



CLEARPOINT[®]
NEURO

WHEN YOUR PATH IS UNCLEAR,
WE POINT THE WAY.

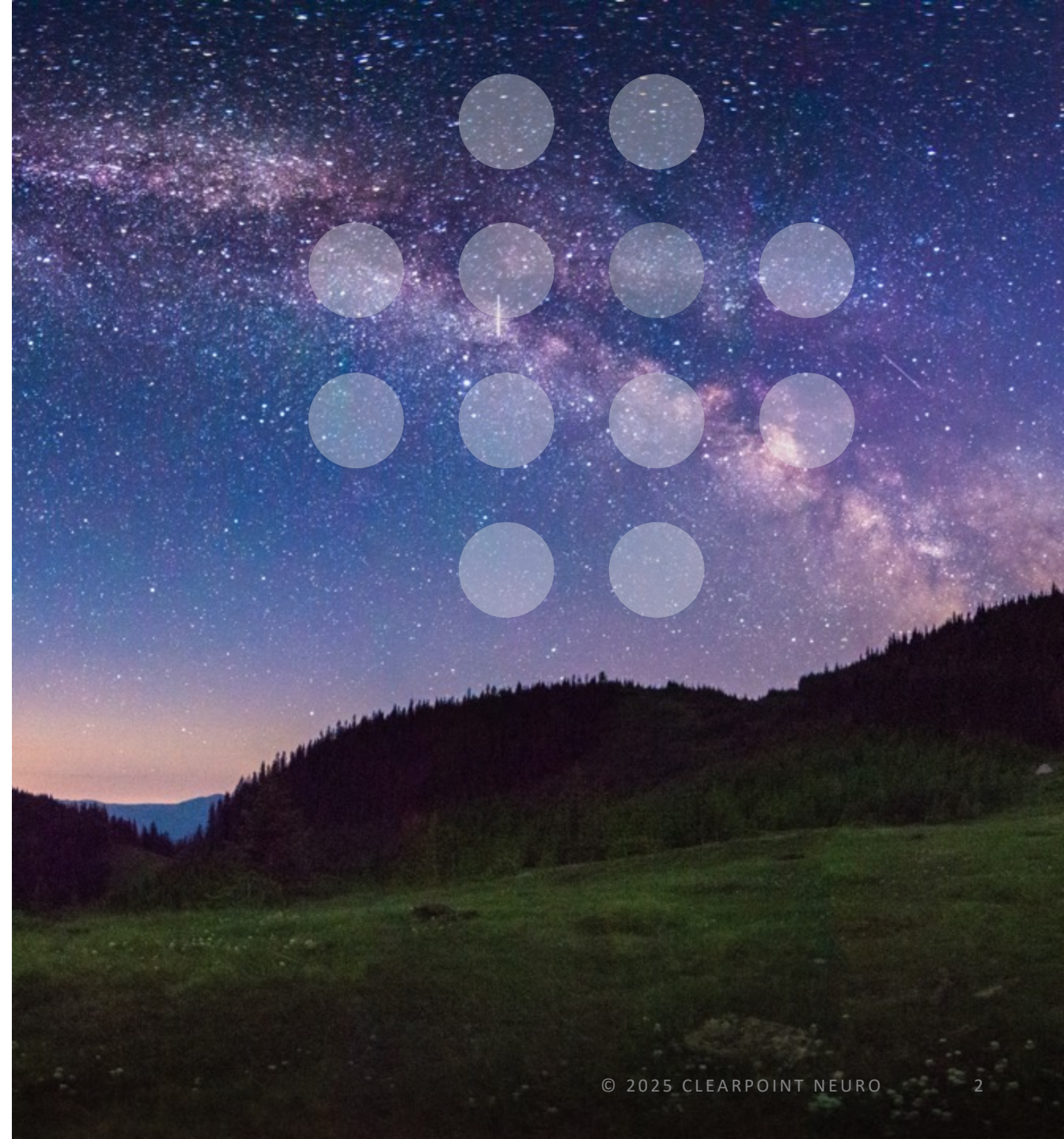
Nasdaq: CLPT

May 2025



DISCLAIMER

This presentation and discussion contain forward-looking statements within the context of the federal securities laws, including the Company's expectation for revenues, gross margin, the adequacy of cash and cash equivalent balances to support operations and meet future obligations, the future market of its products and services, and other performance and results. These forward-looking statements are based on management's current expectations and are subject to the risks inherent in the business, which 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: macroeconomic and inflationary conditions; the introduction of or changes in tariffs, sanctions, or trade barriers; changes in monetary policy; geopolitical trends, such as protectionism and economic nationalism; future revenue from sales of the Company's products and services; the Company's ability to market, commercialize and achieve broader market acceptance for new products and services offered by the Company; the ability of our biologics and drug delivery partners to achieve commercial success, including their use of the Company's products and services in their delivery of therapies; the Company's ability to maintain its current relationships with biologics and drug delivery partners or enter into new relationships with such partners; the Company's expectations, projections and estimates regarding expenses, future revenue, capital requirements, and the availability of and the need for additional financing; the Company's ability to obtain additional funding to support its research and development programs; the ability of the Company to manage the growth of its business; the Company's ability to attract and retain its key employees; and risks inherent in the research, development, and regulatory approval of new products and the new products of its biologics and drug delivery partners. 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, 2024, which has been filed with the Securities and Exchange Commission, and the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2025, which the company intends to file with the Securities and Exchange Commission on or before May 15, 2025. The Company does not assume any obligation to update these forward-looking statements.





CLEARPOINT®
NEURO

OUR COMPANY

We Enable Cell, Gene and Device Therapies by
Offering Precise Navigation to the Brain and Spine

Our Unique Platform Includes Both Proven Clinical
Products Used by Neurosurgeons, and Drug
Development Services Used by BioPharma Partners

CLEARPOINT NEURO EXECUTIVE SUMMARY

A UNIQUE PLATFORM TECHNOLOGY USED FOR CELL AND GENE THERAPY DELIVERY

15+ years building a complete drug delivery ecosystem including navigation solutions, predictive modeling, delivery devices, infusion monitoring software and clinical case support



CURRENT PORTFOLIO PROVIDES ACCESS TO A ≈\$500M MARKET OPPORTUNITY TODAY

Evolved beyond the MRI and into operating room CT navigation, laser ablation therapy, surgical access tools and preclinical CRO services which fuel growth via new product launches and provide path to profitability



A \$10B POTENTIAL MARKET DIVERSIFIED ACROSS 60+ PARTNERS, 20+ INDICATIONS*



Combination device success, proprietary technology and deep FDA experience provide our BioPharma partners with a meaningful head start, and our investors with a Portfolio-like biotech strategy

100+ ACTIVE GLOBAL CENTERS



An expanding global installed base of regional treatment centers are scaling capacity to be ready for additional cell and gene therapy patients to be treated with a unified platform

A GROWING & PASSIONATE TEAM



Our dedicated team of engineers, scientists and clinical specialists wake up every morning focused on the future of neurosurgery and drug delivery - *This is all that we do...*

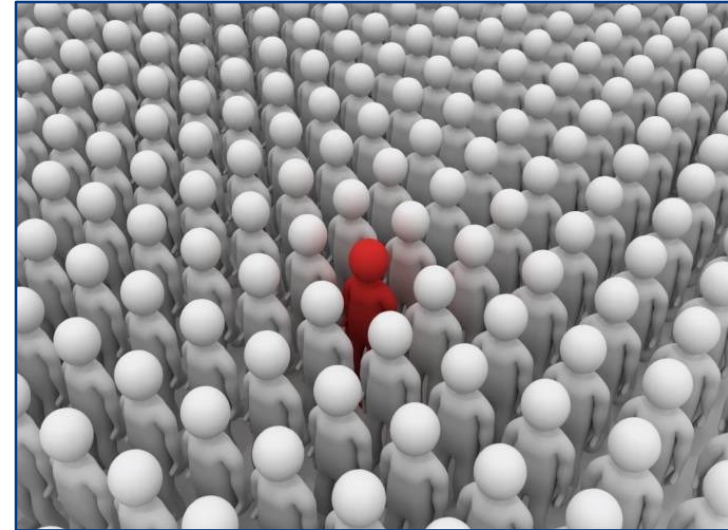


The Future of Cell and Gene Therapy is Not Coming... It is **HERE TODAY**

More than **30 million people** in the U.S. are estimated to suffer from **severe and debilitating neurological disorders**:

- Parkinson's Disease (≈1,000,000)
- Essential Tremor (≈7,000,000)
- Epilepsy (≈2,900,000)
- Huntington's Disease (≈41,000)
- Rare Childhood Genetic Disorders (≈25,000)
- Dementia and Alzheimer's Disease (≈6,900,000)
- Tumor and Glioblastoma (≈280,000)
- Severe OCD (≈1,000,000)
- Treatment Resistant Depression (≈2,900,000)
- ALS and Spinal Cord Injury (≈300,000)
- Stroke Rehabilitation (≈7,000,000)
- Neuropathic Pain (≈2,000,000)

Neurological diseases cost Americans nearly \$800 billion annually. The only way to decrease these costs is to improve treatment.

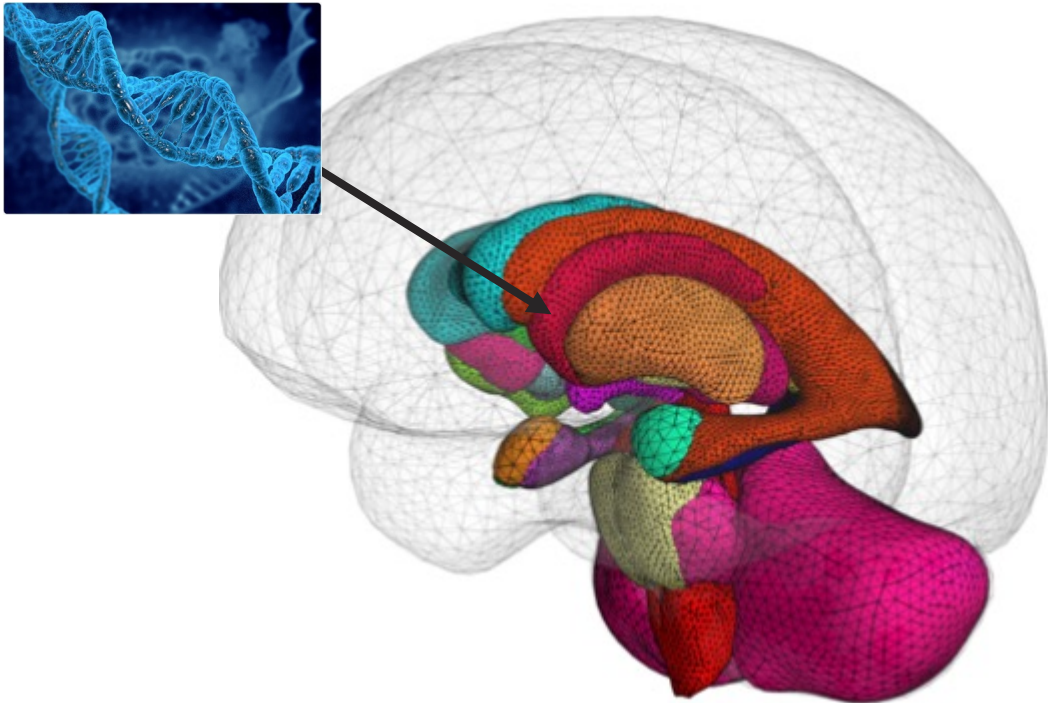


Despite some available treatments, **very few of these patients** undergo a direct surgical intervention to improve their **quality of life...**

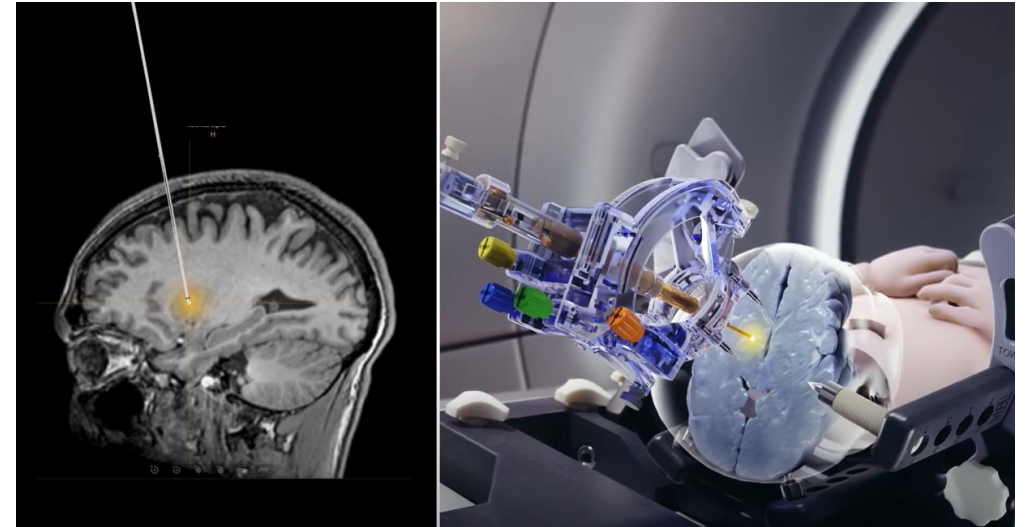
The Future of Cell and Gene Therapy is Not Coming... It is **HERE TODAY**

Our Goal is to Help More Patients by Addressing **Two Primary Barriers to Treatment**

- 1** We will **partner** to Develop Device, Cell and Gene Therapies that may cure the **underlying disease** and restore function...



- 2** We will **Enable** fast, minimally invasive, asleep procedures for a **more comfortable and predictable patient experience**...



The Future of Cell and Gene Therapy is Not Coming... It is **HERE TODAY**

1 Partner has received FDA approval for a neuro gene therapy that is co-labeled with ClearPoint

FDA NEWS RELEASE

FDA Approves First Gene Therapy for Treatment of Aromatic L-amino Acid Decarboxylase Deficiency

For Immediate Release:

November 14, 2024

The U.S. Food and Drug Administration approved Kebilidi (eladocogene exuparvovec-tneq), an adeno-associated virus vector-based gene therapy indicated for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency. Kebilidi is the first FDA-approved gene therapy for treatment of AADC deficiency.

“Clinical advancements in the field of gene therapy continue to lead to the discovery and availability of innovative treatment options for rare diseases that are otherwise difficult to manage,” said Peter Marks, M.D., Ph.D., director of the FDA’s Center for Biologics Evaluation and Research (CBER). “Today’s approval underscores our commitment to help make safe and effective treatments available for patients in need.”








The FDA also authorized the SmartFlow Neuro Cannula, an infusion tube inserted into a target in the brain (parenchymal tissue), to deliver Kebilidi. The SmartFlow Neuro Cannula is currently the only FDA authorized device indicated for use to administer Kebilidi. The FDA granted authorization of the SmartFlow Neuro Cannula to ClearPoint Neuro, Inc.

7 Partners have programs selected for expedited review - the FDA recognizes the urgency



The Future of Cell and Gene Therapy is Not Coming...it is **HERE TODAY**

7 Active Clinical-Stage Partners have been selected for expedited review, including:

	Indication	RMAT	Fast Track	Clinical Status
	AADC Deficiency	-	-	Approved
	Huntington's Disease	✓	-	Trials in US, EU
	Parkinson's Disease	✓	-	Trials in NorthAm
	Epilepsy (MTLE)	✓	-	Trials in the US
	Parkinson's Disease	✓	✓	Trials in US, EU
	Parkinson's Disease	-	✓	Trials in the US
	Frontotemporal Dementia	-	✓	Trials in US, EU

In 2025 Our Journey Enters the **NEXT CHAPTER**

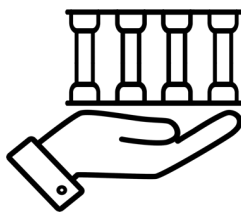
2010 - 2020



Discovery. Design.

- Neurosurgeon-Led Ideation
- Unique MRI Navigation
- Initial FDA Clearance and Product Revenue
- Accumulation of Clinical Trial Experience Using SmartFlow
- Maestro A.I. Software Development
- Initial IP Generation and Licenses
- NASDAQ Listed

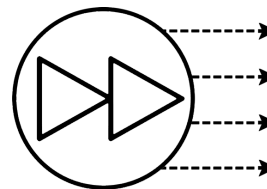
2021 - 2024



Funded. Foundation.

- 100+ Activated Customers
- 60+ Biopharma Partners
- 20+ Potential Disease Indications*
- Preclinical Team Creation
- Operating Room Product Launch
- Laser Therapy Product Launch
- 100+ Owned & Licensed Patents
- EU MDR Certification
- Expanded, Audit-Ready Manufacturing in California
- Leadership Team Complete

2025 - 2027



Fast. Forward.

- Grow into an estimated, existing \$500M Market Opportunity
- 150 Activated Customers
- First Commercial CGT Launched
- GLP Preclinical Capability
- Operating Room Nav Growth
- Laser Therapy Growth
- MR Drill and Access Growth
- 'Harmony' Software Launch
- New Routes of Administration
- Operational Cash Breakeven

2028+



Essential. Everywhere.

- \$10B Potential Revenue Opportunity
- 'Combination Product' Regulatory Designation for multiple cell and gene therapy indications
- Meaningful Revenue from Sophisticated BioPharma Deal Structures beyond product sales including royalty and milestone payments, co-development
- One Unified Platform with both MR and Operating Room Capability and Workflows
- Additional Global Regulatory Approvals Beyond the U.S. and E.U.

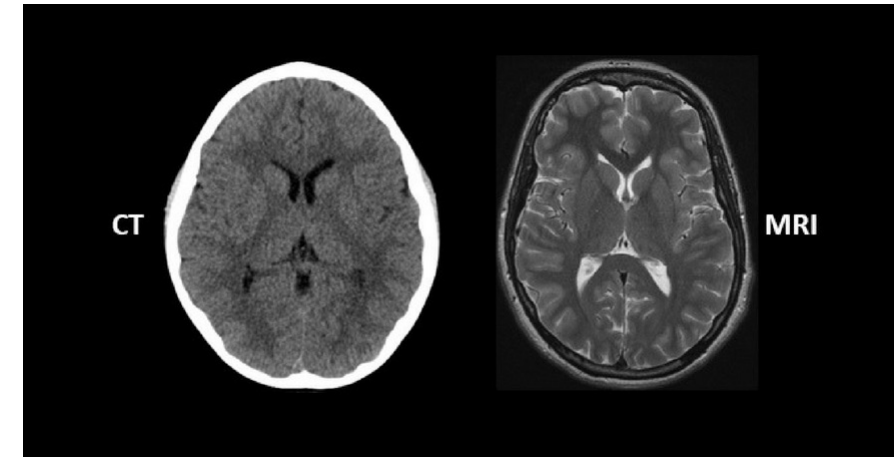
Our Start: Unique Neurosurgery Navigation Guided by Live MRI

Neurosurgery has traditionally been done via open craniotomy or by using CT guidance in the operating room



The historical limitations of CT accuracy would often require patients to remain awake for hours-long brain surgery to confirm the location and impact of technologies like DBS

ClearPoint believed that building a navigation system that could harness the power of live MRI would be accurate enough that **the patient could be comfortably asleep for this minimally invasive procedure**



The ClearPoint SmartFrame family of products uses MR-safe materials and enables surgeons to **Decide, Guide & Confirm using live MR Imaging to achieve sub-millimetric accuracy**

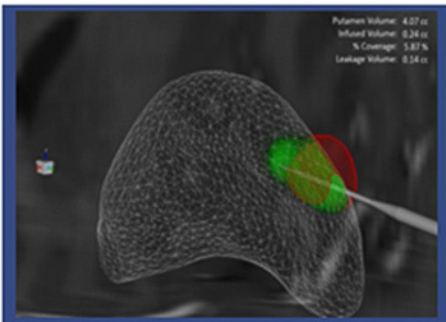
Our Start: Decide, Guide & Confirm



Pre-Plan Trajectory
and **DECIDE**
Entry Point



Automatically **GUIDE**
Precision Adjustments
Prior to Insertion



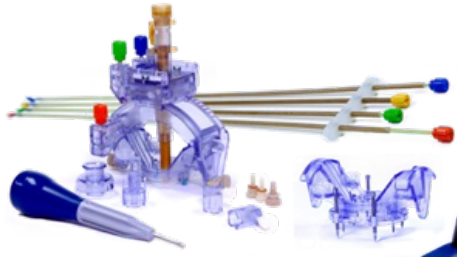
CONFIRM
Quality of Delivery Into
Permanent Record

Three Primary Use Cases demonstrate the value of the ClearPoint Neuro Navigation System:

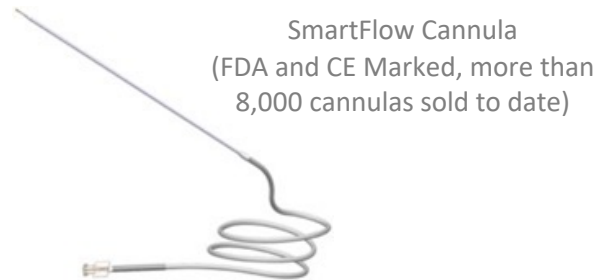
1. Functional neurosurgeons could confidently place DBS electrodes with the **patient comfortably asleep**
2. Neuro-oncologists could perform **entire tumor laser ablations in one room instead of having to transport the patient from the OR to the MRI**
3. BioPharma researchers could confirm that cell and gene therapies are not only **delivered to a precise location**, but could also **confirm proper coverage** of the target structure before closing the patient

Our Start: Assemble the Building Blocks

Leveraging our **unique platform** and **dedicated team**, we developed and acquired essential technologies necessary to complete the entire ecosystem for MR-Guided Navigation with a focus on cell and gene therapy delivery



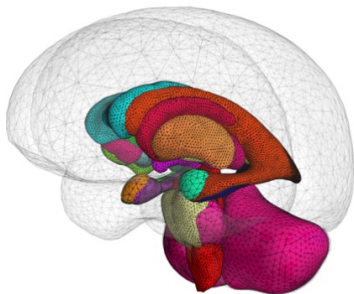
SmartFrame XG and Surgical
Accessory Kit



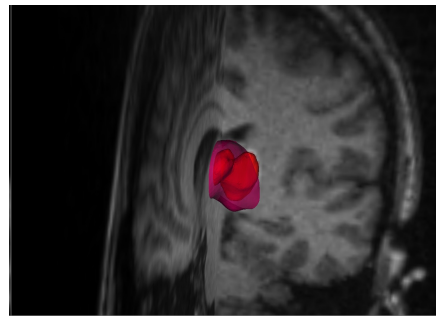
SmartFlow Cannula
(FDA and CE Marked, more than
8,000 cannulas sold to date)



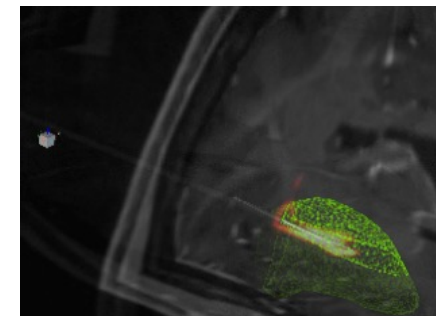
Radial Branching Cell Therapy Devices
and Spinal Infusion Anchors
(Investigational Use Only)



ClearPoint Maestro Brain Model
Segmentation and Image Fusion



3D Peri-procedural Infusion
Monitoring Software
(Investigational Use Only)



Biophysical Modeling of patient
specific drug infusions
(Investigational Use Only)

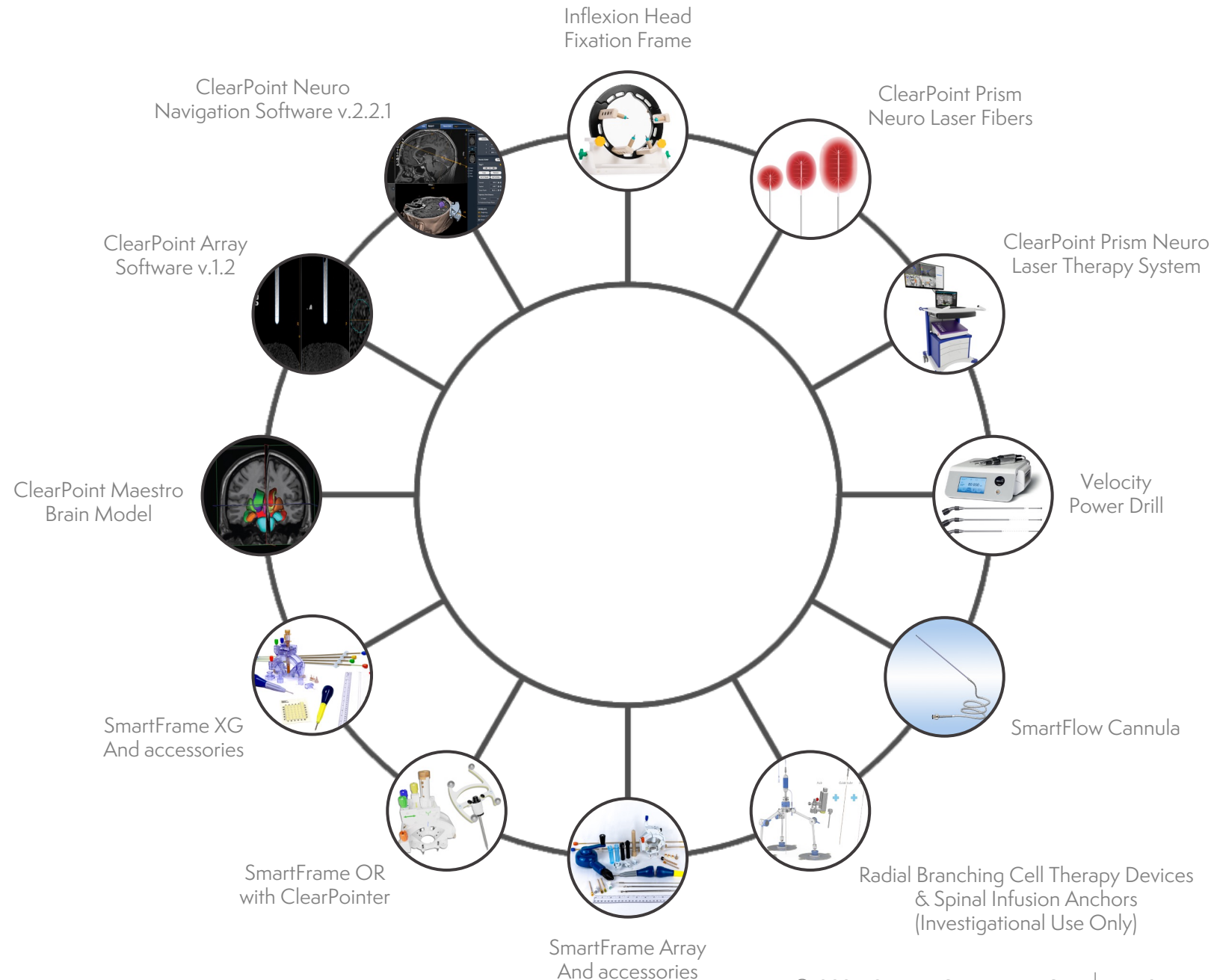
Building the Business

ClearPoint Neuro built a **complete and unique ecosystem of clinical and preclinical products** and has achieved regulatory approvals in multiple geographies

This proven technology has **more than 10 years of experience** and been used in **more than 7,000 procedures** to date

Demand for our platform has grown driven by the **promise of cell and gene therapies, new DBS indications, and the expansion of laser therapy**

ClearPoint Neuro activated a record **25 new Global Customers** in 2024



Funded. Foundation.

Building the Business: Our Four-Pillar Growth Strategy Remains **Our Foundation**

1 BIOLOGICS & DRUG DELIVERY



uniQure



60+
INDUSTRY &
ACADEMIC
PARTNERS



2 NEUROSURGERY NAVIGATION



Medtronic



3 LASER THERAPY & ACCESS



4 GLOBAL SCALE

100+
GLOBAL
CENTERS



PHILIPS



Medtronic

CLEARPOINT NAVIGATION
IS COMPATIBLE WITH
MAJOR DIAGNOSTIC AND
INTRAOPERATIVE MRI
AND CT SCANNERS

Banner Health Tucson
Baptist Memorial Hospital-Memphis
Barnes-Jewish Hospital
Barrow Neurological Institute/St. Joseph's Hospital
Benioff Children's Hospital
Beth Israel Deaconess
Boston Children's Hospital
Brigham & Women's Hospital
Brown University / Rhode Island Hospital
Carilion Clinic
Children's Hospital of Alabama
Children's Mercy Hospital
Children's National Hospital
CHOA Scottish Rite
Cincinnati Children's Hospital
Cincinnati Jewish Hospital
Cleveland Clinic Hospital
Cook Children's Hospital
Corewell Health
Dallas Presbyterian Hospital
Dartmouth-Hitchcock
Duke University
Emory University
Froedtert Hospital
Hackensack University Medical Center
Henry Ford Health
Henry Ford West Bloomfield Hospital
Hospital of University Pennsylvania
Houston Methodist Hospital
INOVA Fairfax
JFK University Medical Center
Johns Hopkins University
Kaleida Health
Kettering Health
Loma Linda University Health
Lucile Packard Children's Hospital
Massachusetts General Hospital
Mayo Clinic in Arizona
Mayo Clinic in Florida

MD Anderson Cancer Center
MedStar Georgetown University Hospital
Memorial Sloan-Kettering Cancer Center
Methodist Hospital San Antonio
Mt. Sinai West
Nationwide Children's
Northwestern Central DuPage
Ochsner Medical Center
Ohio State University
Oregon Health & Science University
Orlando Health Arnold Palmer Hospital for Children
Prisma Health
Riverside Methodist Hospital
Rutgers/Robert Wood Johnson
San Francisco VA Health Care System
Southern Arizona VA Health Care System
Stanford University
Sunnyside Kaiser Permanente
Tampa General Hospital
Texas Children's Hospital
University of Alabama at Birmingham
University of California Los Angeles
University of California San Diego
University of California San Francisco
University of Colorado
University of Florida Jacksonville
University of Kansas Medical Center
University of Maryland Medical Center
University of Michigan
University of Minnesota
University of North Carolina (UNC) Health
University of Oklahoma Medical Center
University of Utah
University of Wisconsin
USC Keck Hospital
UT Southwestern Medical Center
Wolfson Children's Hospital
Yale University

100+
GLOBAL
CENTERS NOW
ACTIVATED

Charité – Universitätsmedizin Berlin (Berlin, Germany)
Fondazione I.R.C.C.S. Istituto Neurologico Carlo Besta (Milan, Italy)
Great Ormond Street Hospital (London, UK)
Hôpital Fondation Rothschild (Paris, France)
Hospital Israelita Albert Einstein (São Paulo, Brazil)
Hospital Santa Joana (Recife, Brazil)
Mazowiecki Szpital Bródnowski (Warsaw, Poland)
Meyer Children's Hospital (Florence, Italy)
Policlinico Umberto I (Rome, Italy)
Rigshospitalet (Copenhagen, Denmark)
Sahlgrenska Universitetssjukhuset (Gothenburg, Sweden)
Skånes Universitetssjukhus Lund (Lund, Sweden)
Santobono Children's Hospital (Naples, Italy)
Universitätsklinikum Tübingen (Tübingen, Germany)
Universitätsklinikum Düsseldorf (Düsseldorf, Germany)
Universitätsklinikum Freiburg (Freiburg, Germany)
University Hospital of Wales (Cardiff, UK)

Charles River Labs (Laval, Canada)
Charles River Labs (Lyon, France)
Charles River Labs (Mattawan, Michigan)
Children's Hospital of Philadelphia
Envol Biomedical (Florida)
Labcorp (Madison, Wisconsin)
Prisys Biotechnologies (Shanghai, China)
TIDU GENOV - Institut du Cerveau (Paris, France)
University of Pennsylvania Gene Therapy

Funded. Foundation.

Building the Business

We have invested in the Development, Quality and Supply infrastructure to build confidence for both hospitals and BioPharma partners

We are not a start-up company but an **experienced and sophisticated medical device extension** for any cell and gene therapy company

ClearPoint Neuro assets available to our partners:

- HQ & Training Facility in Solana Beach, California
- Research Laboratory in San Diego, California
- Manufacturing Facility in Carlsbad, California
- ISO 13485 / MDSAP / EU MDR Certified QMS
- Significant and positive experience with BioPharma Audits, FDA and Global Notified Body inspections



Building the Business

Key Products:



Marked Platforms

HEADQUARTERS

Solana Beach, CA

2024 REVENUE

\$31.4M^(A)

PATENTS ISSUED

100+^(D)

EMPLOYEES

100+

MANUFACTURING

Carlsbad, CA

CASH & CASH EQUIVALENTS

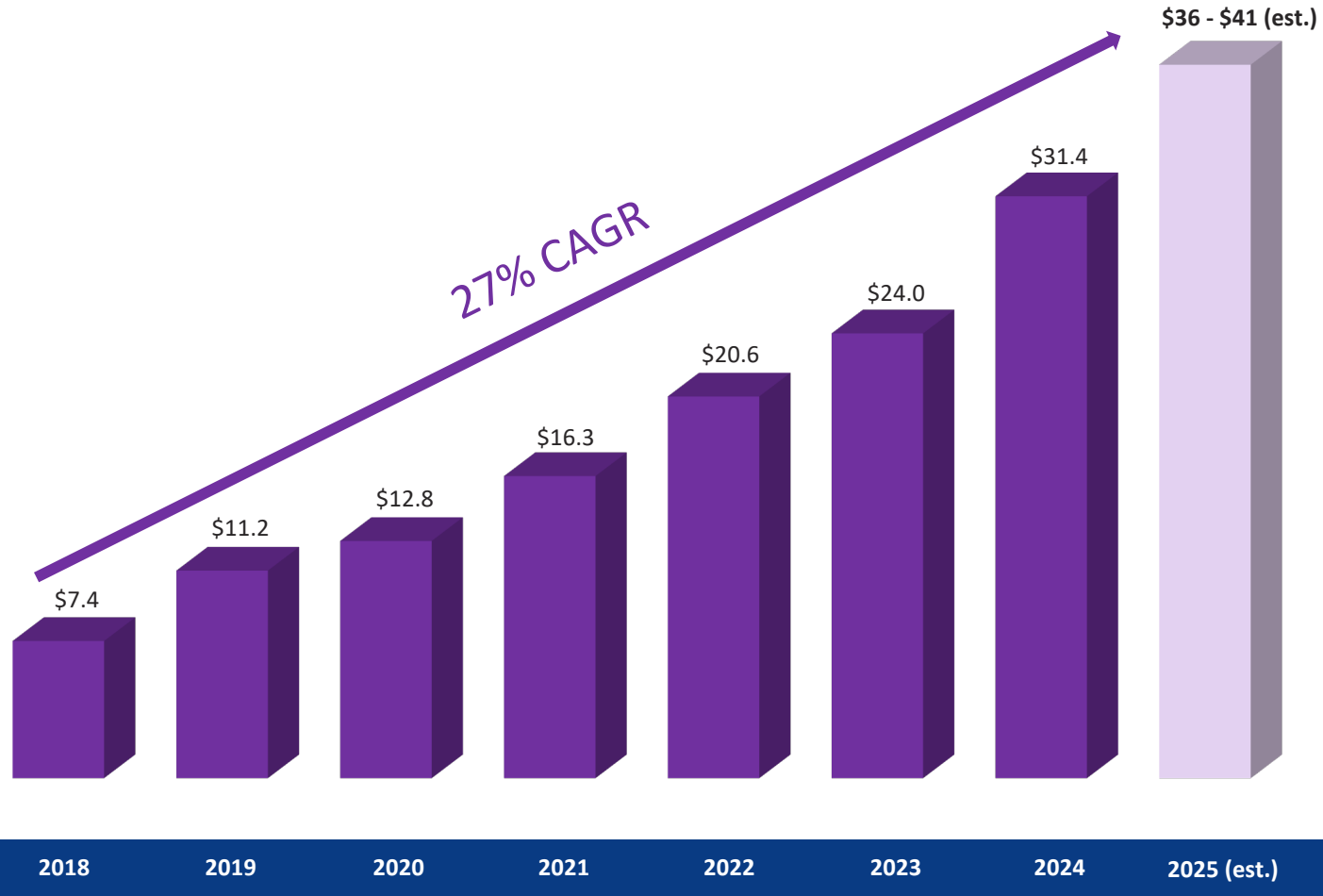
\$12.4M^(B,C)

GROSS MARGIN

61%^(B,E)

2024 Operational Cash Burn

(\$9.0M)^(A)



(A) For the year ended December 31, 2024
(B) Unaudited, as of, and for the quarter ended, March 31, 2025
(C) Excludes Gross Proceeds of \$33.5M received on May 12, 2025
(D) Including owned and licensed patents
(E) For the Trailing Twelve Months (TTM)

Building the Business

EXECUTIVE LEADERSHIP TEAM

Experienced leadership team with decades of leadership in medical devices, pharmaceuticals, and clinical research.



Joe Burnett
President &
Chief Executive Officer



Danilo D'Alessandro
Chief Financial
Officer



Jeremy Stigall
Chief Business
Officer



Mazin Sabra
Chief Operating
Officer



Ellisa Cholapranee
General
Counsel



Megan Faulkenberry
Vice President
of Quality



Lyubomir Zagorchev, PhD
Vice President of Clinical
Science & Applications



Mary McNamara-Cullinane
Vice President
of Regulatory Affairs



Ernesto Salegio, PhD
Vice President of Translational
& Preclinical Research



Rob Korn
Vice President
U.S. Commercial Sales

In 2025 Our Journey Enters the **NEXT CHAPTER**

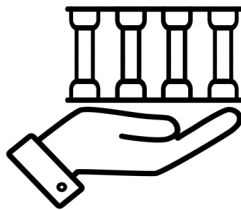
2010 - 2020



Discovery. Design.

- Neurosurgeon-Led Ideation
- Unique MRI Navigation
- Initial FDA Clearance and Product Revenue
- Accumulation of Clinical Trial Experience Using SmartFlow
- Maestro A.I. Software Development
- Initial IP Generation and Licenses
- NASDAQ Listed

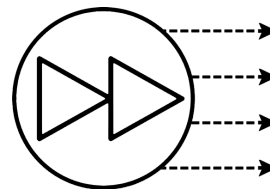
2021 - 2024



Funded. Foundation.

- 100+ Activated Customers
- 60+ Biopharma Partners
- 20+ Potential Disease Indications*
- Preclinical Team Creation
- Operating Room Product Launch
- Laser Therapy Product Launch
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- Leadership Team Complete

2025 - 2027



Fast. Forward.

- Grow into an estimated, existing \$500M Market Opportunity
- 150 Activated Customers
- First Commercial CGT Launched
- GLP Preclinical Capability
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- 'Harmony' Software Launch
- New Routes of Administration
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2028+



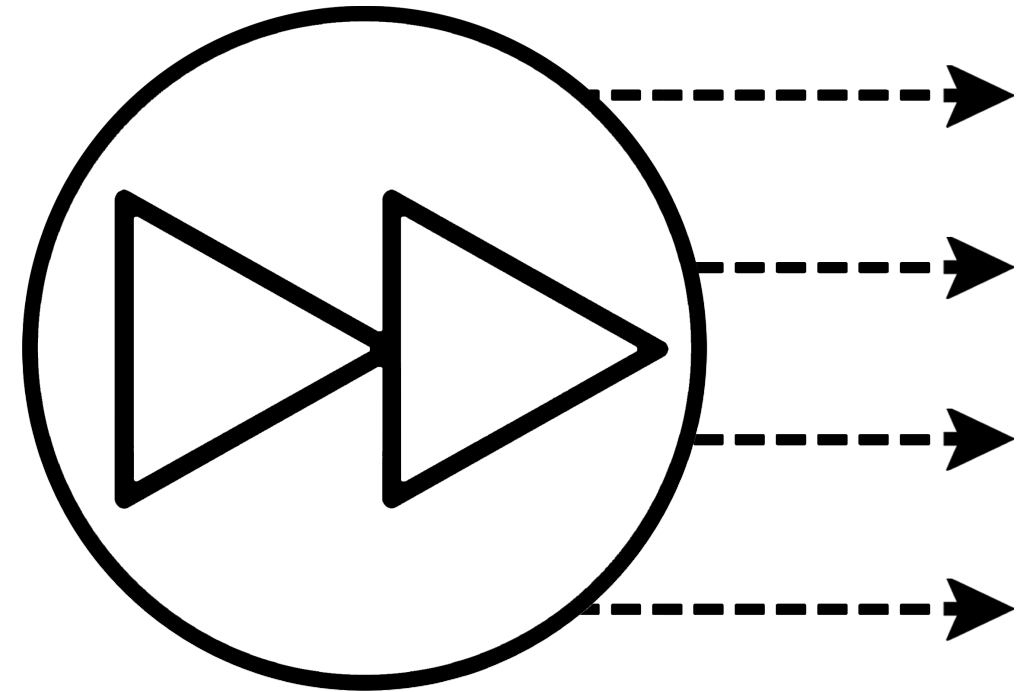
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- Meaningful Revenue from Sophisticated BioPharma Deal Structures beyond product sales including royalty and milestone payments, co-development
- One Unified Platform with both MR and Operating Room Capability and Workflows
- Additional Global Regulatory Approvals Beyond the U.S. and E.U.

We are Pointing the Way for a Cell and Gene Therapy Future: **Fast. Forward.**

Our commitment to hospitals & BioPharma partners is to help prepare for tens-of-thousands of anticipated new patients who will be seeking these restorative therapies

1. **Extend Our Lead** in Neuro Drug Delivery by leveraging our complete and unique ecosystem of both products and drug development services
2. **Evolve our Portfolio** to focus on fast, simple, predictable procedures in both the MRI and Operating Room to increase hospital throughput
3. **Expand our Base** of global activated centers to increase capacity and ensure access of these novel cell and gene therapies



Fast. Forward.

OUR FOUR PILLAR GROWTH STRATEGY CONTINUES 2025-2027

GLOBAL SCALE
ACTIVATE 150 CENTERS &
GROW REVENUE FASTER THAN OPEX **4**

LASER THERAPY & ACCESS
COMPLETE PRISM LASER &
VELOCITY DRILL LAUNCHES **3**

NEUROSURGERY NAVIGATION
EXPAND INTO THE OPERATING ROOM &
CREATE A UNIFIED SOFTWARE PLATFORM **2**

BIOLOGICS & DRUG DELIVERY
ADD PRECLINICAL GLP SERVICES &
NEW ROUTES OF ADMINISTRATION **1**

2025

2027

Fast. Forward.

OUR FOUR PILLAR GROWTH STRATEGY CONTINUES 2025-2027

GLOBAL SCALE

Expand Global Footprint to 150+ Centers
Perform Procedures w/ Remote Clinical Support
Show path to 70%+ Margins & Cashflow Breakeven

4

LASER THERAPY & ACCESS

Add 1.5 Tesla PRISM for full market access
Add Ablation Coverage & Predictive Thermal Modeling
Launch MRI Conditional Power Drill to reduce procedure time

3

NEUROSURGERY NAVIGATION

Show Compatibility with Existing Third-Party Navigation w/ SmartFrame OR
Expand into the Operating Room w/ ClearPoint Duet and 3.0 Software
Launch Maestro CT, Non-Rigid Fusion, Area-of-Activation and DTI Harmony Software

2

BIOLOGICS & DRUG DELIVERY

Expand Neuro Preclinical CRO Services and Capacity to include larger GLP Study Capability
Expand Partnerships to Include Co-Development, Commercial Pricing, Drug Clinical Milestones & Royalty Based Agreements
Execute on Development Pipeline for Drug Infusion Monitoring/Modelling, Intracranial Cell Therapy and Spinal Routes of Administration

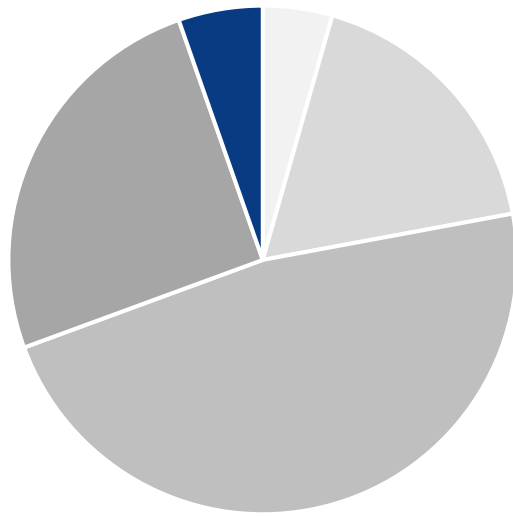
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2025

2027

GLP Services & New Routes of Administration

2025 Estimated Preclinical & Clinical Trial Market (≈\$300M)



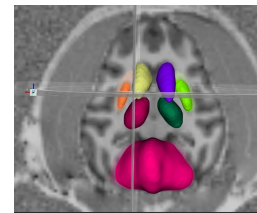
- Consulting, Bench Testing and Co-Development Services
- Pilot Pre-Clinical Testing (non-GLP)
- FDA Submission Preclinical Testing (GLP)
- Clinical Trial Products & Support Services
- Current CLPT Share

Market Growth Drivers:

- Improved BioPharma funding environment
- Additional cell and gene therapies entering the 'funnel'
- Partner progression into larger spend GLP studies and clinical trials
- Successful implementation of FDA 'Expedited Review' pathways including RMAT offering faster clinical trials and less capital required

Market Share Drivers:

- Addition of GLP capability and increased study capacity
- Expansion to ClearPoint Advanced Laboratories ('CAL')
- Product portfolio expansion including new routes of administration
- More custom-development and strategic partnerships w/ BioPharma



GLP Preclinical Services and Image Analysis Lab
(Expected 2H 2025)



New Routes of Administration
(Investigational Use Only)

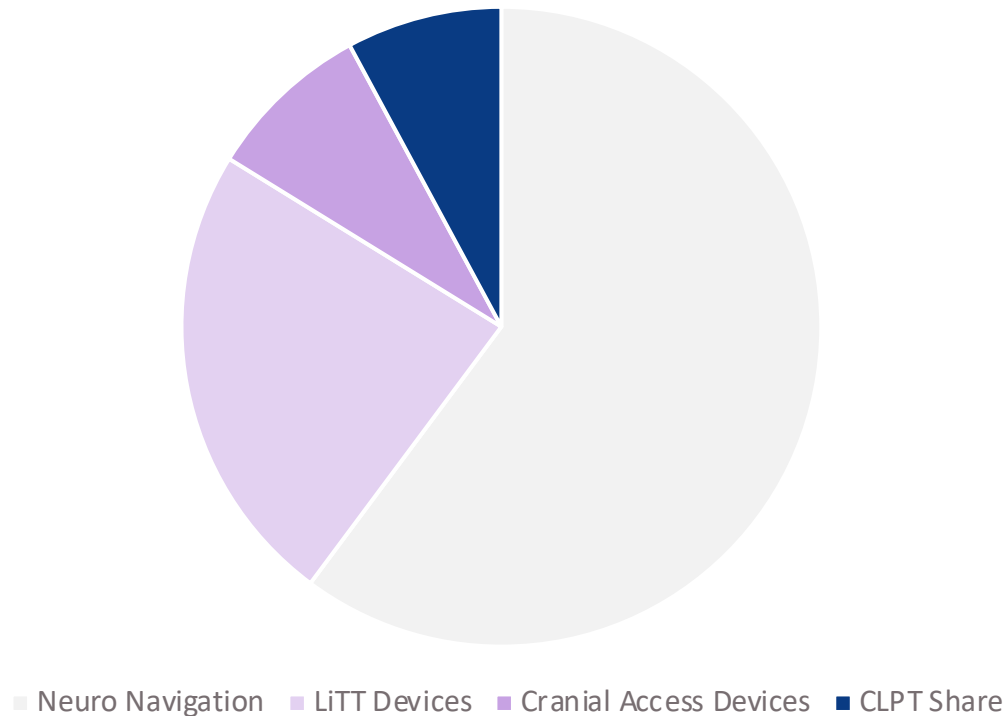
Coverage Estimation and Biophysical modeling
(Investigational Use Only)

Assumptions:

- 150 active cell and gene therapy programs globally
- 7.5 years average program duration
- 200 patients studied clinically on average as part of trials

Neuro Navigation, Therapy and Access Product Growth

2025 Estimated Neuro Navigation, Laser
Therapy & Cranial Access Market (≈\$200M)



Estimated Market Size, Growth Drivers, and Share Drivers are based on internal estimates and assumptions, market trends, and customer insights. Assumptions may not reflect actual future performance.

Market Growth Drivers:

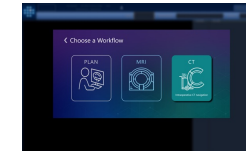
- Asleep DBS FDA Clearance and Patient Awareness
- New DBS Indications including Epilepsy, OCD, Depression, BCI
- Increased hospital throughput of laser therapy compared to open surgery
- Improved laser insurance decisions and awareness
- Additional global approvals

Market Share Drivers:

- 3.0 Software for proficient, mirrored CLPT workflow in the MRI and OR
- Asleep, simultaneous workflows for fast procedures, low radiation
- 1.5 Tesla PRISM Laser approval for full market access
- Velocity Alpha MR Drill for faster cranial access times



SmartFrame OR
and ClearPointer™



ClearPoint 3.0 Software
w/ CT Functionality
(FDA Cleared January
2025)



SmartFrame DUET w/
flexible MRI & CT
workflows
(Expected 2026)



1.5 Tesla PRISM
(Expected 2H 2025)



Adeor Velocity MRI
Conditional Power Drill
(Pending FDA Clearance)

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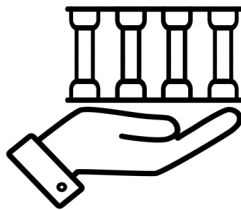
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- Initial IP Generation and Licenses
- NASDAQ Listed

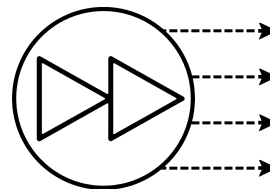
2021 - 2024



Funded. Foundation.

- 100+ Activated Customers
- 60+ Biopharma Partners
- 20+ Potential Disease Indications*
- Preclinical Team Creation
- Operating Room Product Launch
- Laser Therapy Product Launch
- 100+ Owned & Licensed Patents
- EU MDR Certification
- Expanded, Audit-Ready Manufacturing in California
- Leadership Team Complete

2025 - 2027



Fast. Forward.

- Grow into an estimated, existing \$500M Market Opportunity
- 150 Activated Customers
- First Commercial CGT Launched
- GLP Preclinical Capability
- Operating Room Nav Growth
- Laser Therapy Growth
- MR Drill and Access Growth
- 'Harmony' Software Launch
- New Routes of Administration
- Operational Cash Breakeven

2028+



Essential. Everywhere.

- \$10B Potential Revenue Opportunity
- 'Combination Product' Regulatory Designation for multiple cell and gene therapy indications
- Meaningful Revenue from Sophisticated BioPharma Deal Structures beyond product sales including royalty and milestone payments, co-development
- One Unified Platform with both MR and Operating Room Capability and Workflows
- Additional Global Regulatory Approvals Beyond the U.S. and E.U.

The FDA & Global Notified Bodies Recognize the Urgency

1 Partner has received FDA approval for a neuro gene therapy that is co-labeled with ClearPoint

FDA NEWS RELEASE

FDA Approves First Gene Therapy for Treatment of Aromatic L-amino Acid Decarboxylase Deficiency

For Immediate Release:

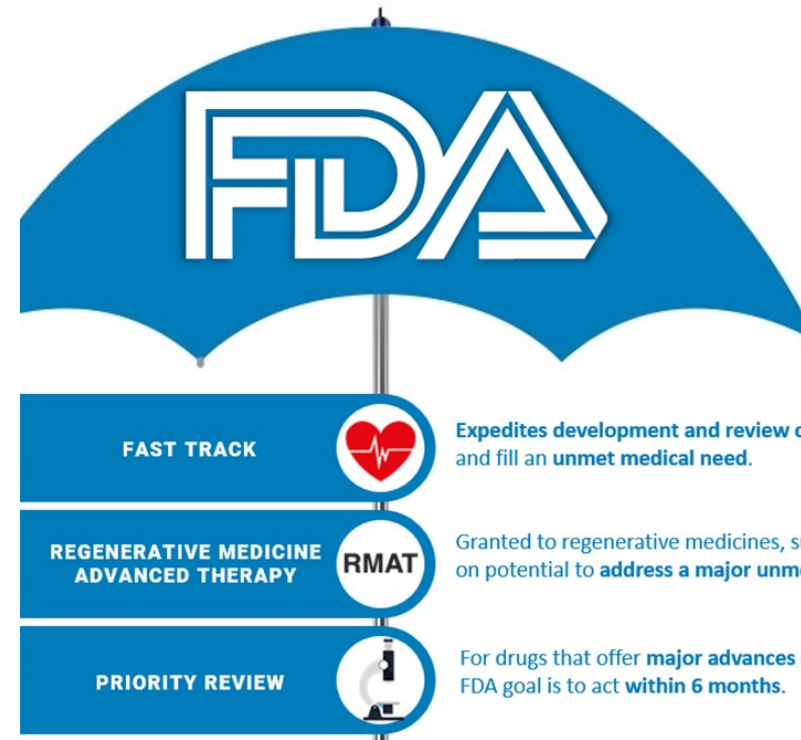
November 14, 2024

The U.S. Food and Drug Administration approved Kebilidi (eladocogene exuparvovec-tneq), an adeno-associated virus vector-based gene therapy indicated for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency. Kebilidi is the first FDA-approved gene therapy for treatment of AADC deficiency.

“Clinical advancements in the field of gene therapy continue to lead to the discovery and availability of innovative treatment options for rare diseases that are otherwise difficult to manage,” said Peter Marks, M.D., Ph.D., director of the FDA’s Center for Biologics Evaluation and Research (CBER). “Today’s approval underscores our commitment to help make safe and effective treatments available for patients in need.”

The FDA also authorized the SmartFlow Neuro Cannula, an infusion tube inserted into a target in the brain (parenchymal tissue), to deliver Kebilidi. The SmartFlow Neuro Cannula is currently the only FDA authorized device indicated for use to administer Kebilidi. The FDA granted authorization of the SmartFlow Neuro Cannula to ClearPoint Neuro, Inc.

7 Partners have programs selected for expedited review - the FDA recognizes the urgency



Essential. Everywhere.

ClearPoint has **60+ Active BioPharma Programs** across **20+ indications** including **DBS, LiTT**

BENCHTOP TESTING



- Device Compatibility Testing
- Infusion Pump Testing
- Custom Device Development
- Performance Assessment
- Device Comparisons / Bridging

PRECLINICAL STUDIES



- Running Preclinical Studies
- Surgical Planning & Guidance
- Writing IACUC / Study Protocols
- Dosing and Surgical Support
- Post-Infusion Reporting

CLINICAL TRIALS



- Surgical Guidance
- Procedure Pre-Planning
- On-Site Clinical Support
- Inventory Management
- Data / Infusion Reporting

Sophisticated Partnerships are Enabled by the **ClearPoint Ecosystem of Products & Services**

We provide the creative flexibility to structure agreements as an **essential and long-term supplier**

ClearPoint May Provide to BioPharma:

- Assurance of Supply
- Access to FDA Device Dossier
- Redundant Global Manufacturing
- Contracted Commercial Pricing
- Licenses to Key Intellectual Property
- Custom Device Development
- Clinical Specialist Procedural Support
- Dedicated Inventory Locations
- Extensive Audit Access & Experience
- Supply Continuity and Reliability



ClearPoint May Secure from BioPharma:

- Demand Planning
- Purchasing Commitments
- Minimum Device Purchases
- Co-Development Design Fees
- Strategic Retainer Agreements
- Clinical Milestone Payments
- Premium Commercial Pricing
- Royalties on Drug Revenue
- Preclinical Service Purchases
- Multiple Program Collaborations

CLPT is like a **Portfolio of BioPharma** without drug development costs or binary outcomes








More than **30 million people** in the U.S. are estimated to suffer from **severe and debilitating neurological disorders**:

- Parkinson's Disease (≈1,000,000)
- Essential Tremor (≈7,000,000)
- Epilepsy (≈2,900,000)
- Huntington's Disease (≈41,000)
- Rare Childhood Genetic Disorders (≈25,000)
- Dementia and Alzheimer's Disease (≈6,900,000)
- Tumor and Glioblastoma (≈280,000)
- Severe OCD (≈1,000,000)
- Treatment Resistant Depression (≈2,900,000)
- ALS and Spinal Cord Injury (≈300,000)
- Stroke Rehabilitation (≈7,000,000)
- Neuropathic Pain (≈2,000,000)

ClearPoint Neuro is Diversified Across:

- 60+ BioPharma Partners
- 20+ Indications including device, cell and gene therapies
- Redundant Partners for multiple indications
- Many Partners with multiple programs
- Additional device treatments including DBS, Laser, BCI

Many shots on goal with a path to operational cash breakeven:

	Indication	RMAT	Fast Track	Clinical Status
	AADC Deficiency	-	-	Approved
	Huntington's Disease	✓	-	Trials in US, EU
	Parkinson's Disease	✓	-	Trials in <u>NorthAm</u>
	Epilepsy (MTLE)	✓	-	Trials in the US
	Parkinson's Disease	✓	✓	Trials in US, EU
	Parkinson's Disease	-	✓	Trials in the US
	Frontotemporal Dementia	-	✓	Trials in US, EU

If just 1% of patients with diseases under expedited review are treated each year, at current ASPs that would yield more than \$250M in additional CLPT revenue

CLEARPOINT NEURO EXECUTIVE SUMMARY

A UNIQUE PLATFORM TECHNOLOGY USED FOR CELL AND GENE THERAPY DELIVERY

15+ years building a complete drug delivery ecosystem including navigation solutions, predictive modeling, delivery devices, infusion monitoring software and clinical case support



CURRENT PORTFOLIO PROVIDES ACCESS TO A ≈\$500M MARKET OPPORTUNITY TODAY

Evolved beyond the MRI and into operating room CT navigation, laser ablation therapy, surgical access tools and preclinical CRO services which fuel growth via new product launches and provide path to profitability



A \$10B POTENTIAL MARKET DIVERSIFIED ACROSS 60+ PARTNERS, 20+ INDICATIONS*



Combination device success, proprietary technology and deep FDA experience provide our BioPharma partners with a meaningful head start, and our investors with a Portfolio-like biotech strategy

100+ ACTIVE GLOBAL CENTERS



An expanding global installed base of regional treatment centers are scaling capacity to be ready for additional cell and gene therapy patients to be treated with a unified platform

A GROWING & PASSIONATE TEAM



Our dedicated team of engineers, scientists and clinical specialists wake up every morning focused on the future of neurosurgery and drug delivery - *This is all that we do...*



Sources

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