

Changing the Treatment
Paradigm for Patients
with Iron Deficiency
Anemia

**Corporate Presentation**April 2024



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# Shield is an Innovative Specialty Pharmaceutical Company

- Accrufer/Feraccru (ferric maltol), is the only oral iron broadly indicated for use in adults suffering from iron deficiency, with or without anemia. FDA and EMA approved.
- Significant Market Opportunity competing against OTC irons due to prevalence of GI tolerability issues and high rates of discontinuations
- Experienced Executive Team based in US with extensive commercialization expertise
- Ex-US partnerships providing compelling milestones and royalties over next few years

# **Strong US Momentum Building**

- Signed co-commercialization agreement with Viatris at end of '22 and launched 100-person sales team in May '23
- Achieved 77,000 total U.S. Accrufer® prescriptions in '23 (3x vs 2022)
- Q1 Revenues of \$4.0m through 28,800 U.S. Accrufer<sup>®</sup> prescriptions in Q1 2024
- Steady Improvements in Average Net Selling price of Accrufer® from \$119/Rx in 1H '23 to \$145/Rx in 2H '23
- Broad patient access to Accrufer® with PBM's,
   Commercial Insurers, Medicaid and patient access programs
- Aiming to turn cash flow positive in H2 '25



### Iron Deficiency (ID) without & with Anemia (IDA): 15MM U.S. Patients:

#### A Source of Morbidity and Mortality

Caused by malnutrition, malabsorption, or bleeding

Associated with many diseases, especially women's health, IBD, CKD, CHF, oncology, aging

Results in numerous signs, symptoms, and negative outcomes across a range of body systems

**IDA** may further exacerbate chronic inflammatory conditions, with even mild anemia leading to increased mortality



Increased risk of preterm labor, perinatal complications, newborn and maternal mortality in pregnancy



Higher IBD symptom burden Decreased QoL in IBD

Higher pre-dialysis mortality and ESRD Higher CV hospitalizations in CKD

Headache, vertigo, syncope

Cognitive impairment

Restless legs syndrome



Fatigue, tachycardia, cardiac murmur, angina, dyspnea

Increased hospitalizations



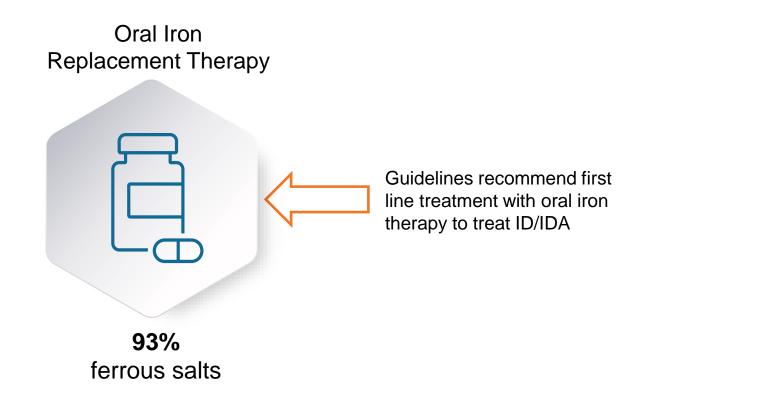
Higher morbidity, mortality, hospital length of stay, and re-admissions in major surgery





ID, iron deficiency; IDA, iron deficiency anemia; IBD, inflammatory bowel disease; CKD, chronic kidney disease; CHF, congestive heart failure; QoL, quality of life; ESRD, end-stage renal disease: CV, cardiovascular

## **Current Treatment Paradigm Across Patients by HCPs**







# Universal Problem: Patients Are Struggling To Treat IDA Because They Can't Tolerate The GI Side Effects Of Oral Iron Salts

Oral ferrous salts dissociate in the stomach. Unabsorbed Fe+ generates reactive oxidative species (ROS), causing irritation and damage to the intestinal lining and GI side effects

Up to 60% of patients will discontinue treatment with ferrous salts

If ID/IDA left untreated, Primary care and OBGYN often forced to refer their patients to a specialist for IV iron infusion



## **Consistent Treatment Paradigm Across All Patients**





# Significant Window of Opportunity Exists ACCRUFeR



A tolerable oral iron that effectively normalizes and maintains Hb, ferritin, and TSAT levels and avoids the need for patients requiring IV iron



# Accrufer®: Demonstrated Efficacy, Established Safety and Unprecedented Tolerability

Proprietary Accrufer® maltol formulation and unique MOA delivers a total of 60mg<sup>1</sup> of elemental iron to the small intestine<sup>2</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 12¹ (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

Currently running pediatric study with new liquid formulation to meet FDA/EMA requirements.

Last patient enrolled end Q3 2024, potential indication expansion in 2025



### A Significant Market, Ripe for Innovative Disruption



~20 MILLION

Estimated number of individuals with anemia in the U.S.\*

#### 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 OB/GYN 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



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

# OUR COMMERCIAL PARTNERSHIP MISSION





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





### **Global Partnerships Continue to Progress**

#### Deals include upfronts, milestones & double-digit royalties

VIATRIS <sup>™</sup> United States	NORGINE  EU+1	KYE Pharmaceuticals  Canada	KP 알국피미 KOREA PHARMA	China + <sup>2</sup>
Co-Commercial Agreement, Dec. 2022 100-person combined sales team in place	Sold over 90,000 packs in 2023 Y/Y increase of ~10%	Decision on approval in 2024	PK Study completed File for approval in mid-2024	Phase 3 Study ongoing Approval 2H 2026
\$30m in available sales milestones	Royalties and milestone payment upon approval for Pediatrics in EU	Approval milestone Double-digit royalties on net sales	Mid-teens royalties on net sales	Approval Milestone Double-digit royalties on net sales

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

- 1 Norgine: European Union, UK, Norway, Australia, New Zealand, other non-EU Countries
- 2 ASK Pharma: China, Hong Kong, Macau, Taiwan
- 3 Under assumption of constant currencies



### Financial Highlights for 2023 (unaudited)



#### Revenues and Other Income of \$17.5m (2022 - \$6.2m)

- 3x increase of net product revenue from Accrufer® sales in US to \$11.6m
- Average Net Selling Price for Accrufer® increased to \$145 per prescription in H2 (\$119 H1)
- Other income of \$4.4m includes remainder of \$5.0m upfront payment from Viatris



**Operating Loss for Period of \$31.1m (2022 - \$49.8m)** 



#### Cash and Cash Equivalents of \$13.9m at YE 2023

Debt facility of \$20m with SWK Holdings



#### **2024 Business Priorities**

Grow Accrufer®
TRx and Gross to
Net

Q1 2024

\$4m Net Revenues US Accrufer®

~28,800 TRx's

~\$140 net sales/Rx

Increase Prior Authorization (PA) submission rates

Path to Cash Flow Positive in H2'25

Q1 2024

Cash balance of \$10.4m

Revised Revenue
Covenants with SWK Loan

New \$10.0m Accounts
Receivable Facility

Expand Global
Patient Access to
Ferric Maltol

Q1 2024

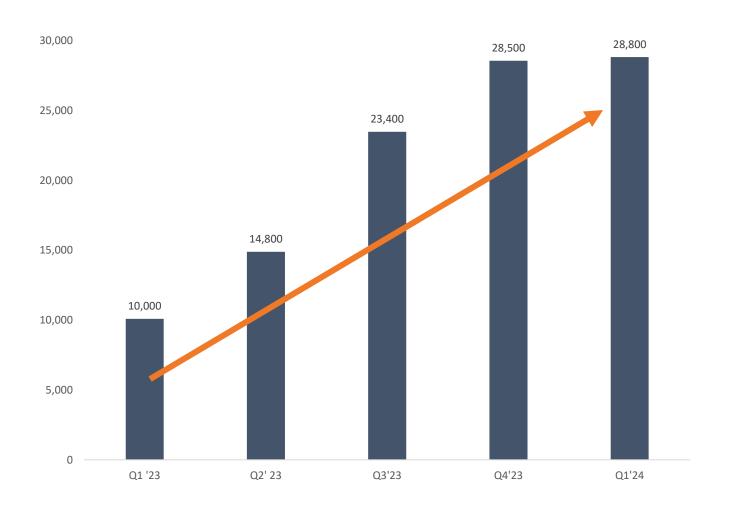
KP Pharma (Korea) PK Study completed, filing for approval 2H '24

Kye Pharmaceuticals (Canada) Health Canada to provide decision in 2024

Pediatric study expected completion in 2024



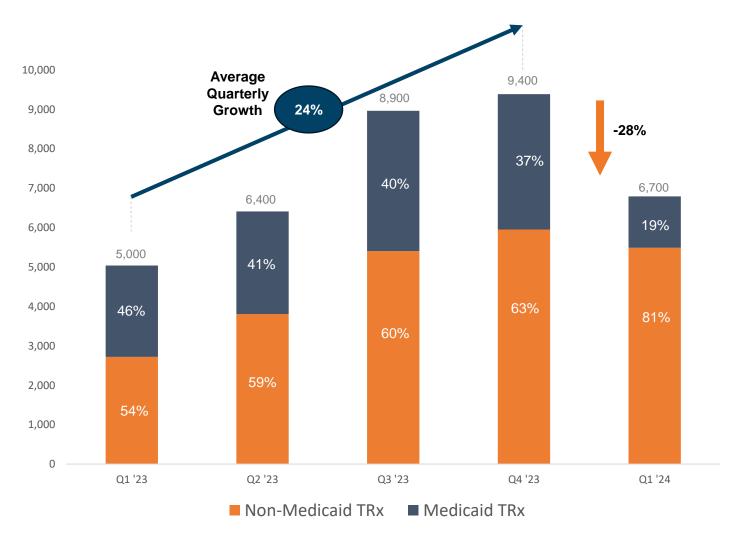
### Positive Growth Trajectory of Accrufer following Sales Expansion Achieved 28,800 Prescriptions in Q1 2024



- Q1 Growth of 1% vs Q4 (174% vs Q1 '23)
- Strong growth in California and New York (+29%) offset by decline in Texas (-28%) due to change in Medicaid Pharmacy Benefit Manager (PBM)



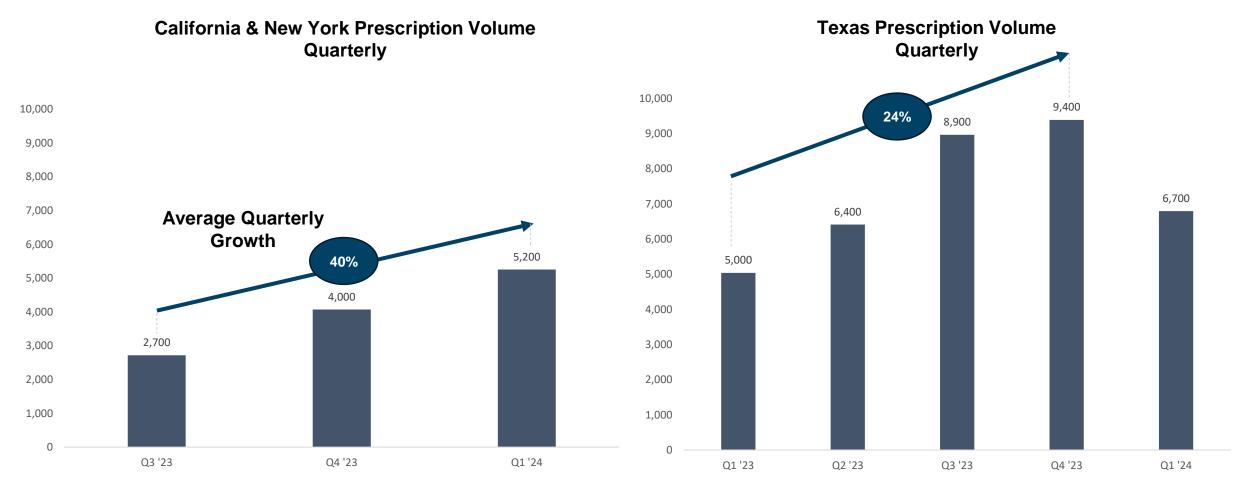
### Transition and Lack of Texas Medicaid PBM in 1st Quarter Impacts Growth



- Texas represented 35% of all Accrufer TRx in 2H 2023
- Growing average of 24% Q/Q with strong demand from HCP's
- Transition in Medicaid PBM in Texas created significant inconsistencies in Prior Authorization (PA) approvals for Medicaid Prescriptions
- New PBM in place on April 1



# Following Medicaid Access in Q3, NY and California showing significant growth



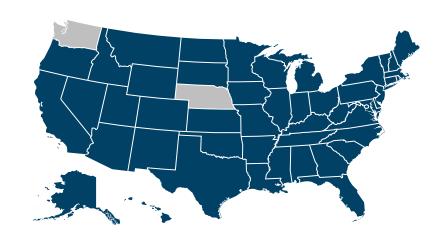


#### **Broad Access to Accrufer® for HCP's and Patients**

#### **Commercial Plans and PBM's:**



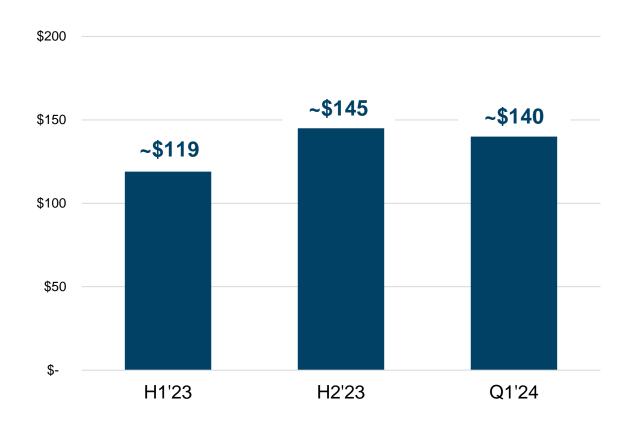
#### **State Medicaid Programs**



Shield offers Comprehensive Patient Access Program available for Commercial Patients where patients pay no more than \$25/month for Accrufer®



# Positive underlying improvements for GTN offset by Texas Medicaid issue

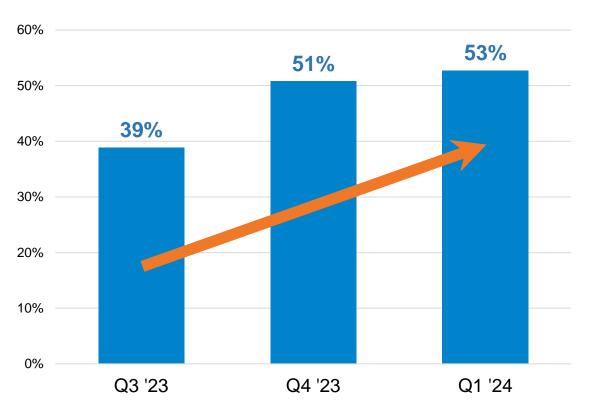


- Positive improvements in Medicaid Best Price and PA Submissions in Q1 offset by decline in paid prescriptions in Texas
- Favorable base rebates with commercial payors helps reset Medicaid Best Price
- Positive Increase in Prior Authorization (PA) Submission Rates following changes to patient access programs implemented in Q4



# PA Submission Rates Increasing following changes to Patient Access Programs in Q4

#### **PA Submission %**



Changes to Patient Access Program in October requiring submission of Prior Authorization (PA) to access \$25 cash price

Increased PA Submission Rate key driver for improvement in Gross to Net/ Average Net Selling Price

New Field Access Team hired and deployed as of April 1<sup>st</sup> to provide education and support to offices regarding Prior Authorizations



# Expect to turn cash flow positive in H2 2025 utilizing current resources and access to the new accounts receivable facility

# \$10m Accounts Receivable Financing

Sallyport Commercial Finance has provided Shield with a \$10m accounts receivable financing with favorable terms<sup>1</sup>

# Amended Revenue Covenant on \$20m debt

SWK Holdings and Shield have agreed to amend the Financial covenant of 'minimum revenue targets' associated with the current \$20m debt financing. The final payment fee was revised from 6.0% to 6.5%. All other financial terms remain the same as previously disclosed

# Cash Flow Positive in H2 2025

Investment focus directly tied to supporting Accrufer® and proactively managing working capital including securing the \$10m Accounts Receivable Financing



<sup>.</sup> The facility has been provided for a period of 12 months with an option to renew at existing terms. The facility will be secured by Accrufer® accounts receivables in the US and will bear an interest rate of WSJ Prime + 3.0% on funds deployed.

<sup>2</sup> The revised minimum revenue targets are disclosed in the company press release dated April 30 2024

## **Key Milestones in 2024**

Grow Accrufer®
TRx and Gross to
Net

Growth in US Accrufer® TRx and Revenues

Continued Improvement in GTN

Increase Prior Authorization (PA) submission rates

Path to Cash Flow Positive in H2'25

Cash balance of \$10.4m

Revised Revenue Covenants with SWK Loan

New \$10.0m Accounts
Receivable Facility

Expand Global
Patient Access to
Ferric Maltol

KP Pharma (Korea) filing for approval 2H '24

Kye Pharmaceuticals (Canada)
Health Canada to provide
decision in 2024

ASK (China) complete enrollment of Ph 3 study

Complete enrollment of pediatric study





# **Thank You!**

**Greg Madison – Chief Executive Officer Santosh Shanbhag – Chief Financial Officer** 

www.shieldtherapeutics.com/

