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# Advancing Pharmacogenetic Testing to the **point-of-care**

Year End Results:  
30 June 2023

30 November 2023

**genedrive**



# genedrive plc (LSE : GDR): Executive team

## James Cheek | Chief Executive Officer

- Appointed in September 2023.
- Over 20 years of commercial and operational experience in a variety of diagnostic fields.
- Prior roles with Roche, Beckman Coulter and Cepheid. Former Board Executive at BIVDA, BIVDA representative to the NHS Supply chain Board, Chairman of the BIVDA procurement working party.

## Russ Shaw | Chief Financial Officer

- Appointed in April 2022
- Over 25 years of international experience across multiple sectors including life-sciences, technology and the industrials.
- 10 years as Finance Director at Driver Group plc, an AIM quoted company operating in the engineering and construction industry.
- CFO of several private companies in recent years and is a qualified Accountant and Treasury professional.

## Dr Gino Miele | Chief Scientific Officer

- Appointed September 2023.
- Considerable experience in the development of molecular diagnostic technologies and systems. Has held position of R&D Director at genedrive since 2015 and its predecessor Epistem since 2011.
- Prior to that Gino served as Associate Director for clinical translational genomics at Wyeth and Pfizer.
- Key driver in the development of the genedrive® system and the recent menu of pharmacogenetic tests.

# genedrive plc (LSE : GDR): Who and What

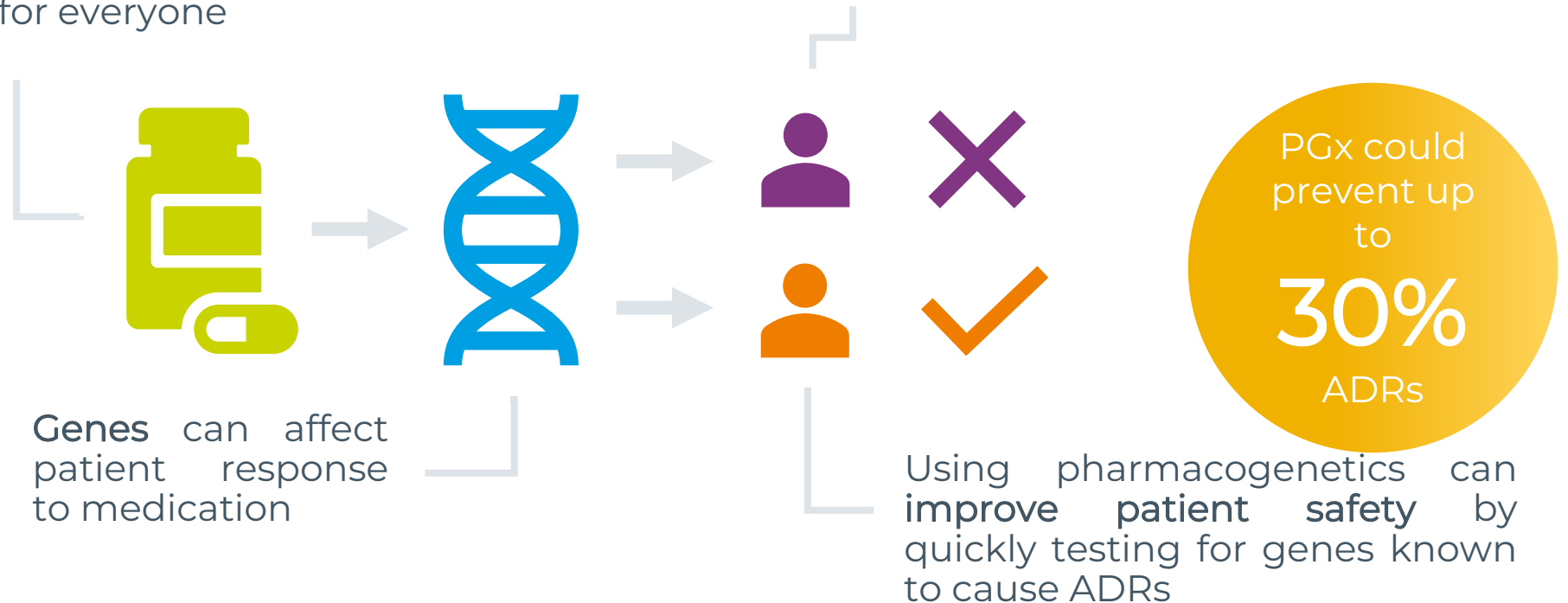
- The Genedrive® device is a low-cost, rapid, simple-to-use point-of-care molecular diagnostic device.
- Our focus is increasingly on emergency medicine applications because the rapid delivery of actionable genetic information is a key strength of our patented technology & expertise.
- We have developed the world's first point of care pharmacogenetic test to help avoid Antibiotic Induced Hearing Loss, and a have a new test available for improving health outcomes in stroke patients.
- NICE EVA conditional recommendation to use our MT-RNR1 test in the NHS. Further evidence required as part of EVA process to lead to full recommendation.
- NICE expected to recommend CYP2C19 genotyping for clopidogrel treatment in Ischaemic stroke patients in early 2024 when their paper on this is due to be published.
- Considering using the FDA break through device program for MT RNR1 test.



# Why Pharmacogenetics?

Medications can work differently for everyone

Some patients may have an unintended, harmful response, known as an **Adverse Drug Reaction (ADR)**




<https://medregs.blog.gov.uk/2023/10/02/the-role-of-genetics-in-medicine-safety/>

# UK Health System – Impact of Adverse Drug Reactions

1. <https://medregs.blog.gov.uk/2023/10/02/the-role-of-genetics-in-medicine-safety/>
2. <https://bmjopen.bmj.com/content/12/7/e055551>

**16.5%**  
UK hospital  
admissions



**15%**   
Inpatients have an  
ADR during their  
stay in hospital



**8000**  
overnight  
stays per  
year

**30%**  
ADRs may be  
preventable  
by PGx



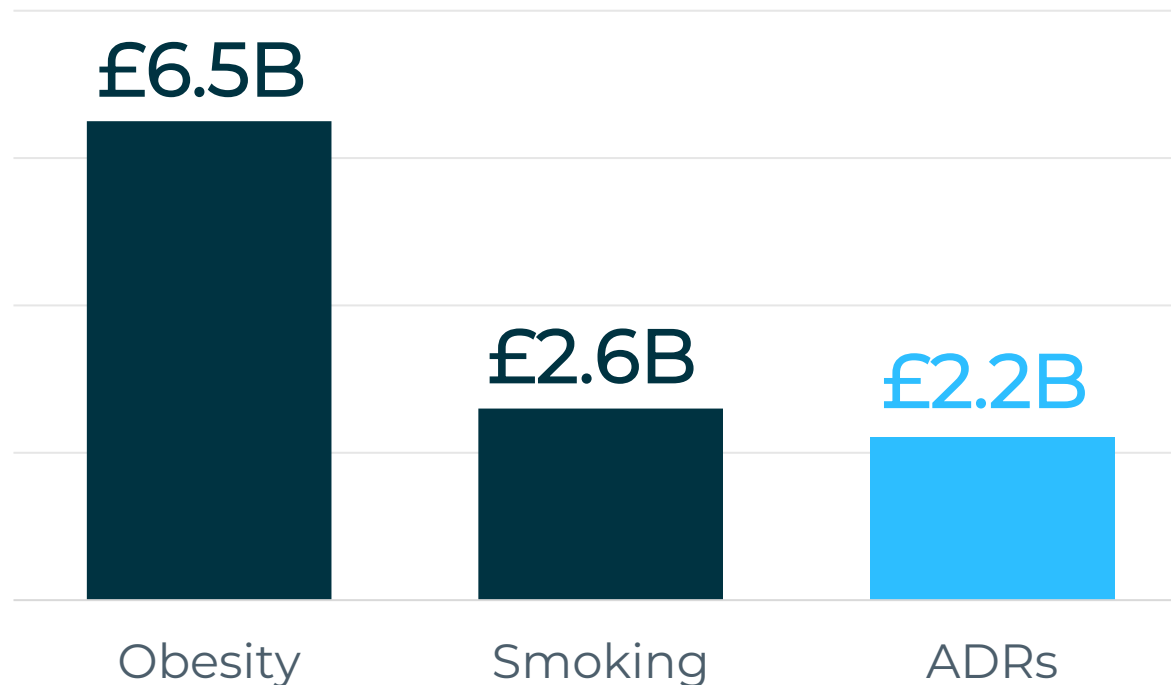
# Adverse Drug Reactions: The Cost

<https://medregs.blog.gov.uk/2023/10/02/the-role-of-genetics-in-medicine-safety>

Obesity: [Government plans to tackle obesity in England - Department of Health and Social Care Media Centre \(blog.gov.uk\)](#)

Smoking: [NHS England » Guide for NHS trust tobacco dependence teams and NHS trust pharmacy teams](#)

## Annual Cost to NHS England



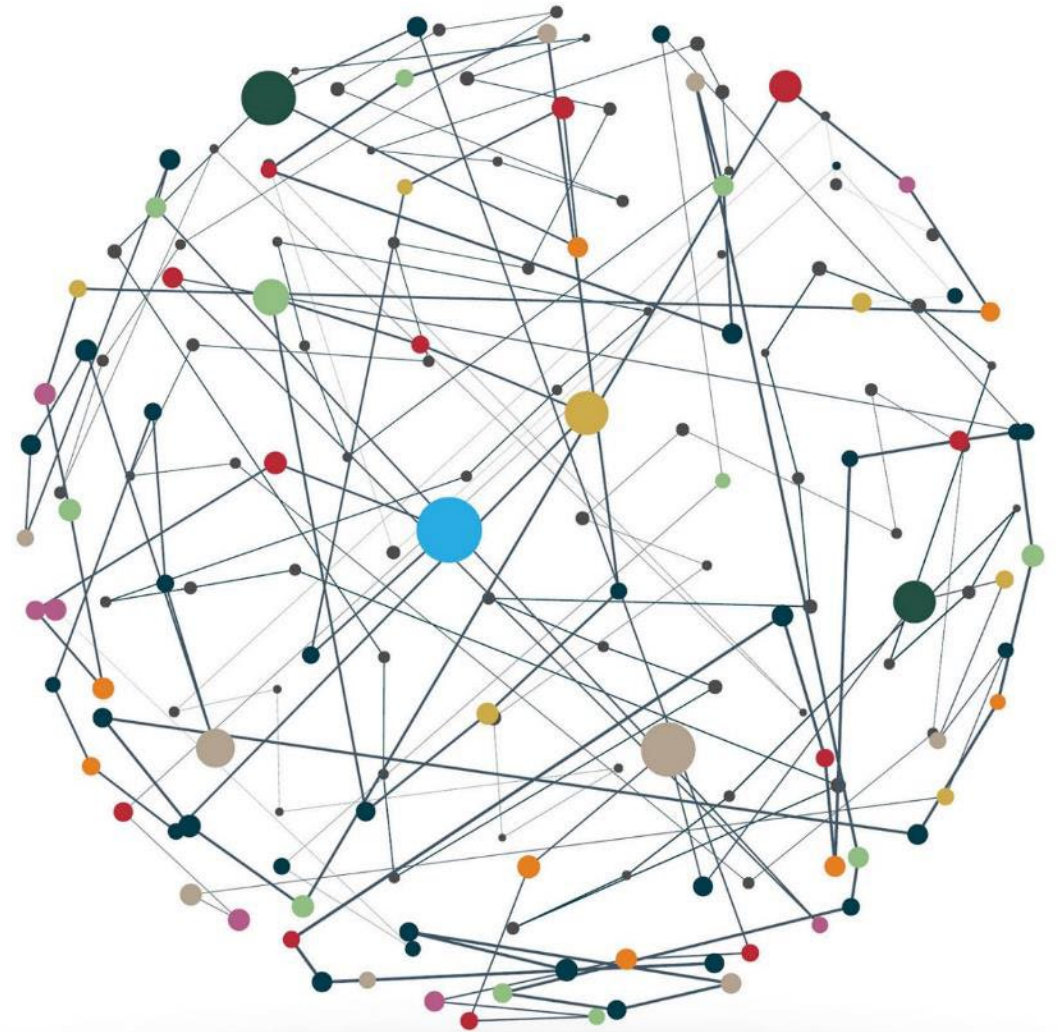
Up to **£660 million** could be saved

genedrive

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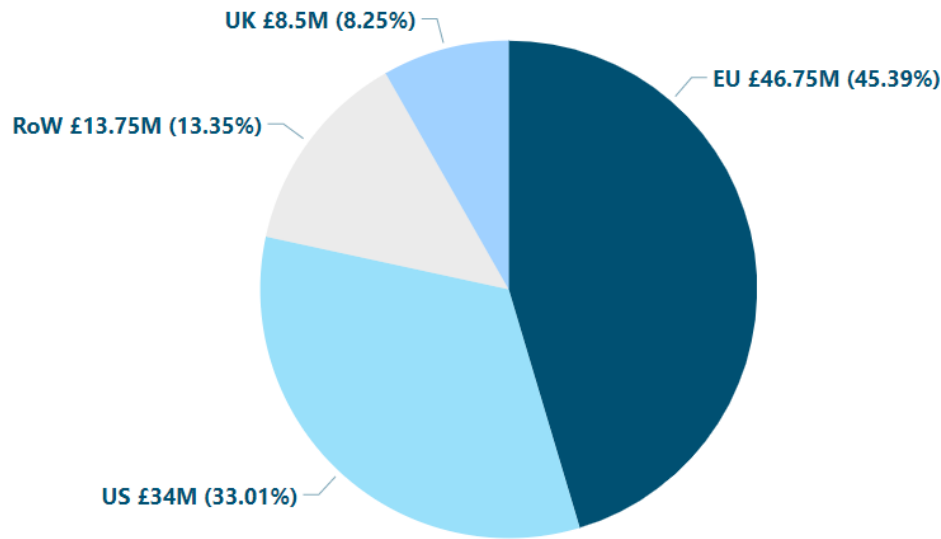
Genedrive®  
MT-RNR1 ID Kit

Antibiotic Induced  
Hearing Loss  
(AIHL)



# AIHL - Antibiotic Induced Hearing Loss (Genedrive® MT-RNR1 ID Kit)

Total Addressable Market Estimate = £100M



Model assumptions:

- International - Extrapolated from population sizes, birth rates, and UK admission to NICU rate
- Based direct sale model

Approximately 100K UK  
NICU admissions

Addressable Global Market  
>£100m

CE Marked

Positive  
Health Economic Case

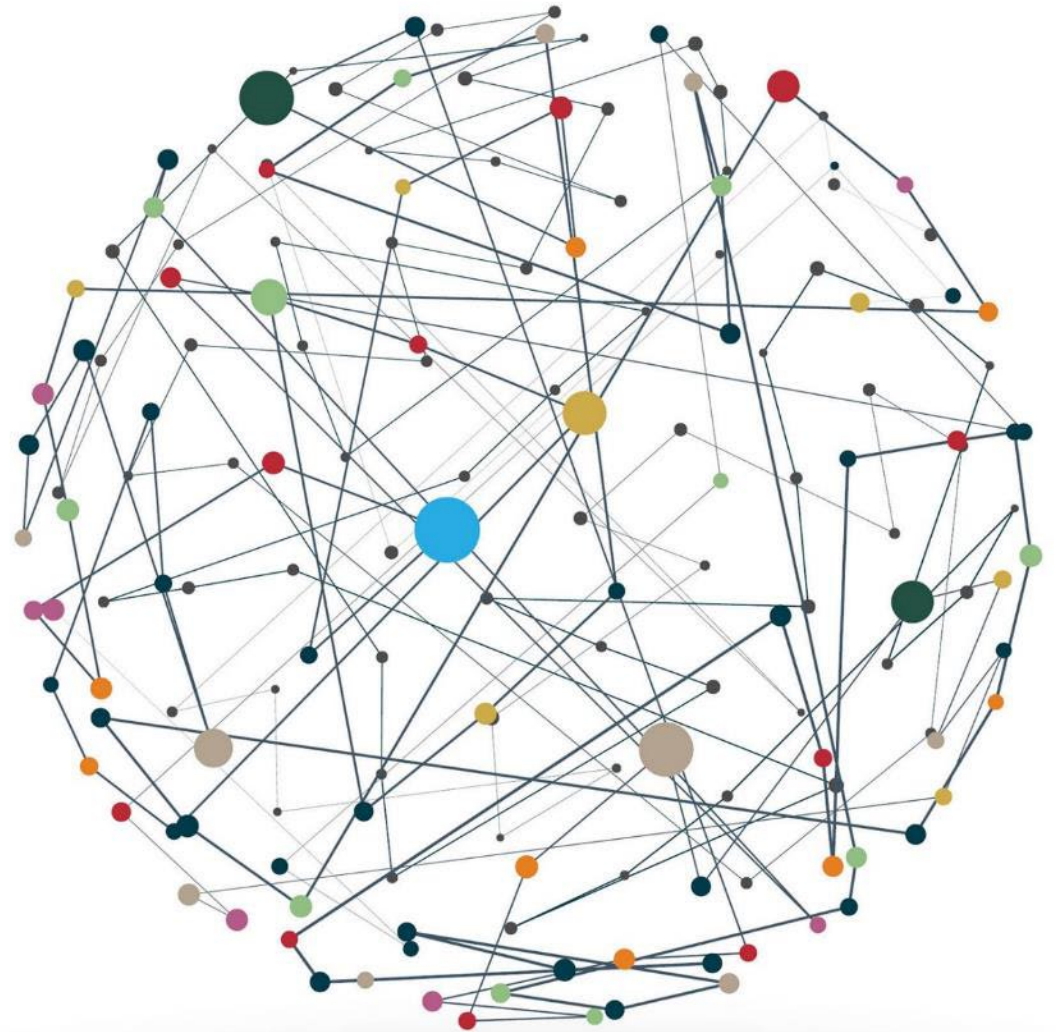
NICE recommended for use  
under EVA



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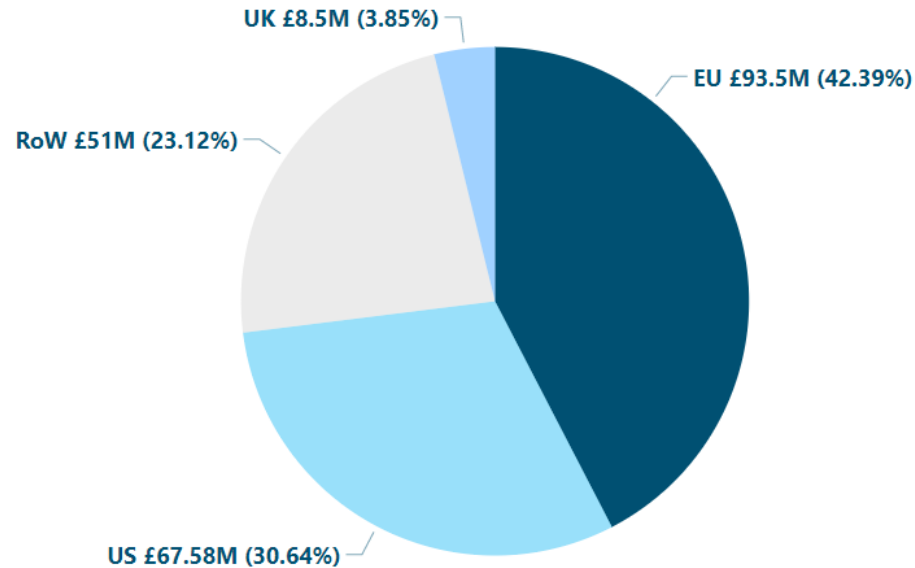
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Genedrive®  
CYP2C19-ID Kit



# Genedrive® CYP2C19-ID Kit (in development)

Total Addressable Market Estimate = £220M



Model assumptions:

- UK - Based on NICE prevalence of stroke
- International – Europe AHA journals USA – CDC
- Row – assumes <10% developed healthcare markets
- Uses end user pricing

Addressable Market for ischemic strokes.

~85K ischaemic strokes per year UK

Up to 30,000 UK patients could get better health outcome

Co-operation with MRI save >£1m in ongoing costs

Under NICE review

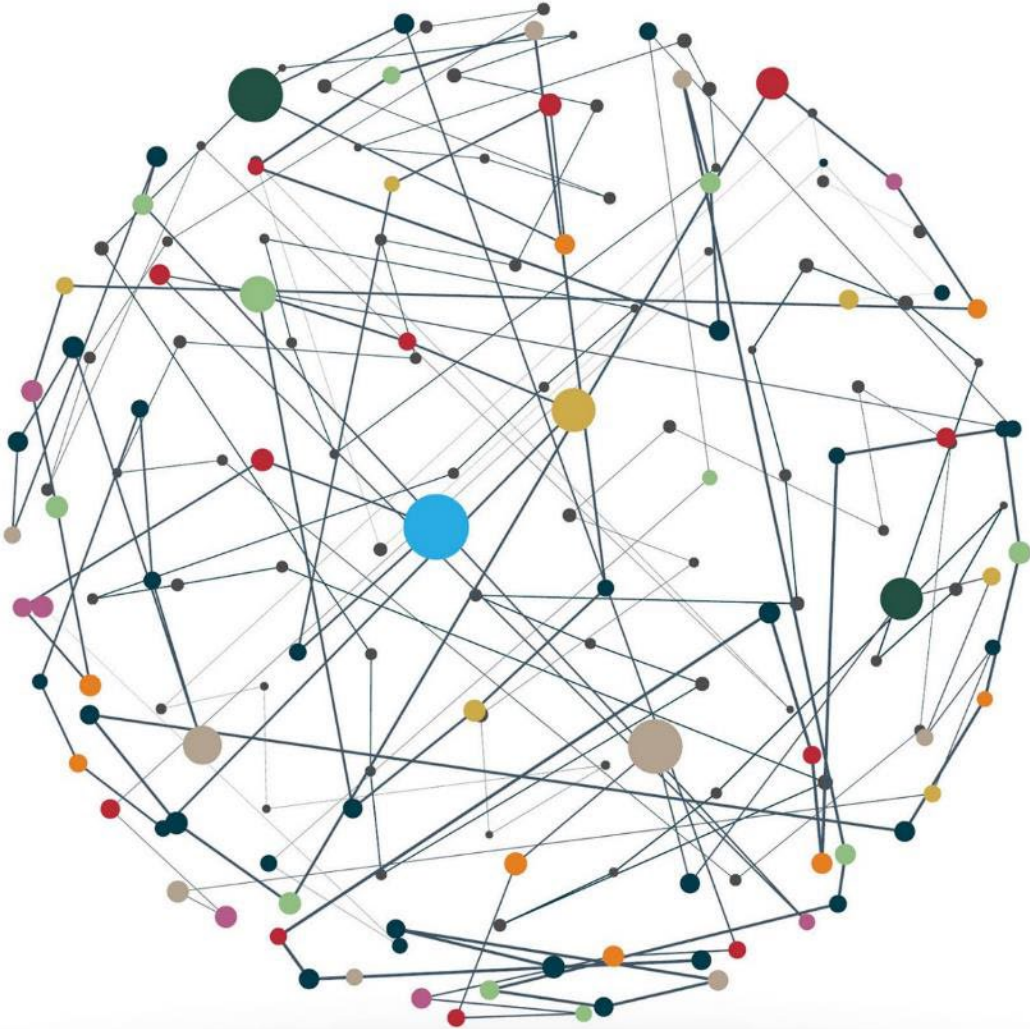
# USA Clopidogrel ADR cost review 2023

*American Journal of Health-System Pharmacy*, Volume 80, Issue 12, 15 June 2023 – Veterans Health Administration

Unadjusted and Adjusted Comparisons of Mean Costs of Hospitalization for Different Drugs Associated With Same Adverse Reaction (at MedDRA HLT Level), Summarized for Fiscal Years 2014-2018

	No. reports	Median (IQR) <sup>a</sup>	Mean (SD) <sup>a</sup>	Model estimate of cost, mean (lower and upper) <sup>b</sup>
<b>Clopidogrel</b>	<b>38</b>	<b>\$13,647 (\$9,547-\$18,581)</b>	<b>\$16,960 (\$13,401)</b>	<b>\$13,265 (\$8,650-\$20,342)</b>
<sup>a</sup> Costs in US dollars adjusted to 2018 value using Consumer Price Index. Median and mean costs derived from raw data.				
<sup>b</sup> Generalized linear model with gamma distribution and Bonferroni correction for multiple comparisons. Model adjusted for age, sex, race/ethnicity, presence of drug-drug interaction, and geographic region.				

Summary  
Financials



# Summary Financials

Income statement	FY23	FY22
	£'000	£'000
Revenue	55	49
R&D costs	(3,924)	(3,871)
Admin costs	(1,355)	(1,793)
Operating loss	(5,224)	(5,615)
Finance costs	(757)	(16)
Loss before tax	(5,981)	(5,631)
Tax	831	956
Loss after tax	(5,150)	(4,675)

## Income statement

- Revenue - RNR1 in routine use
- R&D focused on near-commercialisation product development
- Admin costs reduced £0.4m due to tight cost management
- Finance costs includes £0.7m non-cash fair value adjustment
- R&D reflects reduction in HMRC R&D tax relief rates

# Summary Financials

Cashflow	FY23 £'000	FY22 £'000
Operating loss before changes in working capital	(4,874)	(5,327)
Working capital	113	(433)
Taxation	956	1,166
Net cashflow from operations	(3,805)	(4,594)
Proceeds from investment funding	2,300	7,200
Transaction costs - investment funding	(283)	(506)
Other	(200)	(85)
Net cash flow	(1,988)	2,015
Cash at bank b/f	4,589	2,574
Cash at bank c/f	2,601	4,589
Underlying monthly burn rate:	FY23 £'000	FY22 £'000
Gross	(413)	(487)
Adjusted for taxation	(334)	(390)

## Cashflow

- Operating loss before changes in working capital is £0.5m less than FY22 - reflective of the reduction in overheads
- Working capital inflow £0.1m – £0.5m higher than the £0.4m consumed in FY22 due to reduced stock expenditure
- £1.0m receipt from HMRC R&D tax credit scheme
- Unaudited cash at 23 November 2023 of £1.0m and £0.3m drawdown imminent

## Burn rate

- Underlying cash consumption of £0.4m
- Adjusting for R&D tax credit received, monthly rate reduces to £0.33m

# News flow

## Near Term

- Revenue from additional go-live sites in the UK and abroad for MT RNRI
- Completion of the initial work with the Health Innovation Network for the MT RNRI
- Continue progressing special commissioning for MT RNRI
- Finalise position for FDA registration for MT RNRI
- Further NICE data gathering for full recommendation commences MT RNRI
  
- NICE review for CYP2C19
- Commence testing with MRI for CYP2C19
  
- Continuation of instrument design improvements to facilitate adoption, and expansion of test menu expansion
- Future funding activities to support FDA and product development

## Medium to Long Term

- Commence IVDR registration for CYP2C19
- Launch of CYP2C19 in other territories following IVDR registration
- Commence FDA registration for MT RNRI
- Commence work on multi target pipeline tests

# Summary

Great commercial traction for MT RNR1 both UK and abroad

Real clinical and commercial interest in CYP2C19 both in and outside the UK

First to market with unique Point of Care Pharmacogenetic testing

Investment required for growth capital to support sales strategy