



# Corporate Presentation

October 2024

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**Changing the Treatment  
Paradigm for Patients with Iron  
Deficiency Anemia**



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# Shield Therapeutics

Fast Growing, Mission Driven, Speciality Pharmaceutical Company

ACCRUFer®/FeRACCRU® (ferric maltol), is the only FDA approved oral iron broadly indicated for use in adults suffering from iron deficiency, with or without anaemia. Also approved by EMA and Health Canada.

Vast market opportunity in iron deficiency replacement therapy market. Traditional oral irons often lead to discontinuation due to intolerable GI side effects or insufficient efficacy<sup>1</sup>

Experienced Executive Team with extensive US commercialization expertise

Viatrix co-commercialisation agreement has catalysed commercial expansion, resources and growth for ACCRUFer®

Peak revenue potential of ACCRUFer® of ~\$450M<sup>2</sup>

Strong IP through 2035



1. Stallmach A, Büning C. Ferric maltol (ST10): a novel oral iron supplement for the treatment of iron deficiency anemia in inflammatory bowel disease. Expert Opin Pharmacother. 2015;16(18):2859-2867. doi:10.1517/14656566.2015.1096929

2. Shield management estimate



# Management team



**Anders Lundstrom**  
CEO\*



**Santosh Shanbhag**  
CFO



**Lucy Huntington-Bailey**  
General Counsel



**Andy Hurley**  
Chief Commercial Officer



**David Childs**  
VP, Manufacturing and  
Strategic Alliance



**Dr. Jackie Mitchell**  
VP, Quality, Clinical and  
Regulatory Affairs



\*Board Member and Interim CEO

# Iron Deficiency without & with Anaemia (ID/IDA)

A highly prevalent and serious condition

Significant impact on **quality of life**

Symptoms include **extreme fatigue, headache, vertigo, numbness in extremities, cognitive impairment**

Prevalence is **highest in women of childbearing age and patients with inflammatory conditions**.<sup>1</sup>

Caused by **malnutrition, malabsorption, or bleeding**

## The New York Times

### IRON DEFICIENCY NEWS

Oct 23 -- More Than a Third of Women Under 50 Are Iron-Deficient,



#### Women's Health

- Menorrhagia
- Pregnancy
- Uterine Fibroids



#### Inflammatory bowel disease

- Crohn's disease
- Ulcerative colitis



#### Chronic kidney disease

1. Cappellini MD, Musallam KM, Taher AT. Iron deficiency anemia revisited. J Intern Med. 2020;287(2):153-170. doi:10.1111/joim.13004

# Current treatment options for treating ID/IDA by HCPs



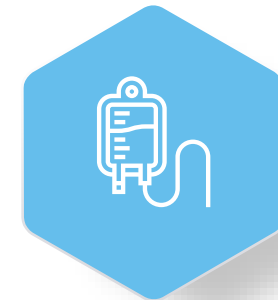
**Rx and OTC**

**ferrous salts “iron salts” are  
93% of volume**

**Mix of branded and generic  
options**

**Oral Iron**

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




**Multiple brands and some generics**

**Requires infusion at hematology or  
hospital clinic**

**Monitor patient for 1 hour post  
infusion for anaphylaxis**

**IV Iron**

# Universal problem: HCP's are struggling to treat IDA because patients can't tolerate the GI side effects of oral iron salts



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

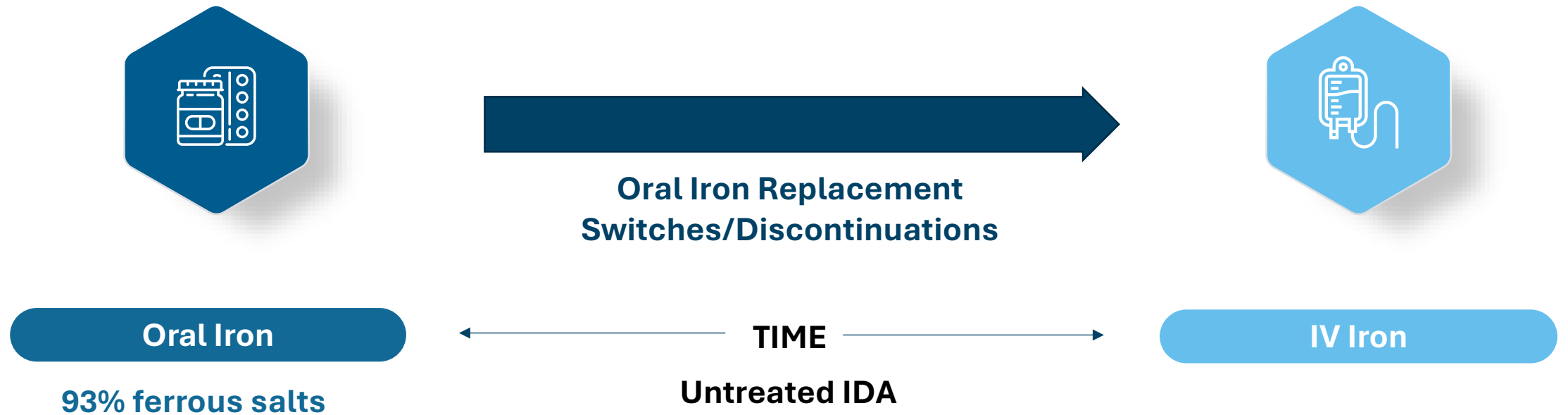
**Up to 70%** of patients can experience GI related side effects<sup>1,2</sup> including bloating, dark stool, nausea distention

Patients comment: “Side effects of oral iron worse than the symptoms of IDA”

**Up to 60%** of patients will discontinue treatment with ferrous (iron) salts primarily due to GI adverse events and lack of effectiveness<sup>3</sup>

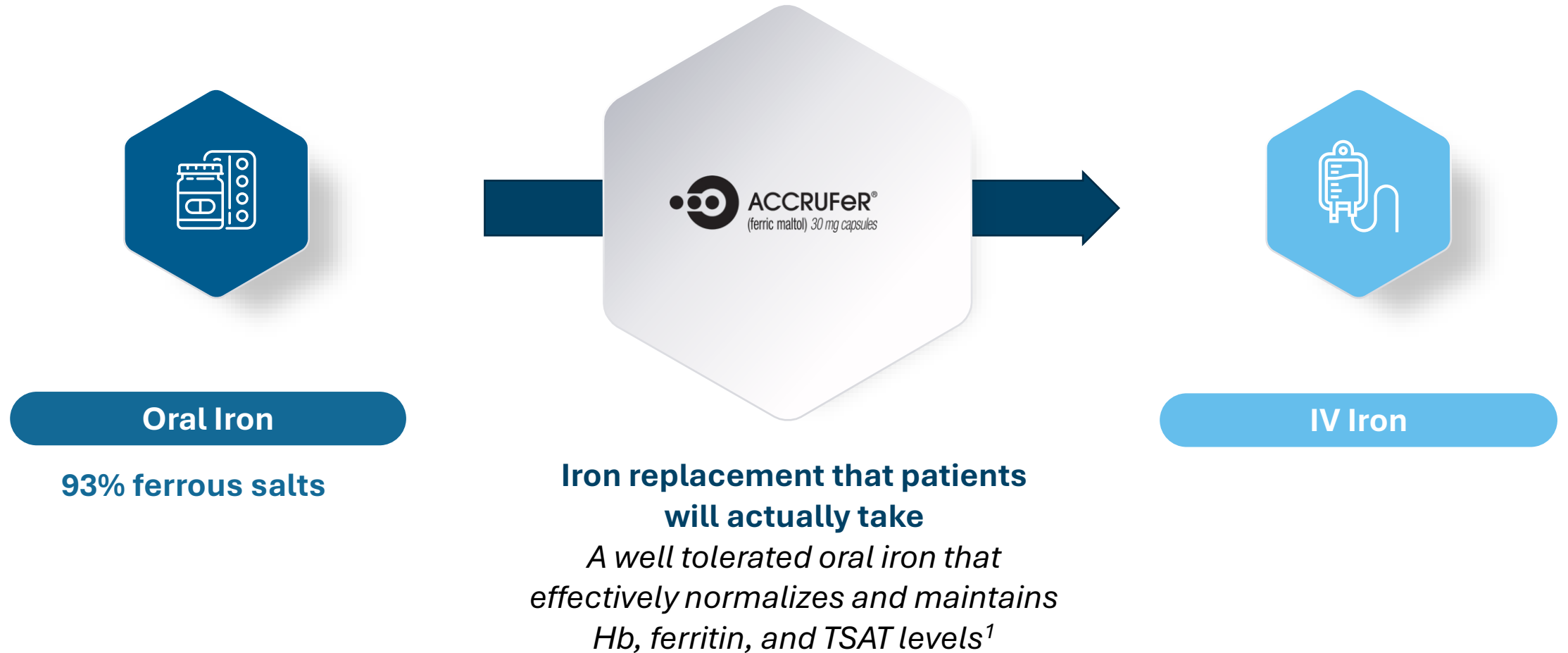
1. DeLoughery TG. Safety of oral and intravenous iron. Acta Haematol. 2019;142(1):8-12. doi:10.1159/000496966.
2. Tolkien Z, Stecher L, Mander AP, Pereira DIA, Powell JJ. Ferrous sulfate supplementation causes significant gastrointestinal side-effects in adults: a systematic review and meta-analysis. PLoS One.
3. Cancelo-Hidalgo MJ, et al. Curr Med Res Opin. 2013;29(4):291-303

# Consistent treatment paradigm across all patients





# Significant window of opportunity exists for ACCRUFer<sup>®</sup>



1. Data from AEGIS 1 and 2 study.

# ACCRUFeR<sup>®</sup> designed for efficacy and tolerability

Unique MOA (mechanism of action) Shields and Delivers Elemental Iron to the Small Intestine <sup>1, 2</sup>

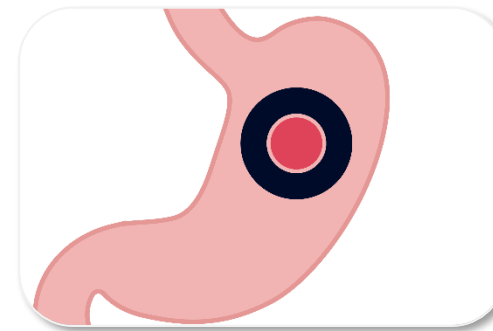
## Proprietary Formulation

ACCRUFeR<sup>®</sup> is formulated in a maltol complex vs. traditional oral irons, provided in ferrous-based formulations

## Low iron dose

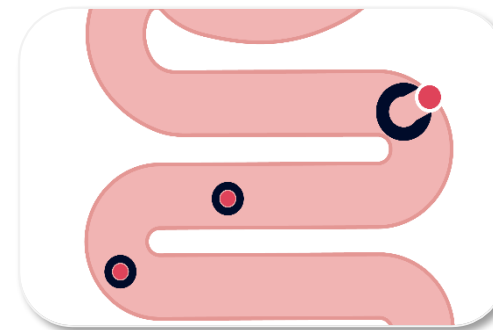
60 mg of elemental iron is delivered by ACCRUFeR<sup>®</sup> daily

### ACCRUFeR<sup>®</sup> remains tightly bound in the stomach



The maltol shield protects iron from the stomach, remaining tightly bound as it passes through

### Dissociates upon uptake in the duodenum



Iron remains bioavailable, chelated, and ready to replenish iron stores.

Excess iron is excreted in the stool

1. ACCRUFeR<sup>™</sup> is dosed at 30mg BID, MOA = mechanism of action
2. ACCRUFeR<sup>®</sup> (ferric maltol) [Prescribing Information]. Austin, TX: Shield Therapeutics, 2019. Revised 02/22.
3. Shield graphic for illustrative purposes only

# ACCRUFeR®: Demonstrated efficacy, established safety and unprecedented tolerability

Data from three Phase 3 Studies in IBD and CKD populations showcase consistent effectiveness to increase and maintain hemoglobin in normal range while providing patients with minimal tolerability challenges

**<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> ( $p < 0.0001$ )

**No patients** treated with ACCRUFeR® in either long-term study **required IV iron intervention** <sup>2,3,4</sup>

## Indication Expansion for Pediatric Patients:

Pivotal Trial of ACCRUFeR® / FeRACCRU® (ferric maltol) in Paediatric Patients with Iron Deficiency Anemia (IDA) proves highly clinically relevant effectiveness

Data will be used to support filing obligations with the US FDA and the European EMA for a paediatric indication in children older than 1 month for ACCRUFeR®/FeRACCRU® in H1 2025

1. dosed at 30mg BID, ACCRUFeR® (ferric maltol) [Prescribing Information]. Austin, TX: Shield Therapeutics, 2019. Revised 02/22. Data from AEGIS 1 and 2 study.
2. Schmidt C, Ahmad T, Tulassay Z, et al. Ferric maltol therapy for iron deficiency anaemia in patients with inflammatory bowel disease: long-term extension data from a phase 3 study. *Aliment Pharmacol Ther.* 2016;44(3):259-270. doi:10.1111/apt.13665
3. Gasche C, Ahmad T, Tulassay Z, et al. Ferric maltol is effective in correcting iron deficiency anemia in patients with inflammatory bowel disease: results from a phase-3 clinical trial program. *Inflamm Bowel Dis.* 2015;21(3):579-588. doi:10.1097/mib.00000000000003146.
4. Pergola PE, Kopyt NP. Oral ferric maltol for the treatment of iron-deficiency anemia in patients with CKD: a randomized trial and open-label extension. *Am J Kidney Dis.* 2021;78(6):846-856.e1. doi:10.1053/j.ajkd.2021.03.020.

# Global partnerships continue to progress

Deals include upfronts, milestones & double-digit royalties



United States

Co-Commercial Agreement, Dec. 2022  
100-person combined sales team in place

**\$30m in available sales milestones**



EU+<sup>1</sup>

Currently commercialized across Europe

**Royalties and milestone payment upon approval for Pediatrics in EU**



Canada

Approved by Health Canada in August 2024

**Revenue-based milestone payments and Double-digit royalties on net sales**



Republic of Korea

Filed for approval; Pending successful review, approval anticipated in 2025

**Mid-teens royalties on net sales**



China +<sup>2</sup>

Phase 3 Study ongoing  
Approval expected in H2 2026

**Approval Milestone  
Double-digit royalties on net sales**

Shield will continue to evaluate further partnerships in selected geographies

<sup>1</sup> Norgine: European Union, UK, Norway, Australia, New Zealand, other non-EU Countries

<sup>2</sup> ASK Pharma: China, Hong Kong, Macau, Taiwan

## Our Commercial Partnership Mission



To make ACCRUFER<sup>®</sup> the oral  
iron of choice in the US



# A significant market, ripe for innovative disruption



**~20 MILLION**

Estimated number of iron deficient individuals with and without anemia in the US\*

## Large, defined market:

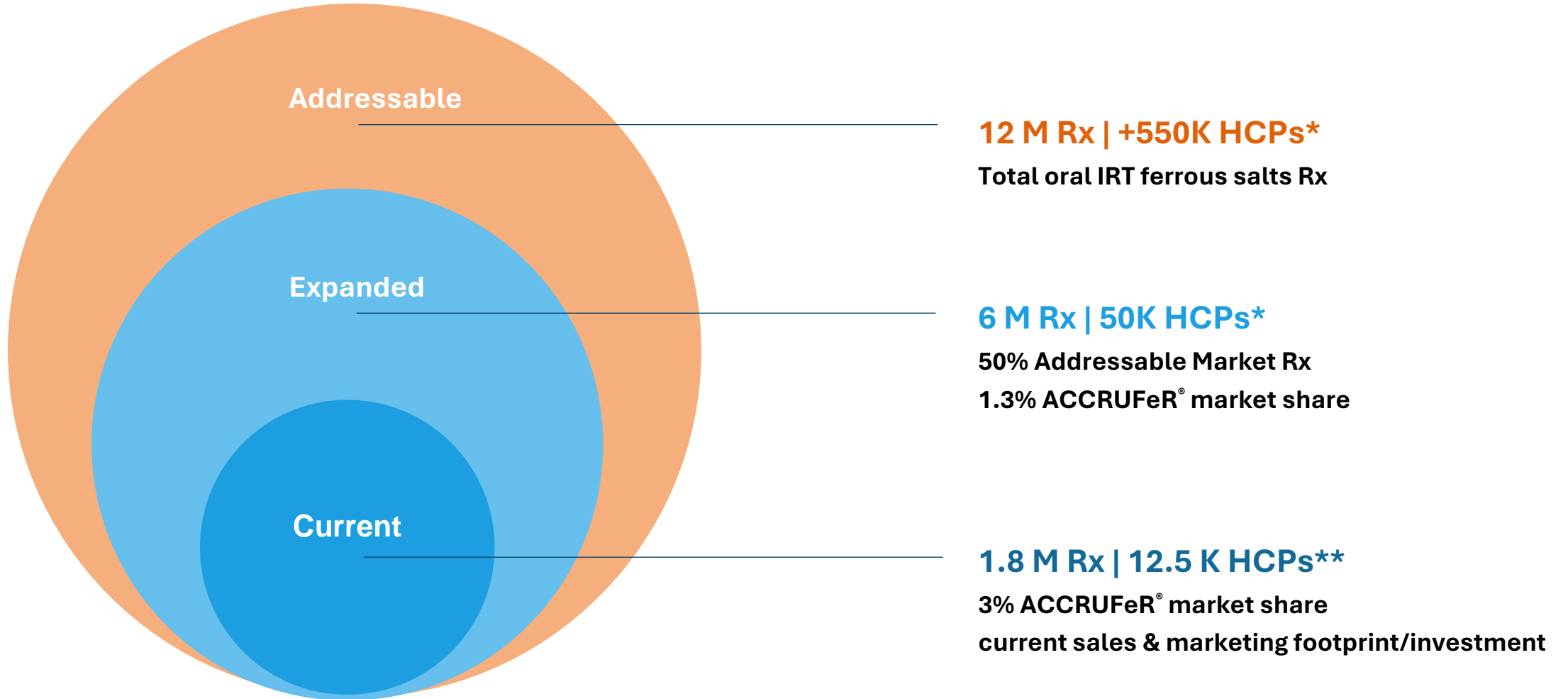
- ✓ ~12M prescriptions per year
- ✓ >85% of prescriptions written by GP's and OB/GYN

**Unsatisfied market driven by  
gastrointestinal related adverse events**

**Little to no innovation among oral iron  
therapies over past decade**



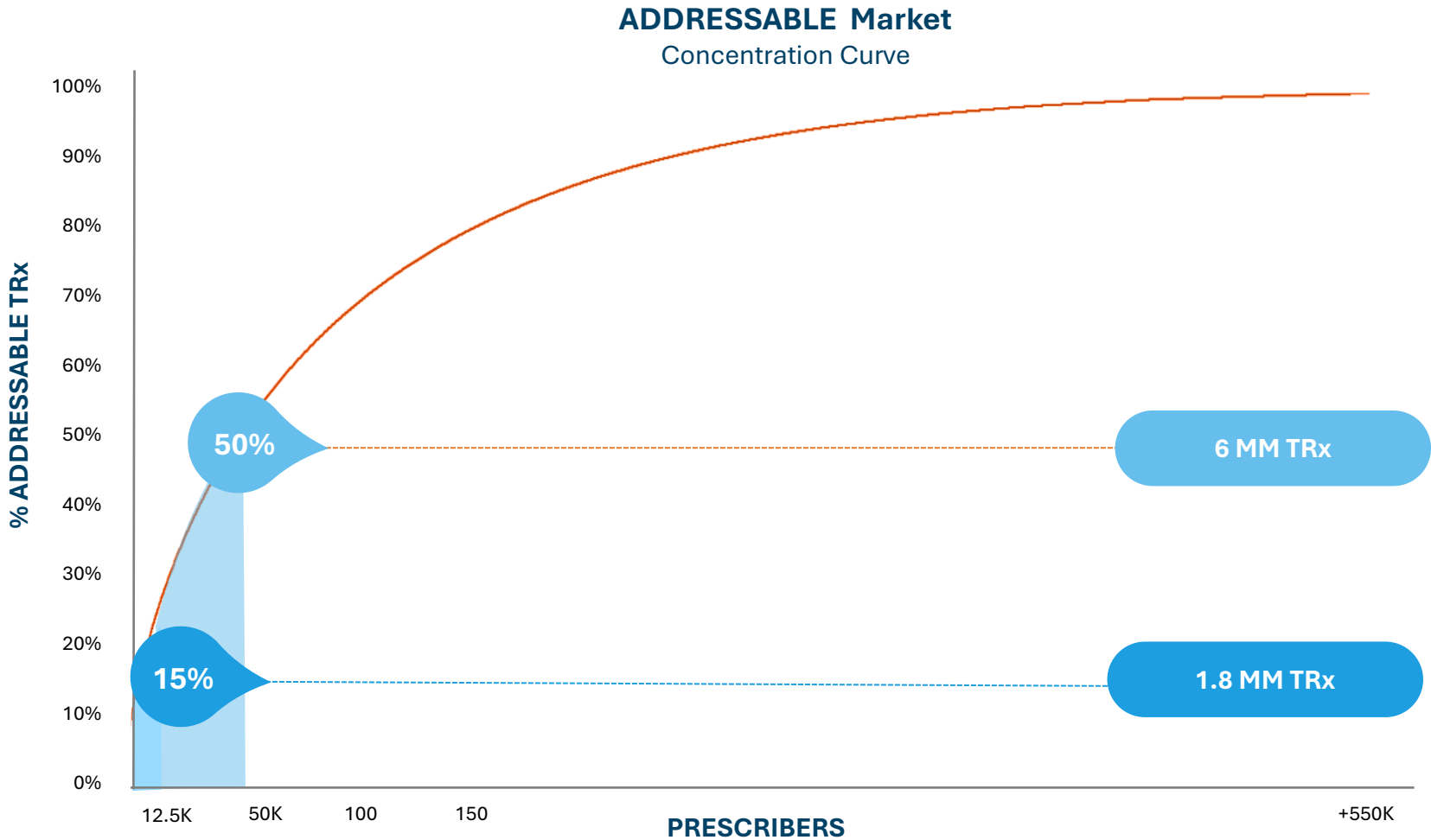
# Total prescription oral iron replacement therapy (IRT) market



\*2023 Rx Data IQVIA Xponent PlanTrak + consignment

\*\*Q3 2024 ACCRUFeR® targets FY 2023 Rx; Market share based on ACCRUFeR®, ferrous sulfate, integra, ferralet, proferrin, ironspan, slow Fe+, iron combo product, and other ferrous elemental irons

# Concentrated prescriber base creates a broader opportunity for ACCRUFeR<sup>®</sup> to realize incremental market share



	HCP	TRx
ADDRESSABLE	+550K	12 MM
EXPANDED	50K	6 MM
CURRENT	12.5K	1.8 MM

# The ID/IDA market is ideal for big upside potential for ACCRUF<sup>®</sup>

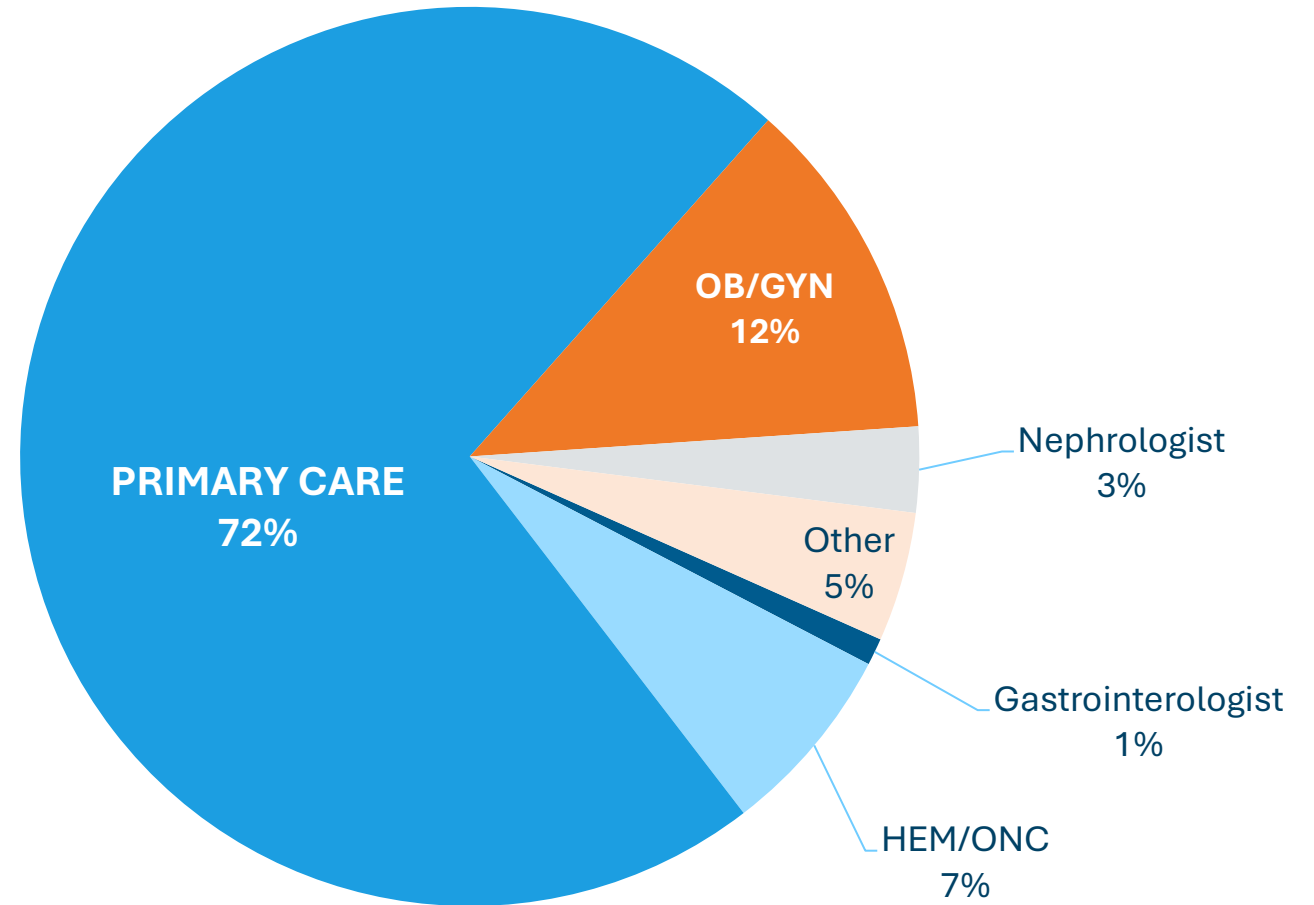
ID/IDA Market Dynamics as Viewed by Shield and Viatrix



- **Large Unmet Need**
- **Concentrated Prescriber Base**
- **Uniquely positioned to address unmet need**
- **Promotionally Sensitive**
- **Minimal Branded Competition**
- **Highly Engageable Audience – HCP and Patients**

# PCPs and OB/GYNs prescribe ~85% of the expanded market

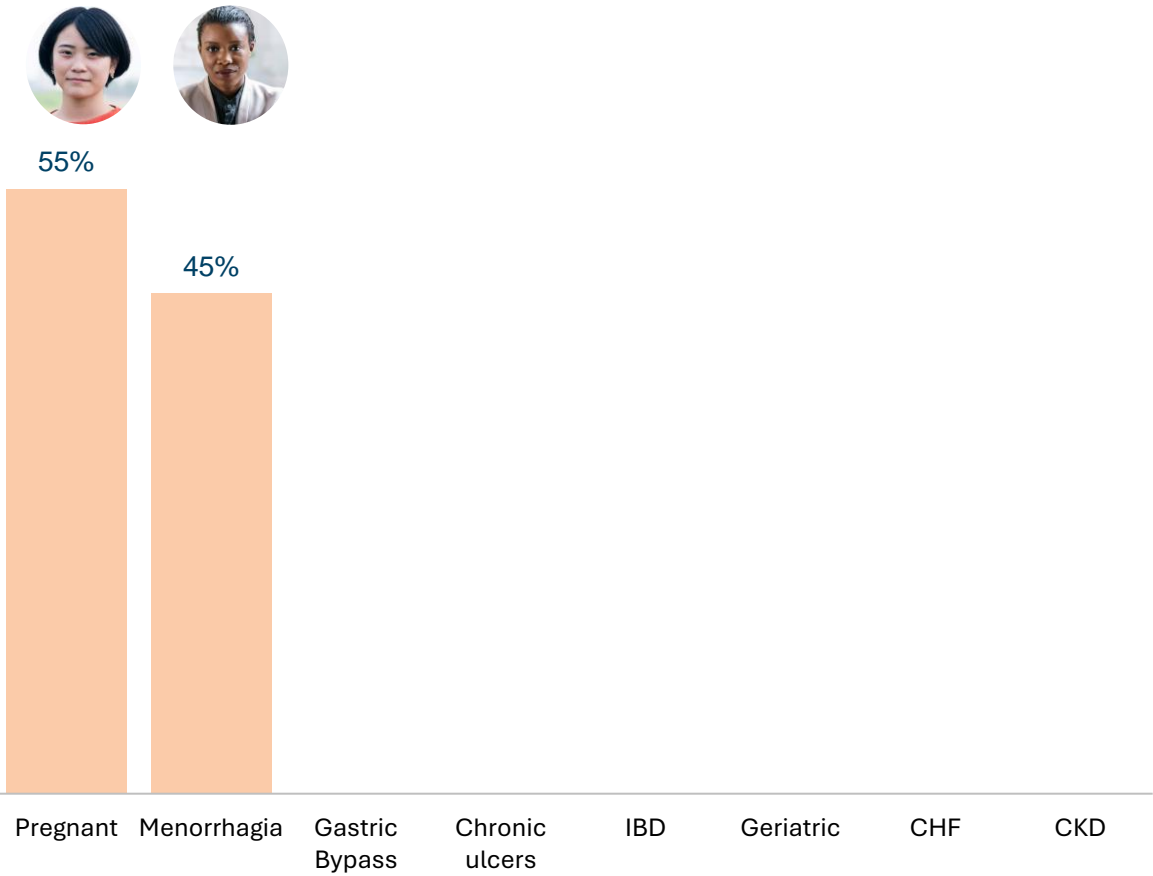
Expanded Market By Specialty\*  
6MM | 50K HCPs



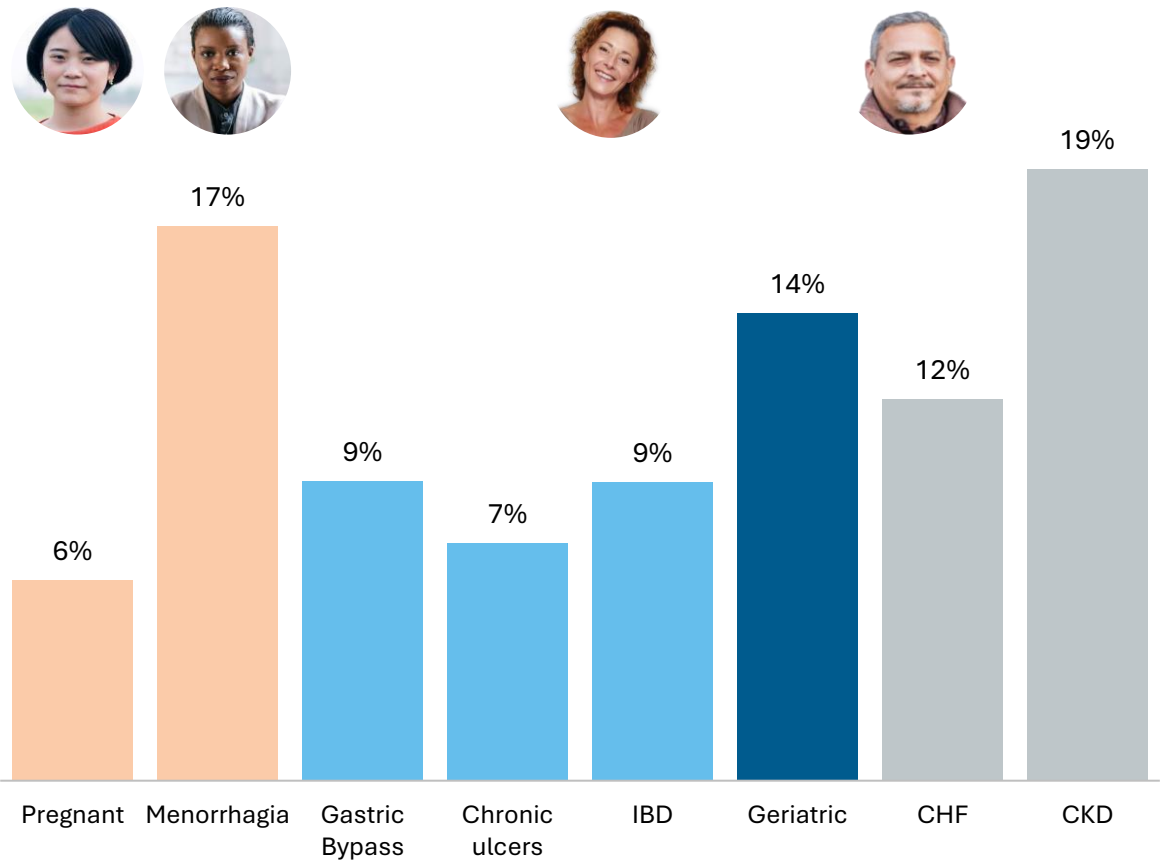
\*2023 TRx Data IQVIA Xponent PlanTrak + consignment

# OB/GYN and PCP ID/IDA Patients

## OB/GYN



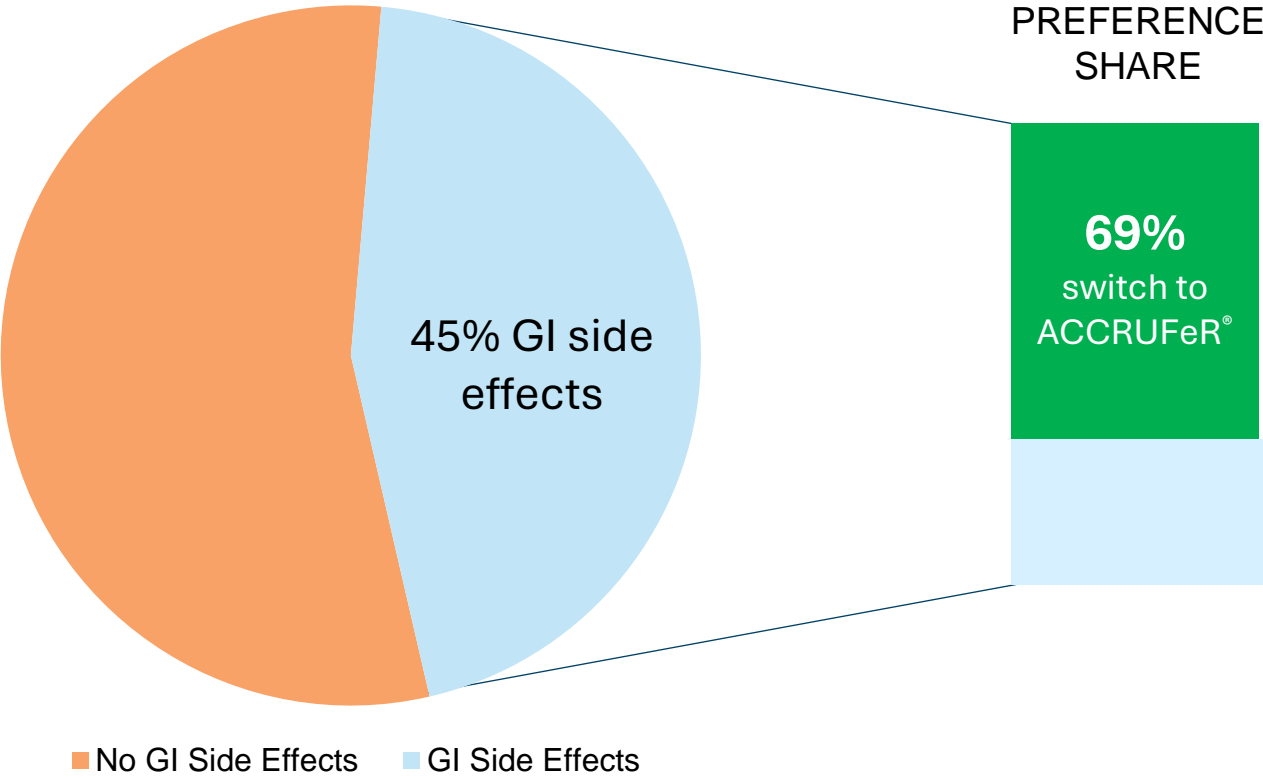
## PCP



HCP QUANT. April 2024 n= 200 HCPs (30 OB/GYN, 170 PCP)

# OB/GYNs and PCPs: high propensity to prescribe ACCRUFer®; Low awareness is a significant barrier to growth

Quantitative Analysis April 2024



LOW unaided awareness of ACCRUFer®		
	PCPs N = 170	OBGYN N = 30
ACCRUFer®	19%	10%
Benchmark	29%	59%

Quantitative Analysis April 2024 n= 200 HCPs (30 OBGYN, 170 PCP)  
Based on clinical profile, \$25, and no PA requirement



# 2024 business priorities

**Growth in  
ACCRUFer®  
Revenues, TRx &  
Gross to Net  
Q3 2024**

\$7.2M ACCRUFer® Net Revenues

c. 43,500 TRx  
*20% growth vs. Q2 2024*

\$167 Net price / Rx  
*\$192 excluding July '24  
vs. \$171 in Q2 2024*

**Increased balance  
sheet and  
operational flexibility  
Q3 2024**

\$7.7M cash and cash equivalents  
*8.1M in Q2 2024*

~10% cost reduction in operating base

Expanding Sallyport AR financing to \$15M

Non-binding term sheet with AOP Health for  
the potential of \$10M of new equity.\*

Goal to be cash flow positive by end of 2025

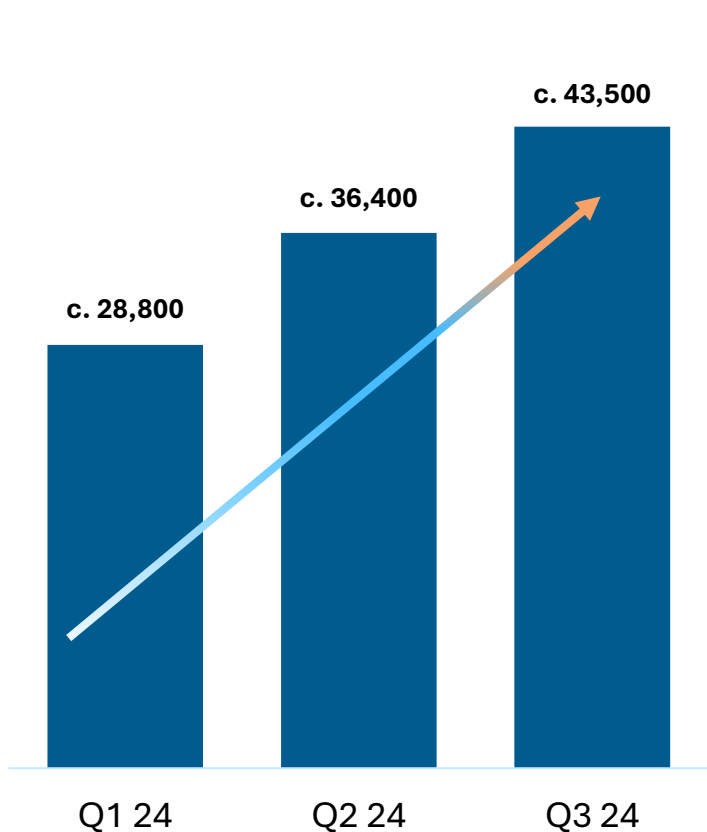
**Expand global  
patient access of  
ferric maltol  
Q3 2024**

Paediatric pivotal trial shows highly  
clinically relevant effectiveness with  
no AE related patient discontinuation

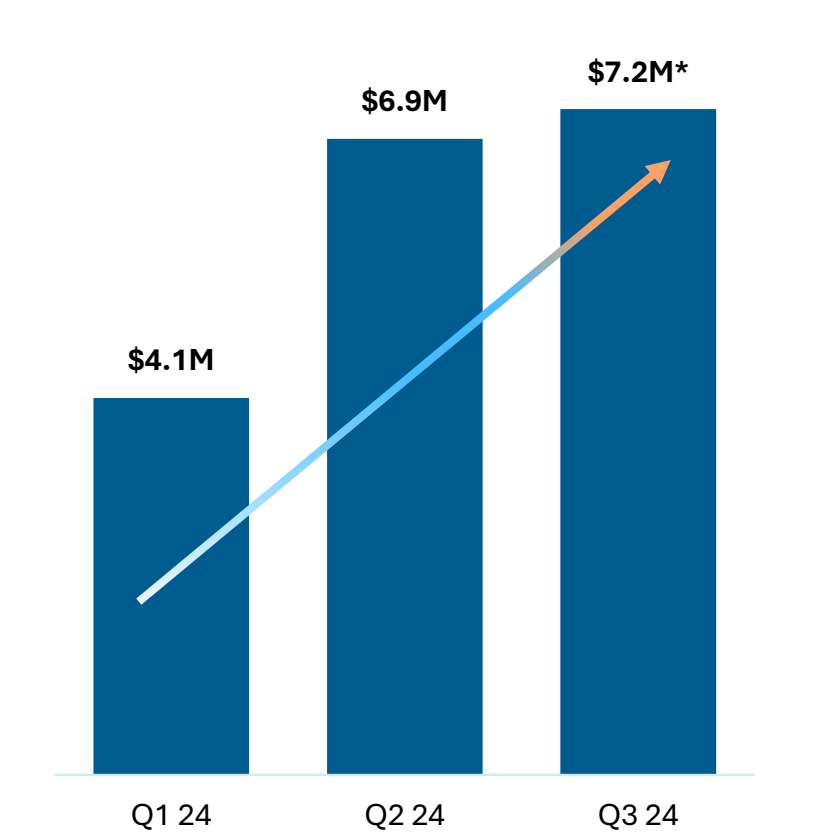
FDA and EMA filing indication in H1 2025;  
€1 million in total development  
milestones expected from Norgine BV

# Continued growth in ACCRUFer® in the US in Q3 2024

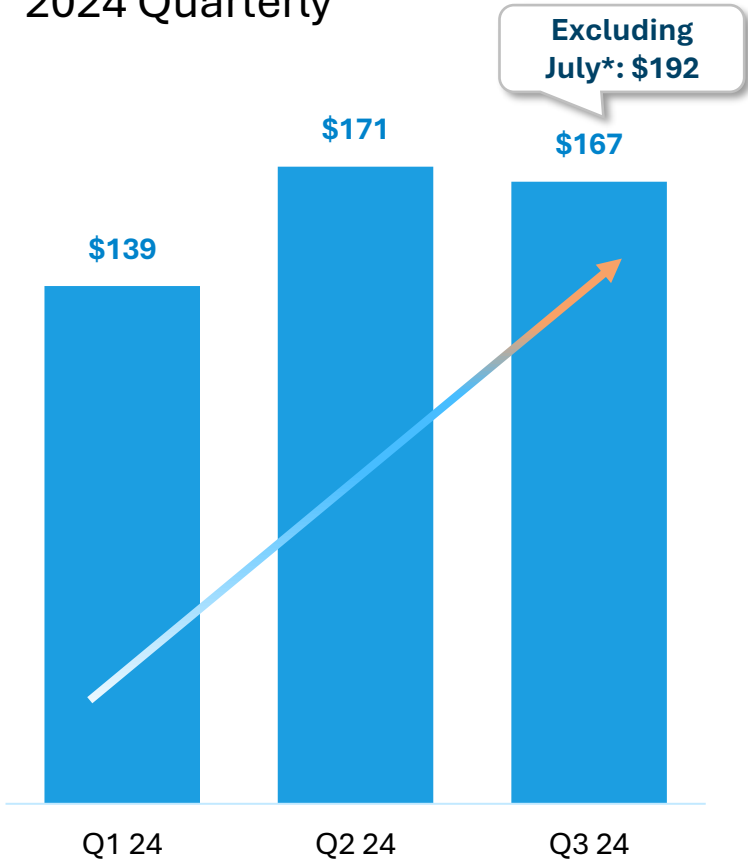
ACCRUFer® TRx  
2024 Quarterly



ACCRUFer® Net Revenues  
2024 Quarterly



ACCRUFer® Net Price Per Script  
2024 Quarterly



\*impact of the summer buying pattern of wholesalers buying ahead of the July 4th weekend during the last week of June

# Goal to be cash flow positive by end of 2025: ACCRUFer® revenues, strengthening balance sheet and ~10% reduction in operating base



## \$20M Term Loan

- Sept. 2028 maturity
- Interest rate SOFR + 9.25%
- Nine quarters interest only periods
- 6.5% final payment fee
- Secured by all assets
- Minimum liquidity and minimum revenue targets covenants<sup>1</sup>



## \$15M AR Factoring

- Expanding from \$10M to \$15M
- Advance rate on eligible ACCRUFer® receivables
- Interest rate: WSJ Prime + 3.0%
- Secured by AR and Inventory
- \$1.0M in restricted cash



## \$5.7M Milestone Monetization

- Monetization of \$11.4M milestone upon ACCRUFer® approval in China
- ACCRUFer® approval in China expected by YE 2026
- Secured by the ASK Milestone<sup>2</sup>

## Potential \$10M Equity Raise

- Non-binding term sheet
- Minimum of \$10M (gross) equity investment<sup>3</sup>
- Subscription Price : 4.0 pence per ordinary share
- AOP Health will hold >50% of the issued STX share capital
- Broader equity offering may be available should the Subscription proceed

<sup>1</sup> The minimum revenue targets are \$16.5m, \$22.5m, \$31.5m, \$38.9m, and \$45.7m in Q2 2024, Q3 2024, Q4 2024, Q1 2025, and Q2 2025+. AR = Accounts Receivable

<sup>2</sup> If the Approval Milestone has not been triggered by 31 December 2026, the Advance (\$5.7m) plus interest at the rate of SOFR+9.25% and an exit fee of 6.5% of the Advance will be payable by Shield to AOP

<sup>3</sup> Conditional upon (i) Rule 9 of takeover code waiver by Takeover Panel (ii) shareholder approval of the waiver (excluding AOP and its concert parties) (iii) shareholder approval of the issue of the securities

# Shield Therapeutics

Fast Growing, Mission Driven, Speciality Pharmaceutical Company



- **Vast market opportunity with significant revenue potential**
- **ACCRUFer<sup>®</sup>/FeRACCRU<sup>®</sup> (ferric maltol) approved by the FDA, EMA, and Health Canada**
- **Shield-Viatris partnership driving growth in ACCRUFer<sup>®</sup> prescriptions, net revenue and net selling price in the US**
- **Global partnerships continue to progress at a steady pace with anticipated milestones and double-digit royalties**
- **Increased balance sheet and operational flexibility**
- **Goal to be cash flow positive by end of 2025**

# Thank You!

**Anders Lundstrom –Chief Executive Officer\***  
**Santosh Shanbhag – Chief Financial Officer**

**[www.shieldtherapeutics.com](http://www.shieldtherapeutics.com)**

