# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

**CURRENT REPORT** 

Washington, D.C. 20549

Pu	irsuant to Section	13 OR 15(d) of the Securities E	Exchange Act of 1934		
	Date of 1	Report (Date of earliest event re November 8, 2022	eported):		
C		POINT NEU	,		
Delaware (State or other jurisdiction of incorporation)		001-34822 (Commission File Number)		58-2394628 (I.R.S. Employer Identification Number)	
	(Add	120 S. Sierra Ave., Suite 100 Solana Beach, CA 92075 ress of principal executive offices, zip	code)		
	(888) 287-9109 (Registrant's telephone number, including area code)		rea code)		
Check the appropriate box below if the Form 8-K fili  Written communications pursuant to Rule 425  Soliciting material pursuant to Rule 14a-12 under the Pre-commencement communications pursuant  Pre-commencement communications pursuant  Securities registered pursuant to Section 12(b) of the	under the Securitieder the Exchange Atto Rule 14d-2(b) uto Rule 13e-4(c) u	es Act (17 CFR 230.425) Act (17 CFR 240.14a-12) Inder the Exchange Act (17 CFR 2	240.14d-2(b))	nt under any of the following provisions:	
Title of each class		Trading Symbol(s)	Name of e	each exchange on which registered	_
Common Stock, \$0.01 par value per si	hare	CLPT		Nasdaq Capital Market	
ndicate by check mark whether the registrant is an emerg Exchange Act of 1934 (§240.12b-2 of this chapter).	ging growth compan	y as defined in Rule 405 of the Secu	rities Act of 1933 (§230.4	105 of this chapter) or Rule 12b-2 of the Securitie	s
f an emerging growth company, indicate by check n accounting standards provided pursuant to Section 13			ded transition period for	Emerging Growth Company complying with any new or revised financial	

#### Item 2.02. Results of Operations and Financial Condition.

On November 8, 2022, ClearPoint Neuro, Inc. (the "Company") issued a press release announcing its financial performance for the third fiscal quarter ended September 30, 2022. 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 8, 2022, the Company posted an updated investor presentation to its website at http://ir.stockpr.com/clearpointneuro/investor-presentations. A copy of the investor presentation is being furnished herewith as Exhibit 99.2. The Company may use the investor presentation from time to time in conversations with analysts, investors and others

The information in Item 7.01 of this Form 8-K, as well as Exhibit 99.2 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith:

Exhibit 99.1 <u>Press Release dated November 8, 2022</u>

Exhibit 99.2 <u>Investor Presentation dated November 8, 2022</u>

Exhibit 104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 8, 2022 CLEARPOINT NEURO, INC.

By: /s/ Danilo D'Alessandro

Danilo D'Alessandro Chief Financial Officer



### ClearPoint Neuro Reports Third Quarter 2022 Results Company Reaffirms 2022 Revenue Forecast

SOLANA BEACH, CA, November 8, 2022 – ClearPoint Neuro, Inc. (Nasdaq: CLPT) (the "Company"), a global therapy-enabling platform company providing navigation and delivery to the brain, today announced financial results for its third quarter ended September 30, 2022.

#### **Third Quarter Highlights**

- Reported quarterly revenue of \$5.1 million, a 13% year-over-year increase;
- Partner PTC Therapeutics' gene therapy treatment Upstaza<sup>™</sup> was granted full marketing authorization by the European Commission. Upstaza will be administered with the Company's SmartFlow<sup>®</sup> Neuro Cannula;
- Added multiple new biologics and drug delivery partners in the quarter to bring the total to approximately 50;
- Announced multiple FDA clearances: the ClearPoint Maestro™ Brain Model, the ClearPoint Prism™ Neuro Laser Therapy System and the 2.1 version of the ClearPoint Neuro Navigation software; and
- Cash and short-term investments totaled \$40.5 million as of September 30, 2022.

#### **Business Outlook**

• The Company reaffirms its full year 2022 revenue outlook of between \$21.0 and \$22.0 million.

"The ClearPoint Neuro Team has continued to execute against our four-pillar growth strategy in the third quarter and remain on track to achieve our previously announced strategic and financial goals for the year," commented Joe Burnett, President and CEO.

"We achieved another strong quarter for revenue despite a historically high case cancellation rate and hospital supply chain disruptions. Our Biologics and Drug Delivery team added multiple new pharma and academic partners bringing our total to approximately 50 and keeping pace at approximately one new partner each month. Three new products were cleared by the FDA in the quarter and are in the process of being deployed in limited market releases before the end of the year. We have now installed a record 10 new systems globally year to date and have the largest active capital funnel in our history.

Particularly of note, the European Commission granted marketing authorization for Upstaza to our partner PTC Therapeutics. Upstaza is the first marketed gene therapy approved anywhere in the world to be dosed by direct infusion into the brain. Consistent with our long term strategy, the Summary of Product Characteristics for Upstaza specifically includes the ClearPoint SmartFlow Neuro Cannula as the device used for minimally invasive infusion of the gene therapy. We believe the approval of Upstaza, delivered with ClearPoint's cannula, demonstrates the viability and potential of our drug delivery partnerships.

At present, we are reaffirming our prior guidance of revenue between \$21.0 and \$22.0 million for the year and continue to maintain a strong balance sheet with over \$40 million in cash and short-term investments enabling the continuation of our four-pillar growth strategy."

#### Financial Results – Quarter Ended September 30, 2022

Total revenue was \$5.1 million for the three months ended September 30, 2022, and \$4.6 million for the three months ended September 30, 2021, which represents an increase of \$0.6 million, or 13%.

Functional neurosurgery navigation and therapy revenue, increased 12% to \$2.4 million for the three months ended September 30, 2022, from \$2.2 million for the same period in 2021. The growth was driven by higher service revenue.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored clinical trials utilizing our products, increased 9% to \$2.2 million for the three months ended September 30, 2022, from \$2.1 million for the same period in 2021. This increase is attributable to a \$0.5 million increase in service revenue, partially offset by \$0.3 million decrease in product revenue.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, increased 32% to \$0.5 million for the three months ended September 30, 2022, from \$0.4 million for the same period in 2021 due to an increase in the placements of ClearPoint capital and software.

Gross margin for the three months ended September 30, 2022, was 72%, as compared to a gross margin of 66% for the three months ended September 30, 2021. The increase in gross margin was due primarily to an increased contribution of service revenue, which carries a higher gross margin relative to product revenue and by lower overhead expenses.

Operating expenses for the third quarter of 2022 were \$7.5 million, compared to \$6.8 million for the third quarter of 2021. The increase was mainly driven by the increase in headcount across the organization and share based compensation.

At September 30, 2022, the Company had cash and cash equivalents and short-term investments totaling \$40.5 million as compared to \$54.1 million at December 31, 2021, with the decrease resulting primarily from the use of cash in operating activities of \$13.1 million.

#### **Teleconference Information**

Investors and analysts are invited to listen to a live broadcast review of the Company's 2022 third quarter on Tuesday, November 8, 2022 at 4:30 p.m. Eastern time (1:30 p.m. Pacific time) which may be accessed online here: https://event.choruscall.com/mediaframe/webcast.html? webcastid=LADbDbTi. Investors and analysts who would like to participate in the conference call via telephone may do so at (888) 272-8703, or at (713) 936-6995 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 8, 2022, 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 Investor website at https://ir.clearpointneuro.com/.

### **About ClearPoint Neuro**

ClearPoint Neuro's mission is to improve and restore quality of life to patients and their families by enabling therapies for the most complex neurological disorders with pinpoint accuracy. Applications of the Company's current product portfolio include deep brain stimulation, laser ablation, biopsy, neuro-aspiration, and delivery of drugs, biologics, and gene therapy to the brain. The ClearPoint Neuro Navigation System has FDA clearance, is CE-marked, and is installed in over 60 active sites in the United States, Canada, and Europe. ClearPoint Neuro is partnered with approximately 50 pharmaceutical and biotech companies, academic institutions, and contract research organizations providing solutions for direct CNS delivery of therapeutics in preclinical studies and clinical trials worldwide. To date, more than 5,000 cases have been performed and supported by the Company's field-based clinical specialist team, which offers support and services to our customers and partners worldwide. For more information, please visit www.clearpointneuro.com.

#### Forward-Looking Statements

Statements in this press release and in the teleconference referenced above concerning the Company's plans, growth and strategies may include forward-looking statements within the context of the federal securities laws. Statements regarding the Company's future events, developments and future performance, the size of total addressable markets or the market opportunity for the Company's products and services, as well as management's expectations, beliefs, plans, estimates or projections relating to the future, are forward-looking statements within the meaning of these laws. Uncertainties and risks may cause the Company's actual results to differ materially from those expressed in or implied by forward-looking statements. Particular uncertainties and risks include those relating to: the impact of the COVID-19 pandemic, global instability, supply chain disruptions, labor shortages, and macroeconomic and inflationary conditions; future revenue from sales of the Company's ClearPoint Neuro Navigation System and other new products offered by the Company; the Company's ability to market, commercialize and achieve broader market acceptance for the Company's ClearPoint Neuro Navigation System and other new products offered by the Company; the ability of our biologics and drug delivery partners to achieve commercial success, including their use of our products and services in their delivery of therapies; and risks inherent in the research and development of new products. More detailed information on these and additional factors that could affect the Company's actual results are described in the "Risk Factors" section of the Company's Annual Report on Form 10-Q for the three months ended June 30, 2022, 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, 2022, which the Company intends to file with the Securities and Exchange Commission on or before November 14, 2022.

#### **Contact:**

Danilo D'Alessandro, Chief Financial Officer

(949) 900-6833

info@clearpointneuro.com

Caroline Corner, Investor Relations

ir@clearpointneuro.com

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

(Dollars in thousands, except for per share data)

For The Three Months Ended

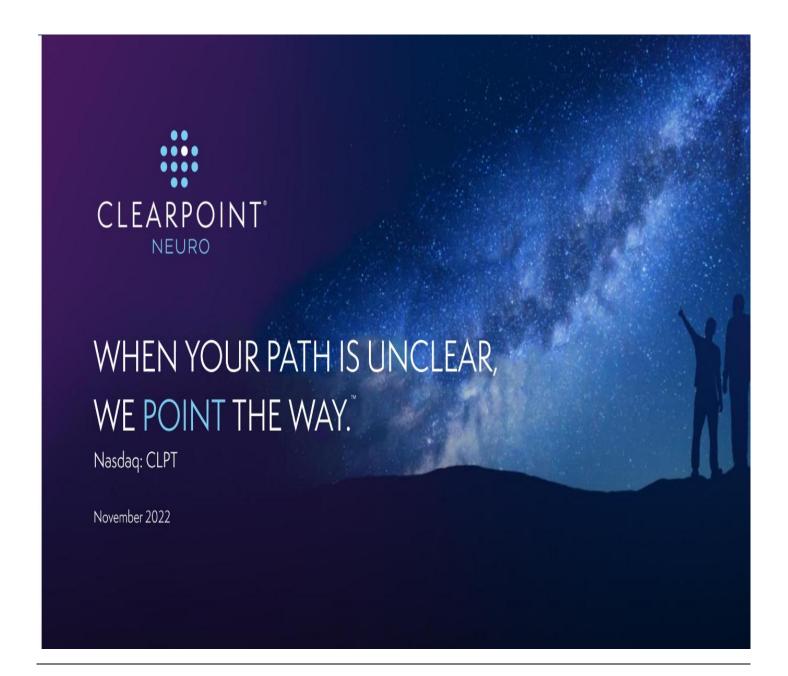
	Septer	September 30,	
	2022		2021
Revenue:			
Product revenue	\$ 3,130	\$	3,338
Service and other revenue	2,016		1,236
Total revenue	5,146		4,574
Cost of revenue	1,434		1,533
Gross profit	3,712	-	3,041
Research and development costs	2,453		2,601
Sales and marketing expenses	2,139		1,808
General and administrative expenses	2,915		2,436
Operating loss	(3,795)	-	(3,804
Other expense:			
Other (expense) income, net	(25)		62
Interest income (expense), net	32		(238
Net loss	\$ (3,788)	\$	(3,980
Net loss per share attributable to common stockholders:			
Basic and diluted	\$ (0.15)	\$	(0.18
Weighted average shares used in computing net loss per share:		-	
Basic and diluted	24,497,636		22,522,460
	For The Nine		Ended
	Septer	Months nber 30,	
Revenue:			Ended 2021
Revenue:  Product revenue	Septer	nber 30,	2021
		nber 30,	
Product revenue	\$ 9,750	nber 30,	<b>2021</b> 8,863 3,154
Product revenue Service and other revenue Total revenue	\$ 9,750 5,627	nber 30,	8,863 3,154 12,017
Product revenue Service and other revenue Total revenue Cost of revenue	Septer 2022  \$ 9,750 5,627 15,377	nber 30,	8,863 3,154 12,017 4,078
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit	Septem           2022           \$ 9,750           5,627           15,377           5,162	nber 30,	8,863 3,154 12,017 4,078 7,939
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit Research and development costs	Septem           2022           \$ 9,750           5,627           15,377           5,162           10,215	nber 30,	8,863 3,154 12,017 4,078 7,939 6,208
Product revenue Service and other revenue Total revenue Cost of revenue	Septem           2022           \$ 9,750           5,627           15,377           5,162           10,215           7,270	nber 30,	8,863 3,154 12,017 4,078 7,939 6,208 5,061
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit Research and development costs Sales and marketing expenses	Septem 2022       \$ 9,750       5,627       15,377       5,162       10,215       7,270       6,171	\$	8,863 3,154 12,017 4,078 7,939 6,208 5,061 6,062
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit Research and development costs Sales and marketing expenses General and administrative expenses Operating loss	Septem           2022           \$ 9,750           5,627           15,377           5,162           10,215           7,270           6,171           8,637	\$	8,863 3,154 12,017 4,078 7,939 6,208 5,061 6,062
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit Research and development costs Sales and marketing expenses General and administrative expenses Operating loss	Septem           2022           \$ 9,750           5,627           15,377           5,162           10,215           7,270           6,171           8,637	s	8,863 3,154 12,017 4,078 7,939 6,208 5,061 6,062 (9,392
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit Research and development costs Sales and marketing expenses General and administrative expenses Operating loss Other expense:	\$ 9,750 5,627 15,377 5,162 10,215 7,270 6,171 8,637 (11,863)	\$	<b>2021</b> 8,863
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit Research and development costs Sales and marketing expenses General and administrative expenses Operating loss Other expense: Other expense, net	Septem           2022           \$ 9,750           5,627           15,377           5,162           10,215           7,270           6,171           8,637           (11,863)           (22)	\$	8,863 3,154 12,017 4,078 7,939 6,208 5,061 6,062 (9,392
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit Research and development costs Sales and marketing expenses General and administrative expenses Operating loss Other expense: Other expense, net Interest expense, net	Septem           2022           \$ 9,750           5,627           15,377           5,162           10,215           7,270           6,171           8,637           (11,863)           (22)           (165)	\$	8,863 3,154 12,017 4,078 7,939 6,208 5,061 6,062 (9,392
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit Research and development costs Sales and marketing expenses General and administrative expenses Operating loss Other expense: Other expense, net Interest expense, net Net loss	Septem           2022           \$ 9,750           5,627           15,377           5,162           10,215           7,270           6,171           8,637           (11,863)           (22)           (165)	\$ \$ \$	8,863 3,154 12,017 4,078 7,939 6,208 5,061 6,062 (9,392
Product revenue Service and other revenue Total revenue Cost of revenue Gross profit Research and development costs Sales and marketing expenses General and administrative expenses Operating loss Other expense: Other expense, net Interest expense, net Net loss Net loss per share attributable to common stockholders:	Septem       2022       \$ 9,750       5,627       15,377       5,162       10,215       7,270       6,171       8,637       (11,863)       (22)       (165)       \$ (12,050)	\$ \$ \$	8,863 3,154 12,017 4,078 7,939 6,208 5,061 6,062 (9,392 (60 (809)

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

		eptember 30, 2022 (Unaudited)	December 31, 2021
ASSETS			
Current assets:			
Cash and cash equivalents	\$	18,712	\$ 54,109
Short-term investments		21,749	_
Accounts receivable, net		3,411	2,337
Inventory, net		8,284	4,938
Prepaid expenses and other current assets		1,658	508
Total current assets		53,814	61,892
Property and equipment, net		629	539
Operating lease rights of use		1,866	2,241
Software license inventory		485	519
Licensing rights		850	265
Other assets		94	125
Total assets	\$	57,738	\$ 65,581
A LA DIA MENERA AND STOCKAMOA DEDCA FOLLATIVA			
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:	_		
Accounts payable	\$	1,387	\$ 427
Accrued compensation		2,187	2,604
Other accrued liabilities		1,249	537
Operating lease liabilities, current portion		537	507
Deferred product and service revenue, current portion		735	 678
Total current liabilities		6,095	4,753
Operating lease liabilities, net of current portion		1,535	1,939
Deferred product and service revenue, net of current portion		351	264
2020 senior secured convertible note payable, net		9,879	 9,838
Total liabilities		17,860	16,794
Commitments and contingencies			
Stockholders' equity:			
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at September 30, 2022 and December 31, 2021		_	_
Common stock, \$0.01 par value; 200,000,000 shares authorized; 24,500,832 shares issued and outstanding at September 30, 2022; and 23,665,991 issued and outstanding at December 31, 2021		245	237
Additional paid-in capital		185,615	182,482
Accumulated deficit		(145,982)	(133,932)
Total stockholders' equity		39,878	48,787
Total liabilities and stockholders' equity	\$	57,738	\$ 65,581

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

	For The Nine N Septem	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (12,050)	\$ (10,261)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for doubtful accounts	(92)	170
Depreciation and amortization	224	113
Share-based compensation	2,954	1,153
Payment-in-kind interest	_	285
Amortization of debt issuance costs and original issue discounts	41	73
Amortization of lease rights of use, net of accretion in lease liabilities	400	400
Accretion of discounts on short-term investments	(159)	_
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(982)	(848)
Inventory, net	(3,318)	(682)
Prepaid expenses and other current assets	(1,150)	(599)
Other assets	31	(28)
Accounts payable and accrued expenses	1,255	1,418
Lease liabilities	(400)	(312)
Deferred revenue	144	(27)
Net cash flows from operating activities	(13,102)	(9,145)
Cash flows from investing activities:		
Purchases of property and equipment	(214)	(130)
Acquisition of licensing rights	(678)	_
Purchase of short-term investments	(21,590)	
Net cash flows from investing activities	(22,482)	(130)
Cash flows from financing activities:		
Proceeds from public offering of common stock, net of offering costs	_	46,785
Proceeds from stock option and warrant exercises	263	584
Proceeds from issuance of common stock under employee stock purchase plan	260	_
Payments for taxes related to net share settlement of equity awards	(336)	(542)
Net cash flows from financing activities	187	46,827
Net change in cash and cash equivalents	(35,397)	37,552
Cash and cash equivalents, beginning of period	54,109	20,099
Cash and cash equivalents, end of period	\$ 18,712	\$ 57,651
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	\$ —	\$
	<u>—————————————————————————————————————</u>	Φ
Interest	\$ 351	\$ 495



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, the size of total addressable markets or the market opportunity for the Company's products and services, as well as management's expectations, beliefs, plans, estimates or projections relating to the future, are forward-looking statements within the meaning of these laws. Uncertainties and risks may cause the Company's actual results to differ materially from those expressed in or implied by forward-looking statements. Particular uncertainties and risks include those relating to: the impact of the COVID-19 pandemic and global instability, supply chain disruptions, labor shortages, and inflationary conditions; future revenue from sales of the Company's ClearPoint Neuro Navigation System and other new products offered by the Company; the Company's ability to market, commercialize and achieve broader market acceptance for the Company's ClearPoint Neuro Navigation System and other new products offered by the Company; the ability of our biologics and drug delivery partners to achieve commercial success, including their use of our products and services in their delivery of therapies; and risks inherent in the research and development of new products. More detailed information on these and additional factors that could affect the Company's actual results are described in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2021, and the Company's Quarterly Report on Form 10-Q for the three months ended June 30, 2022, 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, 2022, which the Company intends to file with the Securities and Exchange Commission on or before November 14, 2022.



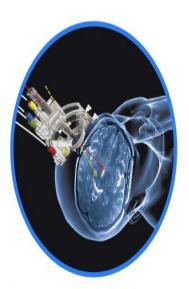
## Our Company

# ClearPoint Neuro: <u>Two</u> Opportunities, <u>One</u> Platform





- A Common Installed Base Platform and Clinical Specialist Support team
- 35 Active Indications totaling more than 1 million patients diagnosed annually
- A \$12B+ Potential Total Addressable Market

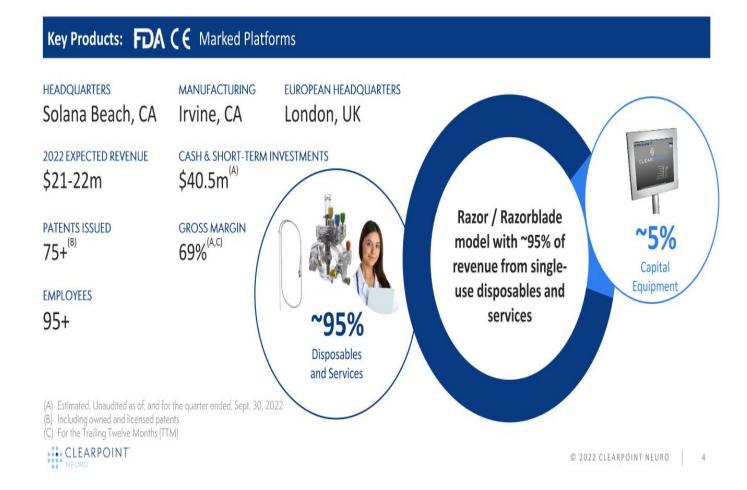


- (1) A Biologics & Drug Delivery Enabling Company with;
  - A unique portfolio of Navigation Tools, Infusion Cannulas, Pre-Clinical and Clinical Services
  - Approximately 50 active pharma/biotech, academic and contract research organization partners
- (2) A Neuro Navigation and Device Company with;
  - A growing portfolio of Navigation, Therapy and Access Devices supporting DBS, Laser Ablation, Biopsy and Brain Computer Interface implantation
  - An expanding global installed base of more than 60 centers



## Our Company

# ClearPoint Neuro: A Proven Platform



# Limitations of Traditional Stereotactic Neurosurgery

# Lack of Real-Time Image Guidance

### PRIMARY CHALLENGE

For minimally invasive procedures to be successful, the surgeon needs imaging to see into the head

MRI is the best imaging tool for the brain

Large, metallic frames are not MRI compatible







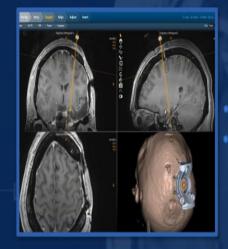
Big Iron companies like Siemens and Philips are innovating to make interoperative MRI scanners more accessible



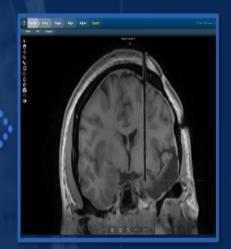


Video source: https://www.youtube.com/watch?v=PsL9B7ftbG4

# Our Platform - Procedure Overview The ClearPoint® Neuro Navigation System







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

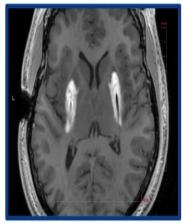




## Our Platform

# SmartFrame® XG

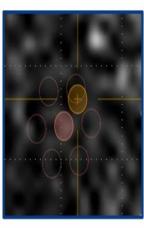




SmartFrame XG Trajectory Tower with ClearPoint 2.1 Software

# SmartFrame Array™





SmartFrame Array Tower with "virtual array" Software and next generation robotic system with increased automation and enabling software\*

ClearPoint plans to translate more than 10 years of experience and over 5,000 cases performed in the complex MRI suite into unique and competitive products for the Operating Room

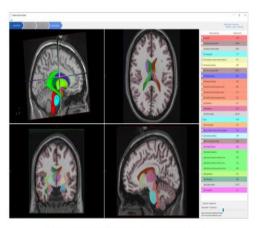
© 2022 CLEARPOINT NEURO

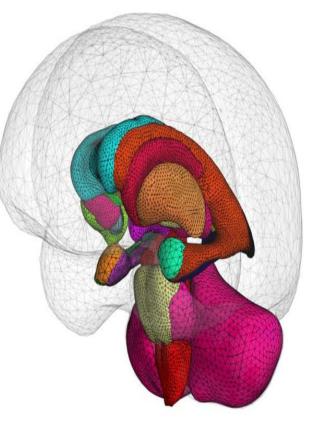
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### Our Platform

# The ClearPoint 'Maestro' Brain Model\* Licensed and Jointly Developed with Philips

- 1. Shape Constrained, triangular mesh model enables point-based correspondence across multiple subjects.
- 2. Fast and capable of peri-procedural imaging without CPU acceleration.
- 3. This model is the basis for future navigation tools, for both the MRI suite and OR, across Biologics & Drug Delivery, DBS Navigation, Brain Computer Interface, Laser Ablation and more.







\*The ClearPoint Maestro\*\* Brain Model is only available in the United States.

# Broad and Growing User Base of Leading Neurosurgery Centers

# 60+ Centers in the US, Canada and EU... and Growing Globally

UC San Francisco
Stanford University
Lucile Packard Children's Hospital
Benioff Children's Hospital
San Francisco VA
USC Keck Hospital
UC San Diego
Mayo Clinic in Arizona
University of Colorado
University of Utah

Cook Children's Hospital Texas Children's Hospital MD Anderson Cancer Center

Houston Methodist Hospital Univ. Kansas Medical Center

Dallas Presbyterian Hospital Cincinnati Jewish

Children's National

Banner Health Tucson Ohio State University

University of Oklahoma Medical Center

Methodist Hospital San Antonio Barnes-Jewish Hospital

Froedtert Hospital

CLEARPOINT

University of Wisconsin
University of Michigan
University of Minnesota
Cleveland Clinic
Northwestern Central DuPage
Nationwide Children's
Le Bonheur
INOVA Fairfax
Cincinnati Children's Hospital

Charles River Labs – Laval
Charles River Labs – Mattawan
Children's Mercy Hospital
CHOA Scottish Rite
Carilion Clinic
UPMC
Hos. Univ. of Pennsylvania
University of Alabama at Birmingham
Children's Hospital of Alabama

Rigshospitalet (Copenhagen, Denmark)
Mazowiecki Szpital Bródnowski (Warsaw, Poland)
Hôpital Fondation Rothschild (Paris, France)
Skånes Universitetssjukhus Lund (Lund, Sweden)
University Hospital of Wales (United Kingdom)
Universitätsklinikum Düsseldorf (Düsseldorf, Germany)
Universitätsklinikum Freiburg (Freiburg, Germany)
n Policlinico Umberto I (Rome, Italy)

Emory University Mt. Sinai West Yale University Weill Cornell

Johns Hopkins University Boston Children's Hospital Massachusetts General Hospital Brigham & Women's

Duke University
National Institutes of Health
Memorial Sloan-Kettering
Dartmouth-Hitchcock
Beth Israel Deaconess
Children's Hospital of Philadelphia

University of Virginia Tampa General Hospital Mayo Clinic in Florida

Hackensack Univ. Med. Center

100+ Centers Expected by 2025

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

CLPT PLATFORM RUNS
ON ALL MAJOR SCANNERS

DELIVER BIOLOGICS
AND DRUGS

IMPLANT NEURO
STIMULATION LEADS

LASER THERAPY

**SIEMENS** 



Medtronic

























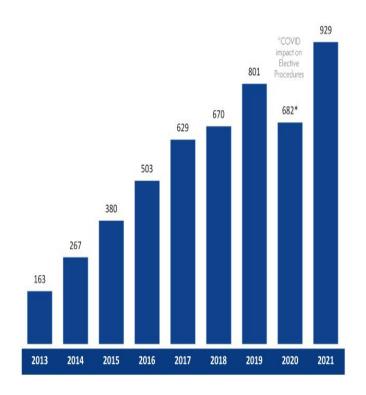


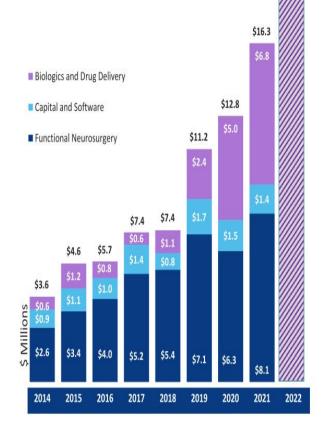


... Approximately 50 active pharma/biotech, academic, and contract research organization partners

2013 - 2022

# Growth in Case Volume and Revenue







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Expected FY22 Revenue

\$21

Pillar 4: Global Expansion

~2 X U.S. Revenue

# ClearPoint Neuro Market Opportunity – United States

~\$12B+ Opportunity: Empowering Multiple Treatment Options for 35+ Indications\*

Indication	atient Population	Annual Incidence	Pillar 1: Drug/Cell Delivery	Pillar 2: DBS & BCI	Pillar 3: Laser Therapy	Incremental Revenu
Parkinson's Disease	1,000,0001	60,0001	00	•	•	\$270 M - \$1.35 B
Drug Resistant Epilepsy	1,000,0002	11,000³	00	•	•	\$49.5 M - \$198 M
Refractory Essential Tremor	3,500,0004	60,0005			0	\$180 M - \$1.08 B
Brain Tumors (n=3) <sup>6</sup>	35,000 <sup>7,8</sup>	13,300 <sup>7,8</sup>	00			\$33.3 M - \$300 M
Severe Obsessive-Compulsive Disorder	500,0009,10	10,0009,10				\$45 M - \$75 M
Dystonia	250,00011	8,00012		•		\$36 M - \$60 M
Rare Genetic/Lysosomal (n=7)13	36,50014-18	3,000 <sup>14,19,20</sup>	00			\$13.5 M - \$67.5 M
Paralysis / Spinal Cord (n=15) <sup>21,22</sup>	331,000 <sup>22-24</sup>	17,900 <sup>23</sup>	00	0		\$80.6 M - \$403 M
Huntington's Disease	30,000 <sup>25</sup>	4,000 <sup>25</sup>	00	0		\$18 M - \$90 M
Auditory Nerve Implant	1,867,000 <sup>26,27</sup>	7,000 <sup>26,27</sup>		0		\$31.5 M - \$63 M
Alzheimer's Disease	6,000,000 <sup>28</sup>	500,000 <sup>28</sup>	00	0		\$1.5 B - \$11.3 B
Severe Major Depressive Disorder	1,000,00010	20,00010,29		0		\$90 M - \$150 M
Stroke Rehabilitation	2,000,00030	610,000 <sup>30</sup>		0		\$1.83 B - \$5.49 B
Frontotemporal Dementia	60,00031	12,000³1	0			\$54 M - \$270 M
						\$4.2 B - \$20.8 B
Commercial U.S & EU ClearPoint procedures today			ClearPoint Neuro Na	avigation Capital, Rob	otics & Disposables	
Active clini			Cannulas, Pumps	MER Probes	Laser Cath., Biopsy	
CLEARPOINT Pre-clinical study/testing			Access Technolo	Access Technologies, Clinical Services, Digital Health		

### ClearPoint Neuro Market Opportunity – United States

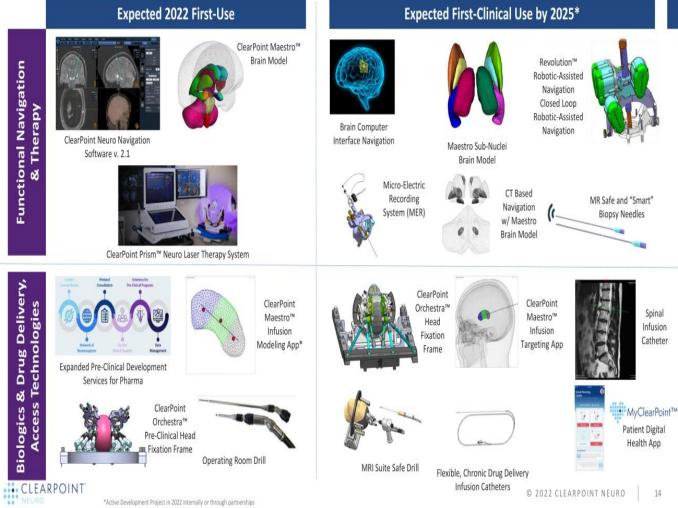
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## Innovation Pipeline

# ClearPoint Neuro is Dedicated to Innovation in the Neuro Space



\*Active Development Project in 2022 internally or through partnerships

### New Global Showcase Site

# ClearPoint Global Training & Innovation Center – Solana Beach, CA

- Simulated training experience for surgeons and staff to perform mock procedures and provide development pipeline feedback
- Showcase new technologies to Pharmaceutical and BCI partners
- Home for Clinical Specialists to support cases remotely without travel









# 4 Pillar Growth Strategy by 2025

Target Indications of > 1,000,000 Patients Diagnosed Each Year Potential Total Addressable Market for CLPT of \$12B+

#### **ACHIEVE GLOBAL SCALE**

Expand Global Footprint to 100 Centers Open WW Training / Remote Support Facility Launch Robotic Platform into MRI and O.R. Release Digital Health Patient Portal Application

### **NEW THERAPY DEVICES**

Enter the Neuro Laser Therapy Market Launch Maestro Brain Model and Therapy Apps Penetrate 'Access' Markets to Improve Efficiency (Drill) Build the 'Smart' Biopsy Market

### **NEURO NAVIGATION FOR DBS & BCI**

Expand into the Operating Room, Enter the MER Market Educate Patients on DBS Options including 'Asleep' and 'Awake' Procedures Participate in Trials for new DBS indications Launch surgical solution for Brain-Computer Interfaces (BCI)

#### **BIOLOGICS & DRUG DELIVERY**

Expand Translational & Clinical Services
Accumulate Additional Global Partners Across Diverse Indications
Execute on Development Pipeline for Intracranial and Spinal Routes of Administration
Expand Partnership Models to Include Milestone Based Collaborative Agreements

2022



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# **CLPT Capabilities**

# **Executive Summary**



### Unique platform technology

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



### Large, growing installed base

in 60+ of 500+ leading
Neurosurgery and research centers
worldwide



### Pipeline of new revenue streams

from product improvements, biologic and drug delivery partnerships and services, standalone therapy products, and Brain Computer Interface Navigation



### Total potential addressable market

> \$12B for our products, pipeline and partnerships



### **Expandable Platform**

with realizable synergies beyond the MRI and into the operating room and radiology suite



### A growing and passionate team

of embedded scientists and specialists





