### 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): February 14, 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)

D Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

D 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  $\Box$ 

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 February 14, 2020, ClearPoint Neuro, Inc. (formerly MRI Interventions, Inc.) (the "Company") issued a press release announcing its revenue outlook for 2020. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On February 14, 2020, the Company also posted an updated investor presentation to its website at http://ir.stockpr.com/mriinterventions/investor-presentations. A copy of the investor presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K. 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 Current Report on Form 8-K, as well as Exhibits 99.1 and 99.2 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 they 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.

Exhibit No.	Description
99.1	Press Release, dated February 14, 2020
99.2	Investor Presentation, dated February 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: February 14, 2020

### MRI INTERVENTIONS, INC.

By: /s/ Harold A. Hurwitz

Harold A. Hurwitz Chief Financial Officer



### For Immediate Release

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### ClearPoint Neuro, Inc. Announces 2020 Revenue Outlook Ahead of Nasdaq Investor Presentation Today

### New U.S. and European Partnership Agreement with PTC Therapeutics Highlights Growth of ClearPoint<sup>®</sup> Gene Therapy Portfolio

**IRVINE, CA, February 14, 2020** – ClearPoint Neuro, Inc. (Nasdaq: CLPT) (the "Company"), a leading platform neurosurgery company, today announced a strategic agreement with PTC Therapeutics, Inc. ("PTC"). The scope of the agreement includes hardware, software, clinical case and market development services for gene therapy cases in the United States and Europe to support PTC's potential commercialization in gene therapy globally upon regulatory approval. In addition to the announcement of this agreement, ClearPoint Neuro today announces the following 2020 Outlook for the company's performance:

- 2020 Revenue expected between \$14.0-\$15.0M, representing growth of approximately 25-35%;
- 2020 Revenue from Biologics & Drug Delivery Products and Partnerships of approximately \$5.0M;
- 2020 Case Volume covered by Clinical Specialists between 900 and 950 cases, representing growth of approximately 15%; and
- 2020 Cash Burn from Operations (not including interest payments) from \$3.0M-\$3.5M

"We have put a tremendous amount of thought and effort into redefining our Company over the past two years," commented Joe Burnett, President and CEO of ClearPoint Neuro, Inc. "This has included the vision, the team, the partnerships, and even the name of our company which officially changed this week to ClearPoint Neuro from MRI Interventions. We are thrilled by the evolution our Company has already undergone and believe we have only scratched the surface of the significant potential ahead."

"We have evolved to become two companies in one", continued Burnett. "On one side, we are a platform medical device company, consistently delivering double digit growth, and continuing to expand our installed base of neurosurgery centers in the U.S. Every year more surgeons and more patients gain access to the ClearPoint system and compatible disposable devices. On the other side of the business, we are a gene therapy and biologics enabling company, providing navigation, drug delivery, and case support to more than 20 companies in this exciting and growing space. Here we currently support pre-clinical and clinical efforts, but we believe that we are on the precipice of potentially explosive growth as these therapies progress through the regulatory process toward commercial launch. We feel that our company represents both scale and purpose through a unique combination of predictable device growth and a potential biologics opportunity, all supported under a common team dedicated to treating the most debilitating neurological disorders.

ClearPoint Neuro's revenue outlook for 2020 includes an expectation that approximately 33% of total revenue will be derived from biologics and drug delivery products and services, up from approximately 20% in 2019, and reflecting the growth of this part of the business.

"When planning for the development and potential commercialization of gene therapy globally, safety, consistency and predictability are crucial constructs that all must be included," commented Marcio Souza, Chief Operating Officer of PTC Therapeutics and ClearPoint Neuro Board Member. "Our agreement with ClearPoint Neuro is designed to provide standardization across all of our centers of excellence as we can maintain consistency in navigation, delivery and clinical support. The more variables we can control, the more successful we believe the outcomes for patients will be."

"As part of our Company's duality in devices and biologics, we are thrilled to deepen our partnership with PTC," commented Jacqueline Keller, Vice President and Program Manager at ClearPoint Neuro for the PTC Partnership. "This new agreement with PTC highlights a 'turn-key' solution for our gene therapy partners, whereby our commercial organization, with deep relationships in the neurosurgery community, can take on the burden of sales and clinical activities in the surgical suite, and allow our partners who are commonly small-molecule focused companies to continue to prioritize their efforts with neurologists, patients and reimbursement administrators. With the capacity to support thousands of cases each year, our team plans to provide this service across multiple companies and indications in neuro."

### About the Company

The Company'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 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.

### Note on Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 regarding the planned offering. Additionally, all statements relating to any closing(s) of, and the amount or use of any proceeds from, the transactions described in this press release are considered to be forward-looking statements. Other forward-looking statements may be identified by the words "guidance", "plan," "anticipate," "believe," "estimate," "expect," "intend," "may," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. Forward-looking statements are subject to risks and uncertainties, and the Company's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of such risks and uncertainties, which include, without limitation, risks and uncertainties associated with market conditions and the satisfaction of closing conditions related to the transactions described in this press release. There can be no assurance that the parties will be able to complete the transactions described in this press release on the terms described herein or in a

timely manner, if at all. 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, 2018, and the Company's Quarterly Reports on Form 10-Q for the periods ended March 31, 2019, June 30, 2019 and September 30, 2019, all of which have been filed with the SEC, as well as the Company's Annual Report on Form 10-K for the year ended December 31, 2019, which the Company intends to file with the Securities and Exchange Commission on or before March 30, 2020. You are urged to carefully consider all such factors. Copies of these and other documents are available from the Company. The forward-looking statements contained herein represent the Company's views only as of the date of this press release the Company does not undertake or plan to update or revise any such forward-looking statements to reflect actual results or changes in plans, prospects, assumptions, estimates or projections, or other circumstances occurring after the date of this press release except as required by law.

### For More Information

ClearPoint Neuro, Inc. Matt Kreps Darrow Associates Investor Relations (214) 597-8200 mkreps@darrowir.com



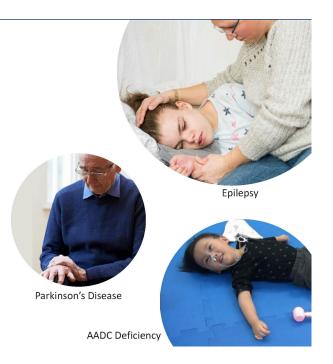
# WHEN YOUR PATH IS UNCLEAR, WE POINT THE WAY.

February 14, 2020 NASDAQ MarketSite, New York City

### 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<sup>®</sup> 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; 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, 2018, and the Company is quarterly Report on Form 10-Q for the three months ended September 30, 2019, both of which have been filed with the Securities and Exchange Commission, and the Company's Annual Report on Form 10-K for the year ended December 31, 2019, which the Company intends to file with the Securities and Exchange Commission on or before March 30, 2020.

Severe Neurological Disorders Impact Millions of Patients and Families Each Year



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

### **Prevalence of Neurological Disorders** Ŷ Ŷ ĥ Ŷ Ŷ ň Ŷ ĥ Ŷ Ŷ Ŷ Å Å Å ñ ň Ř ñ ň ñ Ŷ ň ň Ŷ Ň ň Ŷ Ŷ Ŷ ĥ Ŷ ĥ Ŷ Å Ŷ Ŷ Ŷ ĥ Ŷ Å ņ ņ Ŷ Ŷ ņ Ŷ Ŷ Å Ŷ ĥ Ŷ Ŷ Å Ŷ Ŷ Å ĥ Å Ŷ Ŷ Ŷ Å Ŷ Ŷ Ŷ Ŷ Ř ñ Ŷ ĥ ĥ ĥ Ŷ ពុំ ĥ ĥ Ŷ Ŷ ĥ Ŷ ĥ ĥ ĥ Ŷ ĥ ĥ Ŷ Ŷ Ŷ Å Ŷ Å Ŷ Ň Ŷ ň Ň ň ň Å Å Ŷ Ŷ ň Å ñ ñ

Epilepsy Parkinson's and Essential Tremor Tumor ICH Huntington's Disease

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Surgical Procedures

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ALS

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

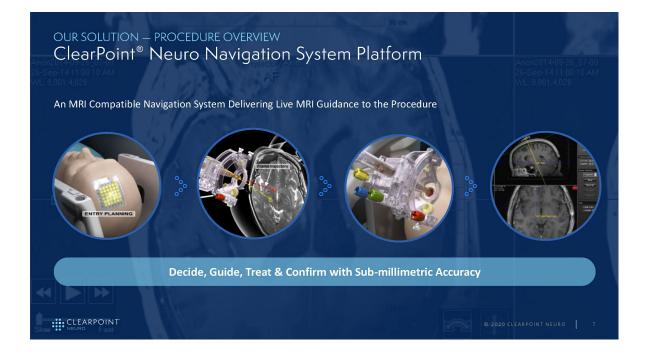
### PRIMARY CHALLENGE

The Skull is not 'See Through'

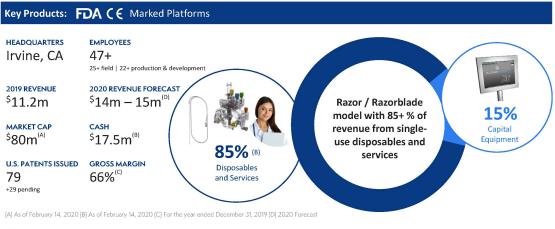
- X-Ray and CT do not show structures of the brain
- Large, Metallic Navigation Frames are not compatible inside an MRI Magnet
- Surgical Image Guidance in the Operating Room is not live but rather 'Co-Registered' to the MRI
- Each Co-Registration calculation introduces error and reduces accuracy

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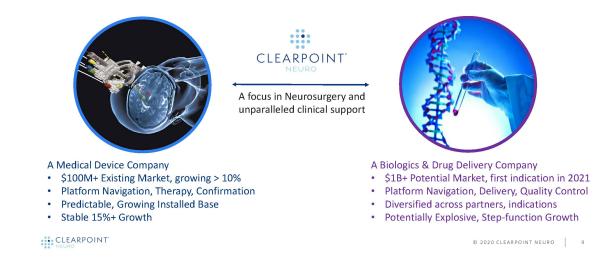




### OUR COMPANY ClearPoint Neuro: A Proven Platform

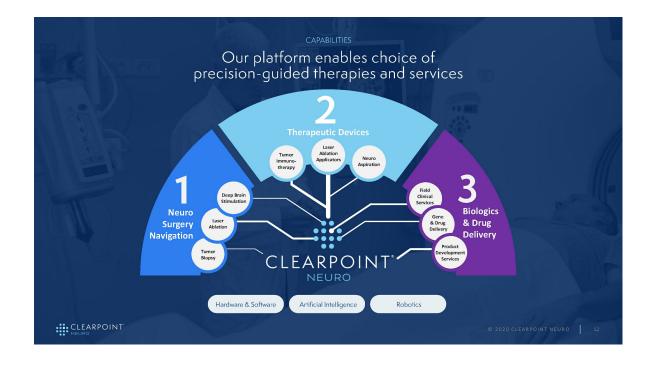


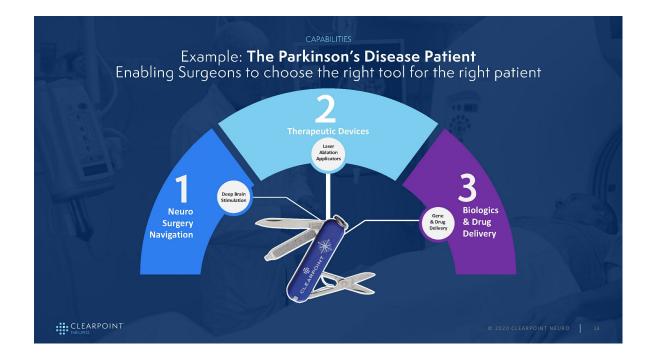
### Our Company ClearPoint Neuro: Two Companies in One









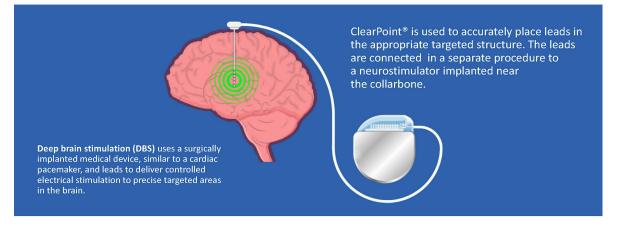


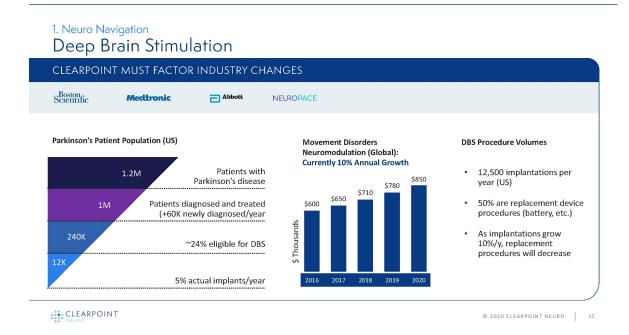


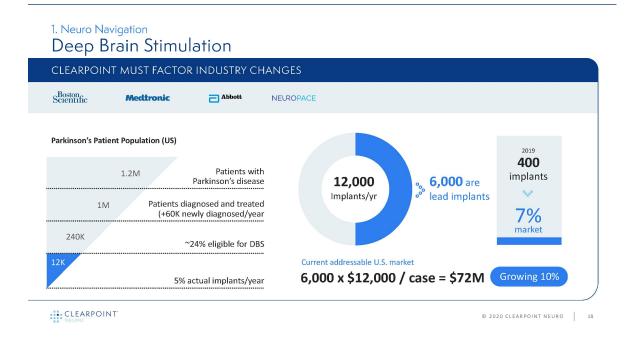


- CIFARF

### 1. Neuro Navigation Deep Brain Stimulation









LITT uses laser energy to destroy unwanted cells

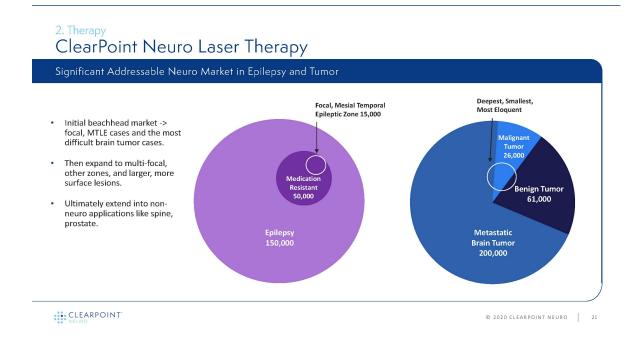
### Laser Interstitial Thermal Therapy

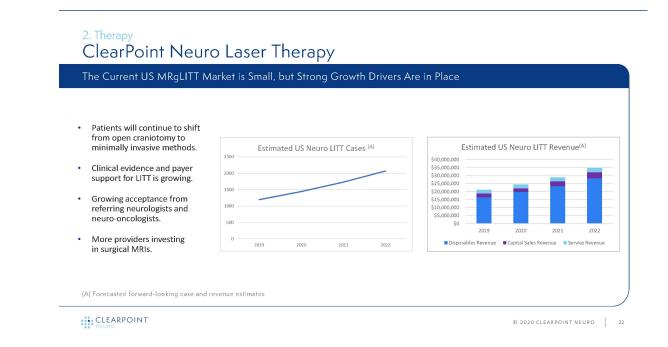
(LITT) is a minimally invasive surgical technique. A laser fiber is inserted through a tiny hole in the skull and then the laser applies energy to the targeted lesion, killing unwanted cells.

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.









### 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. <sup>1</sup>				
	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. <sup>2</sup>				
	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 positure, frequent falling, and difficulty in walking due to impaired ability to coordinate voluntary movements. <sup>3</sup>				
	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. <sup>4</sup>				
References: 1. Brun L, et a	I. Neurology. 2010;75:64-71. 2. Dar	na Farber http://www.danafarberbostonchildrens.org/conditions/brain-tumor/diffuse-pont	ine-glioma.aspx			

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

### 3. Biologics & Drug Delivery Pediatric Indications

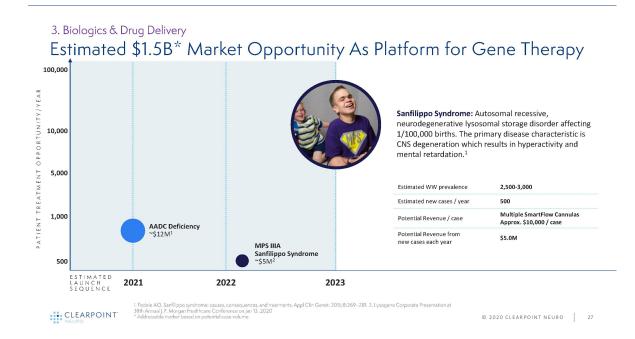
_	Disorder	Description	Non-Clinical	Phase I/II Trial	Pivotal Trial	Commercial
	Sanfilippo A (MPS IIIA)	Autosomal recessive, neurodegenerative lysosomal storage disorder affecting 1/1000,00 births. The primary disease characteristic is CNS degeneration which results in hyperactivity and mental retardation. <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>				

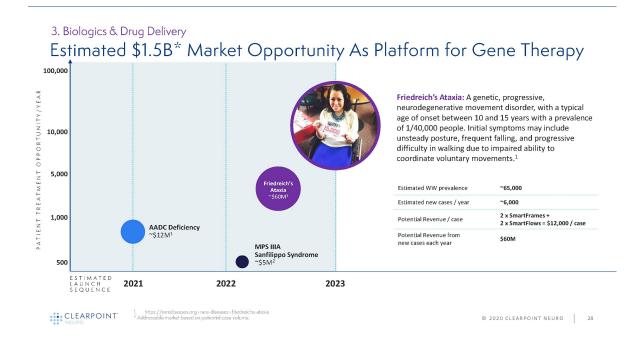
References: 1. Fedele AO. Sanfilippo syndrome: causes, consequences, and treatments. Appl Clin Genet. 2015;8:269–281. 2. Boston Children's Hospital http://www.childrenshospital.org/conditions and-treatments/conditions/g/gm2-gangliosidosis 3. https://giv.nlm.nih.gov/condition/gm1-gangliosidosis

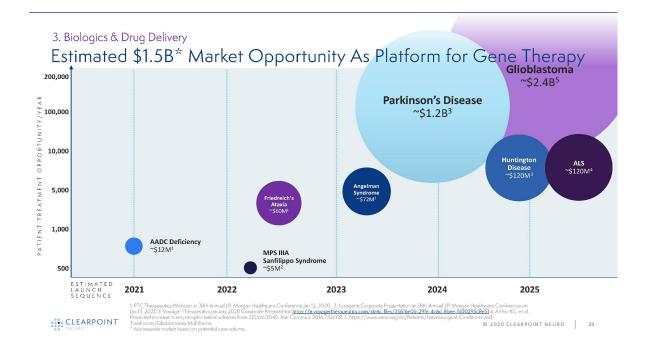
### 3. Biologics & Drug Delivery Adult Indications

	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>				
100	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 causes/syc-20376055 4.	https://www.mayoclinic.org/disea Mayo Clinic <u>https://www.mayoclin</u>	ses-conditions/glioblastama/cdc-203501482, Xu H, et al. Front Aging Neurosci. 2017;9:35 ic.org/diseases-conditions/humingtons-disease/symptoms-causes/syc-20356117_5, Arthur	i2 3. Mayo Clinic https:// r KC, et al. Projected incre	www.mayoclinic.org/disea ase in amyotrophic lateral	ses-conditions/parkinson sclerosis from 2015 to 204	-disease/symptoms- 0
	NT.			0	2020 CLEARPOINT	EURO 25









### 4. Global Scale Achieve Global Scale and Progress Toward Profitability

Established Sales Channel capable of distributing other surgical products

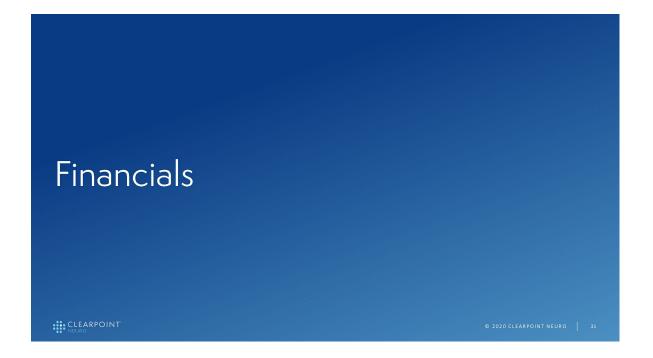
 Current Revenue for non-neuro CLS Laser Applicators

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

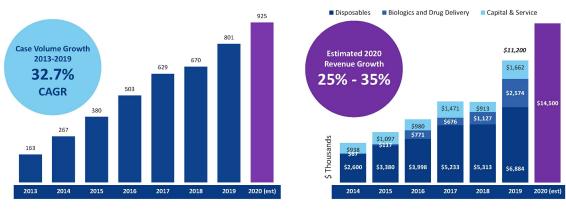
## CE Mark labeling for targeted global expansion when time is right

• Expecting to perform cases in Europe in 2020





### 2013 - 2020 Growth in Case Volume and Revenue



2020 Revenue Forecast Range of \$14.0 - \$15.0 M as of February, 2020

