

# Lifesaving diagnostics

March 2024

**Disclaimer & confidentiality:** the proprietary presentation is given for general informational purposes only and must be kept strictly confidential



# Agenda

- **Introduction: overview of Upfront Diagnostics**
- Deep dive: LVOne, market landscape
- Deep dive: business plan, uses of funds
- Next steps: data room, fundraising process

# UPFRONT | People

Strong team with Co-Founders committed > 6 years to build the business through innovative research

## Senior management team



**Gonzalo Ladreda**  
CEO & Managing Director

- Cambridge Judge Business School
- Forbes 30 under 30 Class of 2023 Europe for Science + Healthcare



**Dr. Joshua Bernstock**  
Chief Medical Officer

- Neurosurgery at Brigham and Women's and Boston Children's Hospitals
- MIT scientist specialized in experimental therapeutic and diagnostics



**Dr. Edoardo Gaude**  
CSO & Executive Director

- PhD University of Cambridge
- Academic + industry research for diagnostic biomarkers



**Marcos Ladreda**  
Product specialist & Executive Director

- Point-of-care development at leading manufacturer
- Products launched in the NHS

## Funding raised to date

**£3.8M**



## Board/Advisors/Investors



**Dr. Tito Bacarese-Hamilton**  
Chairman

- +35 years IVD experience
- Founder of several successful IVD companies



**Ardashir Dubash**  
Non-executive Director/Investor

- Global Healthcare experience



**Dr. Pooja Sikka**  
Board observer

- General practitioner NHS
- Venture capitalist



**Francois Maisonrouge**  
Advisor/Investor

- Global Head of Healthcare at Evercore
- Takeda megadeal \$64bn, Wyeth/Pfizer \$68Bn...



**Andre Spark**  
Advisor/Investor

- Head of CEE Investment Banking at Jefferies



**UPFRONT's mission** is to develop innovative medtech products that can help to reduce disabilities and deaths

“Enabling the longer living and sustainable health for the people of the future”



# UPFRONT | Company in the news recently

[Click to see the BBC media coverage of UPFRONT Diagnostics](#)

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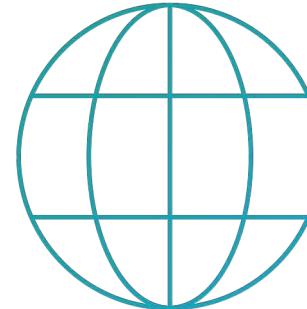
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# UPFRONT | Problem

There are **4m+** Large Vessel Occlusions (LVO) Strokes globally every year.

LVOs account for **30%** of stroke cases but are responsible for **95%** of Disabilities and Deaths



20m  
stroke cases  
worldwide



600,000+  
LVOs in EU/US  
per year



1st  
cause of  
physical disability



>£100bn  
EU/US stroke  
expenditure

## THE PROBLEM:

**ONLY 24 HOSPITALS IN  
ENGLAND CAN TREAT  
LVO STROKES**

**The stroke care pathway is not geared  
for rapid LVO stroke diagnosis and  
significantly delays treatment.**

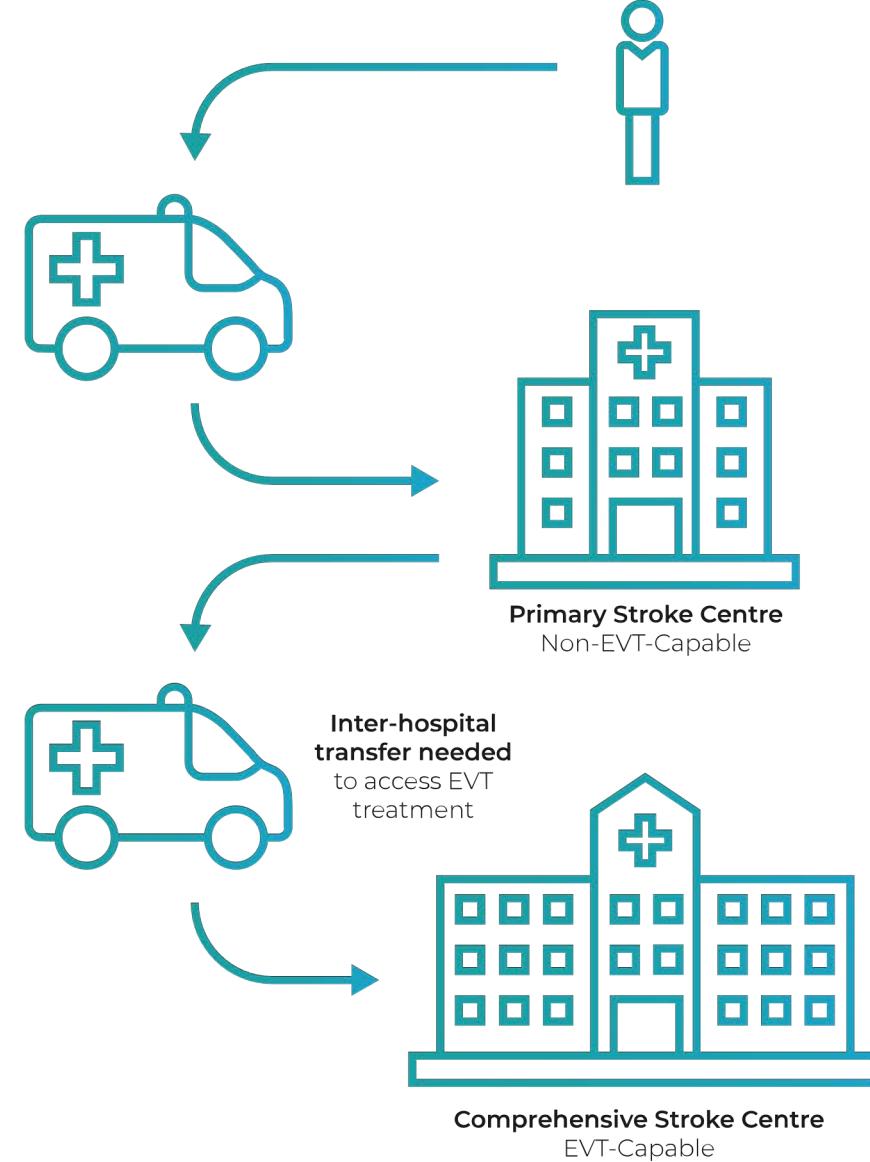
Thousands of patients missing out on  
'miracle' stroke treatment, leaving some  
disabled



**Thousands Denied 'Miracle' Stroke  
Treatment Helping Patients 'Near Death'**

**Bloomberg**

# Inter-hospital transfer causes: treatment delays, disabilities and costs



**27%**  
of LVOs  
receive  
treatment

# UPFRONT | LVO Blood Biomarkers Patented

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Thanks to a £1M Innovate UK grant, Upfront found in and protected 2 new blood biomarkers

*Diagnostics* 2021, 11(7), 1137; <https://doi.org/10.3390/diagnostics11071137>

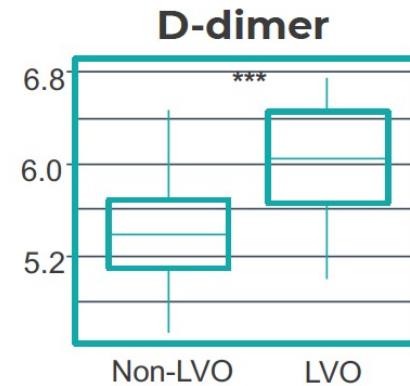
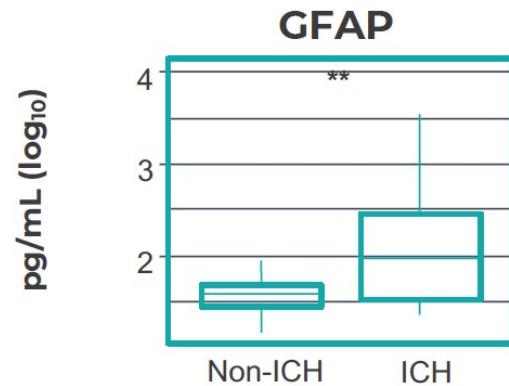


## A Novel Combination of Blood Biomarkers and Clinical Stroke Scales Facilitates Detection of Large Vessel Occlusion Ischemic Strokes



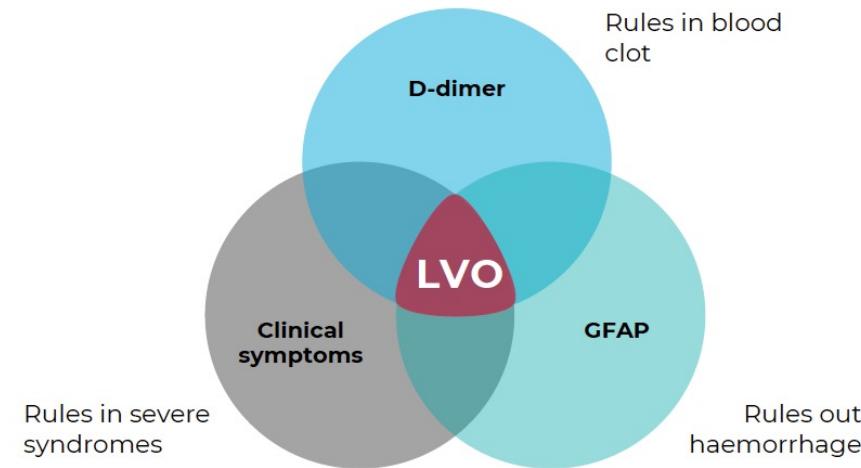
Derivation Cohort  
n=151

Validation Cohort  
n=119



## Combination of biomarkers + clinical scales

	Accuracy	Sensitivity	Specificity
FAST-ED + GFAP + D-dimer	95%	83%	98%



Gaudé et al  
2021

\*<https://www.mdpi.com/2075-4418/11/7/1137>

Innovate UK

Newcastle  
University

# UPFRONT | Rapid LVO Blood Test LVONE

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LVOne is protected with patents worldwide and already used by potential customers

IP



US patent  
granted

PCT patent  
filed



ISO 13485  
Certificate Number  
MD 784164

## Key Milestones



- ✓ Upcoming UKCA approval
- ✓ UK pilot signed in Cambridge (RADIOS)
- ✓ USA Clinical Trials Phase 1
- ✓ UK manufacturing line

< 15 Minutes



> 90% Accuracy



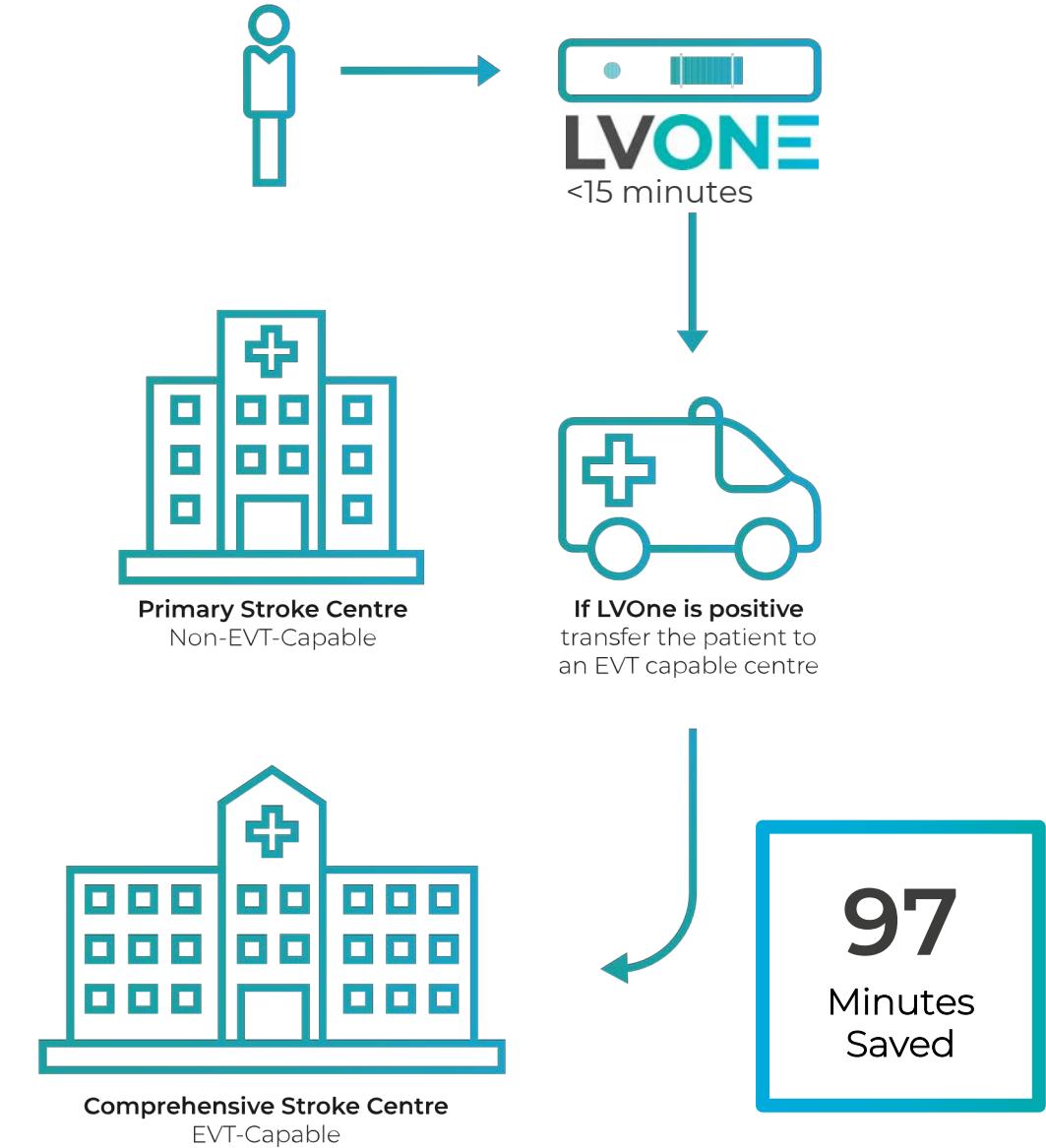
Disposable



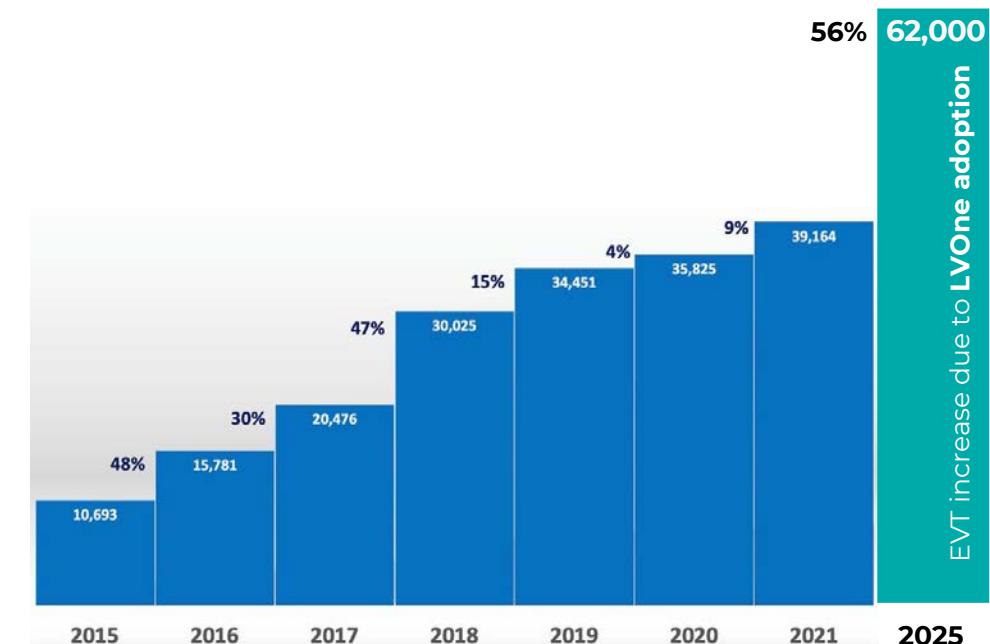
Fingerprick blood

\*Commercialised in boxes of 20 kits

**LVO diagnosis in  
the ambulance  
could save 97  
minutes\*  
of vital time**



**LVONE will  
increase 56% LVO  
stroke treatment  
per year**



Adapted from Rai et al 2022 JNIS

# UPFRONT | Impact of LVONE implementation in the prehospital setting in the UK, United States and Europe

97

minutes saved

Romoli JoS 2020

£11Bn

healthcare saved

See appendix for calculation

60,000

more EVTs

See appendix for calculation

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# UPFRONT | Competitors

LVOne has NO realistic competition on any metric

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LVONE	Portable Scanners	Other Blood Tests	Mobile Stroke Units
LVO Accuracy	95%	84%	70%
Portability	✓	✗	✓
Price/Device	No device needed	£65,000/device	£1,000 - £10,000/month
Price/Test	£620 (Max.)	£1,300*	£100 - £900
Organisation	Upfront Diagnostics	Neural Analytics, Alpha Stroke, Cerebrotech	ABCDx
Specialist Free	✓	✗	✓

\* Price for Neural Analytics' device, NICE Guidelines (UK)

# UPFRONT | Reimbursement/Payors

Adoption of new technology to fight the healthcare system financial crisis

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**Hospitals are going through a financial crisis**  
due to workforce shortages, broken supply chains and inflation



## Adoption of new technology

Global strategy to fight the healthcare financial crisis



↓ Unnecessary transfers  
↑ Efficiency



↓ Days at hospital  
↑ Increase profit margins

# UPFRONT | LVONE cost-effectiveness and pricing

Analysis performed by North East National Institute for Health and Care Research

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Cost-savings

# £440K

Savings for every **1,000**  
suspected stroke patients.

Pricing

# £620/Kit

Could be sold at a maximum  
of **£620** and still be cost  
effective to the NHS

## UK go-to-market - Selected for the Innovative Device Access Pathway (IDAP)

February '24

- 1 out of 8 companies included in UK government program designed to accelerate innovative medical devices that meet an unmet clinical need in the NHS and support their integration into the UK market.
- *“We are very excited to announce the final eight selected technologies in the new IDAP pilot scheme. This is designed to explore how government support can accelerate the development of transformative medical devices from their initial proof of concept through to uptake in the NHS” - Dr Marc Bailey, Medicines and Healthcare products Regulatory Agency Chief Science and Innovation Officer*



# FUNDING FOR INNOVATIVE MEDICAL DEVICES THAT CAN HELP PATIENTS WITH CANCER, STROKE AND ALZHEIMER'S

+++  
+++

**EIGHT TECH COMPANIES TO RECEIVE GOVERNMENT INVESTMENT**



## US go-to-market

- **Pre-submission meeting Feb-2020:** FDA confirmed De Novo pathway as most appropriate for LVOne
- **Pre-submission meeting Mar-2023:** US clinical study requirements and Analytical verification studies
- **Breakthrough device designation** application will be submitted in **mid-2024**
- **Clinical study ready Jacobs Institute (Dr. Adnan Siddiqui and Dr. Jason Davies),** finished before **end-2024**
- **FDA Submission** planned for **end-2024**
- **FDA De Novo** approval before **end-2025**
- **Pilots from January 2026**
- **Interventional + reimbursement** code **2026**



Partnering with Jacobs Institute: strategically located at the heart of both a world-class university research institute and a state-of-the-art hospital, the Jacobs Institute is uniquely positioned to foster collaboration between physicians, engineers, researchers, and entrepreneurs



# UPFRONT | Implementation

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Diversified customer base and long-term customer contracts are key for LVOne go-to-market strategy

## Medical Specialties Objective

Neurologists/ Cardiovascular	Surgery Prescription	Emergency Department
Physician/ Nurses	First Aid	Hospital, Stroke Centre
Paramedic	Emergency	Ambulance
Others (Carrier, Spouse, etc.)	Pre-Hospital	Home, Workplace, etc.

## Segments

Hospital	Surgical Centre	Ambulatory Surgery Centre
Emergency	Post Acute Care	Skilled Nursing Facility
Health Insurance	Preventive	Homecare
Hospital Care	Primary Stroke Care	Comprehensive Stroke Centre

## Distribution Channels

Public	Government	Hospital
	Institution	EMS
Private	Partnership	Corporation
	Retailer	Pharmacy

## Price Levels

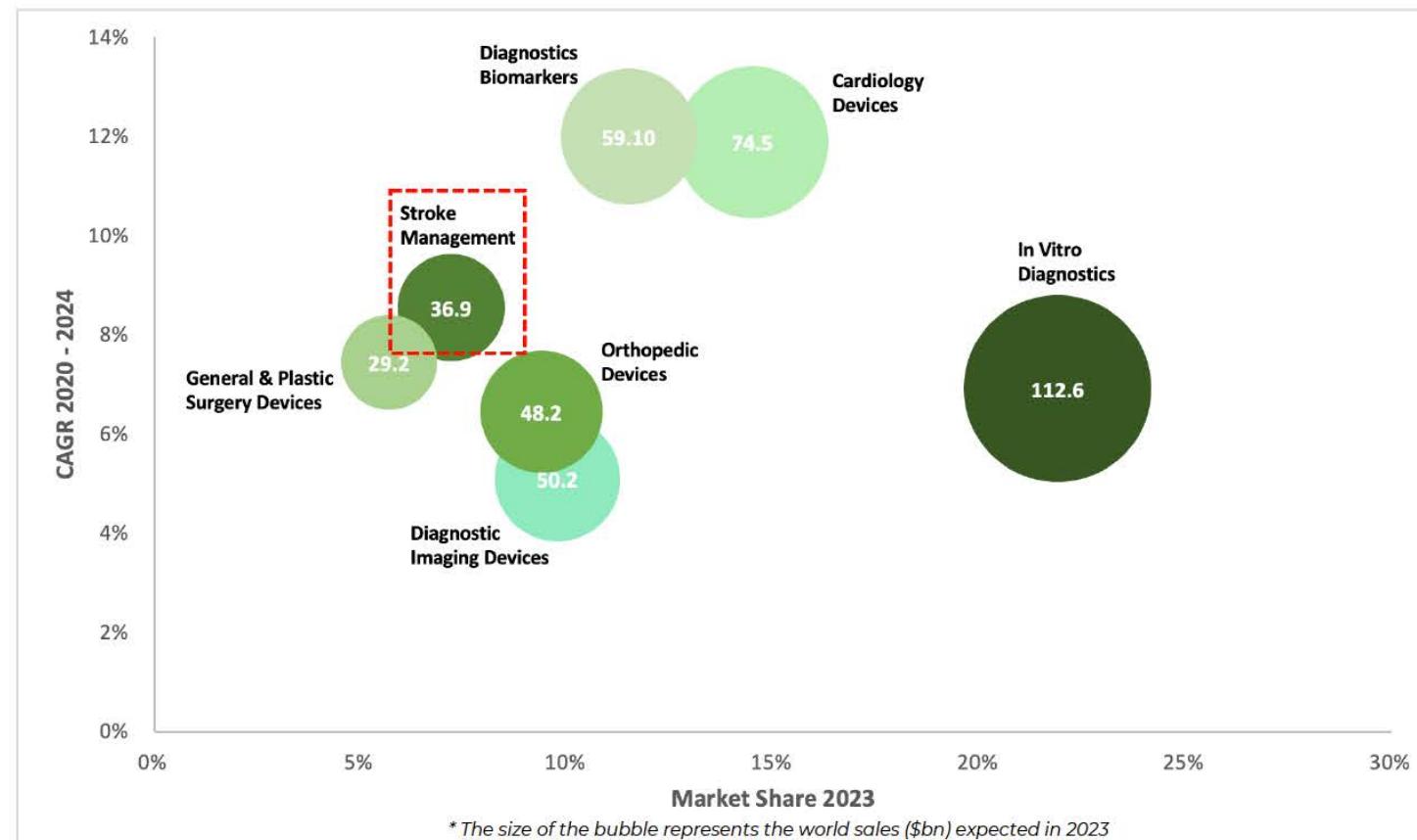
Public	GDP Per Capita	Min £200
	Healthcare Budgets	Avg. £300
Private	% of Turnaround	Min £400
	Geography Demand	Avg. £600

# UPFRONT | Market Opportunity

The Market for stroke is enormous worldwide

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## Medical Devices Segments by Market Share



## Comments

- The global Medical Devices Market size is valued at \$514.2bn in 2023 and is expected to expand at a CAGR of 8.13% until 2030
- A Recent stroke study conducted in the USA indicates on a \$2059.67 billion\* Value of Lost Welfare

LVOne suggests a significant upside potential in the USA with highly conservative assumptions

## Revenues (\$M) at various prices per unit & market share potentials

## Comments

### New Strokes UK, EU, and North America (2026 - 2030)

LVOne Price Per Unit

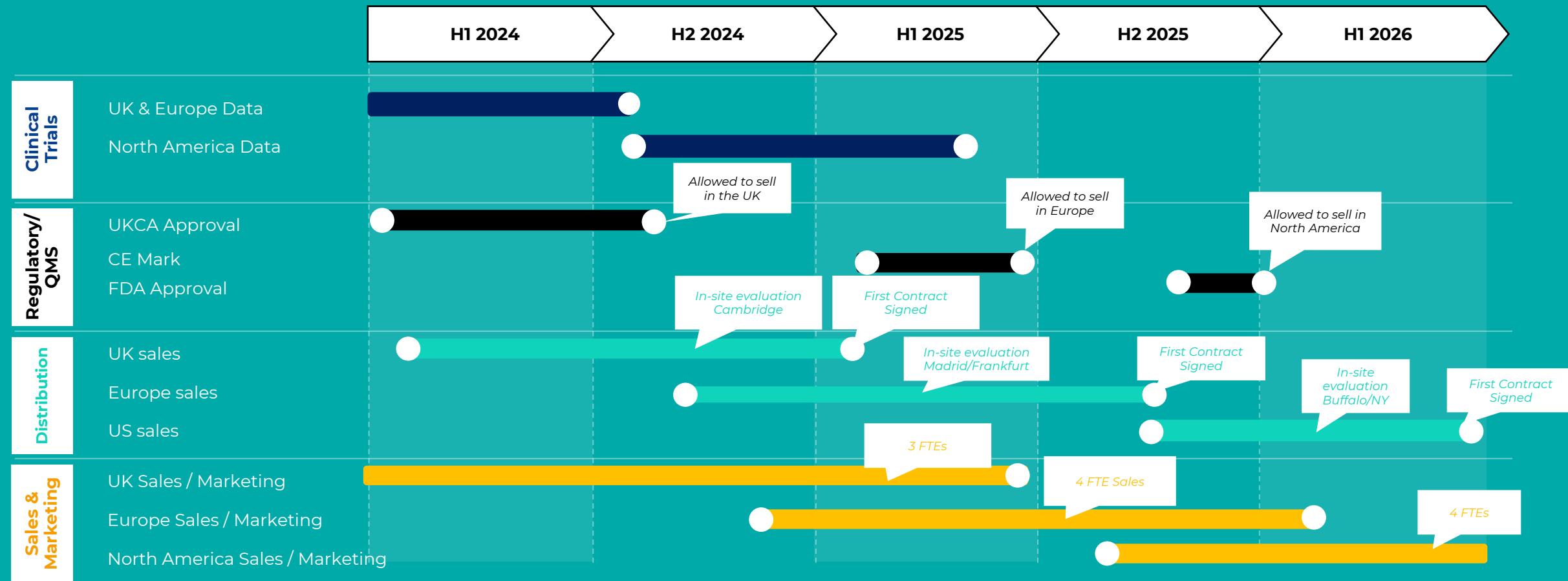
# in Thousands	185	375	570	769	974
% Market Share	5%	10%	15%	20%	25%
\$50	9,265	18,759	28,486	38,459	48,684
\$100	18,530	37,518	56,972	76,918	97,367
\$150	27,795	56,277	85,457	115,377	146,051
\$200	37,059	75,036	\$113,943	153,836	194,735
\$250	46,324	93,795	142,429	192,295	243,419
\$300	55,589	112,554	170,915	230,753	292,102
\$350	64,854	131,313	199,400	269,212	340,786

- Analysis only includes New incidence (New Strokes per annum)
- Phase 2 of the business plan will target stroke prevalence as well (Existing Strokes – i.e., people who have already experienced a stroke)
- Expected stroke incidence and prevalence in 2024: 9.3m

# UPFRONT | Timeline

Four major activity buckets will drive the scale efforts

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# UPFRONT | Funding

We are raising £2,000,000 for 24 months runway (June '24 – May '26)

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## Use of funds

### 1. Access European market

- i. Implementation and early adoption
  - a. United Kingdom (East England)
  - b. Spain (Madrid)
  - c. Germany (Frankfurt)
- ii. Sales team
  - a. Purchase orders
  - b. Distribution
  - c. Customer support
  - d. Reimbursement

### 2. Access US market

- i. US trial at Jacobs Institute (NY/Buffalo)
- ii. FDA "De Novo" approval
- iii. Implementation and early adoption (NY/Buffalo)

### After this round

- i. Mass adoption EU and US
- ii. Interventional UK and US (Grant funding)
- iii. Target other countries & new products

£1M

Implementation  
and adoption

£400K

FDA

Breakthrough &  
De Novo



£2M

£600K

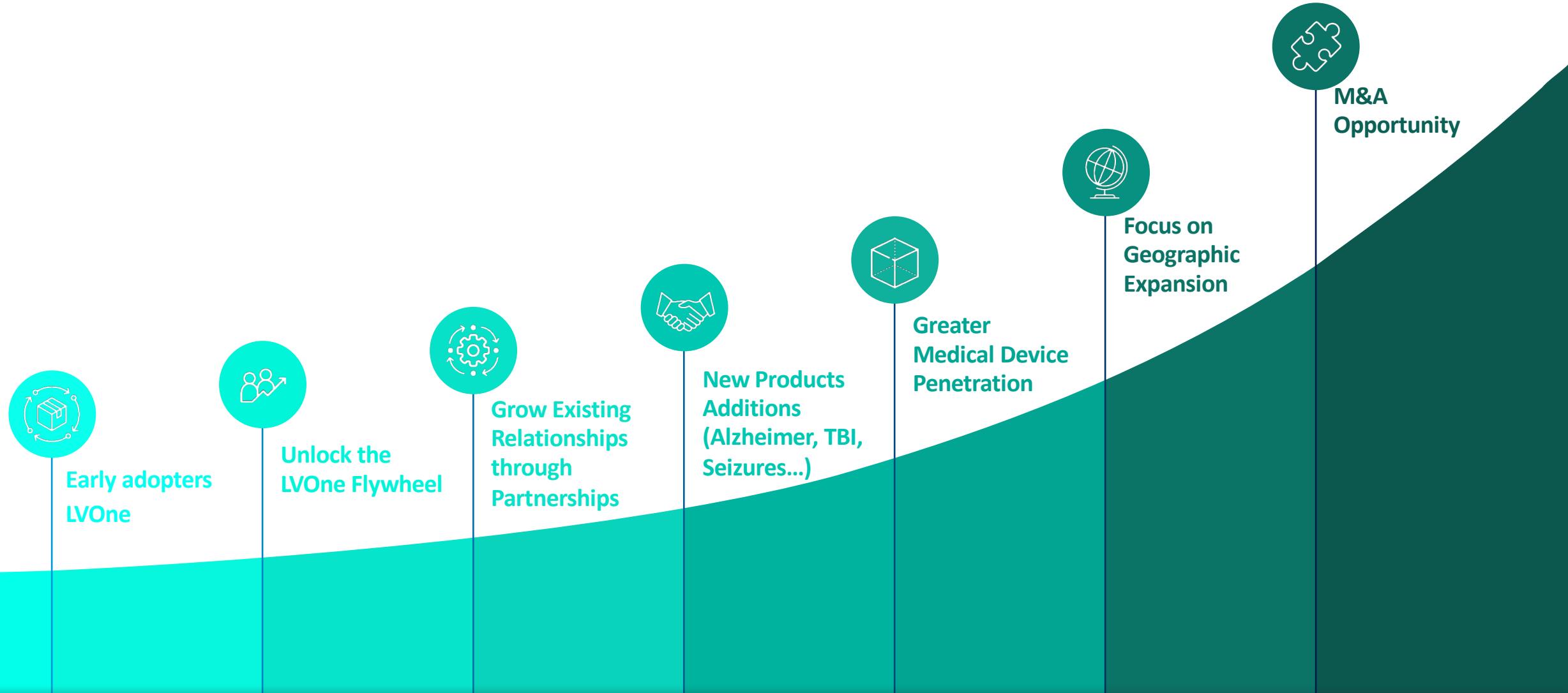
Clinical trials Jacobs  
Institute



# UPFRONT | Future Plan

Multiple vectors for continued growth

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**NHS**  
The Newcastle upon Tyne Hospitals  
NHS Foundation Trust



**NIHR** | Newcastle In Vitro  
Diagnostics Co-operative

**BRH** Brandon Regional Hospital

**Medtronic**

**UAB**  
THE UNIVERSITY OF  
ALABAMA AT BIRMINGHAM

**NHS**  
St George's University Hospitals  
NHS Foundation Trust

**Stroke**  
Association

**NHS**

**GROWTH  
WORKS**

**cpi**

**Innovate UK**

**UNIVERSITY OF  
CAMBRIDGE**  
Judge Business School

**UNIVERSITY OF  
CAMBRIDGE**  
enterprise

**APEX  
VENTURES**

**BIVDA**



**Medicines &  
Healthcare products  
Regulatory Agency**

**NICE**  
National Institute for  
Health and Care Excellence

**NHS**

**Technolleg Iechyd Cymru  
Health Technology Wales**

**Healthcare  
Improvement  
Scotland**

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