

**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 10, 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 November 10, 2020, ClearPoint Neuro, Inc. (the “Company”) issued a press release announcing its financial performance for the third fiscal quarter and nine months ended September 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 November 10, 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 November 10, 2020](#)

[Exhibit 99.2](#) [Investor Presentation dated November 2020](#)

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 10, 2020

CLEARPOINT NEURO, INC.

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



ClearPoint Neuro Reports Third Quarter 2020 Results

Revenue Reaches a Record \$3.5 million

IRVINE, CA, November 10, 2020 – ClearPoint Neuro, Inc. (Nasdaq: CLPT), a medical device company with a portfolio of products focused on enabling therapies for neurological disorders, today announced financial results for its third fiscal quarter ended September 30, 2020.

Third Quarter 2020 Highlights

- Reported record total revenue of \$3.5 million, a 20% increase over the same quarter last year
- Increased biologics and drug delivery revenue to \$1.5 million, a 162% increase over the same quarter last year, driven by new clinical service relationships
- Supported 200 cases in the quarter

“This quarter’s results, with a return to double-digit growth, underscores the dedication and focus of the entire ClearPoint Neuro team,” commented Joe Burnett, President and CEO of ClearPoint Neuro. “As elective procedures increased in the third quarter, our manufacturing employees in our Irvine, CA facility and our Clinical Specialist team on the front lines worked diligently to provide best-in-class support. I’m pleased that hospitals have prioritized our team’s access to support cases, enabling the best service possible. As a result, I am proud to disclose that we supported 200 cases in the quarter. While there remains uncertainty due to the pandemic, our team is being proactive in redeploying our resources to further our engineering efforts and investing in our people and our pipeline of future products and services.

“As we look to the conclusion of the year, we believe that total revenue for 2020, absent a resumption of a partial or full suspension of elective procedures due to the progression of the COVID-19 pandemic, will be in a range of \$12.0 million to \$12.5 million, which would represent growth over the prior year of between 7% to 11%,” continued Burnett. “Nonetheless, it should be kept in mind that our case volume currently represents approximately 80% of our pre-pandemic estimates, and, while hospitals are willing to treat very sick patients, many of these patients are in a high-risk category for COVID-19 based on age or other conditions. As a result, patients, rather than hospitals, are more likely to make the decision to postpone procedures.”

Third Quarter 2020 Financial Results

Total revenues were a record \$3.5 million in the third quarter of 2020, compared to \$2.9 million for the third quarter of 2019, an increase of 20%.

Functional neurosurgery navigation revenue, which consists of disposable product commercial sales related to cases utilizing the ClearPoint[®] system, decreased 1% to \$1.8 million for the third quarter 2020, from \$1.9 million for the same period in 2019. This decrease reflects the continuing effects of the COVID-19 pandemic, in which elective surgical procedures that were postponed or cancelled at the outset of the pandemic have resumed, albeit at volumes that have not yet reached pre-pandemic activity.

Biologics and drug delivery revenues, which include sales of disposable products and services related to customer-sponsored clinical trials utilizing the ClearPoint system, increased 162% to \$1.5 million for the third quarter 2020, from \$0.6 million for the same period in 2019. This increase was due to the establishment of additional relationships with biologic and drug delivery companies that included period-based retainers for ClearPoint Neuro’s clinical services in support of such companies’ clinical trials.

5 Musick, Irvine, California 92618 | Phone: 949.900.6833 | www.clearpointneuro.com

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, decreased 48% to \$0.2 million for the third quarter 2020, from \$0.4 million 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 due to the COVID-19 pandemic.

The Company achieved a gross margin of 80% on its sales for the third quarter 2020, compared to a gross margin of 66% for the same period in 2019. This increase was due primarily to a shift in the mix of revenues by line of business that resulted in service revenues, which bear higher gross margins in comparison to other product lines, representing a greater contribution to total sales for the third quarter 2020, relative to the same period in 2019.

Operating expenses for the third quarter 2020 were \$4.1 million, a 43% 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 59% due primarily to increases in headcount and increased project activity; (b) sales and marketing expenses, which increased 40%, due primarily to increases in headcount of the Company's clinical specialist team; and (c) general and administrative expenses, which increased 33%, due primarily to an increase in company-wide share-based compensation, and a reduction of the allocation of shared departmental resources to production due to the reduced manufacturing activity as an effect of the COVID-19 pandemic.

Operating loss for the third quarter 2020 was \$1.3 million, compared with \$0.9 million for the same period in 2019.

Cash and cash equivalent balances at September 30, 2020 were \$14.7 million.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's 2020 third quarter 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 and selecting "Investors", "News / Events / Presentations", "Events".

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 December 10, 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, 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 60 active clinical sites in the United States. The Company's SmartFlow[®] cannula is being used in partnership or evaluation with more than 25 individual biologics and drug delivery companies in various stages from preclinical research to late stage regulatory trials. To date, more than 4,000 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.

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 June 30, 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 September 30, 2020, which the Company intends to file with the Securities and Exchange Commission on or before November 16, 2020.

Contact:

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info@clearpointneuro.com

Jacqueline Keller, Vice President, Marketing
(949) 900-6833
info@clearpointneuro.com

CLEARPOINT NEURO, INC.
Condensed Consolidated Balance Sheets

	September 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,665,597	\$ 5,695,722
Accounts receivable, net	1,449,333	1,089,917
Inventory, net	3,534,643	3,240,218
Prepaid expenses and other current assets	492,886	357,227
Total current assets	<u>20,142,459</u>	<u>10,383,084</u>
Property and equipment, net	327,055	447,162
Operating lease rights of use	294,583	374,218
Software license inventory	571,800	504,400
Licensing rights	487,640	135,000
Other assets	23,380	82,573
Total assets	<u>\$ 21,846,917</u>	<u>\$ 11,926,437</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,064,121	\$ 965,783
Accrued compensation	1,210,356	1,408,292
Other accrued liabilities	487,768	328,460
Operating lease liabilities, current portion	108,923	113,520
Deferred product and service revenue	767,969	1,016,892
Paycheck Protection Program loan payable, current portion	73,985	—
Total current liabilities	<u>3,713,122</u>	<u>3,832,947</u>
Accrued interest	—	959,659
Operating lease liabilities, net of current portion	205,468	276,669
Deferred product and service revenue, net of current portion	108,816	197,862
2020 senior secured convertible notes payable, net	16,848,396	—
2010 junior secured notes payable, net	—	2,072,583
Paycheck Protection Program loan payable, net of current portion	822,015	—
Total liabilities	<u>21,697,817</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 September 30, 2020 and December 31, 2019	—	—
Common stock, \$0.01 par value; 200,000,000 shares authorized; 15,881,404 shares issued and outstanding at September 30, 2020; and 15,235,308 issued and outstanding at December 31, 2019	158,814	152,353
Additional paid-in capital	117,930,011	117,173,984
Accumulated deficit	(117,939,725)	(112,739,620)
Total stockholders' equity	<u>149,100</u>	<u>4,586,717</u>
Total liabilities and stockholders' equity	<u>\$ 21,846,917</u>	<u>\$ 11,926,437</u>

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

	For The Three Months Ended September 30,	
	2020	2019
Revenues:		
Product revenues	\$ 2,333,550	\$ 2,594,428
Service and other revenues	1,185,637	333,038
Total revenues	<u>3,519,187</u>	<u>2,927,466</u>
Cost of revenues	718,787	983,042
Research and development costs	1,209,048	761,881
Sales and marketing expenses	1,492,948	1,063,143
General and administrative expenses	1,369,900	1,029,929
Operating loss	<u>(1,271,496)</u>	<u>(910,529)</u>
Other income (expense):		
Other income (expense), net	(11,491)	728
Interest expense, net	(201,245)	(213,167)
Net loss	<u>\$ (1,484,232)</u>	<u>\$ (1,122,968)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	<u>\$ (0.09)</u>	<u>\$ (0.08)</u>
Weighted average shares outstanding:		
Basic and diluted	<u>15,724,401</u>	<u>14,053,508</u>

	For The Nine Months Ended September 30,	
	2020	2019
Revenues:		
Product revenues	\$ 6,030,005	\$ 6,952,575
Service and other revenues	3,082,558	1,053,807
Total revenues	<u>9,112,563</u>	<u>8,006,382</u>
Cost of revenues	2,276,927	2,899,837
Research and development costs	2,860,877	2,044,224
Sales and marketing expenses	3,915,920	3,246,912
General and administrative expenses	4,013,493	2,991,305
Operating loss	<u>(3,954,654)</u>	<u>(3,175,896)</u>
Other income (expense):		
Other income (expense), net	(5,360)	8,100
Interest expense, net	(1,240,091)	(726,292)
Net loss	<u>\$ (5,200,105)</u>	<u>\$ (3,894,088)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	<u>\$ (0.33)</u>	<u>\$ (0.31)</u>
Weighted average shares outstanding:		
Basic and diluted	<u>15,556,231</u>	<u>12,477,790</u>

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

	For The	
	Nine Months Ended	
	September 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	\$ (5,200,105)	\$ (3,894,088)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	170,057	105,310
Share-based compensation	762,488	576,012
Amortization of debt issuance costs and original issue discounts	855,598	523,969
Amortization of lease rights of use, net of accretion in lease liabilities	74,734	76,871
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(359,416)	(895,189)
Inventory, net	(323,075)	(908,413)
Prepaid expenses and other current assets	(135,658)	(150,589)
Other assets	59,193	11,899
Accounts payable and accrued expenses	59,711	1,506,279
Accrued interest	(959,661)	—
Lease liabilities	(70,896)	(82,448)
Deferred revenue	(337,969)	746,682
Net cash flows from operating activities	<u>(5,404,999)</u>	<u>(2,383,705)</u>
Cash flows from investing activities:		
Purchases of property and equipment	—	(10,190)
Acquisition of licensing rights	(441,341)	(150,000)
Net cash flows from investing activities	<u>(441,341)</u>	<u>(160,190)</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, net of offering costs	—	7,427,848
Proceeds from stock option and warrant exercises	—	387,426
Repayment of notes payable	(2,837,656)	(2,137,344)
Net cash flows from financing activities	<u>14,816,215</u>	<u>5,677,930</u>
Net change in cash and cash equivalents	8,969,875	3,134,035
Cash and cash equivalents, beginning of period	5,695,722	3,101,133
Cash and cash equivalents, end of period	<u>\$ 14,665,597</u>	<u>\$ 6,235,168</u>
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	\$ —	\$ —
Interest	<u>\$ 1,399,182</u>	<u>\$ 82,621</u>



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

November 2020



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 June 30, 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 September 30, 2020, which the Company intends to file with the Securities and Exchange Commission on or before November 16, 2020.

Severe Neurological Disorders Impact Millions of Patients and Families Each Year



Epilepsy



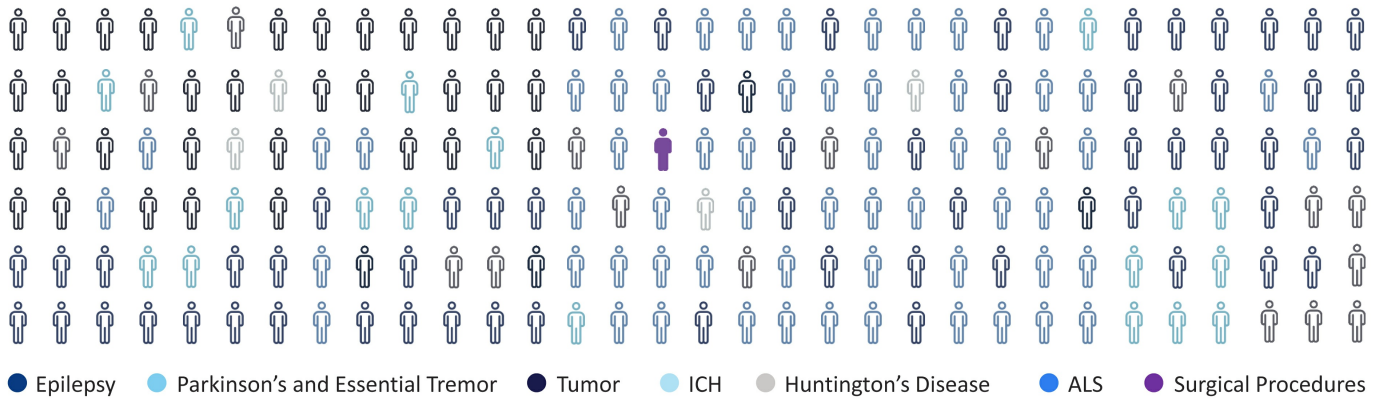
Parkinson's Disease



AADC Deficiency

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

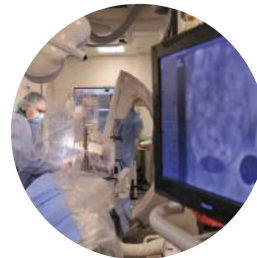
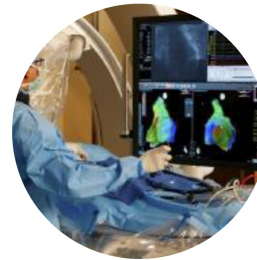
Prevalence of Neurological Disorders



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**



Traditional Stereotactic Neurosurgery is Limited

PRIMARY CHALLENGE

The Skull is not 'See Through'

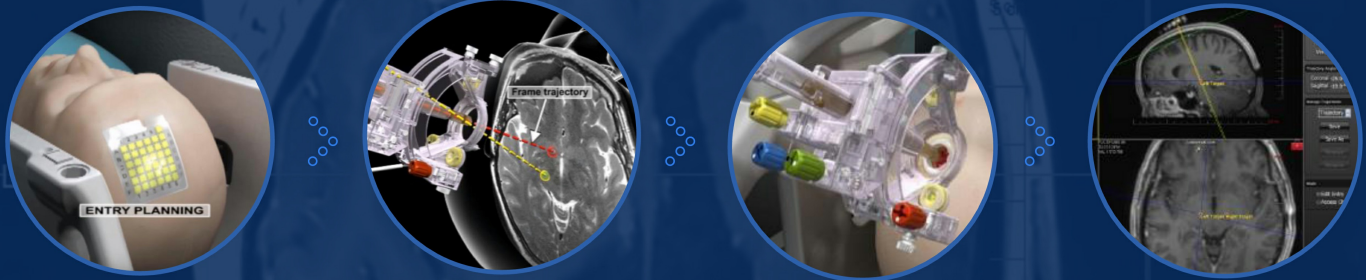
- X-Ray and CT do not show structures of the brain
- Large, Metallic Navigation Frames are not compatible inside an MRI Magnet
- Surgical Image Guidance in the Operating Room is not live but rather 'Co-Registered' to the MRI
- Each Co-Registration calculation introduces error and reduces accuracy



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

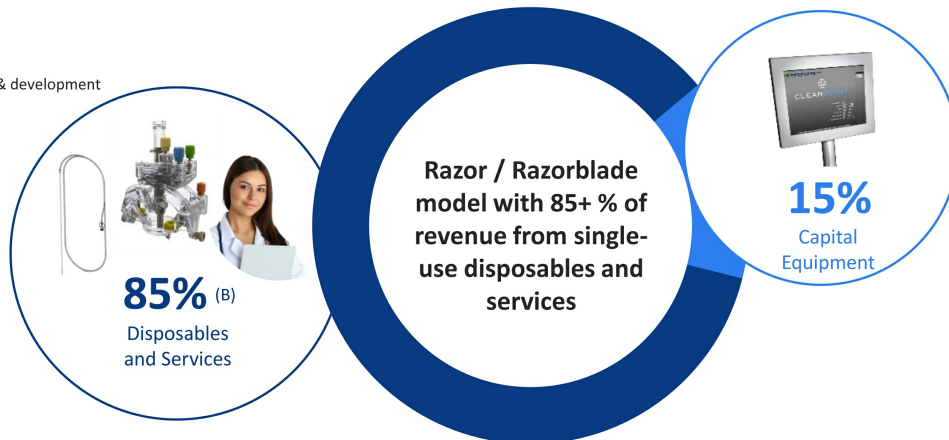
2019 REVENUE*
\$11.2m

CASH
\$14.7m^(B)

MARKET CAP
\$107m^(A)

GROSS MARGIN
66%^(C)

U.S. PATENTS ISSUED
79
+29 pending



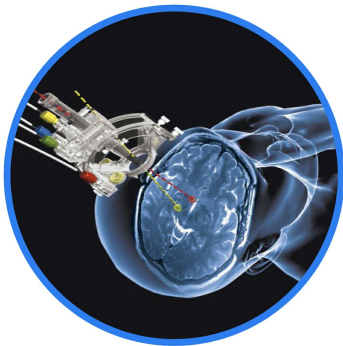
(A) As of November 3, 2020 (B) As of September 30, 2020 (C) For the year ended December 31, 2019



*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.

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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

...with 25 total partners

CLPT PLATFORM RUNS ON ALL MAJOR SCANNERS

SIEMENS



PHILIPS

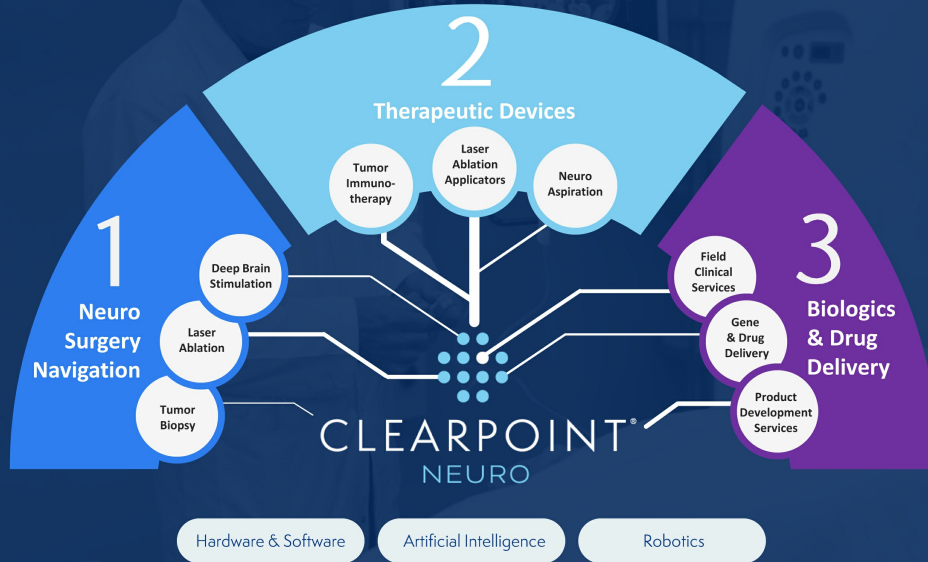
IMRIS 

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11

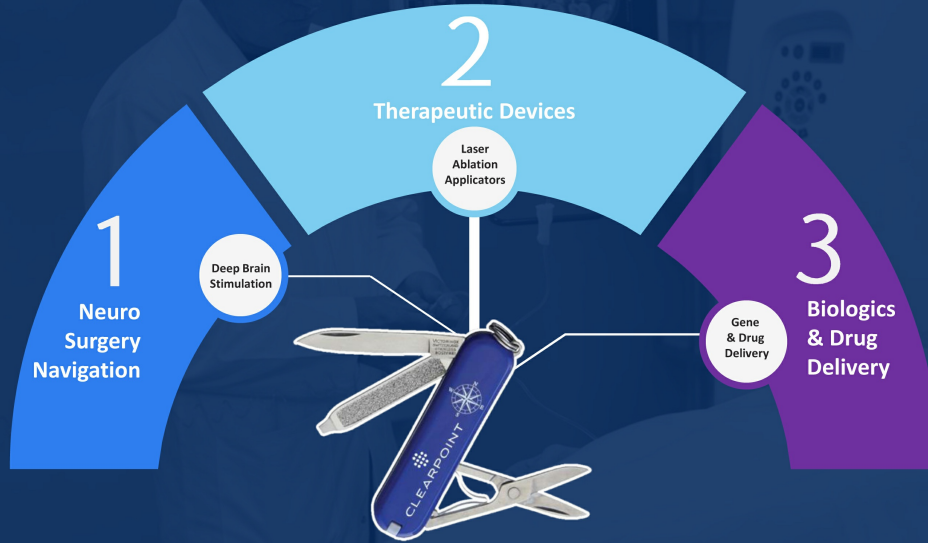
CAPABILITIES

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)

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

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

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

GLOBAL SCALE
Expansion and Leverage

4

BIOLOGICS & DRUG DELIVERY
Growth from New Markets

3

THERAPY
Growth from Existing Markets

2

NEURO NAVIGATION
2019 Base Revenue

1

Growth Strategy

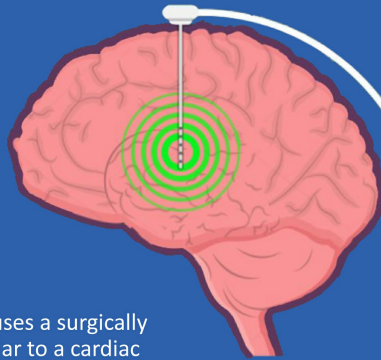
Target Indications of > 150,000 procedures per year represents
Potential Addressable Market for CLPT of \$1B+

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

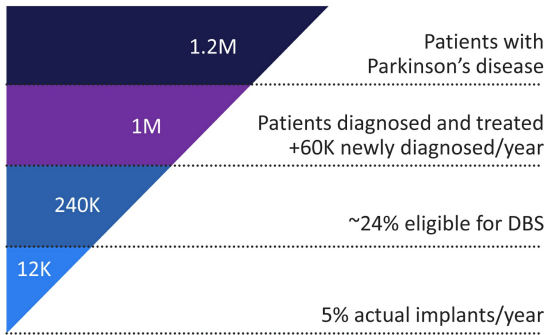
Boston Scientific

Medtronic

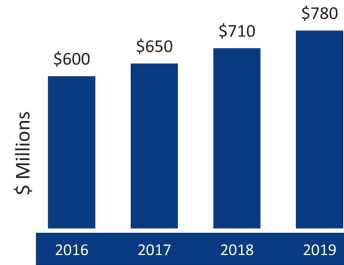
Abbott

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

1. Neuro Navigation Deep Brain Stimulation

CLEARPOINT MUST FACTOR INDUSTRY CHANGES

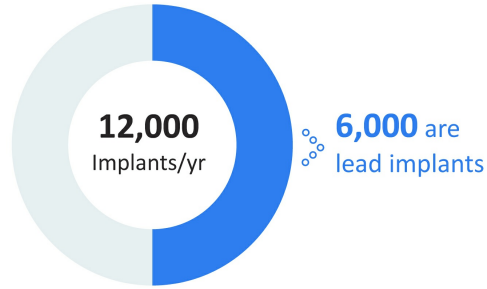
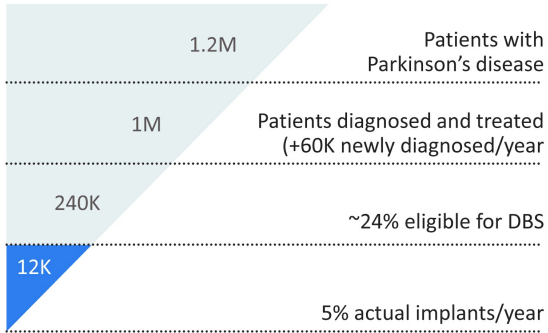
Boston
Scientific

Medtronic

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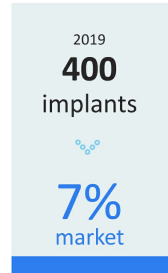
NEUROPACE

Parkinson's Patient Population (US)



Current addressable U.S. market

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



Growing 10%

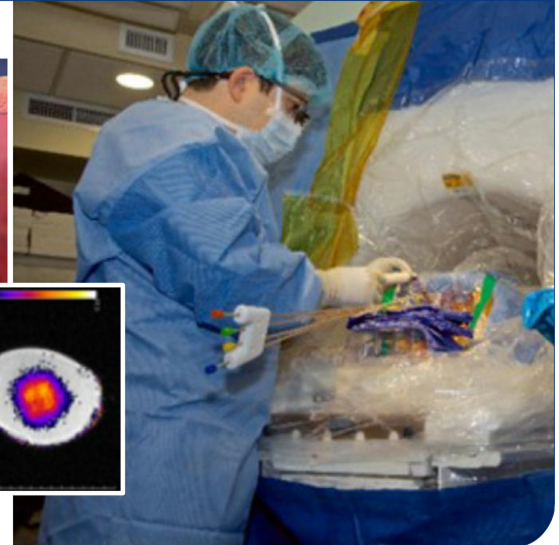
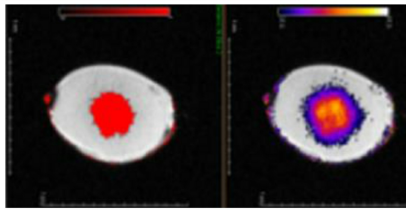
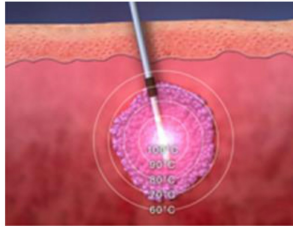
2. Therapy

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.

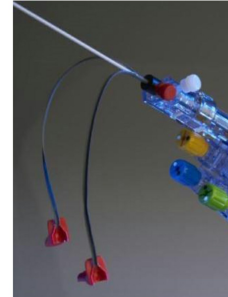
INFLEXION™ Head Fixation Frame



TRANBERG® Laser



ClearPoint® Compatibility Kits

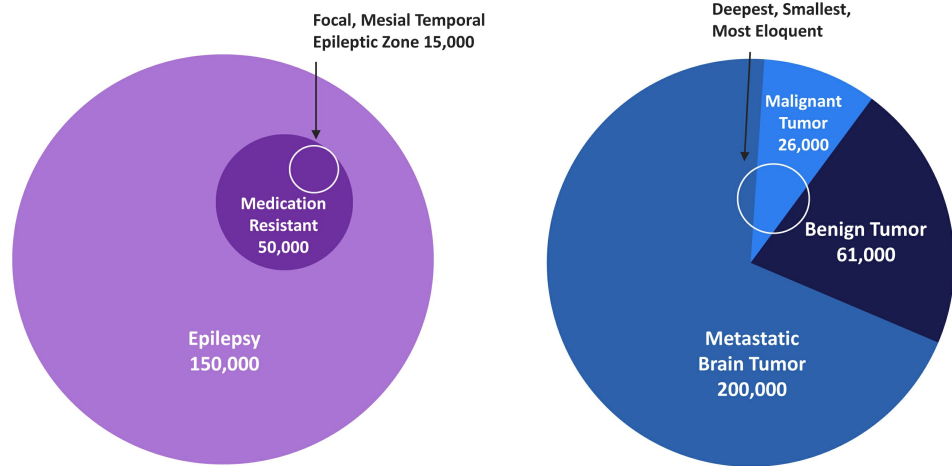


2. Therapy

ClearPoint Neuro Laser Therapy

Significant Addressable Neuro Market in Epilepsy and Tumor

- Initial beachhead market -> focal, MTL 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.

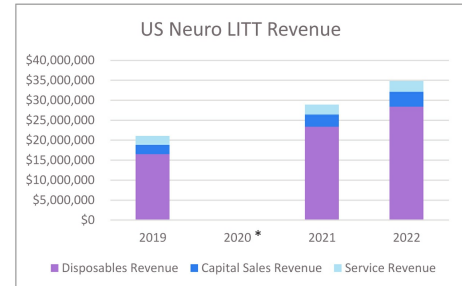
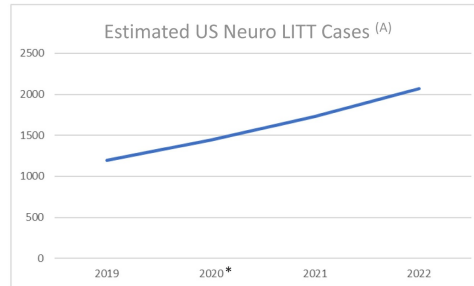


2. Therapy

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

3. Biologics & Drug Delivery




Pediatric Indications

	Disorder	Description	Non-Clinical	Phase I/II Trial	Pivotal Trial	Commercial
	AADC Deficiency	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. ¹	[Progress bar spanning all stages]			
	Diffuse Intrinsic Pontine Glioma (DIPG)	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. ²	[Progress bar spanning Non-Clinical and Phase I/II]			
	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 difficulty in walking due to impaired ability to coordinate voluntary movements. ³	[Progress bar spanning Non-Clinical and Phase I/II]			
	Angelman Syndrome	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. ⁴	[Progress bar spanning Non-Clinical and Phase I/II]			

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 1/100,000 births. The primary disease characteristic is CNS degeneration which results in hyperactivity and mental retardation. ¹	█	█		
	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. ²	█	█		
	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. ³	█	█		

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

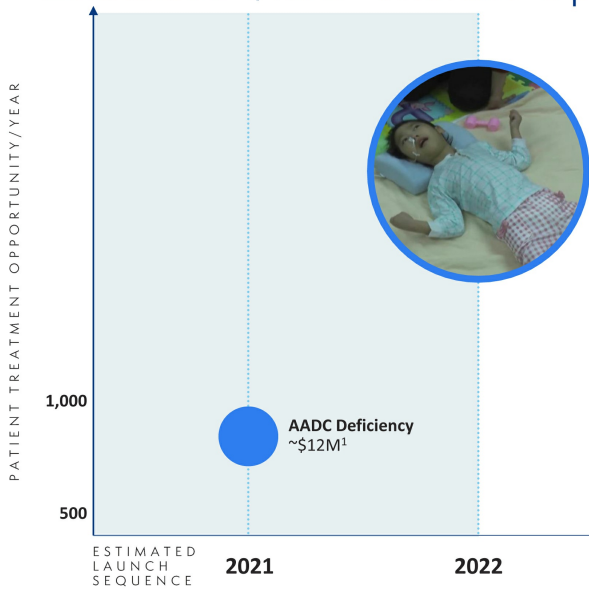
Adult Indications

	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. ^{1,2}	████████████████████	████████████████████		
	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. ³	████████████████████	████████████████████		
	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. ⁴	████████████████████	████████████████████		
	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. ⁵	████████████████████	████████████████████		

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



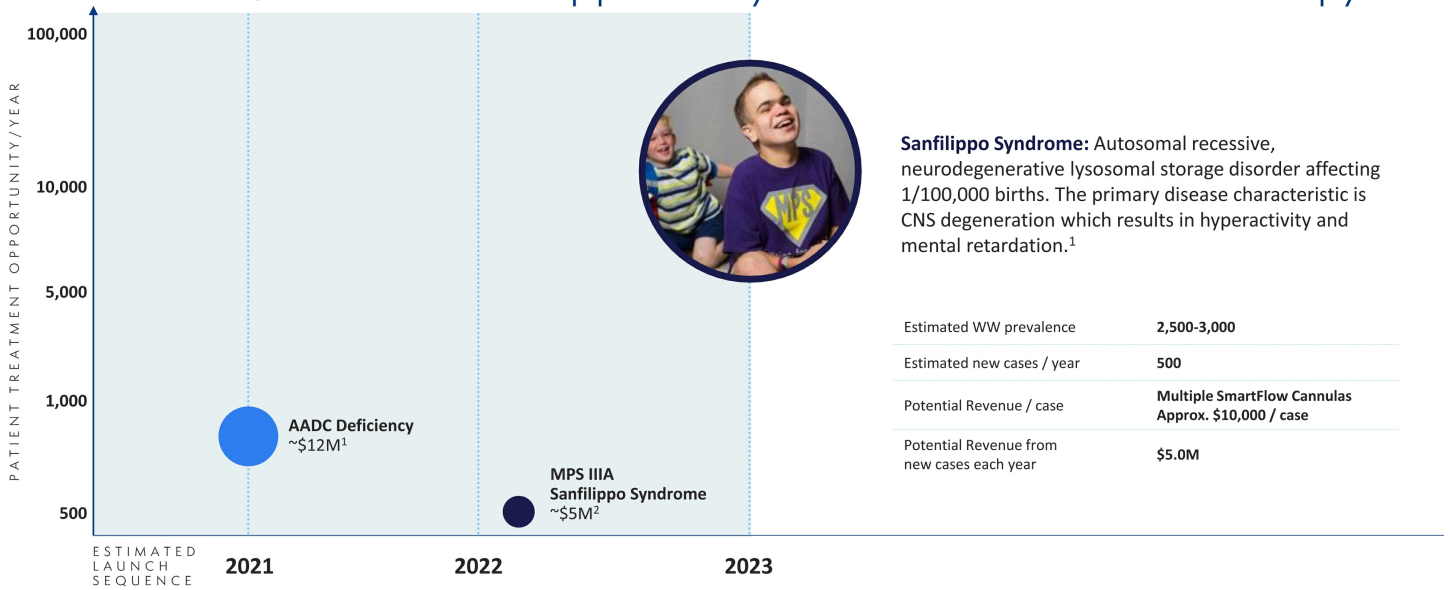
AADC Deficiency syndrome: Rare autosomal recessive disorder caused by mutations in the DDC gene leading to significant deficiencies in dopamine and other neurotransmitters. This causes severe motor dysfunction in infants and children.²

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

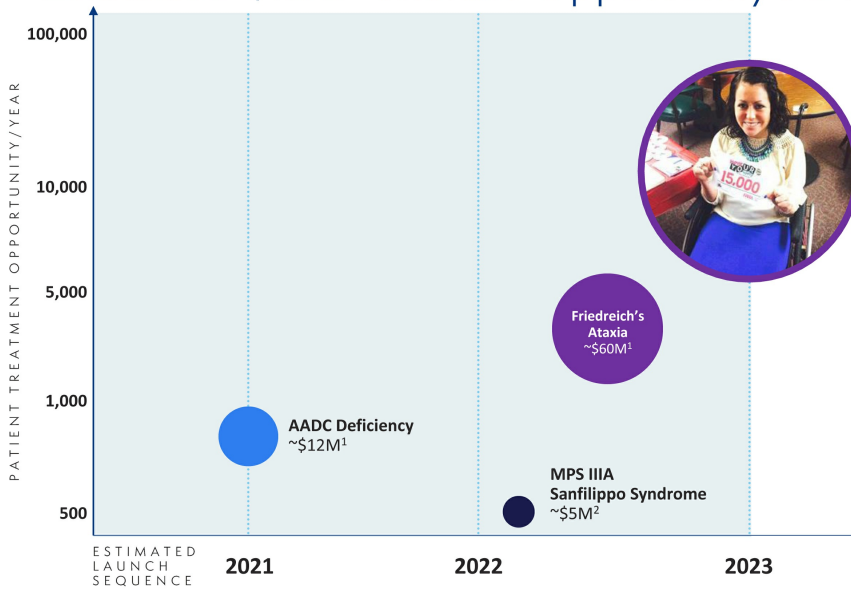


Sanfilippo Syndrome: Autosomal recessive, neurodegenerative lysosomal storage disorder affecting 1/100,000 births. The primary disease characteristic is CNS degeneration which results in hyperactivity and mental retardation.¹

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

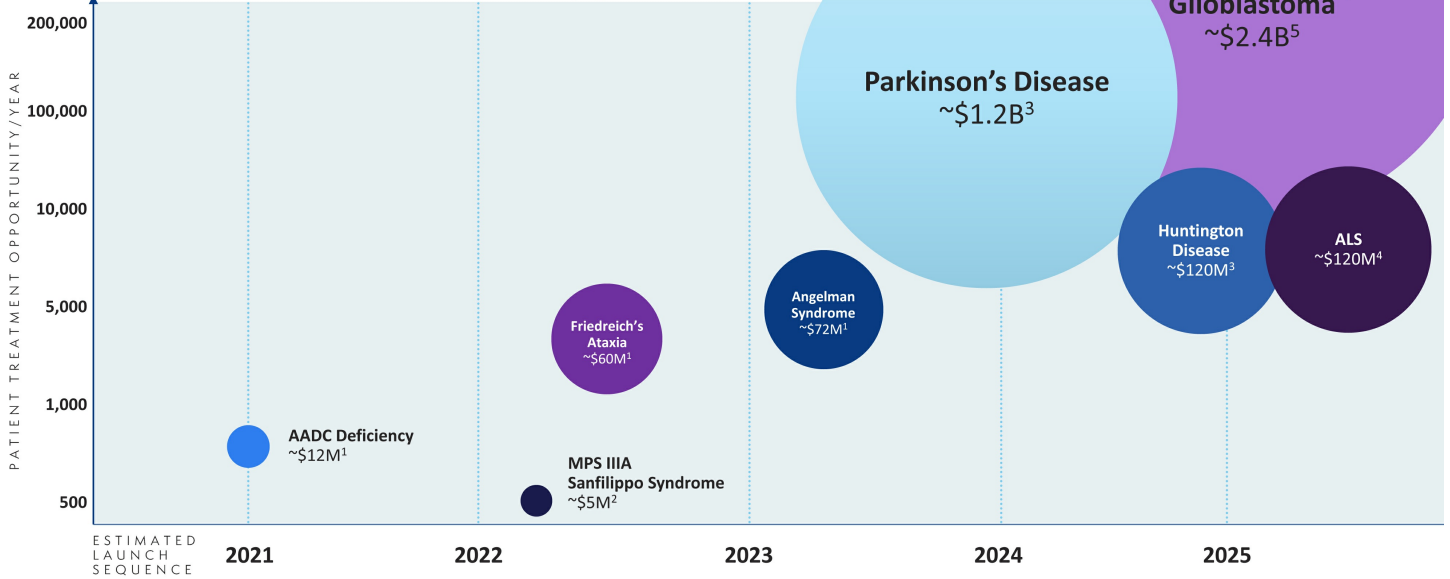


Friedreich's Ataxia: A genetic, progressive, neurodegenerative movement disorder, with a typical age of onset between 10 and 15 years with a prevalence of 1/40,000 people. Initial symptoms may include unsteady posture, frequent falling, and progressive difficulty in walking due to impaired ability to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

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. Nat Commun. 2016;7:12408. 5. <https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Glioblastoma-Multiforme>

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

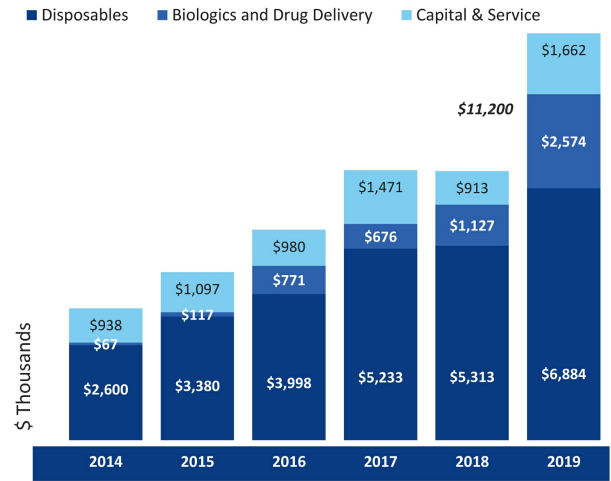
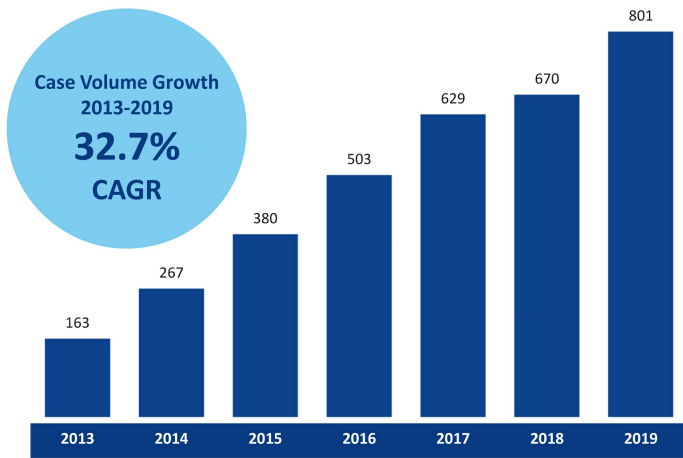
- Expecting to perform cases in Europe in 2021



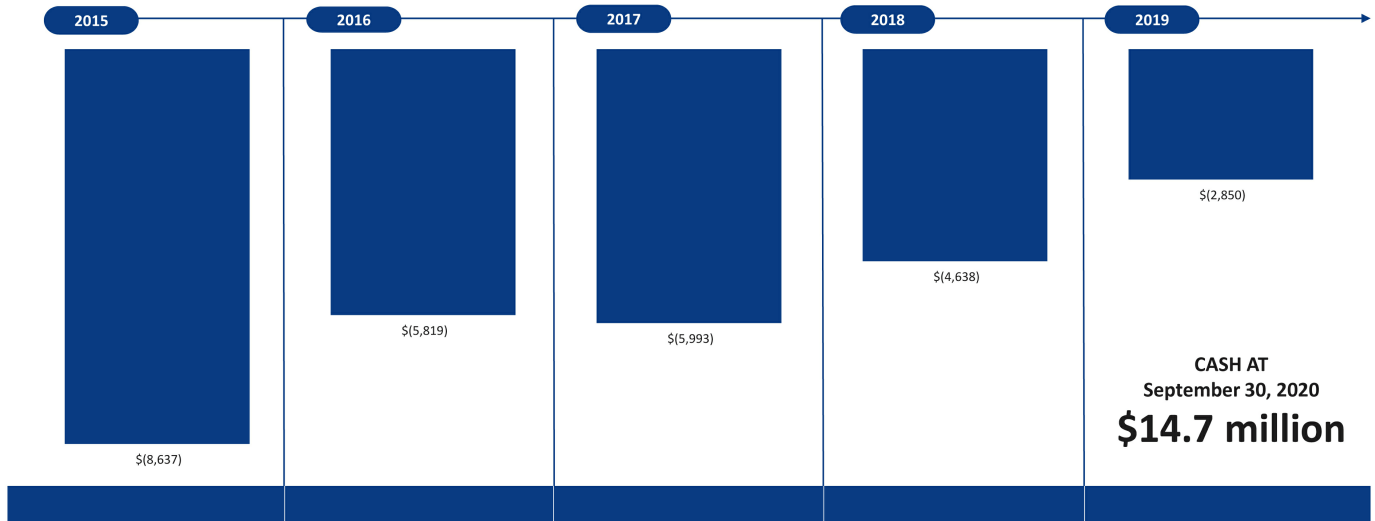
Financials

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

