



# Changing the Treatment Paradigm for Patients with Iron Deficiency Anemia

Corporate Presentation  
April 2024



# Disclaimer

These slides have been prepared by Shield Therapeutics plc (the "Company") solely for your information and for use at a presentation for the purpose of providing background information on the Company, its business and the industry in which it operates. For the purposes of this notice, "presentation" means these slides, any oral presentation, any question and answer session and any written or oral material discussed or distributed during the presentation meeting.

This presentation has not been approved by the United Kingdom Listing Authority under the Prospectus Rules (made under Part VI of the Financial Services and Markets Act 2000, as amended) or otherwise, or by the London Stock Exchange plc. This presentation has not been independently verified and no representation or warranty, express or implied, is made or given by or on behalf of the Company or any of its subsidiaries or subsidiary undertakings, or any of such person's respective directors, officers, partners, employees, agents, affiliates or advisers, as to, and no reliance may be placed for any purpose whatsoever on the information or opinions contained in this presentation or on the completeness, accuracy or fairness thereof.

This presentation does not constitute or form part of, and should not be construed as, any offer, invitation or recommendation to purchase, sell or subscribe for any securities of the Company in any jurisdiction and neither the issue of this presentation nor anything contained herein shall form the basis of or be relied upon in connection with, or act as an inducement to enter into, any investment activity. This presentation does not purport to contain all of the information that may be required to evaluate any investment in the Company or any of its securities and should not be relied upon to form the basis of, or be relied on in connection with, any contract or commitment or investment decision whatsoever. This presentation is intended to present background information on the Company, its business and the industry in which it operates and is not intended to provide complete disclosure upon which an investment decision could be made. The merit and suitability of an investment in the Company should be independently evaluated and any person considering such an investment in the Company is advised to obtain independent advice as to the legal, tax, accounting, financial, credit and other related advice prior to making an investment.

No undertaking, representation, warranty or other assurance, express or implied, is or will be made or given by or on behalf of the Company or any of its subsidiary or subsidiary undertakings, or any of such person's respective directors, officers, partners, employees, agents, affiliates or advisers or any other person as to the accuracy or completeness of the information or opinions contained in this presentation and no responsibility or liability is accepted by any such person for any such information or opinions or for any errors, omissions or misstatements, negligent or otherwise, nor for any other communication written or otherwise. All information in this presentation is subject to verification, correction, completion and change without notice. None of the Company or any of its subsidiary or subsidiary undertakings, or any of such person's respective directors, officers, partners, employees, agents, affiliates or advisers, undertakes any obligation to amend, correct or update this presentation or to provide the recipient with access to any additional information that may arise in connection with it.

The statements contained in this presentation may include "forward-looking statements" that express expectations as to future events or results. Forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes", "estimates", "anticipates", "projects", "expects", "intends", "may", "will", "seeks" or "should" or, in each case, their negative or other variations or comparable terminology, or by discussions of strategy, plans, objectives, goals, future events or intentions. These statements are based on current expectations and involve risk and uncertainty because they relate to events and depend upon circumstances that may or may not occur in the future. There are a number of factors which could cause actual results or developments to differ materially from those expressed or implied by such forward-looking statements. Any of the assumptions underlying forward-looking statements could prove inaccurate or incorrect and therefore any results contemplated in forward-looking statements may not actually be achieved. Nothing contained in this presentation should be construed as a profit forecast or profit estimate. Investors and any other recipients of such communications are cautioned not to place reliance on any forward-looking statements. The Company undertakes no obligation to update or revise (publicly or otherwise) any forward-looking statement, whether as a result of new information, future events or other circumstances.

To the extent available, the data contained in this presentation has come from official or third party sources. Third party industry publications, studies and surveys generally state that the data contained therein have been obtained from sources believed to be reliable, but that there is no guarantee of the accuracy or completeness of such data. While the Company believes that each of these publications, studies and surveys has been prepared by a reputable source, the Company has not independently verified the data contained therein. In addition, certain of the data contained in this presentation come from the Company's own internal research and estimates based on the knowledge and experience of the Company's management in the market in which the Company operates. While the Company believes that such research and estimates are reasonable and reliable, they, and their underlying methodology and assumptions, have not been verified by any independent source for accuracy or completeness and are subject to change without notice. Accordingly, undue reliance should not be placed on any of the data contained in this presentation.

This presentation should not be copied or distributed by recipients and, in particular, should not be distributed by any means, including electronic transmission, to persons with addresses in the United States of America, Canada, Australia, South Africa or Japan, their possessions or territories or to any citizens thereof, or to any corporation, partnership or such entity created or organised under the laws thereof, or any other jurisdiction, where such distribution is unlawful. Any such distribution contrary to the above could result in a violation of the laws of such jurisdictions.

This presentation is confidential and is being supplied to you solely for your information and may not be reproduced, re-distributed or passed on, directly or indirectly, to any other person or published in whole or in part for any purpose. By attending the meeting where this presentation is made or by accepting a copy of this presentation, you agree to be bound by the limitations and restrictions set out above.

## 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® 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

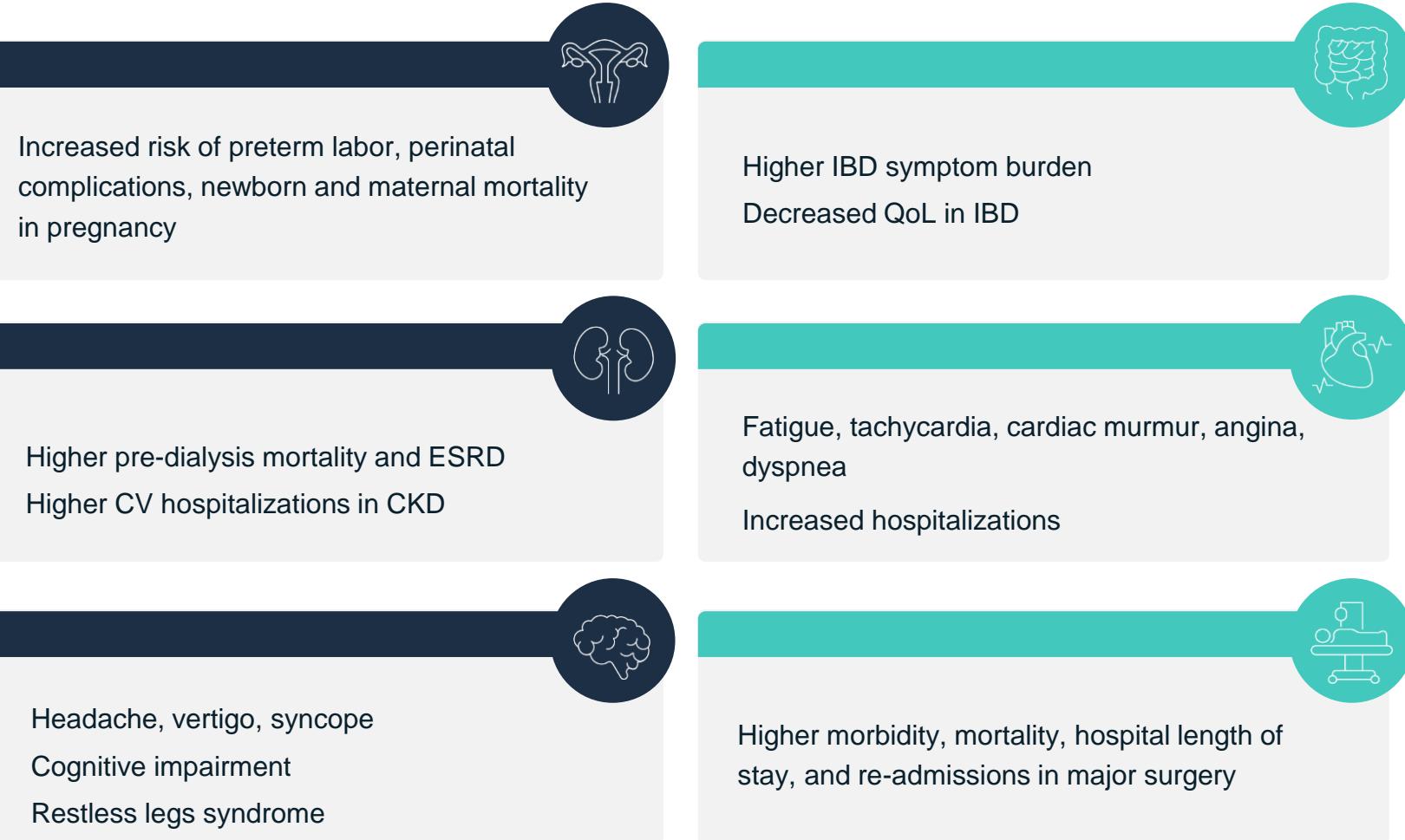
# Iron Deficiency (ID) without & with Anemia (IDA): 15MM U.S. Patients: A Source of Morbidity and Mortality

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**



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.

1. Cappellini MD, et al. J Intern Med. 2020;287(2):153-170.

# Current Treatment Paradigm Across Patients by HCPs

## Oral Iron Replacement Therapy



**93%**  
ferrous salts



Guidelines recommend first line treatment with oral iron therapy to treat ID/IDA



**IV Iron**

# **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

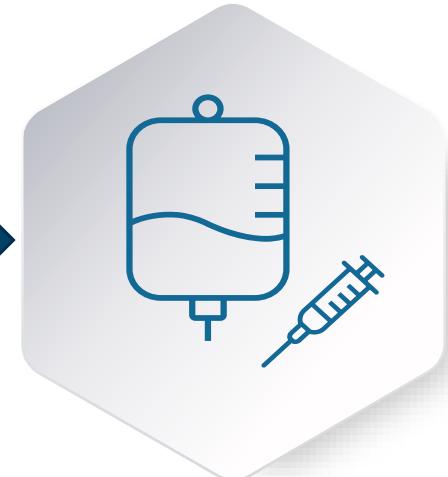
Oral Iron  
Replacement Therapy



93%  
ferrous salts

Oral Iron Switches/Discontinuations

Untreated IDA



IV Iron

# Significant Window of Opportunity Exists ACCRUFeR

Oral Iron  
Replacement Therapy



93%  
ferrous salts

ACCRUFeR



IV Iron

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 12<sup>1</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

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

# 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™	 EU+ <sup>1</sup>	 Canada	 Republic of Korea	 China + <sup>2</sup>
<b>United States</b> 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)

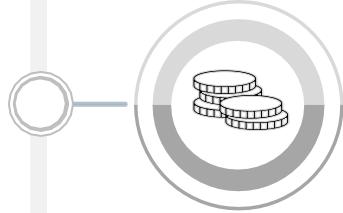


## Revenues and Other Income of \$17.5m (2022 - \$6.2m)

- 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**

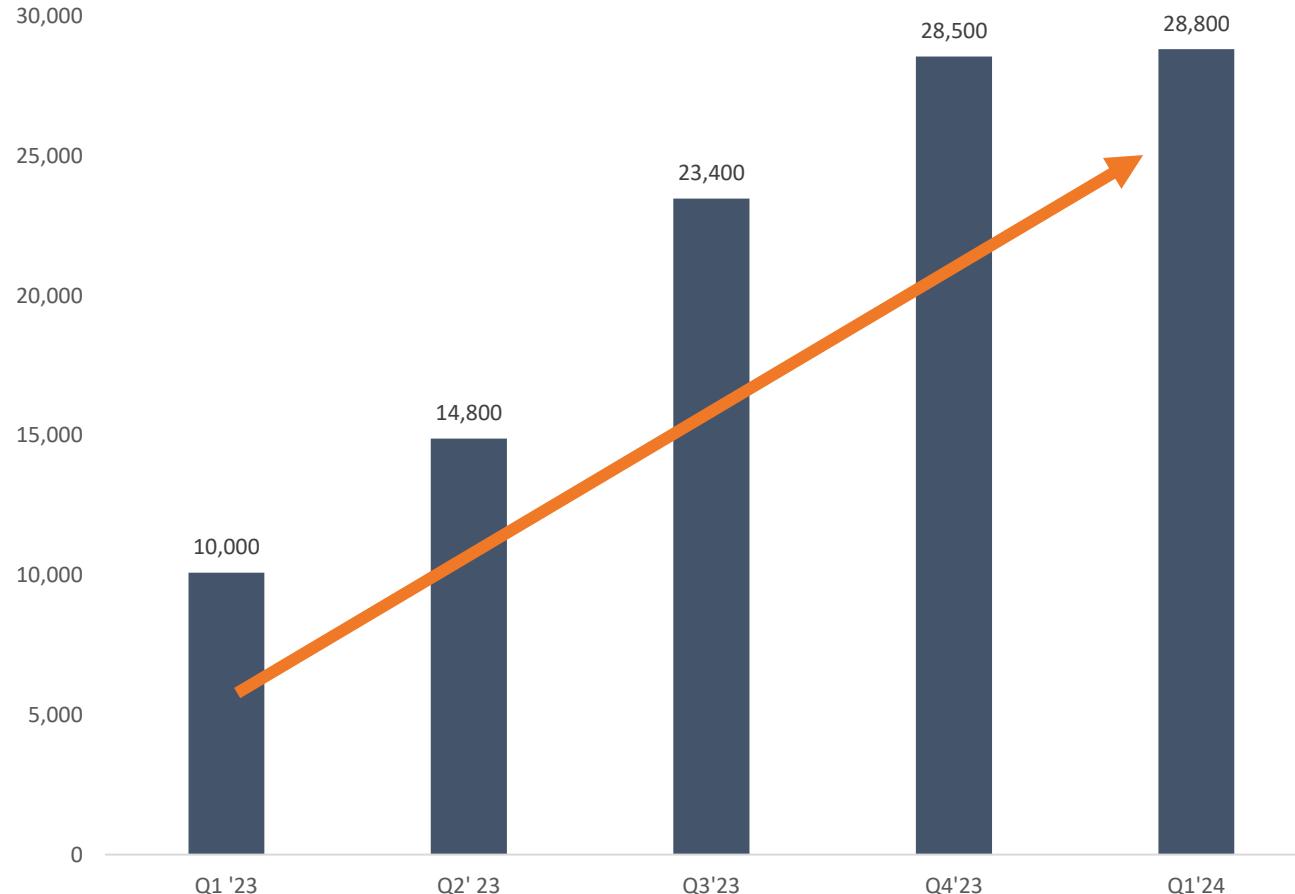
KP Pharma (Korea) PK  
Study completed, filing for  
approval 2H '24

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

Pediatric study expected  
completion in 2024

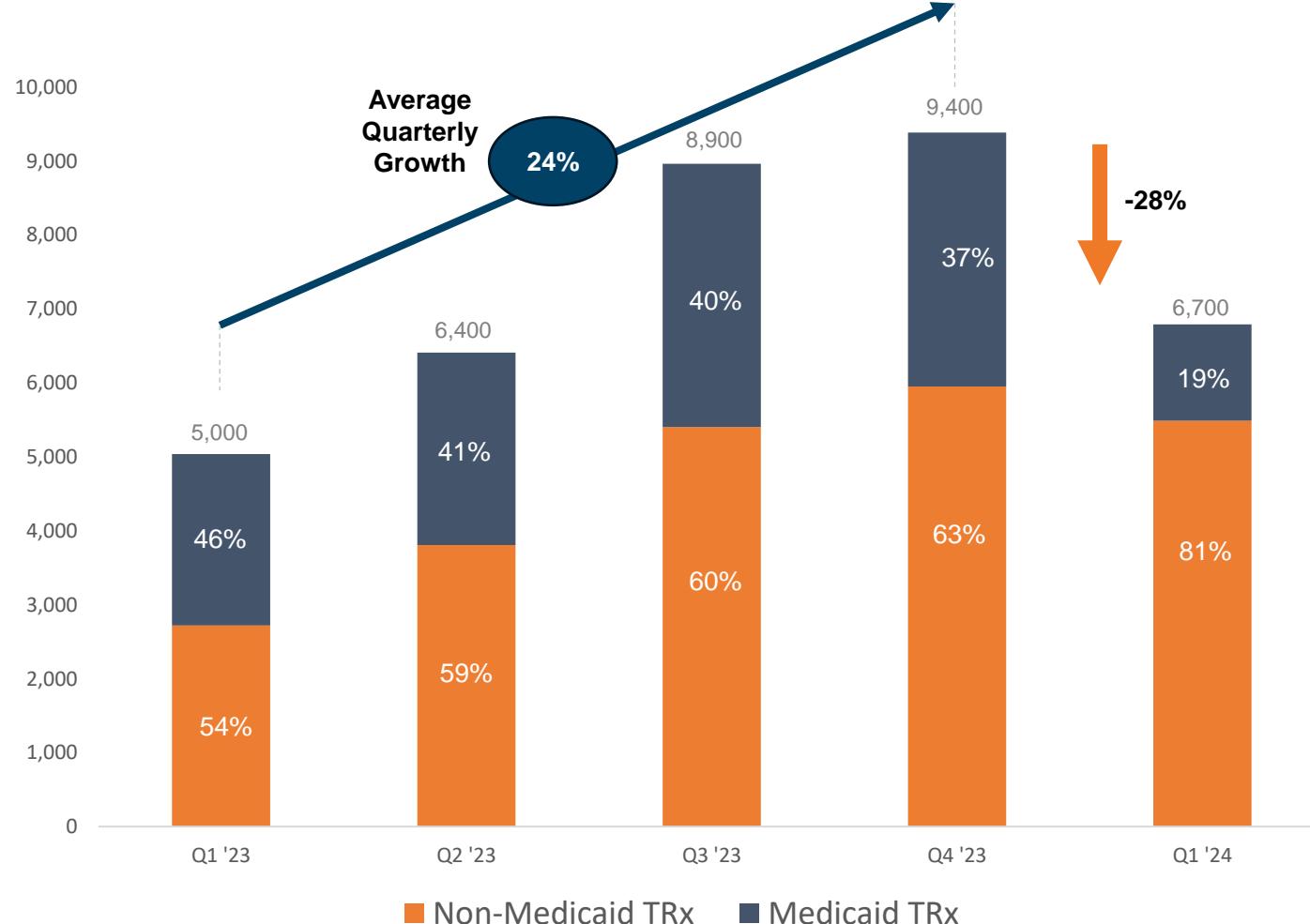
# Positive Growth Trajectory of Accrufer following Sales Expansion

## 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)

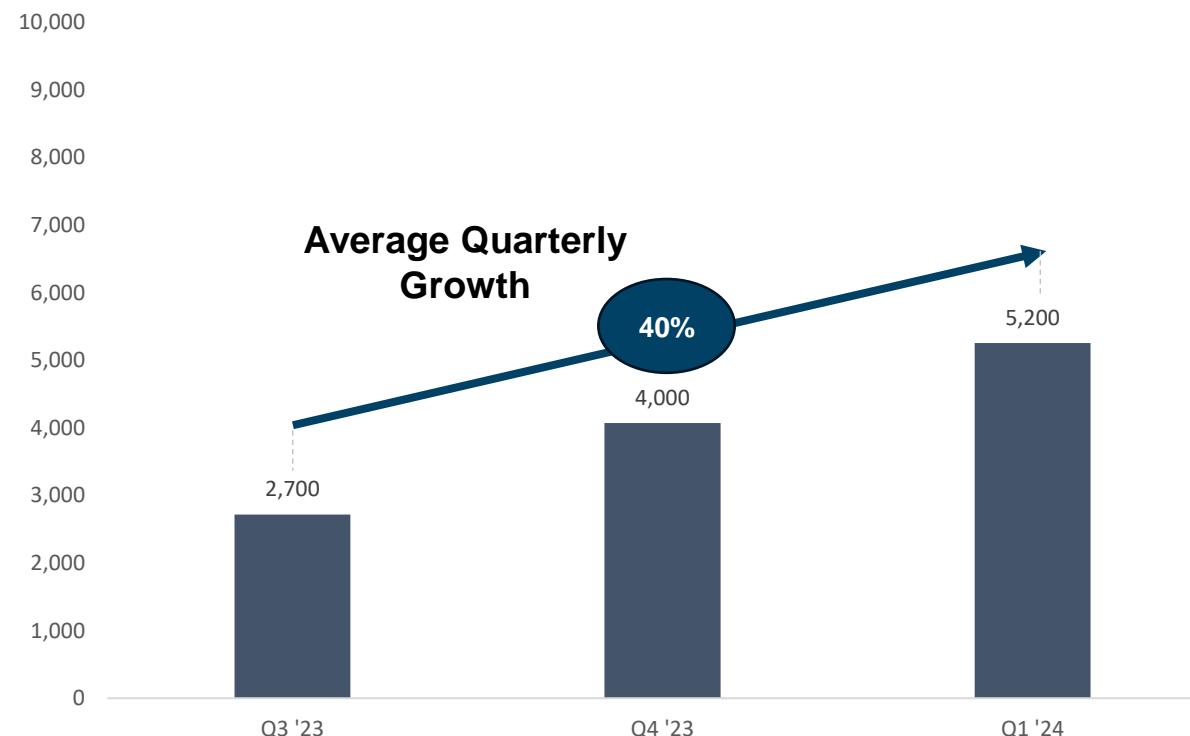
# Transition and Lack of Texas Medicaid PBM in 1<sup>st</sup> Quarter Impacts Growth



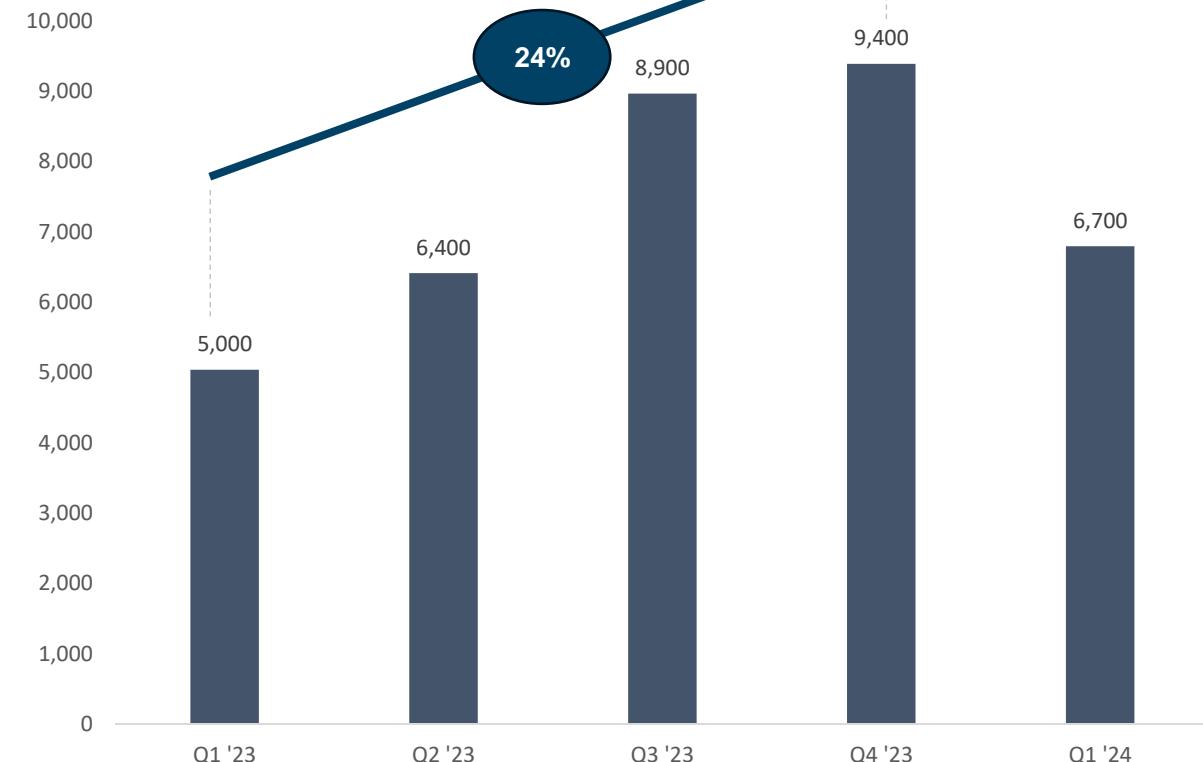
- Texas represented 35% of all Accrufer TRx in 2H 2023
- Growing average of 24% Q/Q with strong demand from HCP's
- Transition in Medicaid PBM in Texas created significant inconsistencies in Prior Authorization (PA) approvals for Medicaid Prescriptions
- New PBM in place on April 1

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

California & New York Prescription Volume  
Quarterly



Texas Prescription Volume  
Quarterly

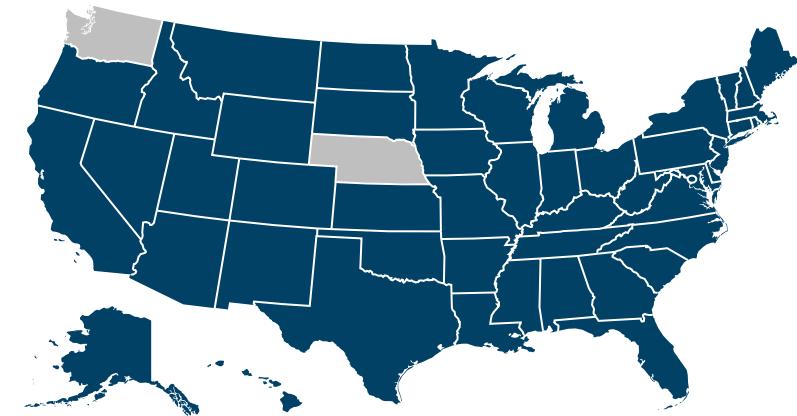


## **Broad Access to Accrufer® for HCP's and Patients**

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

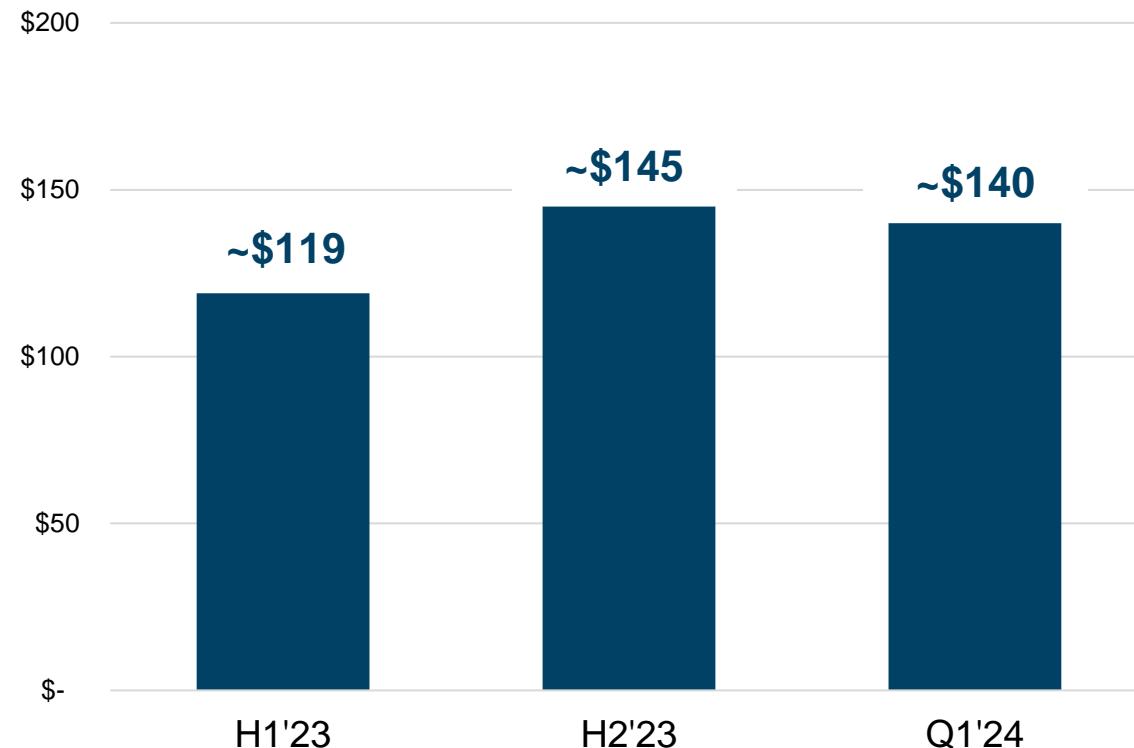


## **State Medicaid Programs**



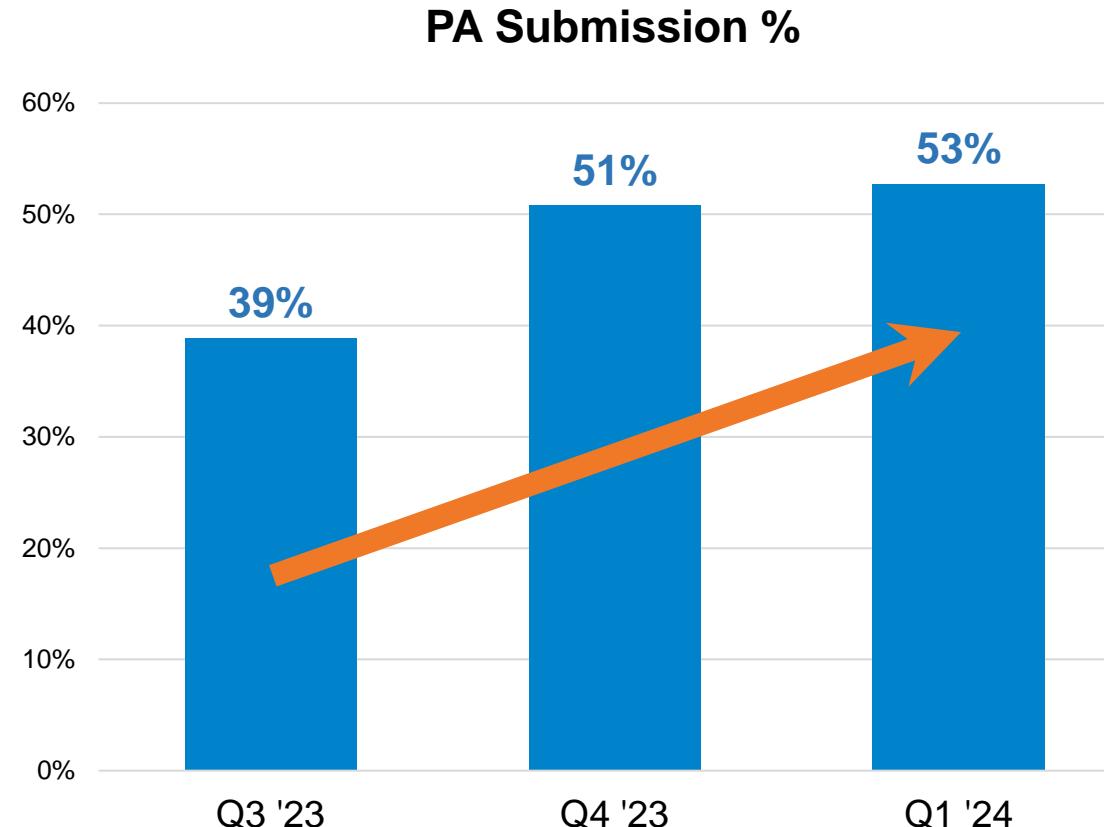
**Shield offers Comprehensive Patient Access Program available for Commercial Patients where patients pay no more than \$25/month for Accrufer®**

## 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



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'<sup>2</sup> 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

# 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/](http://www.shieldtherapeutics.com/)

