

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported):
May 20, 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 7.01. Regulation FD Disclosure.

On May 20, 2020, ClearPoint Neuro, Inc. 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 99.1. The Company may use the investor presentation from time to time in conversations with analysts, investors and others.

The information in Item 7.01 of this Form 8-K, as well as Exhibit 99.1 attached hereto, shall not be deemed “filed” for purposes of Section 18 of the 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, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith:

Exhibit 99.1 [Investor Presentation dated May 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: May 20, 2020

CLEARPOINT NEURO, INC.

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



CLEARPOINT[®]
NEURO

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

May 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 March 31, 2020, both of which have been filed with the Securities and Exchange Commission.

Severe Neurological Disorders Impact Millions of Patients and Families Each Year



Epilepsy



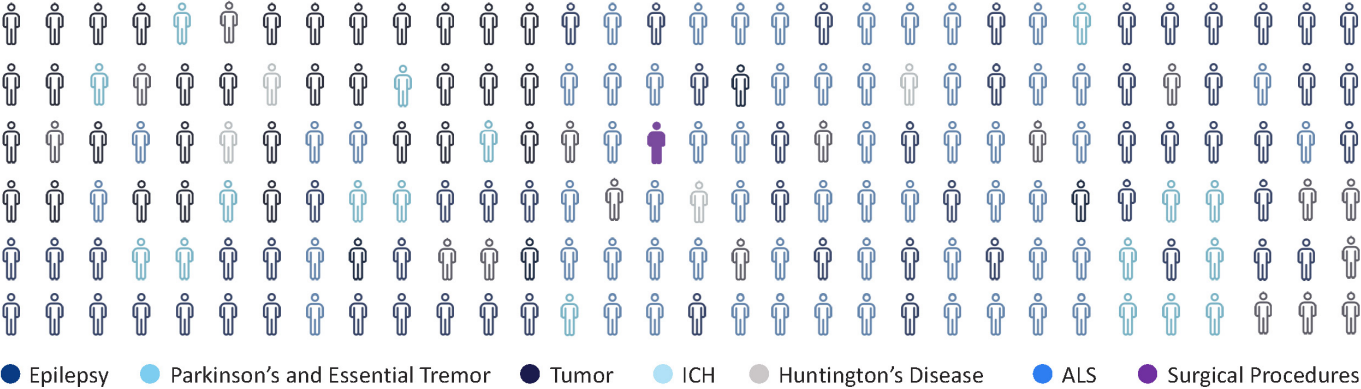
Parkinson's Disease



AADC Deficiency

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

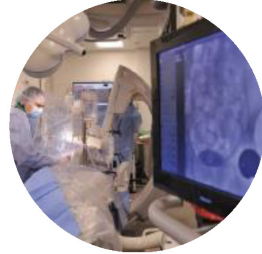
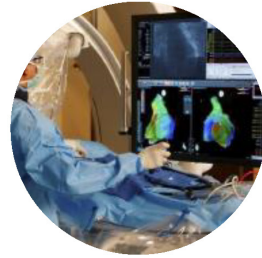
Prevalence of Neurological Disorders



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'

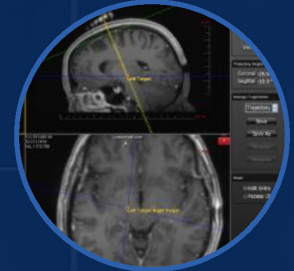
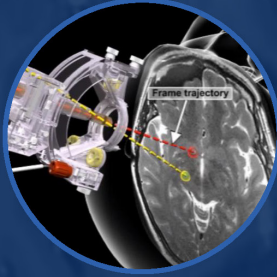
- X-Ray and CT do not show structures of the brain
- Large, Metallic Navigation Frames are not compatible inside an MRI Magnet
- Surgical Image Guidance in the Operating Room is not live but rather 'Co-Registered' to the MRI
- Each Co-Registration calculation introduces error and reduces accuracy



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

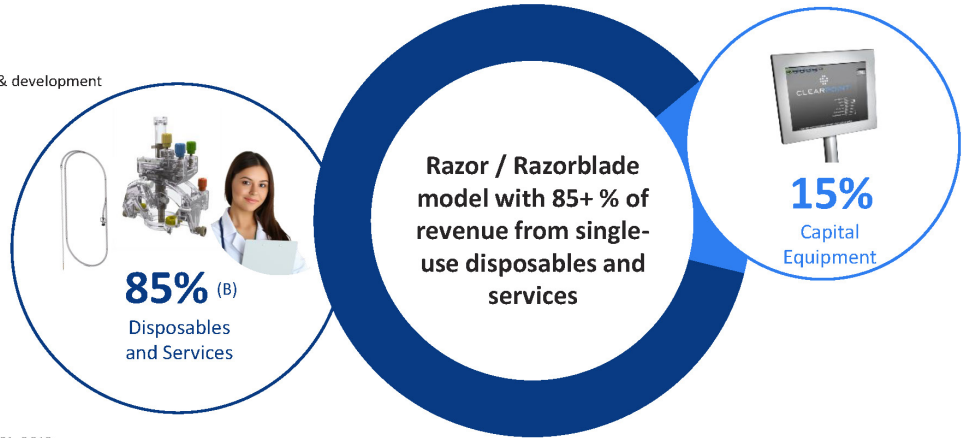
2019 REVENUE*
\$11.2m

CASH
\$17.0m^(A)

MARKET CAP
\$55m^(A)

GROSS MARGIN
66%^(B)

U.S. PATENTS ISSUED
79
+29 pending

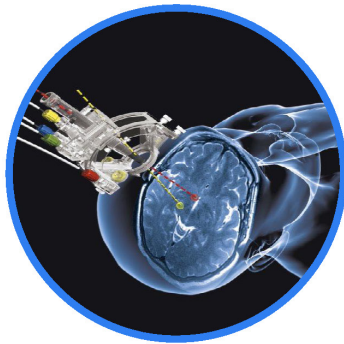


(A) As of March 31, 2020 (B) For the year ended December 31, 2019



*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 focus in Neurosurgery and unparalleled clinical support →



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

ClearPoint® is Installed in 60 Active Clinical Sites at Top US Hospitals and Growing

Strong Commercial Support Team is Already in Place

UC San Francisco
San Francisco VA
Stanford Univ
Lucile Packard (Stanford Children's)
UCSF Benioff Childrens
USC
UC San Diego
Univ of Colo
Univ of Utah
Univ of Arizona
Cook Children's
MD Anderson
Methodist Hosp

Texas-Children's Hosp
Riverside
Henry Ford Health System
Nationwide Children's
Children's Mercy
Kansas Univ Med Center
Univ of Wisconsin
Spectrum Health
Ohio State Univ
Cincinnati Children's
Dallas Presby
Univ of Cincinnati
University of Wisconsin

Cincinnati Jewish
Univ of Michigan
Univ of Minnesota Med Ctr
Brigham & Women's
Boston Children's
Mass General
Mt Sinai West
Yale Univ
Univ of Pitt Med Center
Memorial Sloan Kettering
Hackensack Univ Med Center
Cornell
Central Du Page

Nat. Institutes of Health
Nat Children's Hospital
Children's Hosp of Philadelphia
Univ of Virginia
Emory University
Carilion
Duke University
Children's of Alabama
CHOA Scottish Rite
Willis Knighton
Mayo Clinic Jacksonville
Mayo Phoenix
Dartmouth Hitchcock

University of Pennsylvania HUP
INOVA Fairfax
Le Bonheur
Johns Hopkins
Tampa General
Cleveland Clinic
Beth Israel Deaconess



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
STEMCELL
CORPORATION

CLPT PLATFORM RUNS ON ALL MAJOR SCANNERS

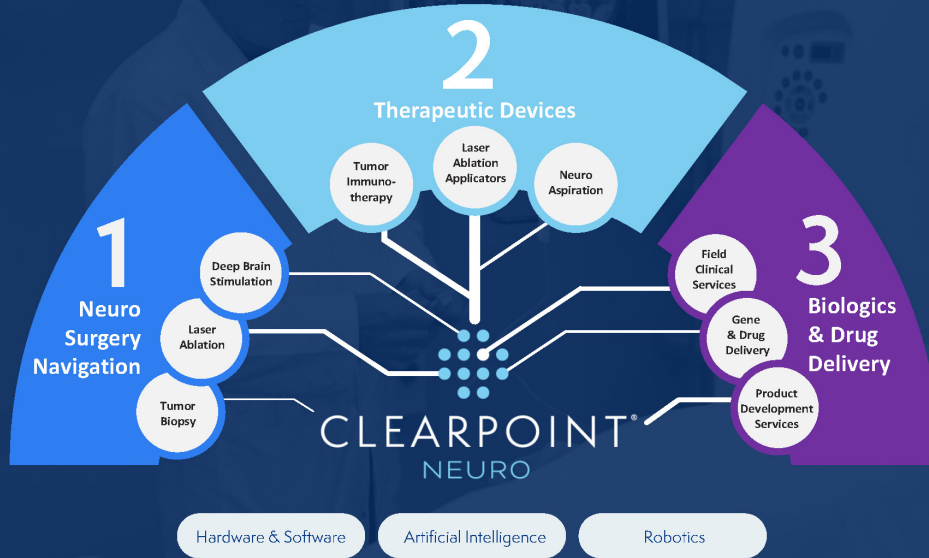
SIEMENS



PHILIPS

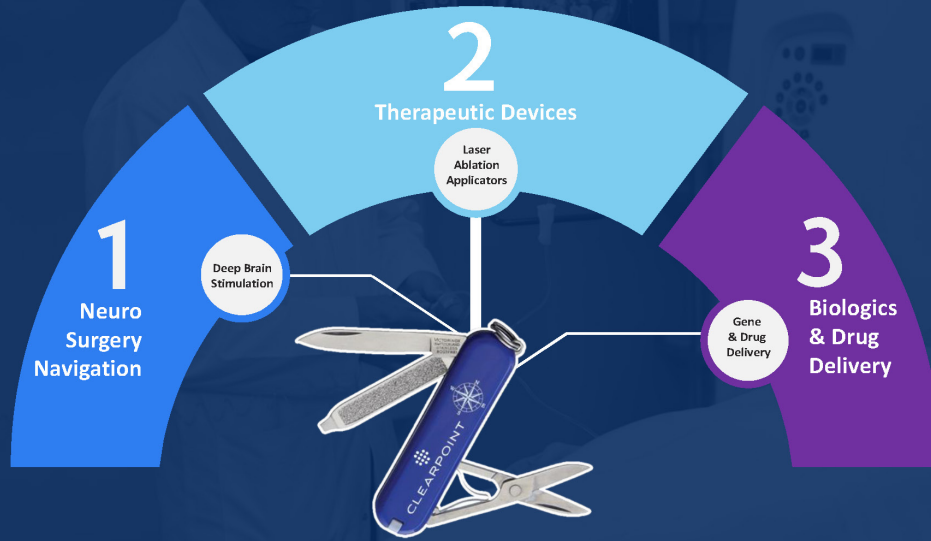
IMRIS 

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

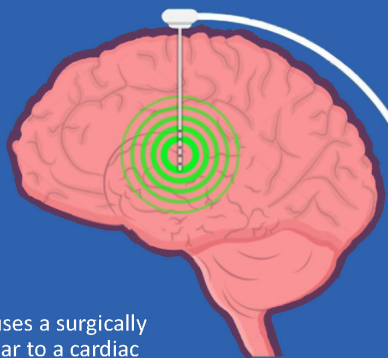
Target Indications of > 150,000 procedures per year represents
Potential Addressable Market for CLPT of \$1B+

2020

2025

Market Opportunity

1. Neuro Navigation 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

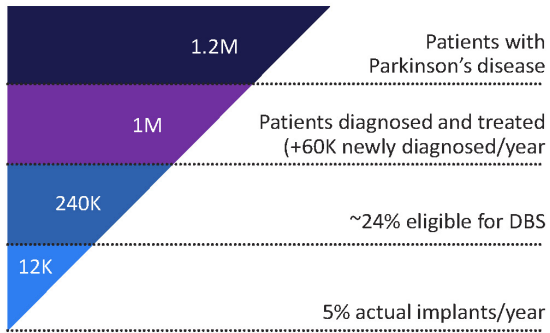
Boston
Scientific

Medtronic

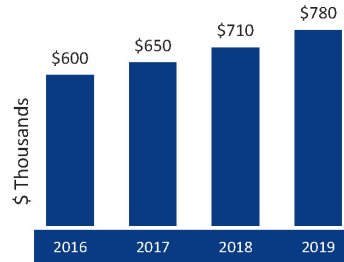
Abbott

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

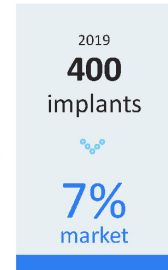
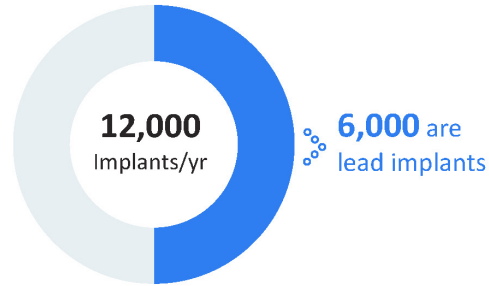
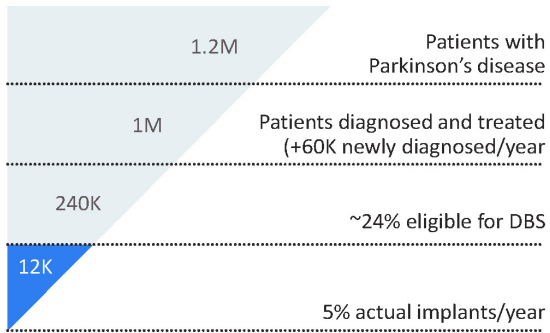
Boston
Scientific

Medtronic

Abbott

NEUROPACE

Parkinson's Patient Population (US)



Current addressable U.S. market

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

Growing 10%

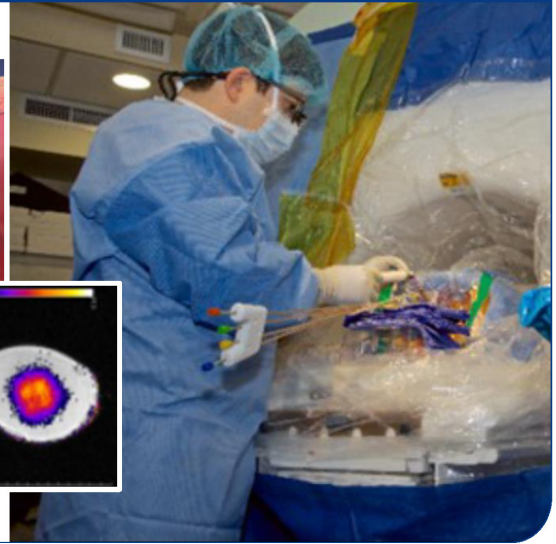
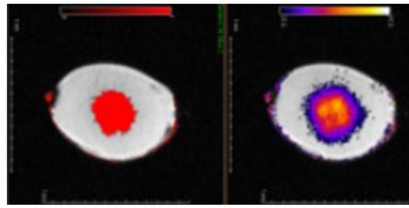
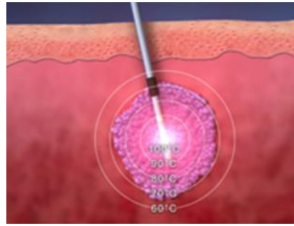
2. Therapy

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.

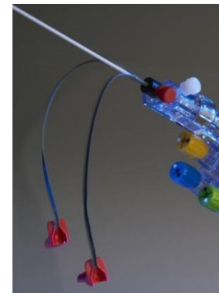
INFLEXION™ Head Fixation Frame



TRANBERG® Laser



ClearPoint® Compatibility Kits

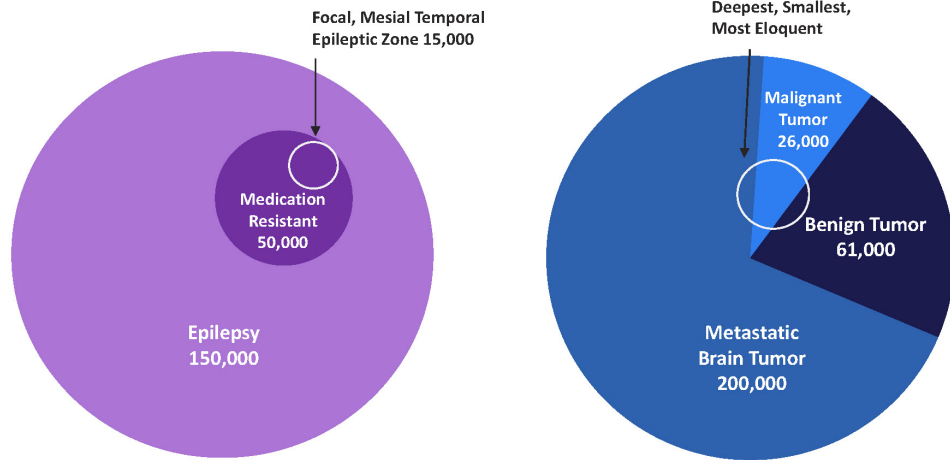


2. Therapy

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.

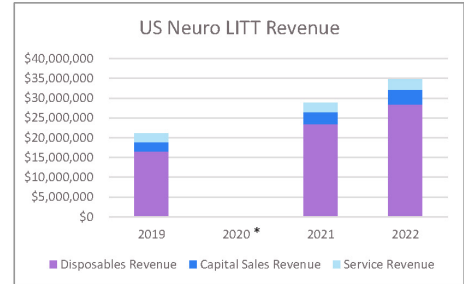
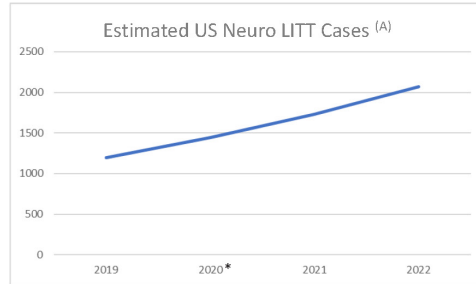


2. Therapy

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

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 Trial]			
	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 Trial]			
	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 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


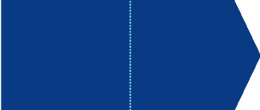






Pediatric Indications

	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. 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

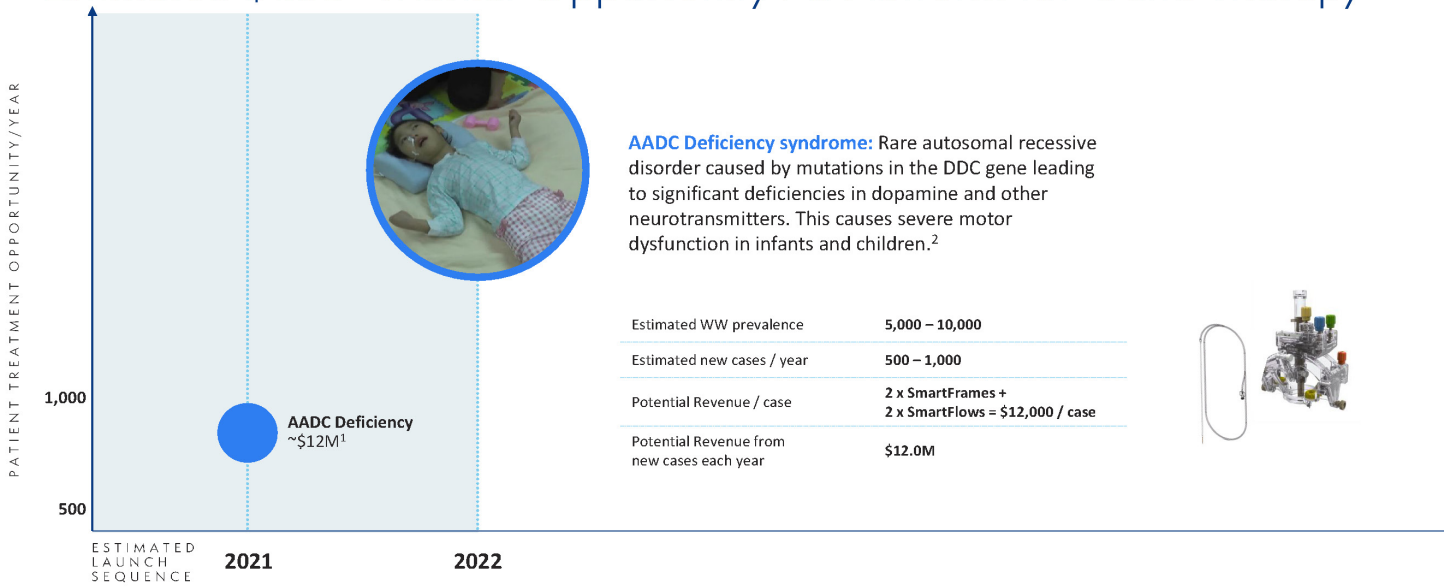
Adult Indications

	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

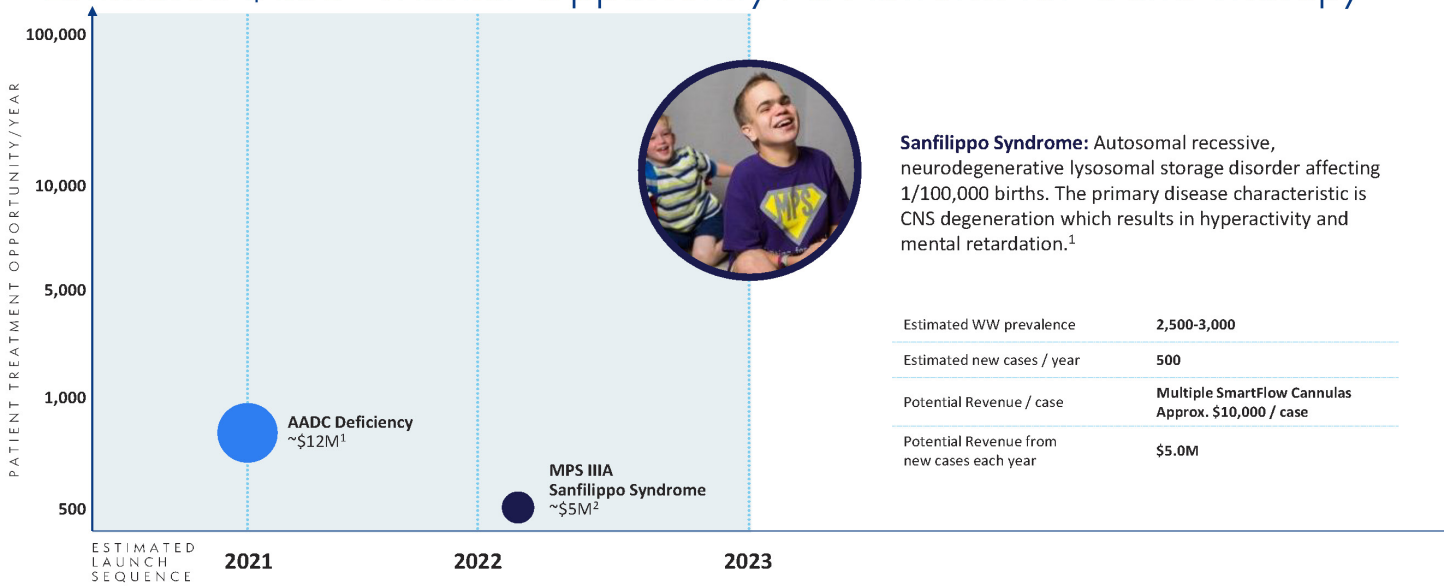
3. Biologics & Drug Delivery

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



3. Biologics & Drug Delivery

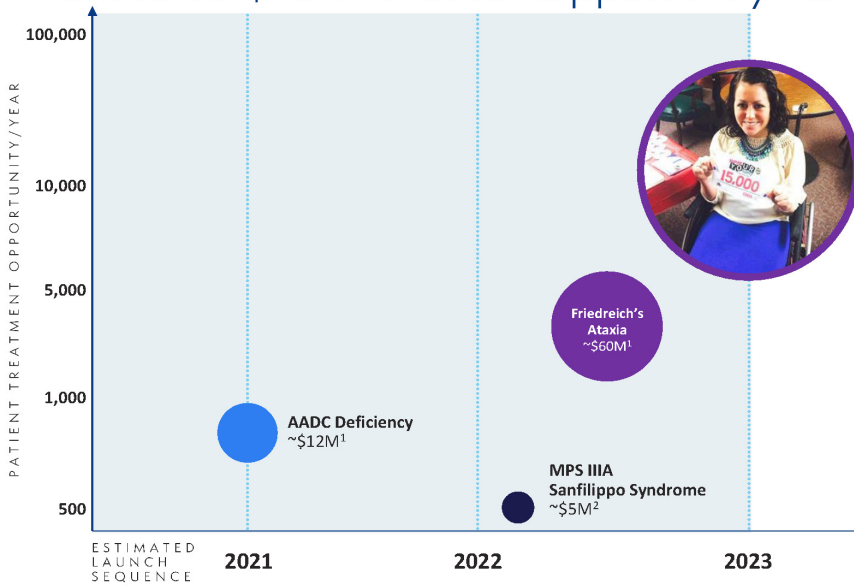
Estimated \$1.5B* Market Opportunity As Platform for Gene Therapy



1. Fedele AO. Sanfilippo syndrome: causes, consequences, and treatments. Appl Clin Genet. 2015;8:269-281. 2. Lysogene Corporate Presentation at 38th Annual J.P. Morgan Healthcare Conference on Jan 13, 2020
* Addressable market based on potential case volume.

3. Biologics & Drug Delivery

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



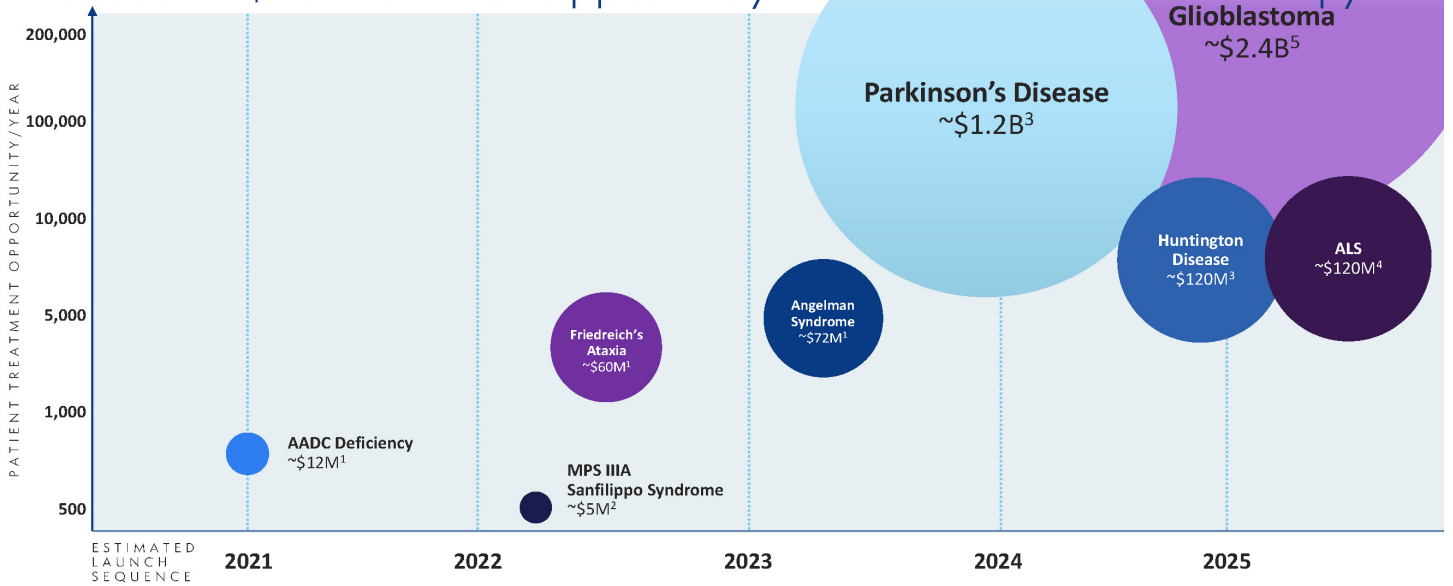
Friedreich's Ataxia: A genetic, progressive, neurodegenerative movement disorder, with a typical age of onset between 10 and 15 years with a prevalence of 1/40,000 people. Initial symptoms may include unsteady posture, frequent falling, and progressive difficulty in walking due to impaired ability to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

¹ <https://rarediseases.org/rare-diseases/friedreichs-ataxia> 2. Lysogene Corporate Presentation at 38th Annual J.P. Morgan Healthcare Conference on Jan 13, 2020
^{*} Addressable market based on potential case volume.

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/356160b-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>.
* Addressable market based on potential case volume.

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

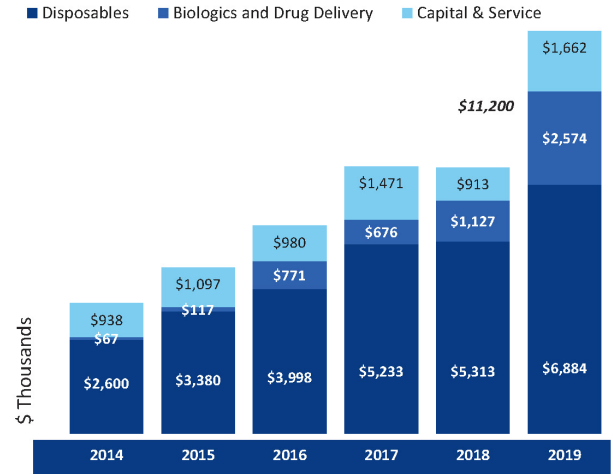
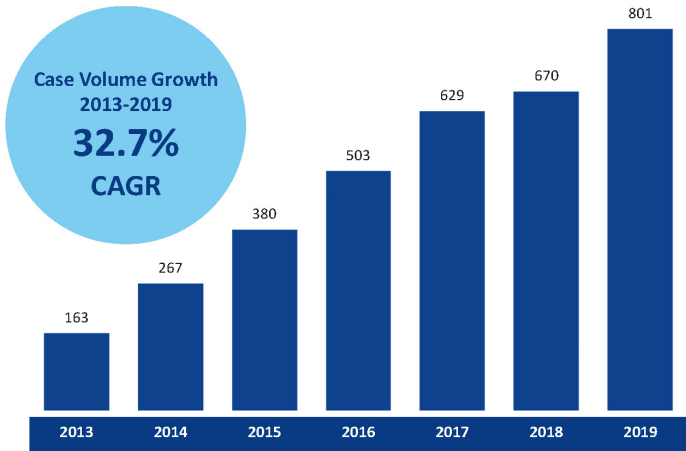
- Expecting to perform cases in Europe in 2020



Financials

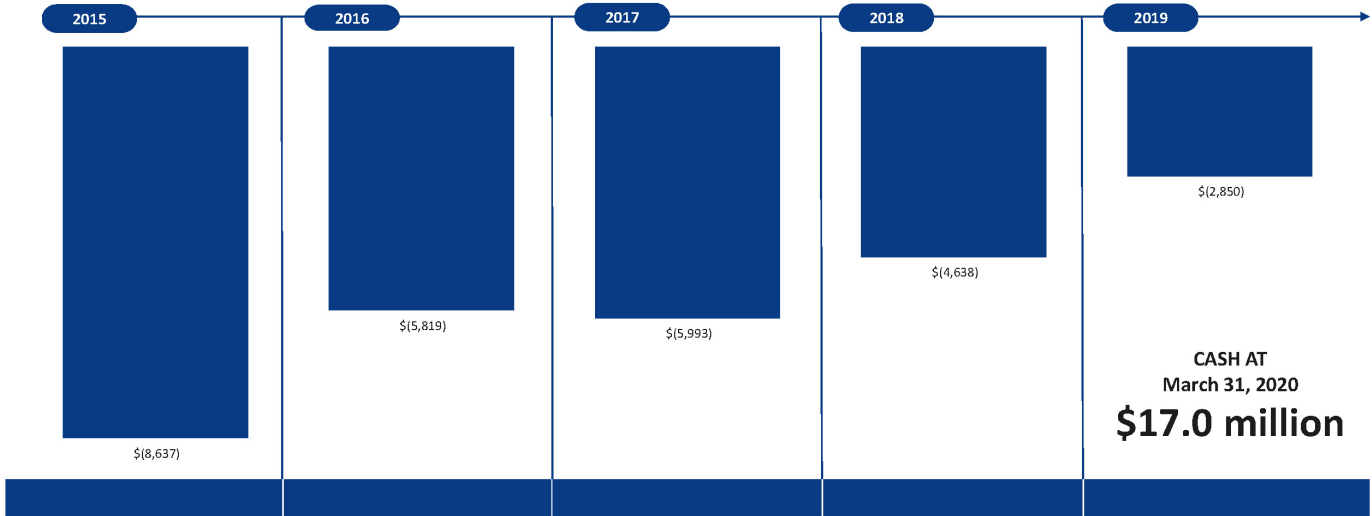
2013 - 2019

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

