



Detecting Cardiovascular Disease risk early
so it can be prevented

2023 Interim Report and Accounts

20 September 2023



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Executive Team and Board

Executive Team



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Introduction: GENinCode

GENinCode

Clinical-genetic diagnostic company using polygenics, bioinformatics and AI to prevent cardiovascular disease (CVD)

Revenue generating: Scale-up and expansion underway in US, UK and EU

CE marked, US CLIA and CAP approved. FDA 510K filing submitted

Significant investment in technology since 2007

Evidence base: Published clinical studies on >75,000 patients over 15 years supporting regulatory approvals

IP-protected tests focused on preventive care, improving patient outcome and reduced costs of treating CVD for healthcare systems

Multiple products, including genetic tests in complementary disease areas of lipids and thrombosis



KAISER PERMANENTE



Indiana
School of Medicine



EVERSANA

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Presbyterian



COLUMBIA
UNIVERSITY

ferrer

Market



Cardiovascular disease (CVD) **is the leading cause of death worldwide**



Over 17.9M deaths annually from CVD, accounting for c.31% of all deaths globally



Global annual cost of CVD to reach >\$1.04Tn by 2030



Unmet need to accelerate genetics in CVD as additive to current standard of care to improve risk assessment and prevent CVD



Global standard of care for assessing CVD requires update to include genetics and enable a step change in predicting the onset, risk assessment and improved treatment of CVD

Operational and Financial

- First half revenues increased 43% to £950k (30 June 2022: £664k) in UK and EU.
- Significant and growing demand for US Early Access Program with over 40 top tier institutions now onboarding.
- Filing of FDA pre-market notification (510k) for CIC-SCORE and CPT PLA (AMA) coding granted.
- Public presentation to CMS for CIC-SCORE inclusion in 2024 Clinical Lab Fee Schedule (CLFS) - \$760/test.
- Publication by American Heart Association (AHA) supporting introduction of polygenic testing for CVD.
- California state licensing, CLIA certification and CAP accreditation received for US laboratory
- Announcement of CIC-SCORE clinical utility study with MedStar to support CMS reimbursement.
- Presentation by Kaiser Permanente on CIC-SCORE for the 'lifetime' risk assessment and prediction of CHD at European Society of Cardiology (ESC) Annual Meeting in August 2023.
- Successful completion of UKAS and ISO13485 accreditation for Hammersmith lab to service NHS demand.
- NHS adoption of LIPID inCode for FH diagnosis in the North of England to deliver comprehensive hypercholesterolemia polygenic testing, improved turnaround times at reduced cost.
- Announcement of LIPID inCode collaboration with University Clinic Dresden, Germany for diagnosis of FH
- CIC-SCORE pilot launched in Extremadura, Spain.
- National Institute for Health and Care Excellence (NICE) issue new Ovarian Cancer guidance - 'draft for consultation' including of Risk of Ovarian Cancer Algorithm (ROCA) test for women at high risk of OC
- Adjusted EBITDA loss of £3.4m (30 June 2022: loss of £2.3m), reflecting Increased investment in support of US and UK launch of Lipid inCode® and Cardio inCode-Score.
- Cash reserves of £5.2m at 30 June 2023 (30 June 2022: £12.4m).



Product Portfolio: Cardiovascular Disease (CVD)



Product Name	Description	CAP ACCREDITED CLIA certified	FDA	UK CA CE	CE
** CARDIO inCode	Assessment of the coronary genetic risk and CVD risk stratification	✓ ✓	✓	✓	✓
: LIPID inCode	Diagnosis and management of hypercholesterolemia	✓	✓	✓	✓
: THROMBO inCode	Diagnosis and management of genetic thrombophilia and thrombosis risk	✓ Q2 2024	✓ Q2 2024	✓	✓
: SUDD inCode	Diagnosis of the cause of sudden cardiac death and familial heart disease	✓ Q3 2024	✓ Q3 2024	✓*	✓*

*Sudd inCode EU clinical lab services under ISO15189

Process, Reporting and Treatment Pathway



1
Sample Collection



2
Sample Sent to Lab



3
Sample Analysis in Lab



4
View Results Online



SITAB Bioinformatics and Online Reporting Tool



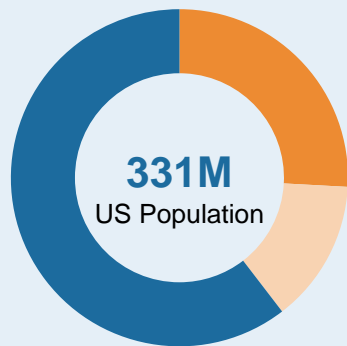
Services & kit product format



SITAB proprietary software and algorithms for analysis and interpretation of data

Cardiovascular Disease is the Leading Cause of Death Worldwide¹

In the US

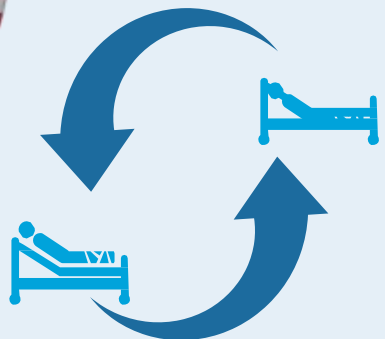


85.6M Americans living with CVD
(Set to rise to 131M over next two decades)⁴



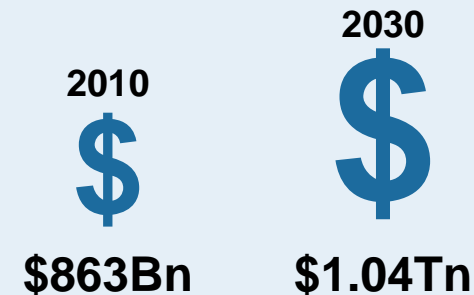
Nearly 1/3rd of all deaths²
655,000 deaths/year³

805,000 heart attacks a year in the US
605,000 first heart attack
200,000 recurrent attacks



\$351Bn
Estimated annual direct and indirect cost of CVD and stroke to US hospitals and lost productivity over **\$351Bn** annually in 2014-15. (Set to rise to **\$818Bn** by 2030)⁵

Global cost of CVD⁶



1. WHO – 2021 : CVD leading cause of mortality
 2. Circulation: 2022;145:e153–e639. DOI: 10.1161/CIR.0000000000001052
 3. www.cdc.gov 2021
 4. Science News: Cardiovascular Disease costs will exceed \$1 Trillion by 2035: February 14 2017
 5. www.acc.org AHA 2019 AHA Heart Disease and Stroke: Stats & www.ahajournals.org Abstract 207:Burden of CVD on Economic Cost. Comparison of outcomes in US and EU
 6. World Heart Federation – Champion Advocates Programme - 2021

US Strategy: CARDIO inCode & LIPID inCode

US Highlights



- Significant new product demand for Early Access Programs with 40 ‘top tier’ institutional sites onboarding
- Interest for both CARDIO inCode and LIPID inCode
- First US revenues anticipated in Q4 2023



Regulatory:

- **CAP and CMS CLIA certification** for GENinCode US Inc laboratory in Irvine, California.
- **FDA 510K submission:** Discussions ongoing with FDA. Expected approval Q1 2024.



Reimbursement:

- **CARDIO inCode CPT PLA coding (0401U) approved** by American Medical Association.
- **Pricing:** Presented CARDIO inCode for inclusion in **CMS 2024 Clinical Lab Fee Schedule - \$760/test**
- **MoIDx** submission for reimbursement in preparation for filing. Commencing discussions with CMS and payers



Commercial Operations:

- **Expansion of EAP’s and sales team.** KOL focus, education and implementation.
- **Revenue Cycle Manager (RCM) Senergene** handling US billing, benefits investigation, and cash collection.
- Service based revenues as well as collaborative clinical cardiogenetic opportunities now emerging.



Publications:

- Kaiser Permanente abstract presented at ESC in August 2023.
- Multiple publications anticipated over coming year on clinical utility of PRS by Kaiser Permanente.
- US AHA/ACC now considering guideline changes for PRS to stratify patients at high genetic risk.



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US Strategy: Key Strategic Partnerships

Clinical Assessment



Clinical assessment of **CARDIO inCode** as a CVD risk enhancer

Clinical Validation



CARDIO inCode clinical validation and expansion of collaboration for clinical utility

Clinical Utility/
Commercial Implementation



CARDIO inCode phased introduction via clinical utility to engagement in healthcare system

Clinical Utility



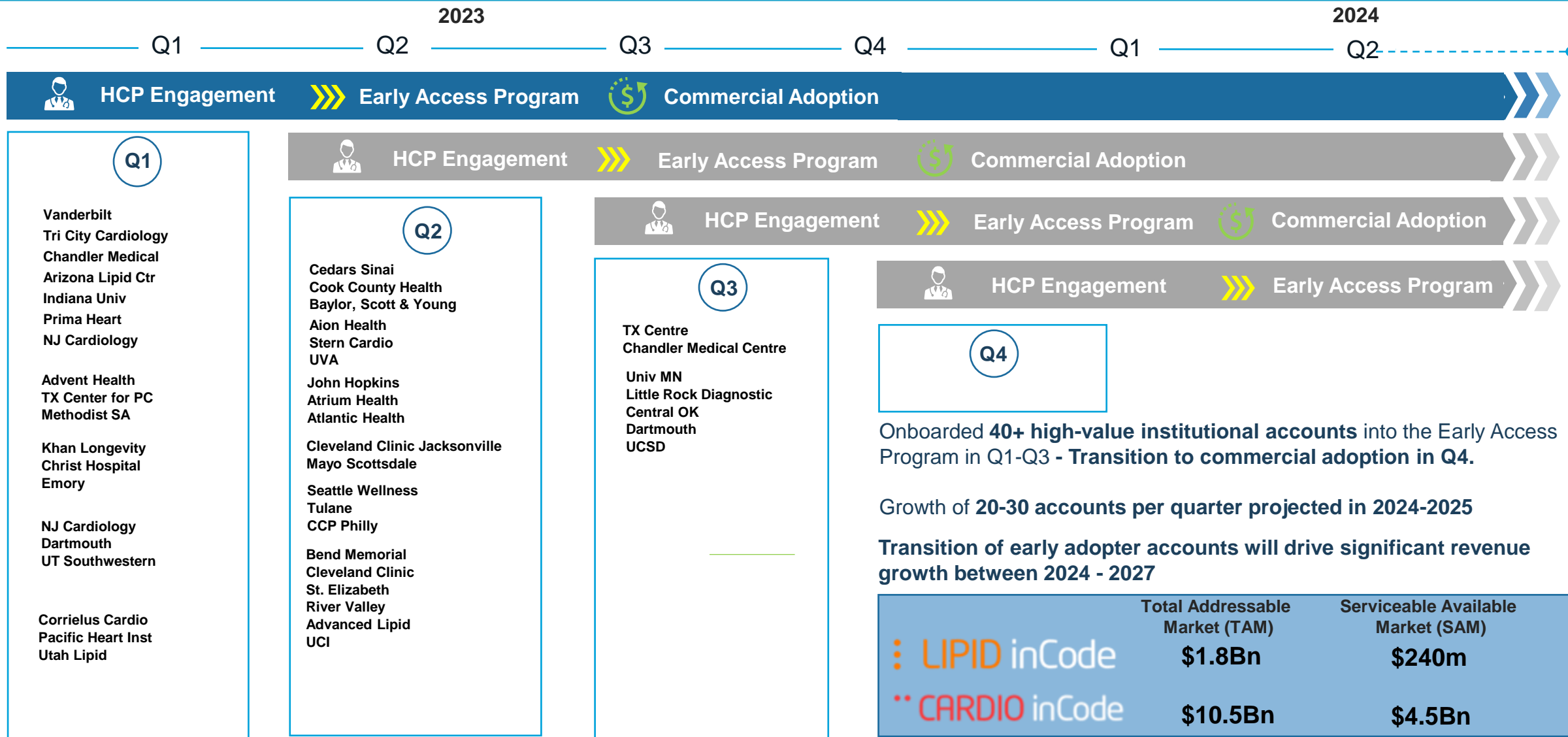
Clinical assessment of **CARDIO inCode** in NYP Quality Care physician network



Early Access Program Sites – 40+ Institutional and Community Sites



Early Access to Product Adoption 2023



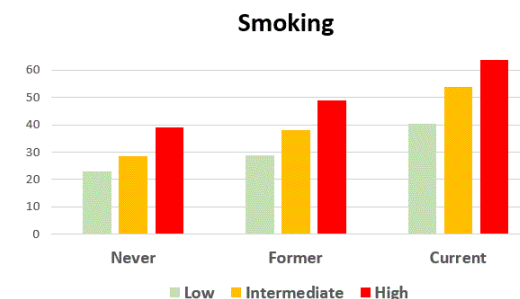
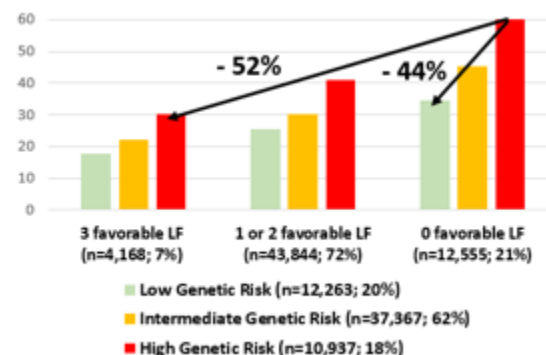
CARDIO inCode: ESC Abstract Kaiser Permanente

- Kaiser Permanente GERA cohort – Over 60k patients multi-ethnic (European, African American, Latino and Asian)
- 14 Year average follow up (2007 – 2022)

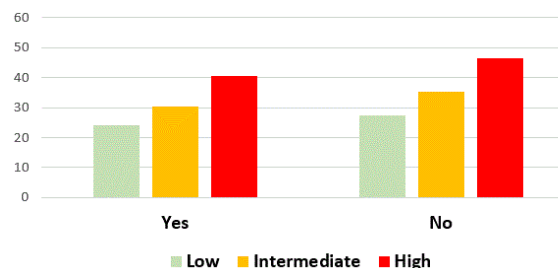
Results

- Genetic and lifestyle factors are independently associated with CHD.
- For individuals with a high genetic risk, a favorable lifestyle is associated with a 52% lower rate of CHD compared with an unfavorable lifestyle.
- PRS identifies individuals with the highest CHD risk. These individuals should be prioritized for lifestyle and therapy advice as they will benefit the most.
- Cholesterol lowering & antihypertensives publications to follow

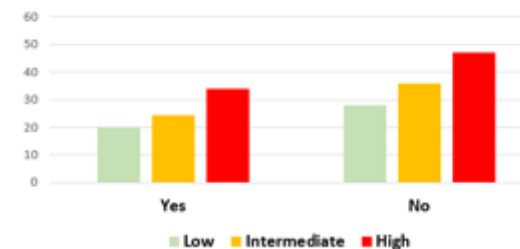
CHD Rates per 10,000 Person-years by Lifestyle Factors and Polygenic Risk



Physical Activity Recommendations



Mediterranean Diet



Numbers Needed to Treat (NNT) to Prevent 1 CHD Event where the Experimental Group is 3 favorable LFs and the Control Group is 0 favorable LFs, by Genetic Risk (PRS).

Low	415
Intermediate	302
High	226

CARDIO inCode: US Market Assessment

Initial CARDIO inCode Target Market: **21M**
 Receptive Physicians ~**8.5M**, if covered by insurance

About half of physicians³ would order **CARDIO inCode**, if covered by insurance, for two types of patients: intermediate risk who are not compliant or controlled, and low risk patients with family history. Prior authorisation, expected by payers, reduces the number of physicians who would order. Assumes physicians expect to order the test once per patient, i.e., no recalculation of risk scores.

(Approx 86M Americans living with CVD)

Target Patients for Cardio inCode <i>(based on physicians interviewed)</i>	Patients in Target Segment	No. Likely to get Prescription
Intermediate Risk¹ Patients inadequately controlling risk e.g., not taking statins or making lifestyle changes (estimated 33% of intermediate-risk patients) ³	9M	4.4M
Low Risk¹ Patients with family history (estimated 13% of low-risk patients) ²	12M	4.1M
Total	21M	8.5M

1. Goff, David C Jr et al. "2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines." Circulation. 2014

2. Moonesinghe, Ramal et al. "Prevalence and Cardiovascular Health Impact of Family History of Premature Heart Disease in the United States/ 2007-2014." JAHA. 2019

3. EVERSANA interviews with 45 potential prescribers of CiC. January 2021. Sample size may not be representative of market opportunity

CARDIO inCode: Reimbursement Rates

Clinical Laboratory Fee Schedule (CLFS)

Cardio inCode

0401U

\$760

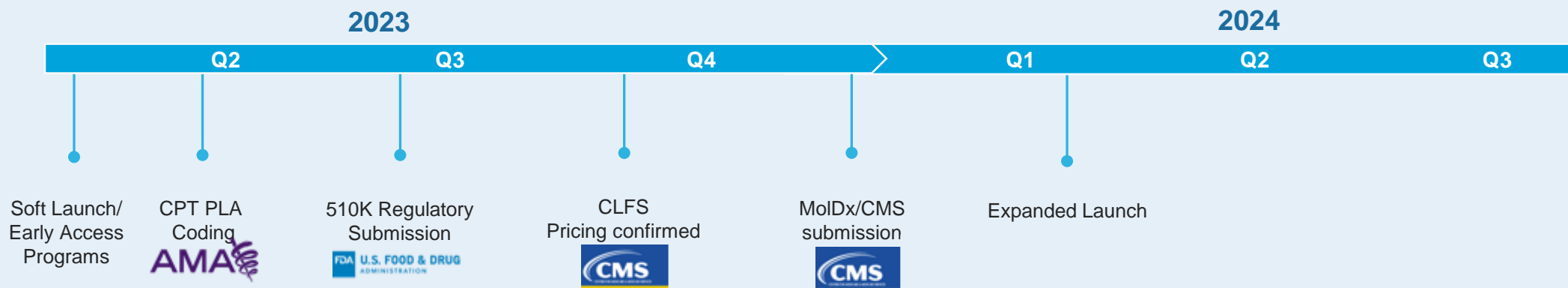
\$760
CLFS Pricing

Key Coding/Reimbursement Activities

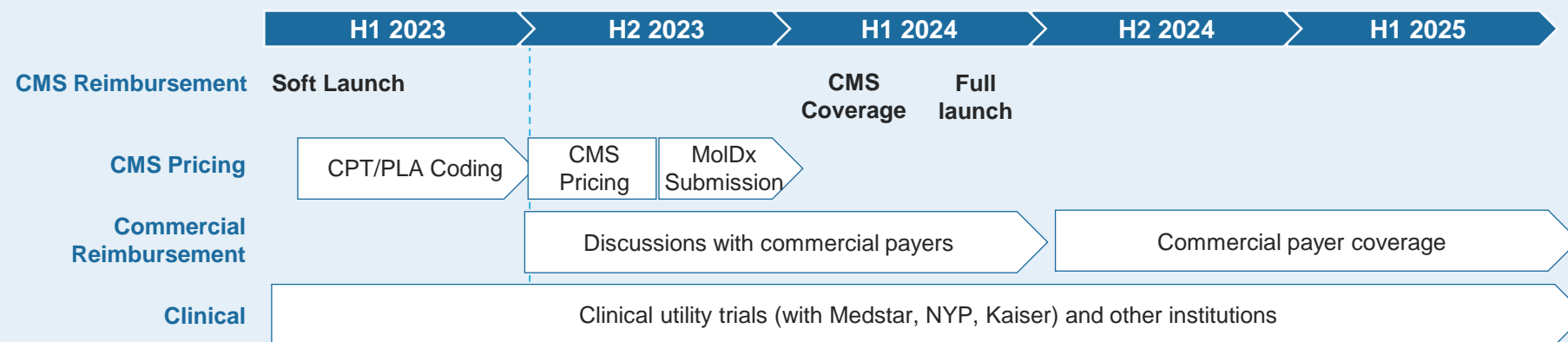
- CARDIO inCode **CPT PLA coding (0401U)** approved by the **American Medical Association**
- **PLA Code 0401U** to be included in **CLFS for 2024**
- Initial discussions with **Medicare (MoIDx)** in Q4
- **Clinical utility studies underway** to support payer tech assessments and dossiers
- Private payer engagement in **Q1 2024**

CARDIO inCode: US Regulatory and Reimbursement Strategy

Indicative US Regulatory Timeline



US Reimbursement Pathway (Coding, Pricing & Reimbursement)



LIPID inCode: US Launch

FH testing represents a \$1.8Bn market opportunity in the US



Value Proposition

Monogenic + Polygenic FH Test

- **FH testing defined as ‘Tier 1’ genomic test** by Centers for Disease Control and Prevention (**CDC**)
- **LIPID inCode will be the first commercially available Monogenic + polygenic FH test** offered on the market
- **Scientific expert panels support the inclusion of polygenic risk** for patients that are negative for monogenic FH



HCP Adoption

Engagement with Key Influencers

- **Targeted engagement plan** focused on engaging top **250 physicians** in lipidology and preventative cardiology
- Supporting key programs and conferences with **FH foundation, National Lipid Association (NLA), and the American Society of Preventative Cardiology (ASPC)**



Access and Distribution

Favorable reimbursement environment

- **Established ICD-10 and CPT Codes for FH Testing** should enable rapid adoption of testing with targeted payers
- **Favorable reimbursement policies** in place for FH testing with **IDNs, regional, and national payers**

LIPID inCode: US Market Assessment

The US target market for **LIPID inCode** includes **1.5M** patients with diagnosed FH and undiagnosed probable FH

Physicians see **LIPID inCode** as a targeted test for patients with suspected, probable, or confirmed familial hypercholesterolemia

Target Patients for LIPID inCode	Patients in Target Segment
Diagnosed FH: 200K Patients ICD-10 code for Familial Hypercholesterolemia (FH) These patients have not been tested for FH genetic variants	0.20M ¹
Undiagnosed Probable FH Predictive modeling based on clinical features in US population	1.3M ²
Total	1.5M

1. Eversana RWD, Familial hypercholesterolemia patient cohort. Sept 2022

2. Kullo et al, Familial Hypercholesterolemia: A reportable disorder. Circulation 2020

LIPID inCode: Reimbursement Rates

Favourable coverage and reimbursement rates in place for FH testing from most national/regional commercial payers

Key Reimbursement Activities

- Established Lipid inCode **billing policy and patient assistance programs (PAP)**
- **Identified key targets** and defined the engagement strategy for **IDNs, national, and regional payers**
- Completing infrastructure build to **support RCM implementation in Q4**
- **Credentialing activities** underway with **targeted payers**
- **Billable testing to start in Q4 2023**
- **In-network contracting to start in Q1 2024**

Clinical Laboratory Fee Schedule (CLFS)

Familial Hypercholesterolemia Panel

LDLR

APOB

PCSK9

LDLRRAP1

\$1,713¹

\$1,198²

Average Reimbursement*

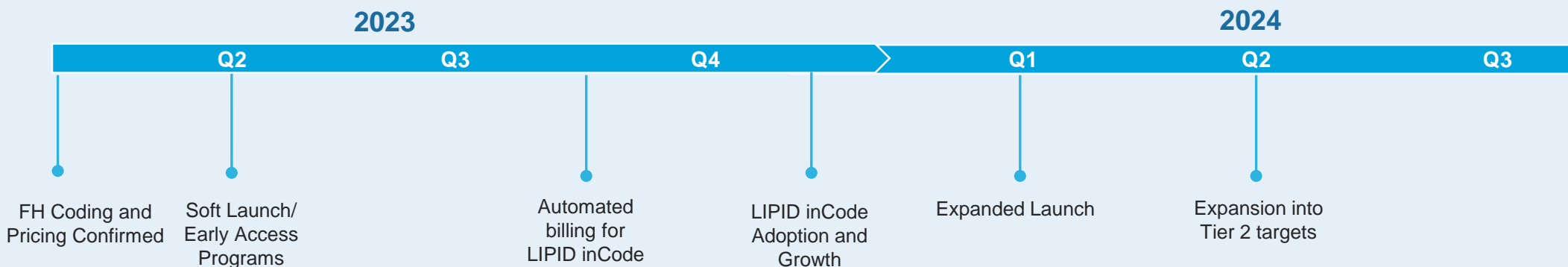
*Average reimbursement for all private payers combined

1. Copy of Clinical Laboratory Fee Schedule, www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched

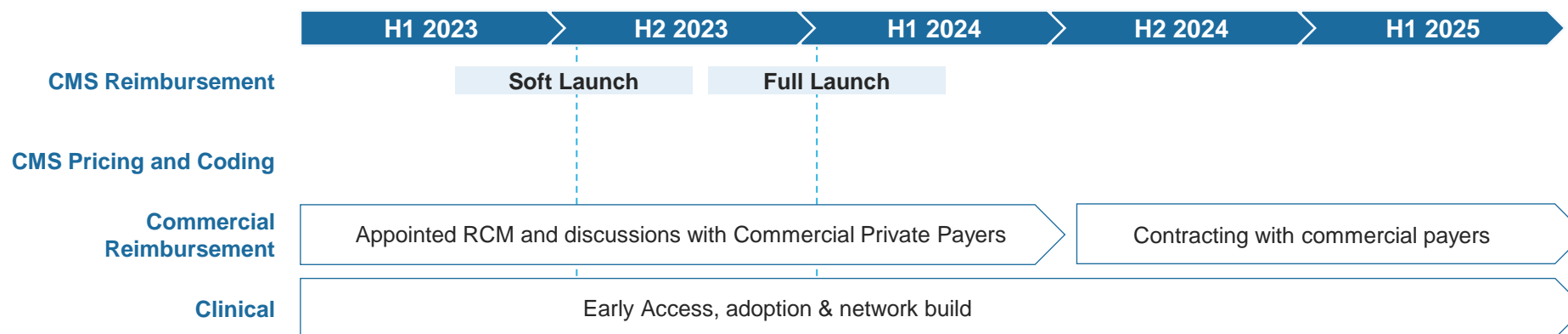
2. Senergene RWD FH testing reimbursement trends, Average reimbursement for targeted private payers tied to CPT codes 81401, 81405, 81406, 81407

LIPID inCode: US CLIA Lab Diagnostic Test

Indicative Regulatory Timeline



US Reimbursement Pathway (Coding, Pricing & Reimbursement)



UK Strategy: Cardiovascular Disease Prevention

Management of cholesterol and CVD genetic risk

Familial Hypercholesterolemia (FH) is a global autosomal (inherited) genetic disorder of lipid metabolism causing raised blood cholesterol, the early onset of cardiovascular disease and premature mortality (mainly from heart attacks). FH responds well to drug treatment so early diagnosis is vital.

- Collaboration with NHS for GENinCode to deliver FH to support **'2019 NHS Long Term Plan'** to increase the detection of people with FH
- **Completed and published** successful NHS FH comparative study in January 2022
- **Successfully completed FH test pilot with NE-AHSN** (Centre of Excellence for familial hypercholesterolemia & NHS FH strategy)
- **Agreed NHS implementation plan** and initial funding with NE-AHSN for introduction of LIPID inCode
- BUPA Cromwell Hospital announcement for LIPID inCode testing - First UK LIPID inCode revenues



Case Study

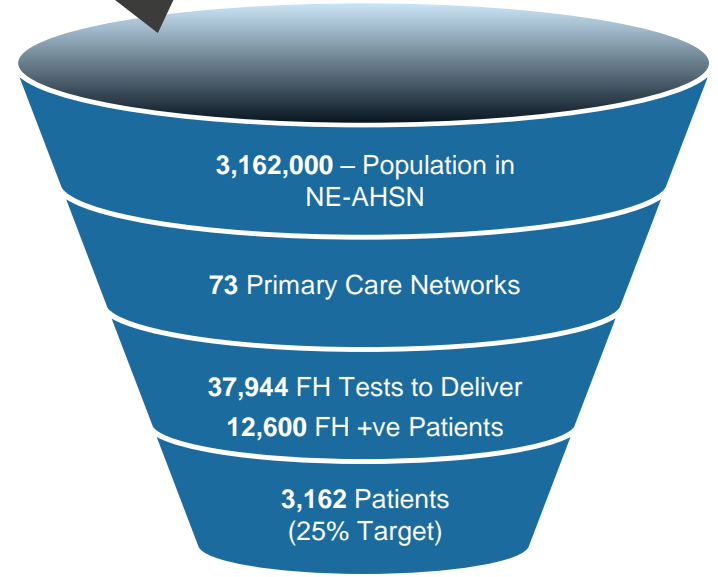
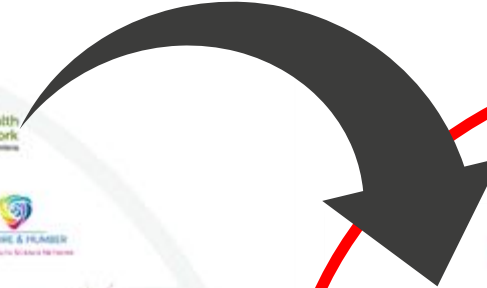
- FH estimated to affect, 1 in 250 of the UK population i.e., between 230k-260k people
- Roughly 7% of this population have been genetically diagnosed in England
- UK NHS target is to detect 25% of FH population by 2024



NHS - AHSN's: Introduction of FH



NHS Long Term Plan to improve FH diagnosis rates to at least **25%** of FH patients by **2024**

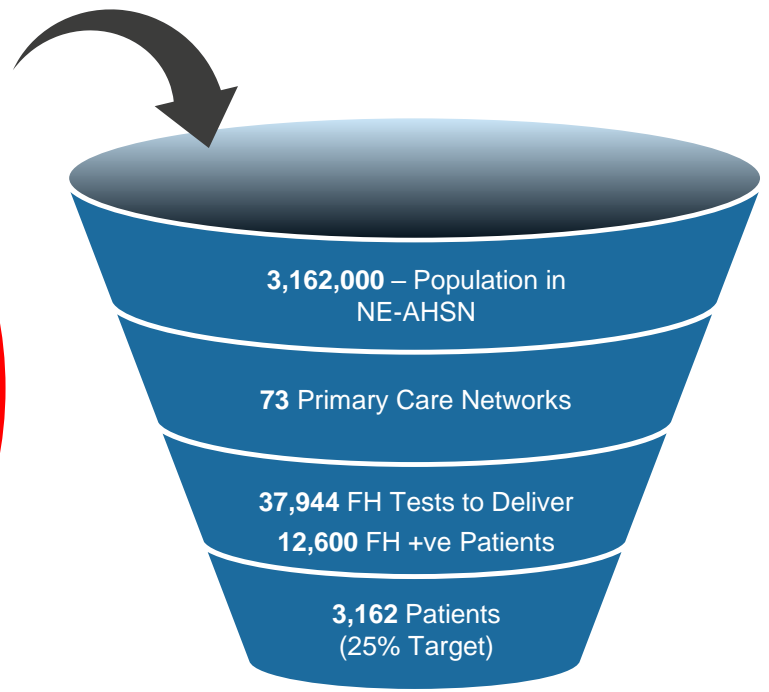
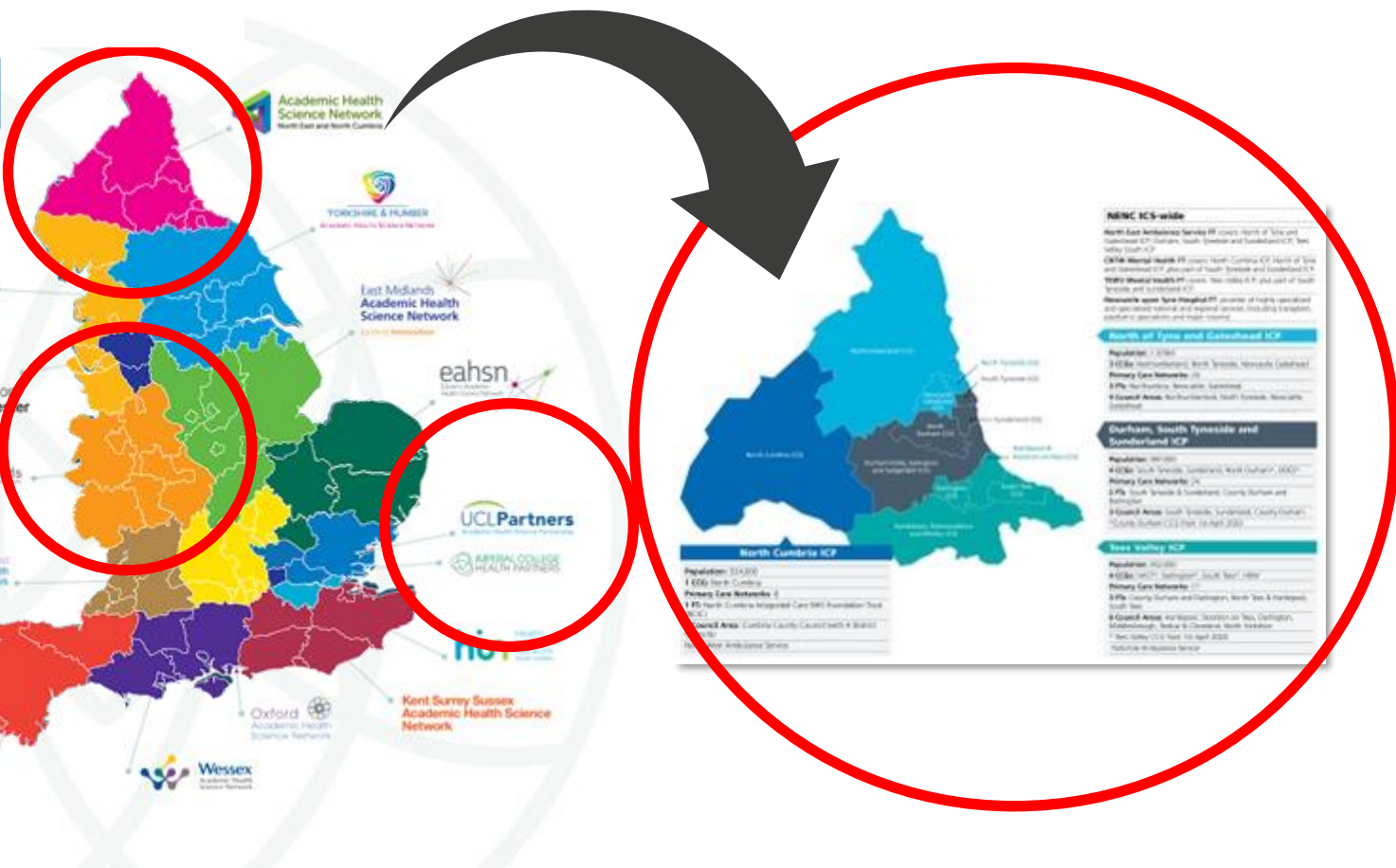


Phased implementation of LIPID inCode now started to help achieve NHS targets

NHS - AHSN's: Introduction of FH



NHS Long Term Plan to improve FH diagnosis rates to at least **25%** of FH patients by **2024**



Phased implementation of LIPID inCode now started to help achieve NHS targets

EU Strategy

- Revenue growth via regional and collaborative partnerships
 - New tenders for THROMBO inCode and LIPID inCode - Incremental revenues and business strengthening
- Roll-out of CARDIO inCode to Spanish regions
 - Extremadura Region – Implementing Cardio inCode® pilot in Primary Care
 - Preparing CARDIO inCode® pilot implementations in Andalucía and Catalunya
- Building strategic alliance for CARDIO inCode, THROMBO inCode and LIPID inCode
 - Synlab – Collaboration in IVF Clinics
 - Longwood – Public healthcare push and increased Spanish tenders
 - Collaborations to extend commercial activities in some LATAM countries
- Expanding direct business operations in Italy
 - Extending collaborations with Fondazione SISA (LIPID inCode)
- Expand LIPID inCode German market opportunity with Uniklinikum (based on NHS model)
- THROMBO inCode product extensions for Oncology

- The ROCA Test is focused on early detection of ovarian cancer in genetically high-risk populations (primarily BRCA1 and BRCA2 pathogenic variants) when deferring preventative surgery
- Steps to NHS commissioning:
 - **Draft NICE Ovarian Cancer guidelines published 15th Sept including recommendation for ROCA surveillance**
 - **Surveillance recommended to be carried out serially every 4 months using ROCA with a call and recall mechanism.**
 - **Final form guidance due for publication March 2024**
- First in class risk assessment for the early detection of familial ovarian cancer
- The ROCA Test is a surveillance test – Not a ‘one off’ DNA based test; Recurring patient revenue
- Low-cost entry, significant know-how and barrier to entry – Mass Gen Hospital, US. Exclusivity, long prospective trials complete
- Focused physician market in gynaecology which fits with NHS model for roll-out
- Discussions starting with NHS on adoption of ROCA for NHS monitoring; Opportunity for collaboration with Pharma to support their treatment franchise

Financial Review: 2023 Interim Results

First half revenues £1.0M, 43% year on year growth

Gross Profit increased to 49% (2022: 43%) due to improving product mix and reducing inflationary pricing pressure from lab service providers

Operating losses £3.6M (2022: (£2.4M)) reflecting growth in staffing and professional costs and ramp up in commercial investment

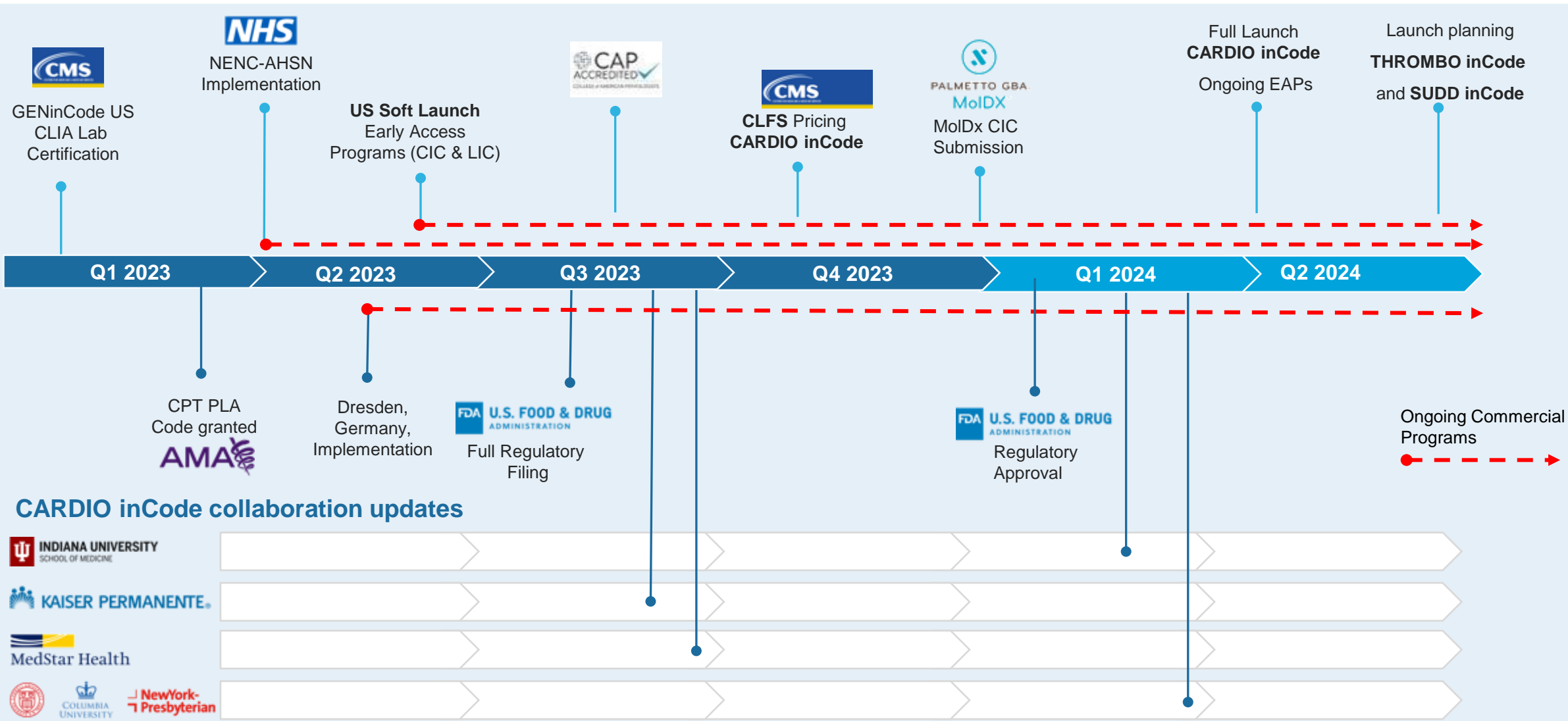
AEBITDA – Increase in admin expenses, personnel and other infrastructure in advance of commercial expansion in US, EU, and the UK

Working capital – Reflects EVERSANA deferred payment structure, and minimal inventory policy

Cash balances – £5.2M at end June 2023, (2022: £9.7M) reflecting tight control over our investment commensurate with growth

Revenues	2022	£0.7M
	2023	£1.0M
Gross Profit	2022	£0.3M (43%)
	2023	£0.5M (49%)
Operating Loss	2022	(£2.4M)
	2023	(£3.6M)
Adjusted EBITDA	2022	(£2.3M)
	2023	(£3.4M)
Cash Reserves	2022	£9.7M
	2023	£5.2M

Key Events and Forecast Newsflow



Summary and Outlook

- Converting US Early Access Programs to commercial sales to drive revenue growth. Expanding UK and EU market growth.
- Advancing CARDIO inCode clinical utility program for CMS reimbursement (MoIDx) submission.
- Advancing FDA regulatory approval for CARDIO inCode.
- Expanding NHS use of LIPID inCode for FH polygenic testing across AHSN network.
- Introduce CARDIO inCode to NHS for genetic risk assessment of Coronary Heart Disease.
- Expand Germany collaboration for LIPID inCode and extend polygenic menu.
- Continue to build EU collaborations in Spain and Italy and develop ongoing discussions with pharmaceutical companies.
- Strengthen commercial, marketing and selling teams for US 2024 sales program.
- NICE proposal for ROCA surveillance of women at risk of OC - NHS commercial development.
- Significant increase in revenue growth targeting breakeven/profit over medium term.



American Heart Association



NewYork-Presbyterian



EVERSANA™



SCHOOL OF MEDICINE



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LIPID inCode: US FH Market Visibility – Diagnosed/Undiagnosed

Total Lives

Commercial	Medicare	Other
50,904,769	32,971,483	8,478,713

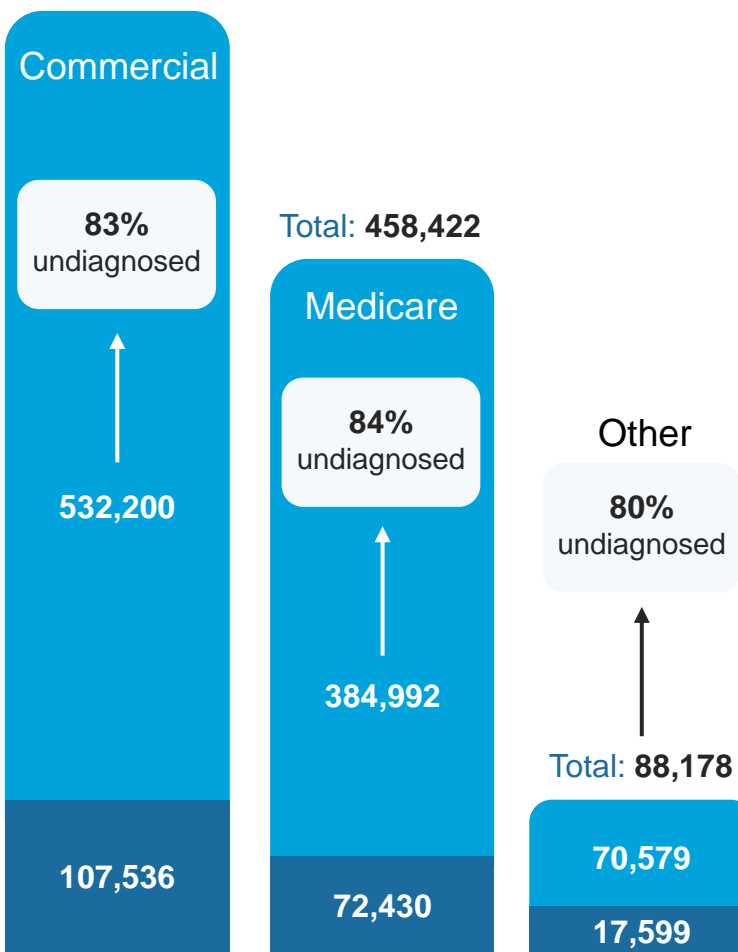
Prevalence of Undiagnosed FH

Commercial	Medicare	Other
1 in 96	1 in 86	1 in 120

Prevalence of Diagnosed FH

Commercial	Medicare	Other
1 in 473	1 in 449	1 in 482

Total: **639,736** individuals with suspected FH



*2018 FOCUS Report includes healthcare encounter data from January to December 2018

45 of the largest health plans and other payers (for example, pharmacy benefit managers, self-insured employers)

*FH Foundation, *FOCUS Real World Data Analysis*, <https://familyheart.org/research-circ-ce-data>

Appendices: P&L

GENinCode plc	H1 2023	H1 2022	+/-	Full Yr 2022
	£'000	£'000	£'000	£'000
Revenue	950	664	286	1,430
Cost of sales	(483)	(381)	(102)	(798)
Gross profit	467	283	184	632
GM %	49%	43%	6%	44%
Administrative expenses	(3,836)	(2,556)	(1,280)	(6,266)
AEBITDA	(3,369)	(2,273)	(1,096)	(5,634)
Depreciation/Amortisation	(174)	(33)	(141)	(163)
Share-based payments	(51)	(56)	5	(102)
Operating Loss	(3,594)	(2,362)	(1,232)	(5,899)
Other Income	110	38	72	173
Finance Charge	(23)	-	(23)	(20)
Loss Before Tax	(3,507)	(2,324)	(1,183)	(5,746)
Corporation Tax	6	(4)	10	187
Loss After Tax	(3,501)	(2,328)	(1,173)	(5,559)
Exchange diff on translation of foreign ops	312	(253)	565	(361)
Loss attributable to equity shareholders	(3,189)	(2,581)	(608)	(5,920)

Appendices: Balance Sheet

GENinCode plc	H1 2023 £'000	H1 2022 £'000	+/- £'000	Full Year 2022 £'000
Assets				
Non-current assets				
Intangible assets	149	176	(27)	161
Property, plant & equipment	545	193	352	653
Right of use asset	310	-	310	349
Goodwill	149	-	149	149
Total non-current assets	1,153	369	784	1,312
Current assets				
Inventory	76	34	42	20
Trade and other receivables	689	501	188	717
Financial assets	22	-	22	16
Cash and cash equivalents	5,183	12,398	(7,215)	9,732
Total current assets	5,970	12,933	(6,963)	10,485
Total assets	7,123	13,302	(6,179)	11,797
Equity				
Shareholders' Equity				
Share capital	958	958	-	958
Share premium	15,551	15,551	-	15,551
Other reserves	249	(26)	275	(114)
Retained deficit	(11,996)	(5,261)	(6,735)	(8,495)
Total equity	4,762	11,222	(6,460)	7,900
Liabilities				
Non-current liabilities				
Trade and other payables	938	1,268	(330)	1,279
Lease liability	249	-	249	285
Contingent consideration	166	-	166	155
Current liabilities				
Trade and other payables	911	802	109	2,078
Lease liability	72	-	72	69
Deferred tax	25	10	15	31
Total liabilities	2,361	2,080	281	3,897
Total equity and liabilities	7,123	13,302	(6,179)	11,797

Appendices: Cash Flow Statement

GENinCode plc	H1 2023 £'000	H1 2022 £'000	+/- £'000	Full Year 2022 £'000
Loss before taxation	(3,507)	(2,324)	(1,183)	(5,746)
Adjustments	600	(36)	636	88
Operating Loss before working capital changes	(2,907)	(2,360)	(547)	(5,658)
Working capital changes	(1,563)	466	(2,029)	1,896
Net cash outflow from operating activities	(4,470)	(1,894)	(2,576)	(3,762)
Investing activities	(38)	(162)	124	(849)
Financing activities	(35)	-	(35)	(47)
Net increase in cash and cash equivalents	(4,543)	(2,056)	(2,487)	(4,658)
Cash and cash equivalents at beginning of period	9,732	14,554	(4,822)	14,554
Exchange gains/(losses) on cash and cash equivalents	(6)	(100)	94	(164)
Cash and cash equivalents at end of period	5,183	12,398	(7,215)	9,732