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## **Business Update & Highlights**

Making Strong Headway Toward our Goal for Accrufer® to be the Brand Leader in Oral Iron Therapy



#### Financing Agreement of US\$10 Million with Existing Shareholder

### Strong Execution of US Strategy Resulting in Acceleration Across all Key Indicators



- Awareness
- Generating Clinical Experience (Prescription Growth)
- Payer Coverage



#### 2021 Financial Results



## **2021 Financial Highlights**

- Revenues of £1.5 million (2020: £10.4 million)
  - £0.9 million royalty income from Feraccru® sales in Europe by Norgine (2020: £0.7 million)
  - £0.1 million net product revenue from Accrufer® sales in US (2020: £nil)
  - £0.5 million upfront payment from Korea Pharm on signing of Korean license agreement (2020: £9.7 million from ASK Pharm on signing of Chinese license agreement)
- Loss for the year of £19.3 million (2020: £2.6 million)
  - £20.0 million operating costs (2020: £8.6 million), including £10.3 million selling costs (2020: £0.3 million)
- Net cash of £12.1 million at 31 December 2021 (2020: £2.9 million); £4.2 million at 31 May 2022
  - £ 29.2 million gross proceeds (£27.8 million net of expenses) raised by means of placing, subscription and open offer in March 2021
  - £1.7 million average monthly cash burn from July 2021 through December 2021



## The Accrufer® Opportunity

#### **Large US Defined Market**

~20M individuals with anemia<sup>1</sup>

13.4M annual oral iron prescriptions (OTC)

80% Rx written by Primary Care and OB/GYN (MDs, NPs, PAs)



Conventional irons (OTC) have poor tolerability and high discontinuation rates

#### **FDA Approved Potential Best in Class Solution**

Accrufer®, an FDA approved therapy, oral iron solution with minimal (<5%) gastrointestinal adverse reactions\*\* and discontinuations<sup>2</sup>



#### **New and Experienced Team**

Senior leadership team has extensive US commercial experience in building brands and launching new products



#### **Market Adoption and Payer Coverage Expanding**

100% growth in prescriptions written during Q1:2022 vs. Q4:2021

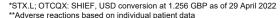
100M covered lives as of June 2022



#### **Significant Revenue Potential**

\$2.2B US market opportunity\*\*\*
Only FDA approved oral iron with broad label in US
Patent coverage thru 2035





\*\*\*Market opportunity is an estimate only, prepared by Shield and based on a number of assumptions made by Shield.

Accrufer® (ferric maltol) [Prescribing Information]. Austin, TX: Shield Therapeutics, 2019. Revised 02/22.



<sup>1.</sup> As estimated by Shield based on a population of c.313M and the study as set out in Hong Le C, et al. PLoS One. 2016;11(11): e0166635.

## Iron Deficiency (ID) with & without Anemia (IDA):

### **A Source of Morbidity and Mortality**

GI Adverse events driven-low-adherence to conventional therapy makes ID/IDA an under-served market

### ~20 MILLION\*

Estimated number of individuals with anemia in the US

28% Increased risk of NICU admission in mothers with IDA<sup>1</sup>

Higher all-cause mortality among mildly iron-**63**% deficient elderly individuals in long-term care facilities<sup>2</sup>

Increased risk for depression among older 93% individuals with IDA<sup>3</sup>

### 13.4 MILLION

Annual prescriptions for oral iron replacement therapy

**40-60%** Estimated overall adherence with oral iron for IDA due to all AFs<sup>4</sup>

Estimated overall adherence with oral iron **50%** for IDA due to GLAFs<sup>5</sup>

> Gastrointestinal side effects drive a cycle of medication switching

ID, iron deficiency, IDA, iron deficiency anemia; AEs, adverse events; GI, gastrointestinal; NICU, neonatal intensive care un

\*As estimated by Shield based on a population of c.313M and the study as set out in Hong Le C, et al. PLoS One. 2016;11(

- Onder G, et al. J Gerontol A Biol Sci Med Sci. 2005;60(9):1168-1172.
- Cancelo-Hidalgo MJ, et al. Curr Med Res Opin, 2013;29(4);291-303
- Tolkien Z, et al. PLoS One. 2015;10(2):e0117383.



## **Iron Deficiency Treatment Algorithm**

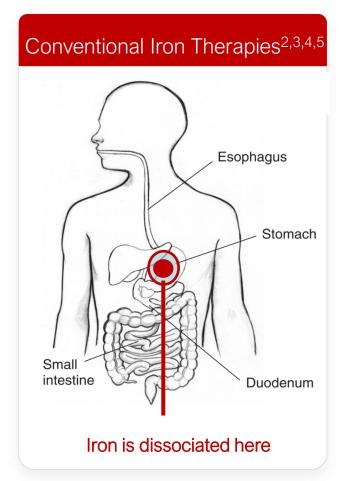
An Unsatisfactory Cycle of Switches and Discontinuations



Patients and Health Care Providers (HCPs) are Seeking a Well-Tolerated and Effective Oral Iron Replacement Therapy

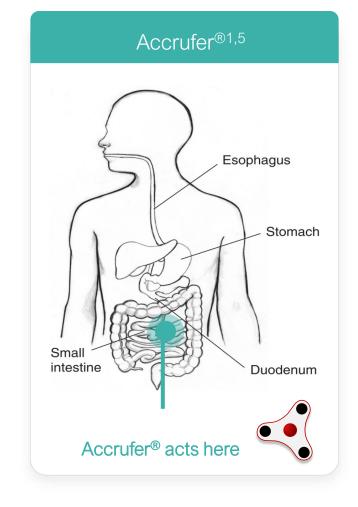


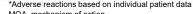
## Accrufer® Effectively Treats Iron Deficiency with <5% adverse reactions\* and discontinuations<sup>1</sup>

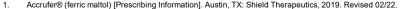


Proprietary Accrufer® maltol formulation and unique MOA delivers elemental iron to the small intestine.<sup>1</sup>

This enables the treatment of iron deficiency with a lower dose of iron and results in low adverse reactions and treatment discontinuations. <sup>1</sup>







Khoury, A., Pagan, K. A., & Farland, M. Z. (2021). Ferric Maltol: A New Oral Iron Formulation for the Treatment of Iron Deficiency in Adults. Annals of Pharmacotherapy, 55(2), 222–229. https://doi.org/10.1177/1060028020941014

Tenenbein M. (1998). Toxicokinetics and toxicodynamics of iron poisoning. Toxicology letters, 102-103, 653-656. https://doi.org/10.1016/s0378-4274(98)00279-3 BokemeyerB, Krummenerl A, Maaser C, et al. Randomized open-label phase 1 study of the pharmacokinetics of ferric maltol in inflammatory bowel disease patients with iron deficiency. Eur J Drug Metab Pharmacokinet. 2017;42:229-238 Presentation

## **Initial US Launch Strategy 2021**

### **Snapshot of an Established Market**

- ~13.4M oral iron prescriptions written annually in US
- Ferrous sulfate most commonly written OTC oral iron
- 80% prescriptions written by Primary Care and OB/GYN (MDs, NPs, PAs)

### **Payers and** Reimbursement

- Commercial and Medicaid payers drive majority of oral iron prescriptions
- Initiate conversations and medical presentations to targeted payers for contract discussions
- Patient out of pocket cost targeted to be equal to OTC iron products

#### **Tactical Execution**

- Prior to July 2021 launch, no market development:
- No Accrufer® awareness or KOL Engagement/Advocacy
- Newly hired contract team including 30 Person Sales Team and 3 Sales Directors targeting ~4000 HCP's
- Newly developed Marketing Materials and Product Website



#### **Accrufer® 2022 Priorities**

Long Term Goal: Accrufer® to be the Brand Leader in Oral Iron Therapy



"Accrufer®, with its unique mechanism of action, clinically meaningful improvements in haemoglobin and low rate of adverse reactions have been a game changer for my patients. Accrufer® has the potential to become the product of choice to treat iron deficiency anaemia in Women's health associated conditions."



## **Amplifying Accrufer® Awareness**

#### **Customer Insights & Medical Education**











**Advisory Boards** 

#### **Digital**

















epocrates<sup>®</sup>



Medscape









#### **Company Websites**





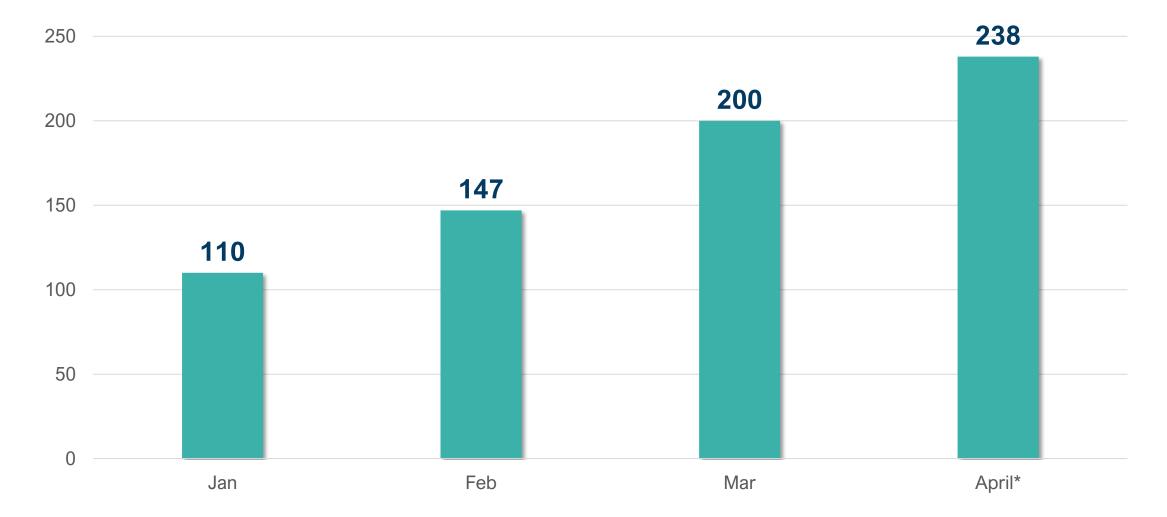


www.accrufer.com

www.accruferhcp.com

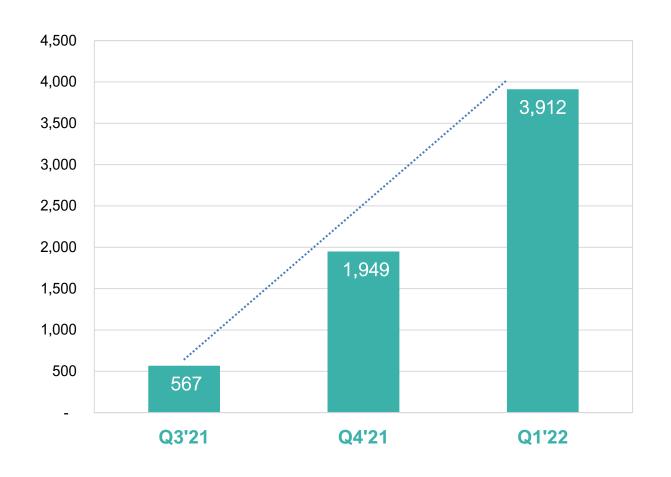


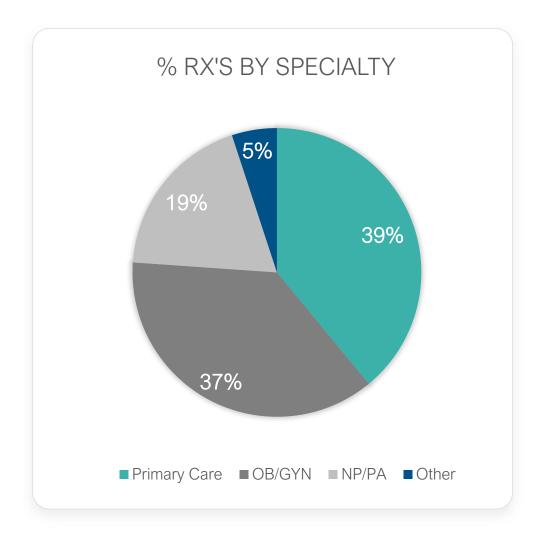
## First Time Writers of Accrufer® Doubled since January





## Accrufer® Prescriptions Accelerating – 100% Growth Q1:2022 vs. Q4:2021







## Accrufer® Payer Access Significantly Increased from 0 to 100M Covered Lives

### Commercial Plans

















### **Medicaid Plans**

**Texas** 

Florida

Georgia

Indiana

Illinois

Kentucky

North Carolina



### **New Additions to US Commercial Team in 2022**

### with Extensive Product Launch Experience



Todd Hayes Head of Sales



Christie Cioffi Head of Marketing



Lori Nemyier
Head of Commercial Operations



Michael Cody Head of Medical Affairs









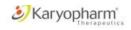
























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## **Financing**

Extends Cash Runway to approximately the End of Calendar 2022

- \$10 Million Shareholder Loan from Existing Shareholder
  - Interest of 7.0% above 12-month USD-LIBOR, payable monthly in arrears, plus arrangement fee of 2%
  - Secured through US IP rights associated with Accrufer®
  - Repayable at a) option of borrower b) in event of new financing (debt or equity) of no less than \$30 million or c) by 31 December 2023
  - Subject to shareholder approval, conversion option to lender at 10% discount or in event of new equity raise on same conditions as other investors
- Various other Financing Opportunities and Strategic Partnerships continue to be pursued to Accelerate Accrufer® Sales Growth and Financing of the Company



## **Key Drivers to Accelerate US Accrufer® Growth**



Field Force Expansion



Amplify Digital
Strategy
&
Direct to Consumer



Data Generation & Infrastructure



## Accrufer®: A \$2.2B U.S. Market Opportunity\* for Iron Deficiency

#### **The Opportunity**

Iron deficiency with or without anemia (ID/IDA), an established and defined market

- ~20M individuals with anemia<sup>1</sup>
- 13.4M prescriptions
- 80% Rx written by Primary Care and OB/GYN (MDs, NPs, PAs)

#### The Problem

Conventional iron products are associated with an estimated 40-60% overall adherence due to all AEs<sup>2</sup> The Solution: Accrufer® - an effective, well tolerated proprietary low-dose oral iron formulation with an adverse rection and discontinuation rate <5%3

#### The Accrufer® Opportunity

To be the 1st Line / 1st Switch Oral Iron

- New Leadership Team has Extensive US Experience, Building Brands and Launching New Products
- Prescriptions are Accelerating: 100% Growth Q1:2022 vs. Q4:2021
- Growing Payer Coverage to 100M lives
- Positive Clinical Experience and Significant Interest among HCP's



# **Thank You!**

**Greg Madison (CEO) Hans-Peter Rudolf (CFO)** José Menoyo, MD (CMO)



