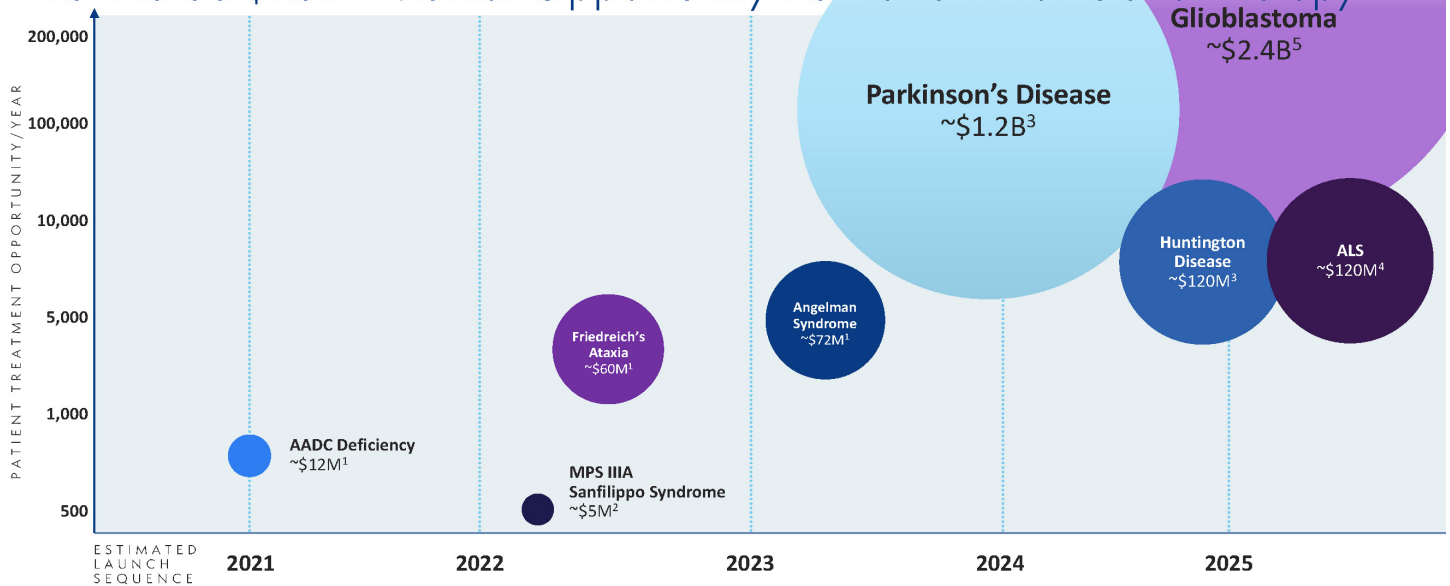


**Friedreich's Ataxia:** A genetic, progressive, neurodegenerative movement disorder, with a typical age of onset between 10 and 15 years with a prevalence of 1/40,000 people. Initial symptoms may include unsteady posture, frequent falling, and progressive difficulty in walking due to impaired ability to coordinate voluntary movements.<sup>1</sup>

Estimated WW prevalence	~65,000
Estimated new cases / year	~6,000
Potential Revenue / case	2 x SmartFrames + 2 x SmartFlows = \$12,000 / case
Potential Revenue from new cases each year	\$60M

### 3. 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 <https://ir.voyagertherapeutics.com/static-files/35616e0b-29fe-4c6d-8bee-fd00295c8e51> 4. Arthur KC, et al. Projected increase in amyotrophic lateral sclerosis from 2015 to 2040. *Net Commun.* 2016;7:12408. 5. <https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Glioblastoma-Multiforme>

\* 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 ALS.

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#### 4. Global Scale

## Achieve Global Scale and Progress Toward Profitability

### Established Sales Channel capable of distributing other surgical products

- Current Revenue for non-neuro CLS Laser Applicators

### Manufacturing Facility in Irvine capable of producing 5x current demand with existing footprint

### CE Mark labeling for targeted global expansion when time is right

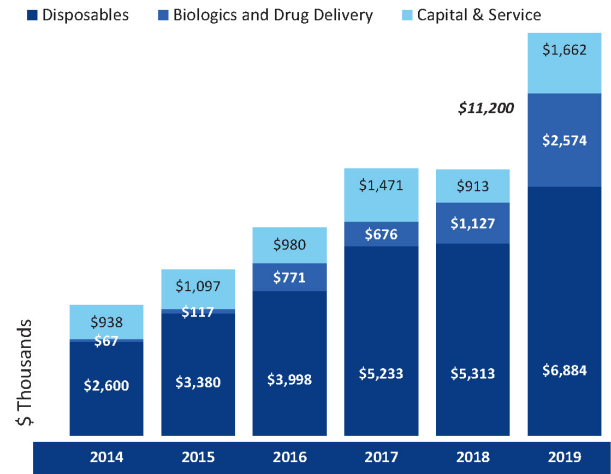
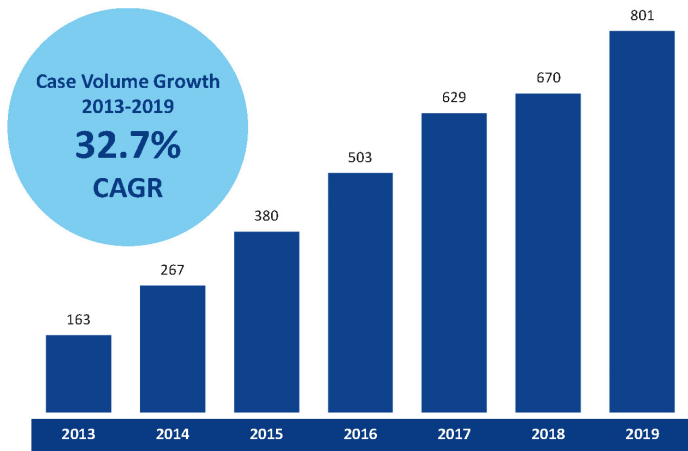
- Expecting to perform cases in Europe in 2021



# Financials

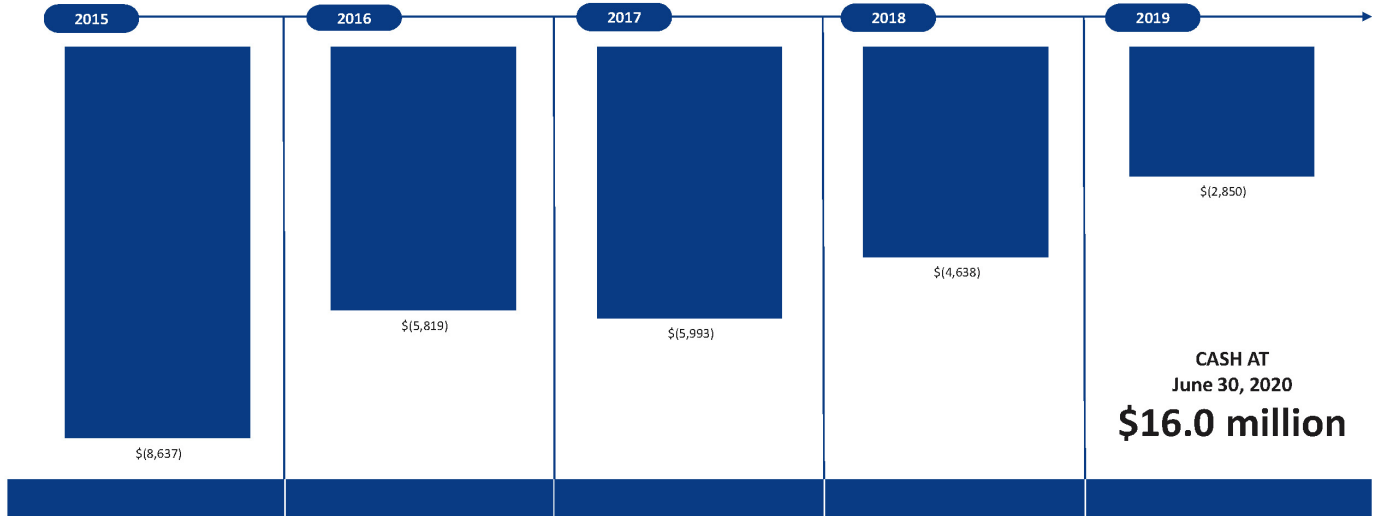


# 2013 - 2019 Growth in Case Volume and Revenue



2015 - 2019

# Cash Flow From Operations



# CLPT CAPABILITIES

## Executive Summary



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



**85%+** of forecast revenue from single-use, high-margin disposables



**Large, Growing installed** base in 60 of 250+ leading Neurology centers in U.S.



**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



**A passionate team** of embedded scientists and specialists

  
CLEARPOINT®  
NEURO

