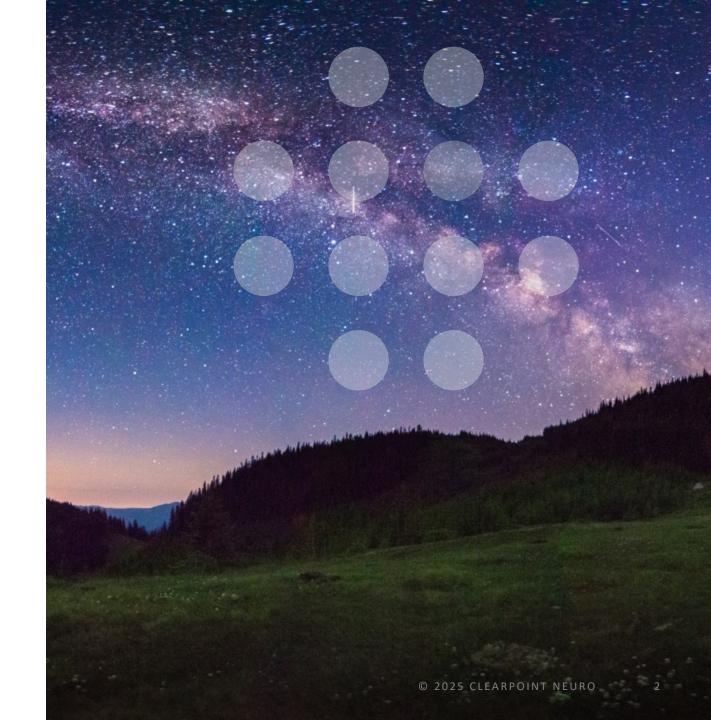
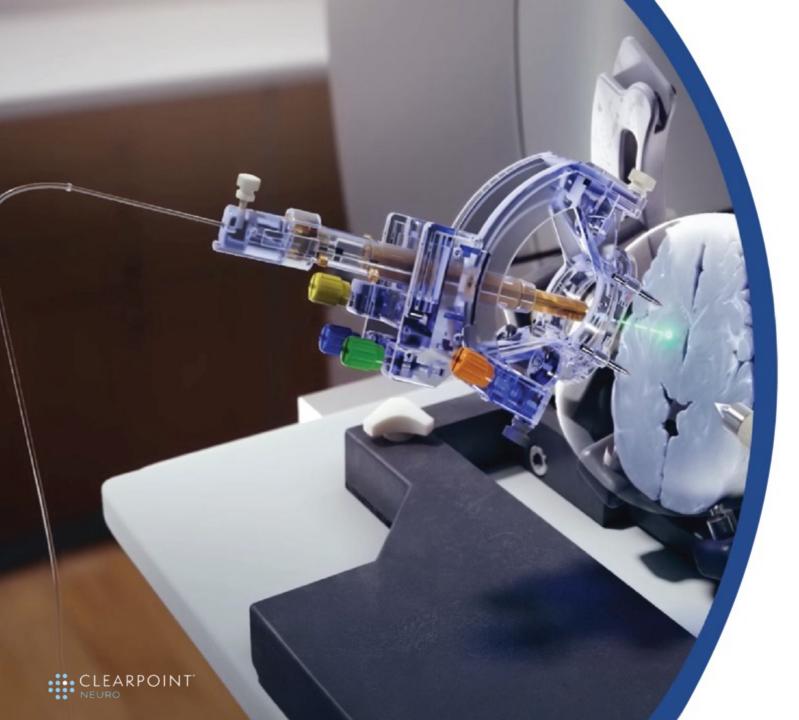


DISCLAIMER

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 the Company's products and services, the Company's belief about the outcome of regulatory interactions with respect to its biotech partners' therapies, the timing of commercialization of such therapies, the market potential for such therapies, the anticipated adoption of the Company's products and services for use in the delivery of gene and cell therapies, 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 forwardlooking 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 the Company's biotech 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 biotech partners or enter into new relationships with such partners; the Company's biotech partners' risks related to the ongoing conduct of their clinical studies, including the risk that such trials will be unable to demonstrate data sufficient to support further clinical development or regulatory approval: the risk that more patient data becomes available that results in a different interpretation then the data already released for gene and cell therapies; risks related to interactions with regulatory authorities, which may affect the initiation, timing and progress of clinical trials and pathways to regulatory approval of the biotech partners' therapies; the limitation or modification of the FDA's eligibility and criteria for its expedited review programs with respect to such therapies; the commercialization and acceptance of gene and cell therapies; the Company's biotech partner's continued use of the Company's products and services in their delivery of gene and cell therapies; 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 biotech partners. For a detailed description of the Company's risks and uncertainties, you are encouraged to review its documents filed with the SEC including the Company's recent filings on Form 8-K, Form 10-K and Form 10-Q. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.







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

CLEARPOINT

NEURO

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...

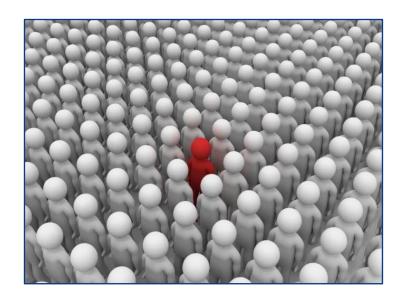
Our Company

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.

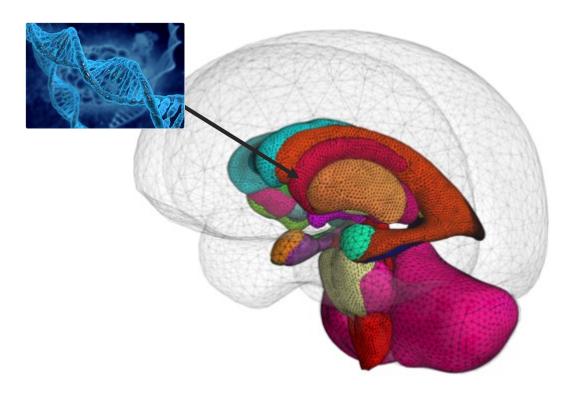


Despite some available treatments, very few of these patients undergo a direct surgical intervention to improve their quality of life...

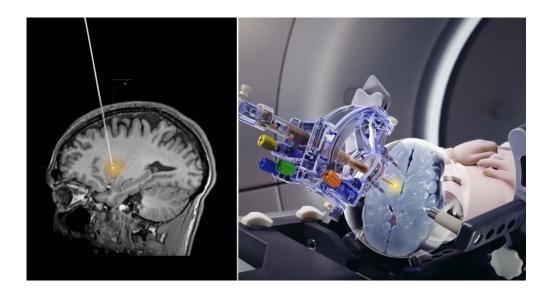
The Future of Cell and Gene Therapy is Not Coming... It is HERE TODAY

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

We will partner to Develop Device, Cell and Gene Therapies that may <u>cure</u> the underlying disease and <u>restore</u> function...



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

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 (eladocagene 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.





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

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

	Indication	RMAT	Fast Track	Clinical Status
PTC THERAPEUTICS	AADC Deficiency	-	-	Approved
uniQure	Huntington's Disease	✓	-	Trials in US, EU
BlueRock	Parkinson's Disease	\checkmark	-	Trials in NorthAm
NEURONA THERAPEUTICS	Epilepsy (MTLE)	\checkmark	-	Trials in the US
AskBio	Parkinson's Disease	\checkmark	\checkmark	Trials in US, EU
REGENXBIO	Hunter Syndrome (MPSII)	\checkmark	\checkmark	Trials in US, Brazil
Aspen	Parkinson's Disease	-	\checkmark	Trials in the US
AVIADOBIO Undisclosed	Frontotemporal Dementia Friedreich's Ataxia	-	✓	Trials in US, EU Trials in the US

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

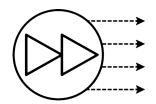
2021 - 2024



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
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- 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.

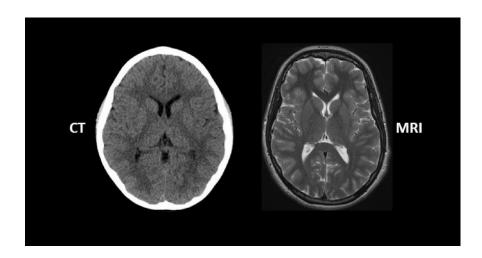
- \$10B Potential Revenue Opportunity
- 'Combination Product' Regulatory
 Designation for multiple cell and gene
 therapy indications
- Meaningful Revenue from Sophisticated BioPharma Deal Structures beyond product sales including royalty and milestone payments, co-development
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- 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**

Discovery. Design.

Our Start: Decide, Guide & Confirm





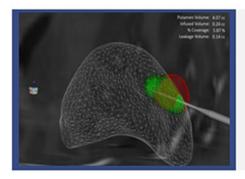
Pre-Plan Trajectory
and **D E C I D E**Entry Point





Automatically **G U I D E**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:

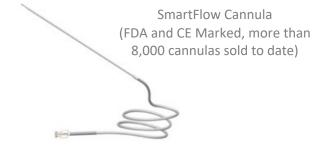
- 1. Functional neurosurgeons could confidently place DBS electrodes with the **patient comfortably asleep**
- 2. Neuro-oncologists could perform entire tumor laser ablations in one room instead of having to transport the patient from the OR to the MRI
- 3. BioPharma researchers could confirm that cell 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

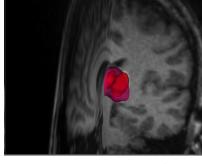
Our Start: Assemble the Building Blocks

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

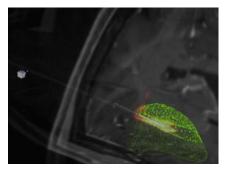




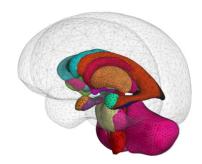
3D Peri-procedural Infusion Monitoring Software (Investigational Use Only)



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



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



ClearPoint Maestro Brain Model Segmentation and Image Fusion

Funded, Foundation,

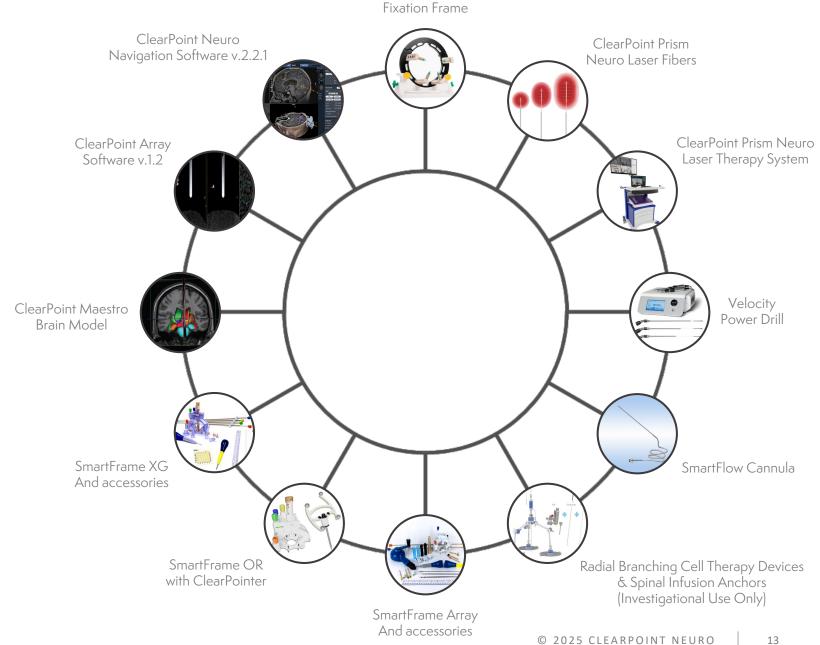
Building the Business

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



Inflexion Head

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

BIOLOGICS & DRUG DELIVERY













60 +INDUSTRY & **ACADEMIC PARTNERS**











NAVIGATION









& ACCESS



















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



Albany Medical Center Hospital

Banner Health Tucson

Baptist Hospital of Miami

Baptist Memorial Hospital-Memphis

Barnes-Jewish Hospital

Barrow Neurological Institute/St. Joseph's Hospital

BayCare Health System

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

Cooperman Barnabas Medical Center

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 East Hospital

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 Hospital San Antonio

University of Alabama at Birmingham

University of California Los Angeles

University of Colifornia Can Diago

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

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) Policlinico Umberto I (Rome, Italy) Rigshospitalet (Copenhagen, Denmark) Sahlgrenska Universitetssjukhuset (Gothenburg, Sweden) Skänes 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)

100+
GLOBAL
CENTERS NOW
ACTIVATED

Charles River Labs (Laval, Canada)
Charles River Labs (Lyon, France)
Charles River Labs (Mattawan, Michigan)
Children's Hospital of Philadelphia
Labcorp (Madison, Wisconsin)
Prisys B otechnologies (Shanghai, China)
U 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:

FDA CE

Marked Platforms

HEADQUARTERS

Solana Beach, CA

2024 REVENUE

\$31.4M^(A)

PATENTS ISSUED

100+^(C)

EMPLOYEES

100+

MANUFACTURING

Carlsbad, CA

CASH & CASH EQUIVALENTS

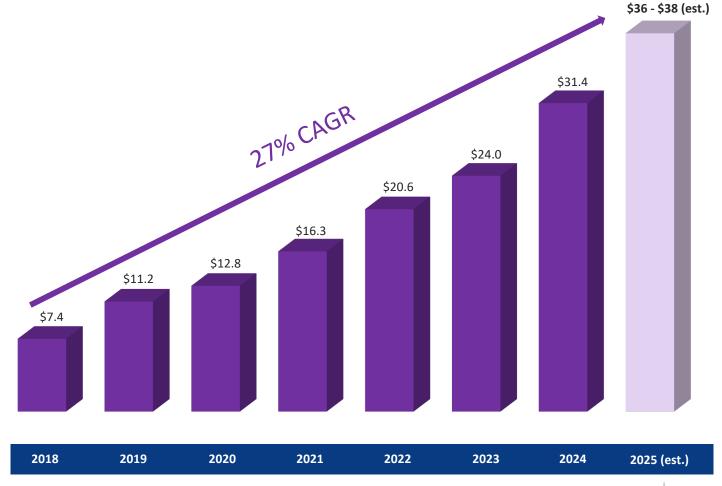
\$38.2M^(B)

GROSS MARGIN

61%^(B,D)

2024 Operational Cash Burn

(\$9.0M) (A)





⁽B) Unaudited, as of, and for the quarter ended, September 30, 2025

(D) For the Trailing Twelve Months (TTM)

⁽C) Including owned and licensed patents

Building the Business



Joe Burnett President & Chief Executive Officer



Megan Faulkenberry Vice President of Quality



Danilo D'Alessandro Chief Financial Officer



Lyubomir Zagorchev, PhD Vice President of Clinical Science & Applications



Jeremy Stigall Chief Business Officer



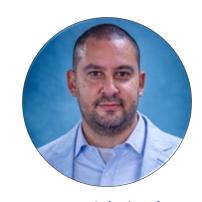
Mary McNamara-Cullinane Vice President of Regulatory Affairs



EXECUTIVE LEADERSHIP TEAM

Experienced leadership team with decades of leadership in

Mazin Sabra Chief Operating Officer



Ernesto Salegio, PhD Vice President of Translational & Preclinical Research



Ellisa Cholapranee General Counsel



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

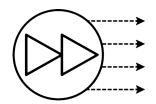
2021 - 2024



Funded. Foundation.

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

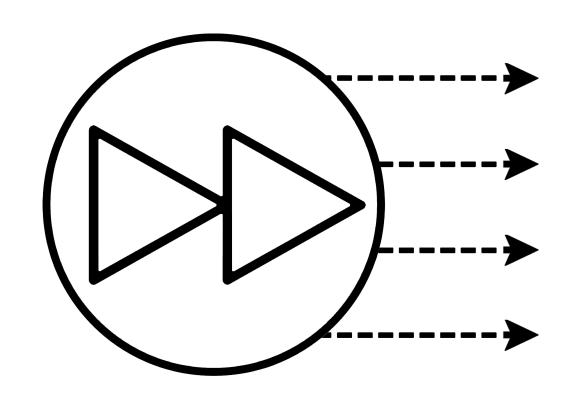
- \$10B Potential Revenue Opportunity
- 'Combination Product' Regulatory
 Designation for multiple cell and gene
 therapy indications
- Meaningful Revenue from Sophisticated BioPharma Deal Structures beyond product sales including royalty and milestone payments, co-development
- One Unified Platform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

Fast. Forward.

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

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





OUR FOUR PILLAR GROWTH STRATEGY CONTINUES 2025-2027

GLOBAL SCALE
ACTIVATE 150 CENTERS &
GROW REVENUE FASTER THAN OPEX

COMPLETE PRISM LASER & VELOCITY DRILL LAUNCHES

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

ADD PRECLINICAL GLP SERVICES &
NEW ROUTES OF ADMINISTRATION

2027

2025



GLOBAL SCALE

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

4

OUR FOUR PILLAR GROWTH STRATEGY CONTINUES 2025-2027

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

1

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

2027

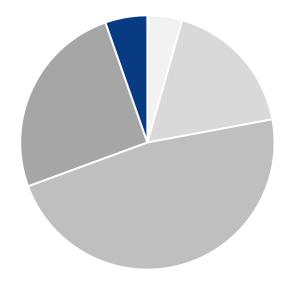
2025



Fast. Forward.

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

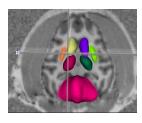
Estimated Market Size, Growth Drivers, and Share Drivers are based on internal estimates and assumptions, market trends, and customer insights. Assumptions may not reflect actual future performance.

Market Growth Drivers:

- 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)

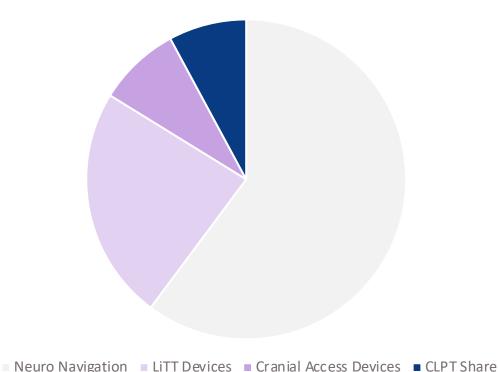
Coverage Estimation and Biophysical modeling (Investigational Use Only)

Assumptions:

Fast. Forward.

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™



1.5 Tesla PRISM (FDA Cleared September 2025)



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





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

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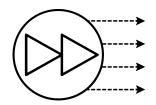
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The FDA & Global Notified Bodies Recognize the Urgency

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 (eladocagene 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.

Partners have programs selected for expediated review - the FDA recognizes the urgency



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



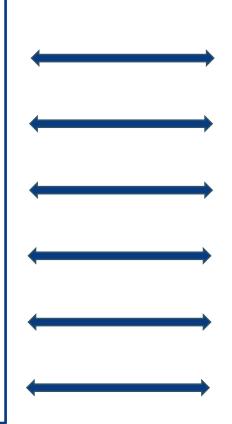
- Surgical Guidance
- Procedure Pre-Planning
- On-Site Clinical Support
- Inventory Management
- Data / Infusion Reporting

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:



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

CLEARPOINT

NEURO

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

Sources

Alzheimer's Association 2024 Alzheimer's Disease Facts and Figures

How Many People in the USA Have Essential Tremor? Deriving a Population Estimate Based on Epidemiological Data - PMC

Parkinson's Disease: Challenges, Progress, and Promise | National Institute of Neurological Disorders and Stroke

Epilepsy Facts and Stats | Epilepsy | CDC

Prevalence of Huntington's Disease in the US (954) | Neurology

What is Friedreich's ataxia? - Friedreich's Ataxia Research Alliance

Angelman syndrome | About the Disease | GARD

Brain Tumor Facts

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Amyotrophic lateral sclerosis estimated prevalence cases from 2022 to 2030, data from the National ALS Registry | National ALS Registry | CDC

Spinal Cord Injury Prevalence In The U.S. | Reeve Foundation

Abbott Initiates Clinical Study to Evaluate the Use of Its Deep Brain Stimulation System to Manage Severe Depression - Sep 4, 2024

The prevalence of neuropathic pain: Clinical evaluation compared with screening tools in a community population - PMC

Deep brain stimulation for obsessive-compulsive disorder: A systematic review of worldwide experience after 20 years - PMC

How common is OCD?

Burden of Neurological Disorders Across the US From 1990-2017: A Global Burden of Disease Study | Dementia and Cognitive Impairment | JAMA Neurology | JAMA Network