



# 2022 Final Results and Q1 2023 Update

27 April 2023

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# Shield is an Innovative Specialty Pharmaceutical Company

Dedicated to making Accrufer® the oral iron of choice

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We deliver innovative specialty pharmaceuticals that address a significant unmet need for patients suffering from iron deficiency, with or without anemia.

Our lead product, Accrufer® (Ferric maltol) is broadly indicated for use in adults across multiple therapeutic categories

## 2022/Early 2023 Accomplishments

- Achieved 25,200 in US Accrufer® prescriptions, up 12-fold, with a 12% sequential growth in Q1 2023 and a strong March
- Implementation of Accrufer® collaborative U.S. sales agreement with Viatris well underway to reach 100-person expanded commercial Team by May 1st
- Fully funded to support operations through to cash flow break-even by YE 2024

## 2023+ US Commercial Milestones

- 2023: Grow US prescriptions to 125,000 – 160,000
- 2025: Grow US prescriptions to 550,000 to 600,000
- 2025: Targeting USD 150 million revenue

# 2022 Financial Highlights

## Investing in further development of US commercial operations

### **Revenues of £4.5 million or US\$5.4 million (2021: £1.5 million or US\$2.1 million), excluding Viatris upfront payment of £4.2 million or US\$5.0 million**

- Net product revenue of £2.9 million from sales of Accrufer® in US (2021: £0.1 million)
- Royalty revenue of £1.4 million from product sales in Europe (2021: £0.9 million)
- Upfront payment of £0.2 million from KYE Pharmaceuticals on signing of licence agreement for commercialisation in Canada (2021: £0.5 million from Korea Pharma)
- Not included in total revenue is upfront payment of £4.2 million (or \$5.0 million), received from Viatris upon execution of co-promote arrangement, recorded as £0.7 million in other income for 2022 and £3.5 million for 2023

### **Operating loss before impairment and R&D expenditure of £24.6 million or US\$29.5 million (2021: £19.5 million or US\$26.8 million)**

- Operating costs of £27.3 million (2021: £20.2 million) include selling costs of £16.0 million (2021: £10.4 million) and general administrative expenses, including depreciation and amortisation) of £11.3 million (2021: £9.8 million)

### **Cash and cash equivalents of £2.8 million or US\$3.4 million at 31 December 2022 (31 Dec 2021: £12.1 million or US\$16.6 million)**

- Equity fundraise and amendment of existing convertible shareholder loan provided additional funding of £16.2 million and £8.2 million to business in January 2023
- Cash on hand of £19.2 million at 31 March 2023



# Recap of Completed Funding Transactions in 2022/23

Fully funded to support operations through to cash flow break-even by end of 2024

Month / Year	Description of Transaction	Net Proceeds in £ million	Net Proceeds in US\$ million
Aug 2022	Execution of convertible shareholder loan with AOP Health International Management (“AOP Health”)	8.0	9.8
Dec 2022	Non-refundable upfront payment from Viartis upon execution of collaborative sales agreement for Accrufer® in US	4.2	5.0
Jan 2023	Net proceeds from equity placing and open offer	16.2	20.1
Jan 2023	Amendment to convertible shareholder loan with AOP Health	8.2	10.0
<b>2022/23</b>	<b>New funding raised for business</b>	<b>36.6</b>	<b>44.9</b>

- Cash on hand of £19.2 million at 31 March 2023
- Balance on convertible shareholder loan from AOP Health of £12.4 million (or US\$15.0 million) at 31 March 2023 (following partial conversions in August 2022 and January 2023)

# A Market Ripe for Innovative Disruption



**~20 MILLION\***

Estimated number of individuals with anemia in the US\*

## Large, defined market:

- ✓ 13.4M prescriptions per year, majority OTC iron
- ✓ Total available US market opportunity of US\$2.3B

**80% of prescriptions written by  
Women's Health and General  
Practitioners**

**Unsatisfied market driven by  
gastrointestinal related adverse  
events and minimal efficacy**

**Little to no innovation among oral iron  
therapies over past decade drives  
complacency for healthcare providers**

# Iron Deficiency, with and without anemia (ID/IDA)

Untreated ID/IDA is a source of morbidity and mortality

**ID/IDA is caused by** malnutrition, bleeding or problems absorbing iron

**Associated with many diseases**, especially women's health, inflammatory bowel disease (IBD), chronic kidney disease (CKD), congestive heart failure, oncology, aging

**Clinical symptoms of anemia** include fatigue, headache, dizziness, tachycardia, reduced cognitive function and decreased ability to work

**Consequences of ID/IDA include increased risk** of hospital admission, pre/post-natal complications, cardiovascular issues, inflammatory disease exacerbations, depression and mortality



## Current Iron Deficiency Treatment Algorithm

An unsatisfactory cycle of switches and discontinuations, mainly due to gastrointestinal side effects

# Accrufer® Designed to Deliver Effectiveness with Tolerability

Proprietary Accrufer® Maltol Formulation and Unique MOA Delivers a Total of 30mg BID of Elemental Iron to the Small Intestine<sup>1</sup>

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## Proprietary Formulation

Accrufer® is formulated in a maltol complex vs. traditional oral irons, provided in ferrous based formulations

## Low iron dose

60 mg of elemental iron is delivered by Accrufer® daily



Accrufer® protects iron within a maltol “shield”, enabling it to pass through the stomach

This “shield” allows Accrufer® to reach the small intestine, where it safely releases the iron dose into the blood stream.

The maltol shield allows the body to achieve more efficient iron uptake at lower doses



# Accrufer® Designed to Deliver Effectiveness with Tolerability

Proprietary Accrufer® maltol formulation and unique MOA delivers a total of 30mg BID of elemental iron to the small intestine<sup>1</sup>

**<5%**

Accrufer® adverse reaction & discontinuation rate<sup>1</sup>

**2.25 g/dl**

Increase in hemoglobin for Accrufer®-treated patients compared to 0.06 g/dl for placebo at week 12<sup>2</sup> ( $p < 0.0001$ )

Data from three Phase 3 studies demonstrated consistent efficacy in both the IBD and CKD populations and supported a broad label as a treatment for patients with iron deficiency and iron deficiency with anemia

# High Performance Executive and Commercial Leadership Team

Poised for success, building on experience with over 30 products launches



**Greg Madison**  
Chief Executive Officer



**Hans-Peter Rudolf**  
Chief Financial Officer



**Andy Hurley**  
Chief Commercial Officer



**Todd Hayes**  
Head of Sales



**Christiana Cioffi**  
Head of Marketing



**Lorraine Nemyier**  
Head of Commercial Operations

SANOFI GENZYME

Deloitte

agenus

AstraZeneca

Stemline

Karyopharm  
Therapeutics

melt  
PHARMACEUTICALS

EY  
Building a better  
world, one idea at a time

Syneos  
Health

ZS  
Pharma

EUSA Pharma

amag  
PHARMACEUTICALS

KERYX  
PHARMACEUTICALS INC.

Crowe

Ocular  
Therapeutix™

SANOFI GENZYME

Karyopharm  
Therapeutics

DRG  
DECISION RESOURCES GROUP

amag  
PHARMACEUTICALS

OC

Dyax

Abbott

SERVIER

SANOFI GENZYME

V

NITROMED

Abbott

IPSEN

## OUR COMMERCIAL PARTNERSHIP MISSION



To make Accrufer® the oral iron  
of choice in the U.S.



# Exclusive, Multi-Year US Co-Commercial Agreement

## Significant Market Opportunity in Iron Deficiency

### Upfront payment

USD \$5 million upon signing

### Start Date

January 1, 2023

### Revenue and Cost Sharing

Net Revenue and Marketing Cost split, with Shield taking a larger share

### Sales Force

Combined 100-person sales team. Each company will pay for its own sales force and related selling costs

### Milestones

Up to USD \$30 million, linked to net sales targets



# Leveraging Viatris' Strength to Accelerate Potential Accrufer® Growth

Driving commercial breadth and accelerating adoption

## Well established commercial infrastructure and prescriber relationships

- 1 Dedicated 50-person Sales Team promoting only Accrufer®
- 2 Best-in-Class digital marketing
- 3 Large experienced market access team with extensive relationships to drive expanded payer access
- 4 Direct to patient capabilities



VIATRIS (USD 14B Market Cap) Brand Strength



# Key Drivers to Accelerate US Accrufer® Growth



**Field Force  
Expansion**



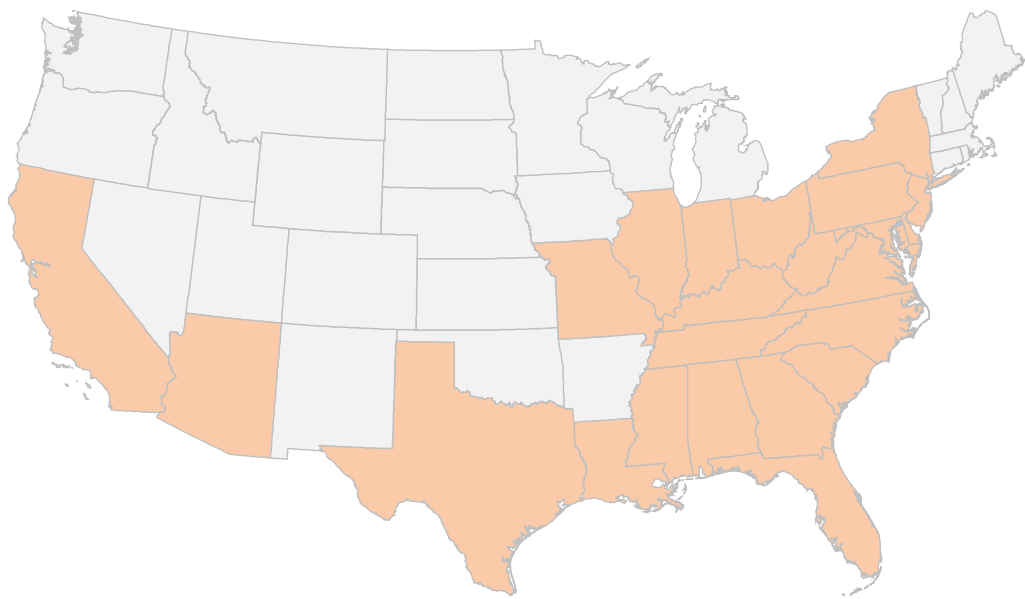
**Amplify Digital Strategy  
& Marketing Initiatives**



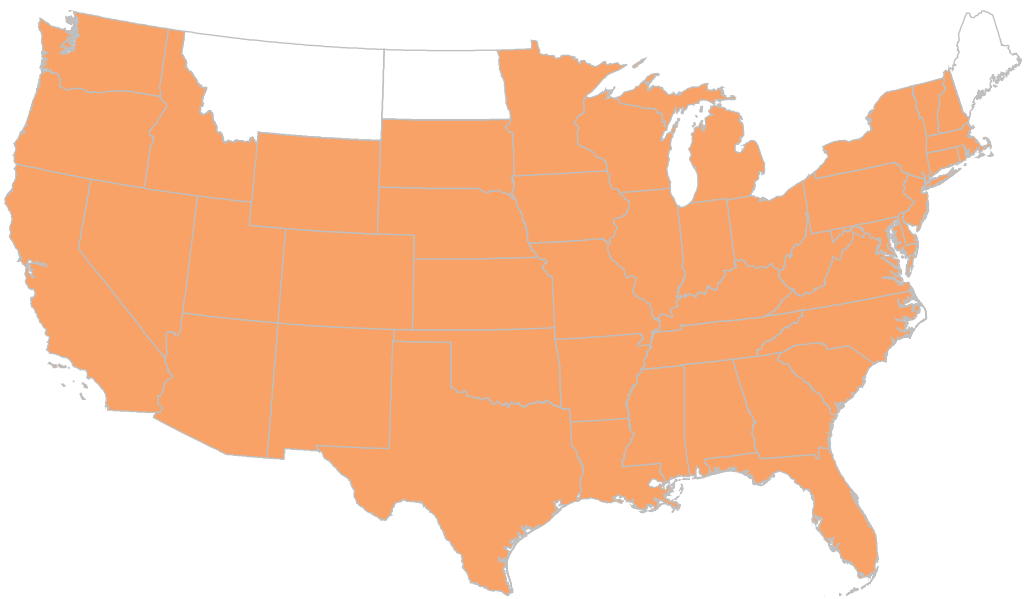
**Expand Market Access  
& Distribution**

# New 100-Person Sales Force Dramatically Increases Reach and Efficiency

*Collectively calling on 12,000+ high prescribing HCP's*



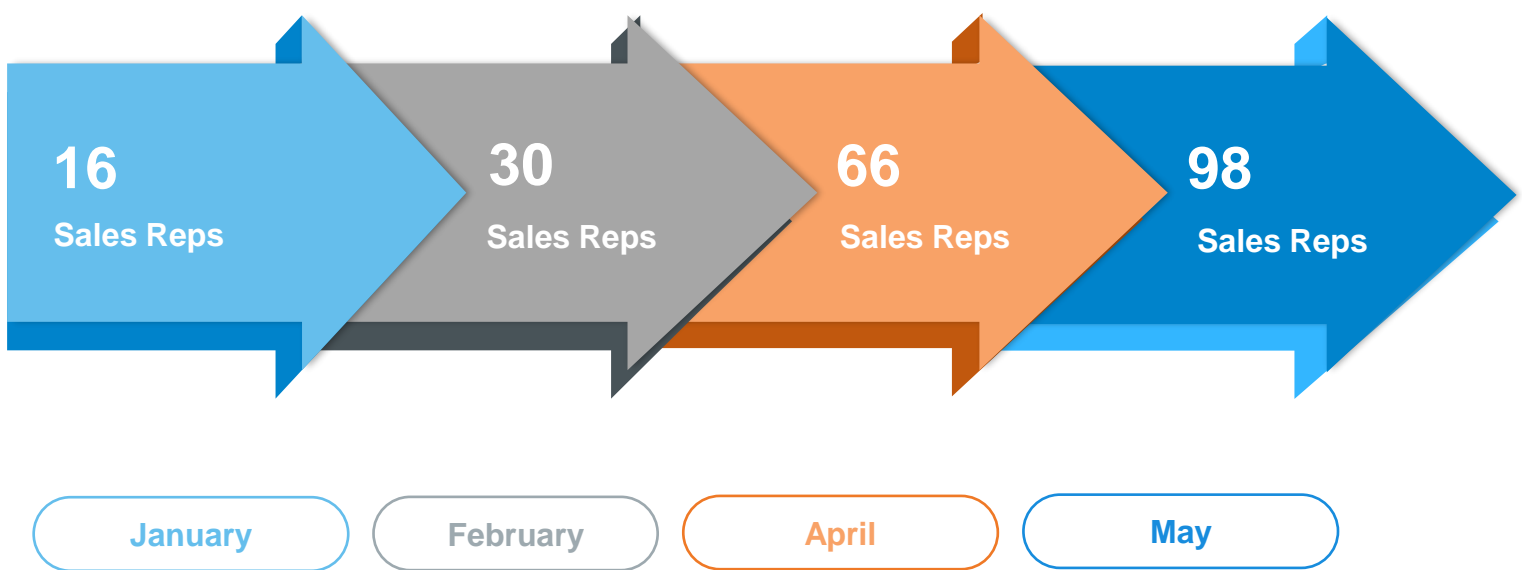
Previous Shield only contract sales team territories\*



New 100-person sales team territories

# Sales Force Expansion on Track for Completion in May

Hiring Profile of New Field Team Highlights Depth of Experience



► **Highly credentialed team**

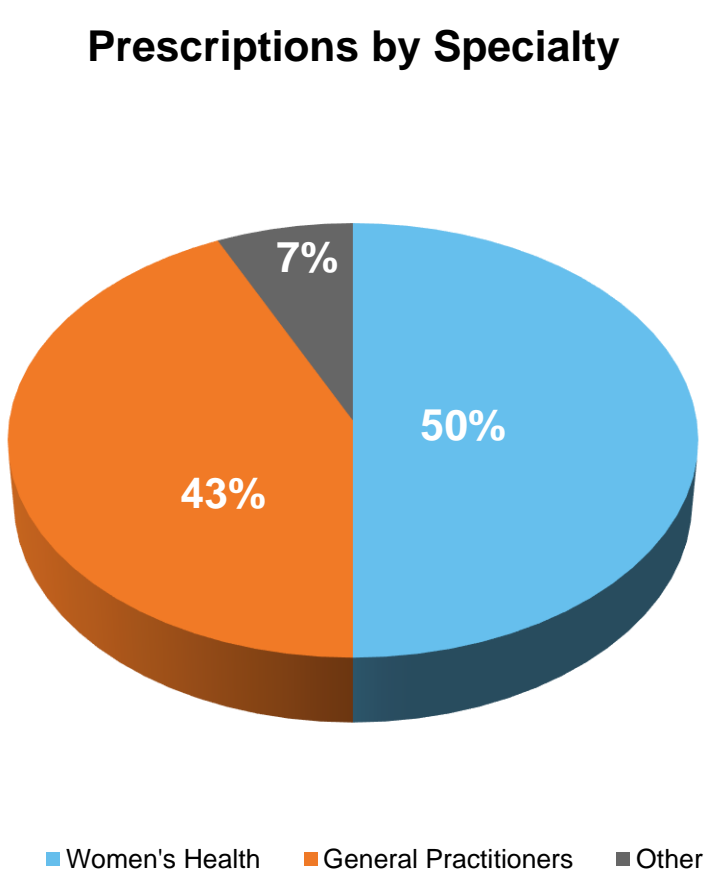
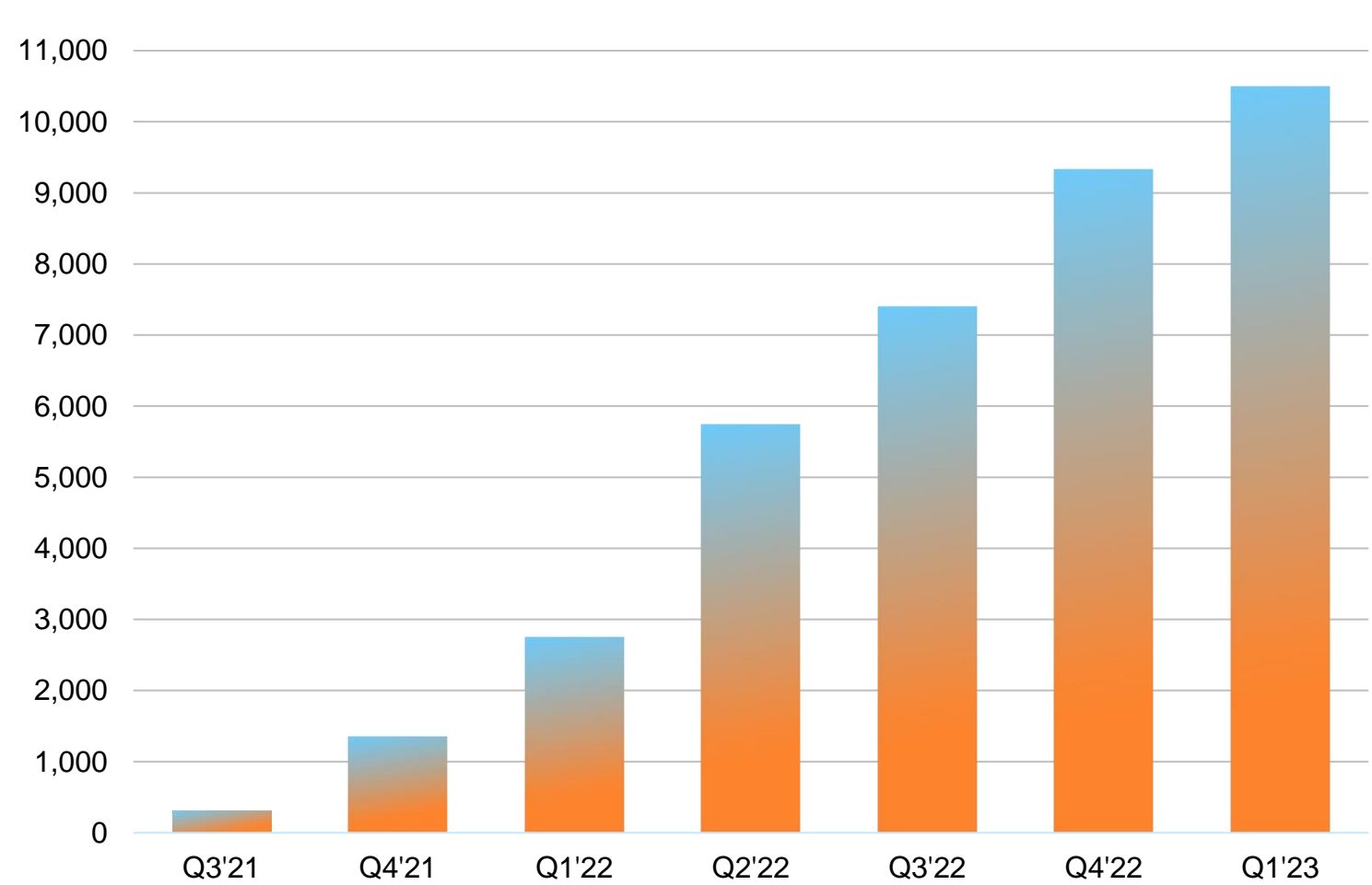
Shield’s new hires selected from a pool of >4,000 candidates

► **Expanded sales and women’s health experience**

On average, sales reps bring 8+ years of sales experience, 4+ years in women’s health

# Accrufer® Prescription Volume continues to climb

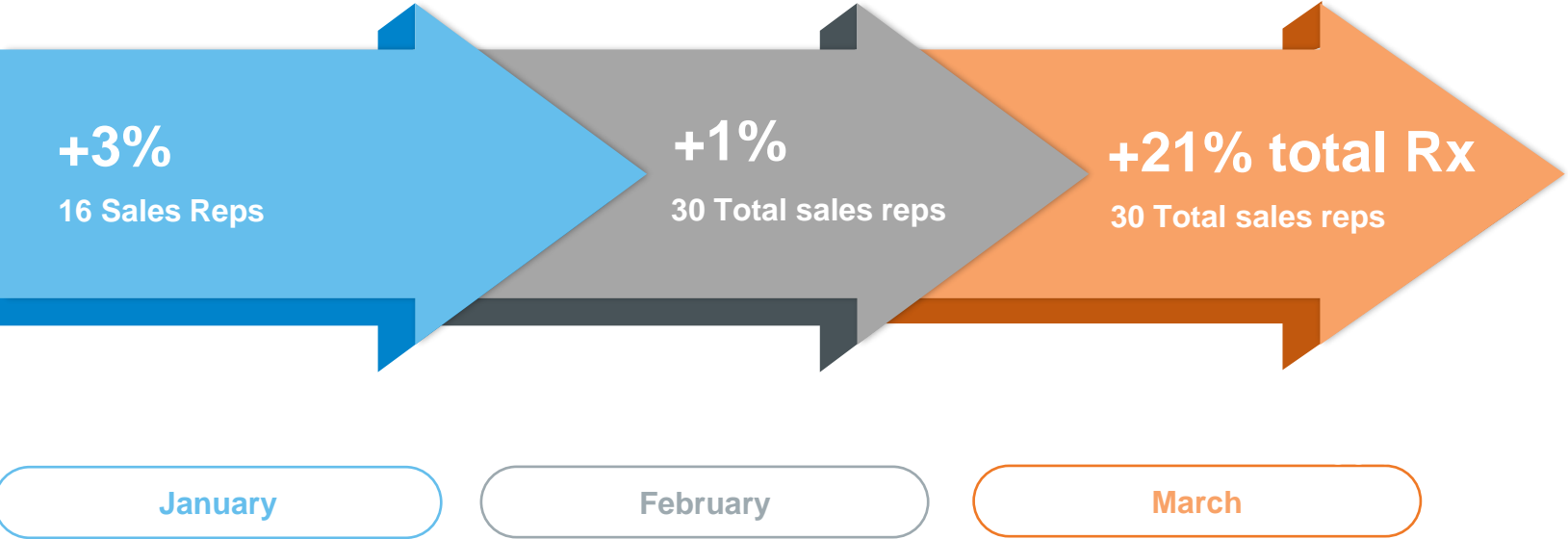
Increase of 12% in Q1:23 over Q4:22 *(while recruiting and training new sales force)*



# +12% Q1 Growth in US Accrufer® Prescriptions Led by March Increases

Q1 2023 Highlights the early impact of the expanded commercial team

KPIs confirm strong Accrufer® traction



► **+11% New Prescription Volume for Q1 2023**

Increasing +7%, +3% and +18% for Jan, Feb and March

► **+24% in New Prescribers**

With -9%, +41% and +71% growth for Jan, Feb and March



# Key Drivers to Accelerate US Accrufer® Growth



**Field Force  
Expansion**



**Amplify Digital Strategy  
& Marketing Initiatives**



**Expand Market Access  
& Distribution**

# The unmet needs of ID/IDA patients are real



Up to **70%** of people taking traditional oral iron report gastrointestinal issues<sup>1,2</sup>



Up to **60%** of patients will discontinue treatment due to adverse reactions<sup>3</sup>

What is meant to make patients feel **better**  
is making them feel **worse**

# Introducing ACCRUFeR®: The World's First Unironic Iron



**LIFE IS FULL  
OF IRONY**

## Your patients don't need it in their iron

Rather than helping them feel better, traditional oral irons can make most patients feel worse. Introducing ACCRUFeR: the only FDA-approved oral iron for all adults with ID/IDA. It's both tolerable and effective, so it can actually do what it's supposed to do.<sup>1-3</sup>

ID, iron deficiency;  
IDA, iron-deficiency anemia.



**ACCRUFeR®**  
(ferric maltol) 30 mg capsules

The Un-ironic Iron

It's time for  
iron without  
the irony

Link unmet needs to branded solution

Stand out in “me too” dormant market  
with a truly differentiated offering

# Disruptive tactics to wake up dormant market



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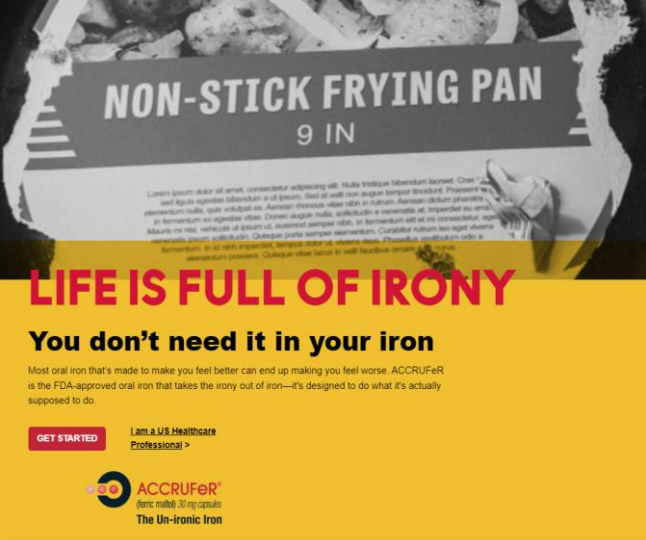
ID, iron deficiency;  
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**ACCRUFeR®**  
(ferrous malate) 30 mg capsules  
The Un-ironic Iron

**Personal Promotion**

- Print tactics
- Digital enablement
- Disruptive HCP engagement



**NON-STICK FRYING PAN**  
9 IN


**LIFE IS FULL OF IRONY**

**You don't need it in your iron**

Most oral iron that's made to make you feel better can end up making you feel worse. ACCRUFeR is the FDA-approved oral iron that takes the irony out of iron—it's designed to do what it's actually supposed to do.

[GET STARTED](#)

[Learn a US Healthcare Professional >](#)



**ACCRUFeR®**  
(ferrous malate) 30 mg capsules  
The Un-ironic Iron

**Non-Personal Promotion**

- Patient & HCP Websites
- Marketing automation for broad reach
- Targeted media tactics



**NON-STICK FRYING PAN**  
9 IN

**LIFE IS FULL OF IRONY**

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**ACCRUFeR®**  
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**Patient / Social Activation**

- Irony in the Real World
- 1-833-NO-IRONY
- Actively reviewing other tactics for patient activation later in '23



# ACOG Congress- 4,000 Women's Health HCP's in attendance

## A booth you can't visit?

### How Ironic

- Unexpected and memorable
- Interactive
- Educational

## Commercial Advisory Board

- 12 Cross-disciplinary KOL's
- Gather insights and engagement over long-term





# Key Drivers to Accelerate US Accrufer® Growth



**Field Force  
Expansion**



**Amplify Digital Strategy  
& Marketing Initiatives**



**Expand Market Access  
& Distribution**

# 100M or ~40% of Eligible Lives Now have Coverage for Accrufer®

## Commercial Plans

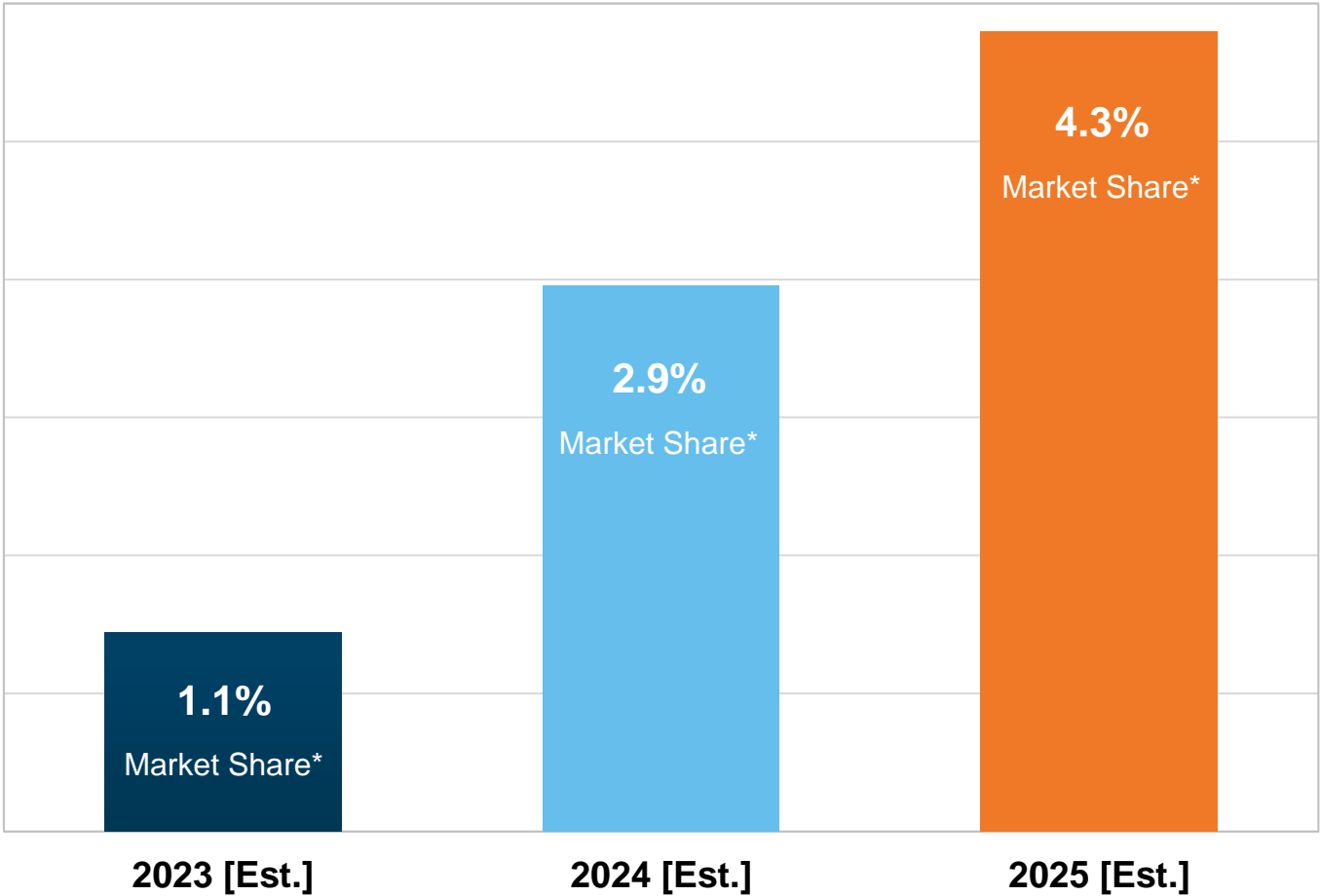


## Robust Patient Access Programs

- ✓ Broad Patient Access programs in place to maximize ability to get patient on Accrufer® at lowest cost (\$0 or \$25 per month)
- ✓ Payer Contracting Strategy allowed for Prior Authorization for simple physician attestation 'tried and failed OTC iron' prior to Accrufer®
- ✓ Partnered with BlinkRx® in Q3:22 to increase "first fill" rates, expand duration of therapy and enhance experience of patients and providers with Accrufer®

# Full Commercial Deployment Drives Potential for Accrufer® Adoption

Accrufer® market share targeting growth to 4.3% by 2025



## Estimated Annual Prescriptions:

**2023**

125,000 – 160,000

**2024**

370,000 – 420,000

**2025**

550,000 – 600,000

# The International Opportunity



# Global Partnerships Continue to Progress

Deals include upfronts, milestones & double-digit royalties



## United States

Co-Commercial Agreement, Dec. 2022  
100-person combined sales team by May 2023

Shared marketing cost & net revenues with larger allocation to Shield



## EU+<sup>1</sup>

Net Sales in Germany and UK increased by c.10%  
Call points re-focused to women's health/GPs

Double-digit royalties on net sales



## Canada

Licence agreement signed in Jan. 2022  
Approval expected mid-2023

Tiered royalties on net sales



## Republic of Korea

Agreement for single PK (pharmacokinetic) study  
Final regulatory study underway

Mid-teens royalties on net sales



## China +<sup>2</sup>

Continuing enrolment for Phase 3 study  
Significant impact due to pandemic restrictions

Double-digit royalties on net sales

**Shield will continue to evaluate further partnerships in selected geographies**

# Resources Expected to Support Operations Through Cash Flow Breakeven, Expected by YE:2024

## Key Financial Highlights<sup>1</sup>

£19.2M (US\$23.0M) <sup>1</sup>	£2.9M (US\$3.5M)	£1.6M (US\$1.9M)	£4.2M (US\$5.0M)
Cash & Investments (Mar 2023)	US Accrufer® Revenue <sup>2</sup>	Royalty/Milestone Revenue, excluding the Viatris upfront	Upfront from Viatris

Shield reported Cash & Investments of £2.8million/US\$3.4 million as of 31 December 2022

## Traded on the LSE-AIM (STX), OTCQX (SHIEF)

5	£48.6M (US\$58.3M) <sup>3</sup>	586M
Covering Analysts	Market capitalization	shares outstanding

1. Cash and Revenue items as of March 31 2023, unaudited  
2. Includes US net product revenue from Accrufer® sales  
3. Market cap as per London Stock Exchange as of 25 April 2023



# Upcoming Milestones Highlight Global Commercial Progress



## Accrufer® US

**Q2 2023:** New field force fully trained/deployed:

**Q2:2023:** First Commercial booth at ACOG

**2023:** Estimated prescriptions delivered 125,000 – 160,000



## Accrufer®/Ferracru® Ex-US

**H2 2023:** KYE Pharma regulatory approval and launch (Canada)

**2024:** Korea Pharma regulatory application & approval (Korea)

Complete enrolment/Topline Results for Pediatric Study (ST-01-305)



## Shield Therapeutics

**Jun 2023:** Annual Shareholders Meeting

**Aug 2023:** Half-Year Trading Update

**Sep 2023:** Half-Year Financial Results

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# Thank You!

**Greg Madison – Chief Executive Officer**

**Hans-Peter Rudolf – Chief Financial Officer**

