GENinCode plc (AIM: GENI)

# **Company Summary**

### **Investment Profile**

- 1. Clinical-genetic diagnostic company predicting the onset of CVD
- 2. Revenue generating, commercially ready portfolio with multiple products
- CE marked product, with FDA initial breakthrough device filing submitted
- Clinical studies on >75k patients over 10 years

#### **Share Information**

Ticker	GENI
Share Price	38.0p
Shares in issue	95.8m
Market Cap	£36.4m
12m Hi/Low	46.5/34.8p

(Source: The London Stock Exchange, November 2021)

# 12-Month Share Price



# Major Shareholders (as of November 2021)

Name	Holding
Jordi Puig	11.82%
Matthew Walls	11.23%
Maven Income and Growth VC	11.08%
Downing 1 VCT plc	11.08%
Santi - 1990 SL	10.84%
Chelverton Asset Management	5.93%
Octopus Investments	4.74%
Equipos Medicos-Biologicos SA	3.73%
Sergio Olivero	3.73%
David Evans	3.46%
Sonia Rodriguez Clemente	3.29%

(Source: company website)

# **Company Overview**

GENInCode plc (AIM: GENI) is engaged in the risk assessment, prediction and prevention of cardiovascular disease ("CVD"). CVD is the leading cause of death worldwide, accounting for approximately 18 million deaths annually by 2030. The Company's products and technology aim to predict the onset of CVD and provide a personalised treatment pathway for patient management. Its products have beeen the subject of clinical studies on over 75,000 patients to assess and predict the onset of CVD.

The Company was incorporated in September 2018 to acquire the assets and IP of Ferrer inCode and Gendiag.exe. The technology and products acquired included Cardio inCode®, Lipid inCode®, Thrombo inCode® and Sudd inCode®. Approximately €50 million has been invested in the R&D of these products since 2007. The Company has begun to commercialise these products in Europe and is now targeting the UK and US.

# **Genetics and Cardiovascular Disease**

CVD accounts for approximately 31% of all deaths worldwide, with the global cost of CVD estimated to reach approximately \$1.04 trillion by 2030. CVD is a broad disease classification which includes heart attack, stroke, heart failure and other vascular heart diseases.

The high prevalence of CVD is a result of both inherited and environmental/lifestyle factors. The inherited component is a result of complex interaction of many genes that confer an increased risk of CVD development, with studies showing that an individual's genetic load contributes 40-50% to the development of CVD.

Additionally, over 60% of cardiovascular events occur in people who are assessed to be at low or medium risk according to classic cardiovascular risk factors such as stress or cholesterol, highlighting the unmet medical need to understand the genetic component that contributes to the onset of CVD.

#### 10 year risk of CVD

RISK CATEGORIES (%)	LOW < 5	MODERATE 5 - 9.9	HIGH 10 - 14.9	VERY HIGH ≥ 15
Distribution of people	65.8%	24.1%	6.4%	3.7%
Distribution of cardiovascular events	25.8%	36.7%	23.3%	14.2%

GENinCode's products combine predictive models of genetics and patient data using classic cardiovascular risk factors and are designed to improve predictive capability and genetic risk assessment to provide a more personalised and tailored treatment pathway.



# **Product portfolio**

The Company's product portfolio draws on genomic precision testing using polygenic (multiple-genes) technology, advanced molecular testing, genotyping and sequencing:

- Cardio inCode: focused on assessing the coronary genetic risk and cardiovascular risk
- Lipid inCode: focused on the diagnosis and management of hypercholesterolemia
- Thrombo inCode: focused on the diagnosis and management of genetic thrombophilia and thrombosis risk
- **Sudd inCode**: focused on the diagnosis of the cause of sudden cardiac death and familial heart disease

The Company's key products are CE-Marked with Cardio inCode, Thrombo inCode and Lipid inCode generating revenues in Europe. Discussions with the FDA are ongoing regarding Breakthrough Device Designation for Cardio inCode, with preparations underway for de-novo filing for launch of Cardio inCode in 2022.

# Commercialisation strategy

In Europe, the Company continues to build its business and recently announced sales and distribution arrangements to support its expansion in Spain. The Company is preparing Cardio inCode® for piloting for public health CVD risk assessment in the Spanish regions and expanding its sales team and collaborative partners in Italy and France.

As part of its US expansion strategy, the Company recently announced a commercialisation agreement with EVERSANA Life Sciences Services, which will act as

the Company's US commercial services provider for the Company's products.



EVERSANA has experience across many commercialisation areas, including reimbursement, pricing intelligence, market access and payor services, and represents a strong US commercial partner capable of accelerating GENinCode's growth in the US market.

The Company is in discussions to collaborate with Indiana University Health and New York Presbyterian to introduce the GENinCode technology and to access their Primary Care Patient networks. The proposed collaborations will initially introduce Cardio inCode® and Thrombo inCode® to the networks and provide primary care clinical application of the GENinCode products once FDA regulatory approval has been obtained.

Earlier this year, GENinCode announced a collaboration with Royal Brompton and Harefield hospitals (RB&H) to provide CVD clinical genetic testing. RB&H is part of Guy's and St Thomas' NHS Foundation Trust, the largest specialist heart and lung centre in England and one of the largest in Europe.

In the NHS Long Term Plan 2019, the NHS identified CVD as the single largest condition where lives can be saved by the NHS over the next 10 years. Under the collaboration, the Company will deliver its portfolio of polygenic CVD products and reporting systems, commencing with Lipid inCode® for the diagnosis of hypercholesterolemia. GENinCode will also jointly collaborate with RB&H to develop new genetic CVD tests based at the RB&H Genetics & Genomics Laboratory in London.

The RB&H collaboration will enable the launch of the Company's commercial strategy to incorporate polygenic CVD testing in the UK.

# **Management Team**



# **Matthew Walls Chief Executive Officer**

Matthew became CEO of GENinCode on incorporation September 2018. Between September 2018 and October 2019 he was also Chairman of Concepta plc (now MyHealthChecked plc).

Prior to that, Matthew was CEO and Executive Chairman of Atlantis Healthcare, a leading international patient behavioural change company.

Paul Foulger has been CFO of GENinCode since January 2021. He was previoualy CFO of PredictImmune, a company focused on immunemediated inflammatory diseases. Prior to joining PredictImmune, Mr Foulger spent 10 years at EKF Diagnostics Holdings plc as well as a number of other public and private companies.

# Meet GENinCode plc

You can view the latest Company presentation and register to receive future presentations by signing up with Investor Meet Company here.

# Forecasts (Source: Consensus forecasts compiled by Walbrook PR)

	DEC'21 (Est.)	DEC'22 (Est.)	DEC'23 (Est.)
Sales (£m)	1.2	3.1	11.2
EBITDA (£m)	(6.6)	(11.2)	(13.3)
PBT (£m)	(6.9)	(11.2)	(10.9)