



Corporate Presentation

August 2024

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



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Shield Therapeutics

Fast Growing, Mission Driven Specialty Pharmaceutical Company

Vast market opportunity in iron deficiency replacement therapy market. Traditional oral irons often lead to discontinuation due to intolerable GI side effects or insufficient efficacy¹

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

Experienced Executive Team based in US with extensive US commercialization expertise

Viartis co-commercialization agreement catalyzed commercial expansion, resources and growth for ACCRUFer®

Peak Revenue potential of ACCRUFer® of ~\$450M²

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 Anemia (ID/IDA)

Highly prevalent and a 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**.¹

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



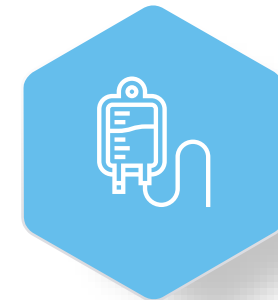
Rx and OTC

**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⁺) generates reactive oxidative species (**ROS**), causing irritation and damage to the intestinal lining **and gastrointestinal (GI) side effects**

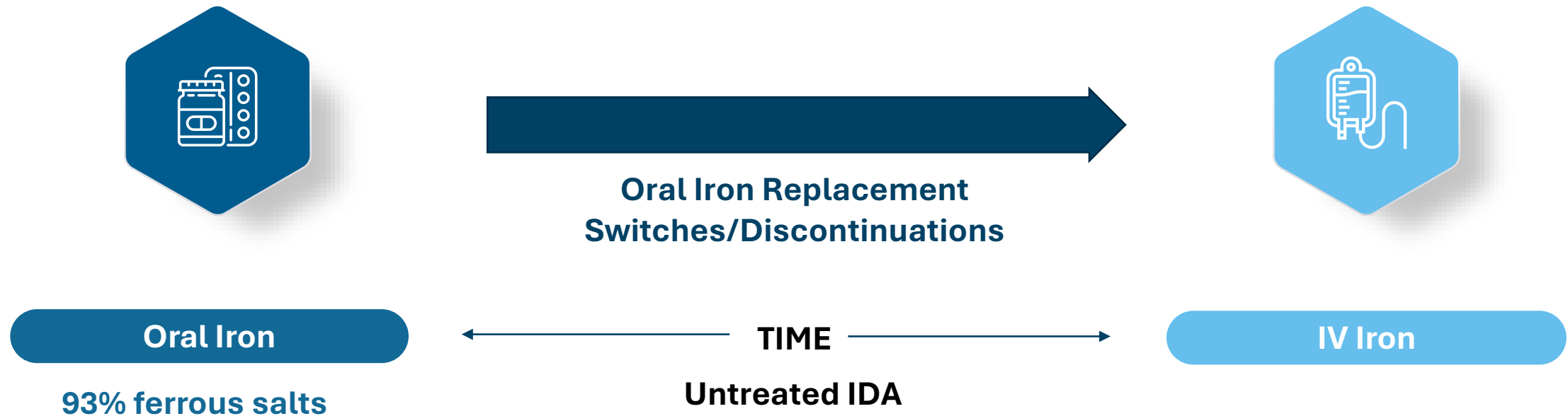
Up to 70% of patients can experience GI related side effects^{1,2} including bloating, dark stool, nausea distention

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

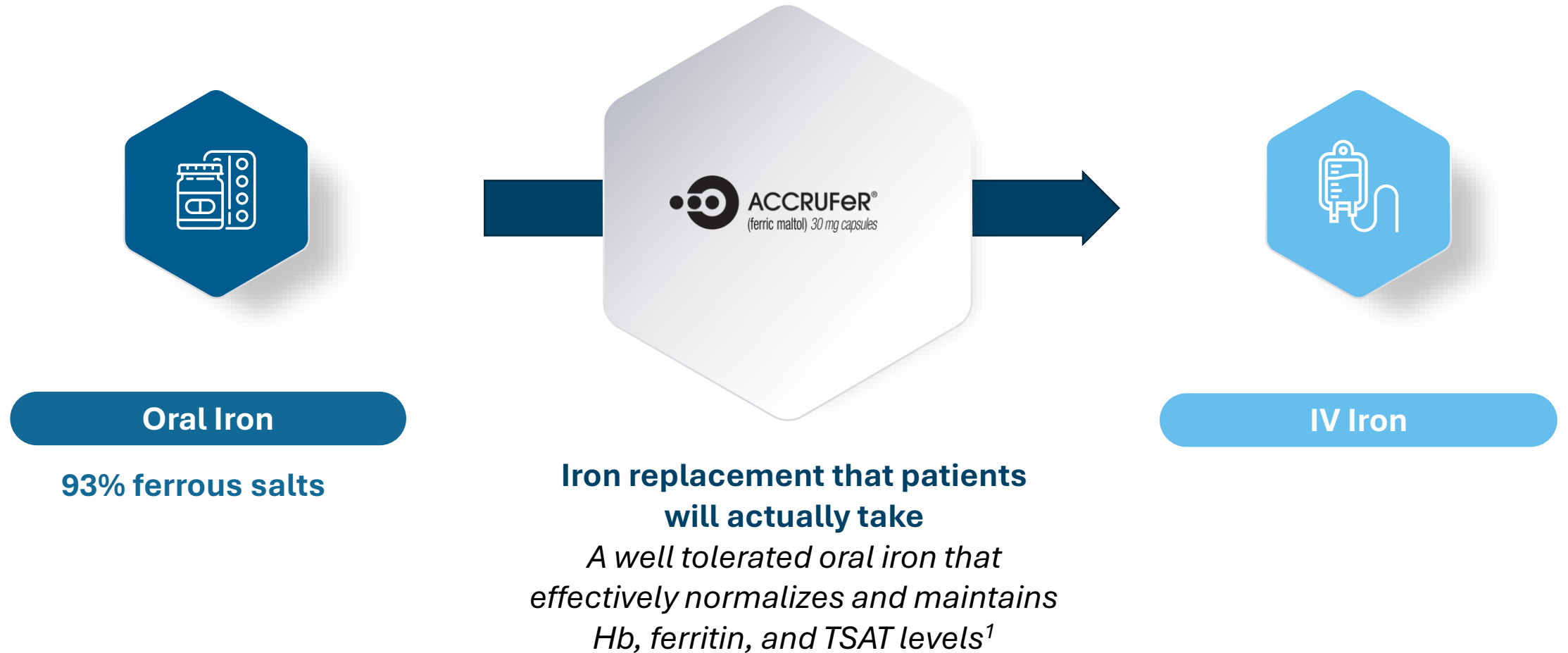
Up to 60% of patients will discontinue treatment with ferrous (iron) salts primarily due to GI adverse events and lack of effectiveness³

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[®]



1. Data from AEGIS 1 and 2 study.

ACCRUFerR[®] designed for efficacy and tolerability

Unique MOA (mechanism of action) Shields and Delivers Elemental Iron to the Small Intestine ^{1, 2}

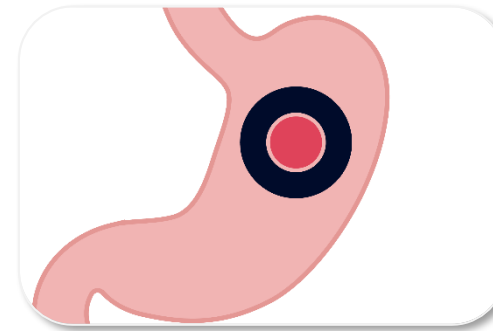
Proprietary Formulation

ACCRUFerR[®] is formulated in a maltol complex vs. traditional oral irons, provided in ferrous-based formulations

Low iron dose

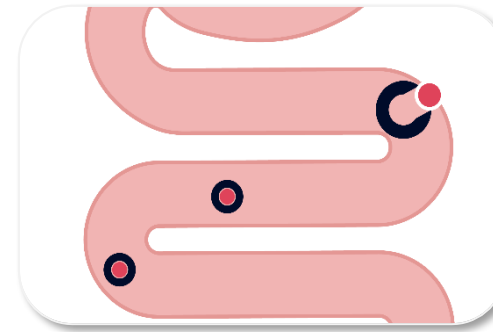
60 mg of elemental iron is delivered by ACCRUFerR[®] daily

ACCRUFerR[®] 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. ACCRUFerR[™] is dosed at 30mg BID, MOA = mechanism of action
2. ACCRUFerR[®] (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 rate¹

2.25 g/dL Increase in hemoglobin for ACCRUFeR®-treated patients compared to 0.06 g/dL for placebo at week 12¹ ($p < 0.0001$)

No patients treated with ACCRUFeR® in either long-term study **required IV iron intervention** ^{2,3,4}

Indication Expansion for Pediatric Patients:

Shield recently completed, a required pediatric study with a new liquid formulation in patients 6 months to 16 years of age

- Final topline results expected in late August
- Potential indication expansion in 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+¹

Sold over 90,000 packs in 2023
Y/Y increase of ~10%

Royalties and milestone payment upon approval for Pediatrics in EU



Canada

Decision on approval expected in 2024

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



Republic of Korea

PK Study completed
File for approval in mid-2024

Mid-teens royalties on net sales



China +²

Phase 3 Study ongoing
Approval H2 2026

**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

Our Commercial Partnership Mission



To make ACCRUFER® 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*

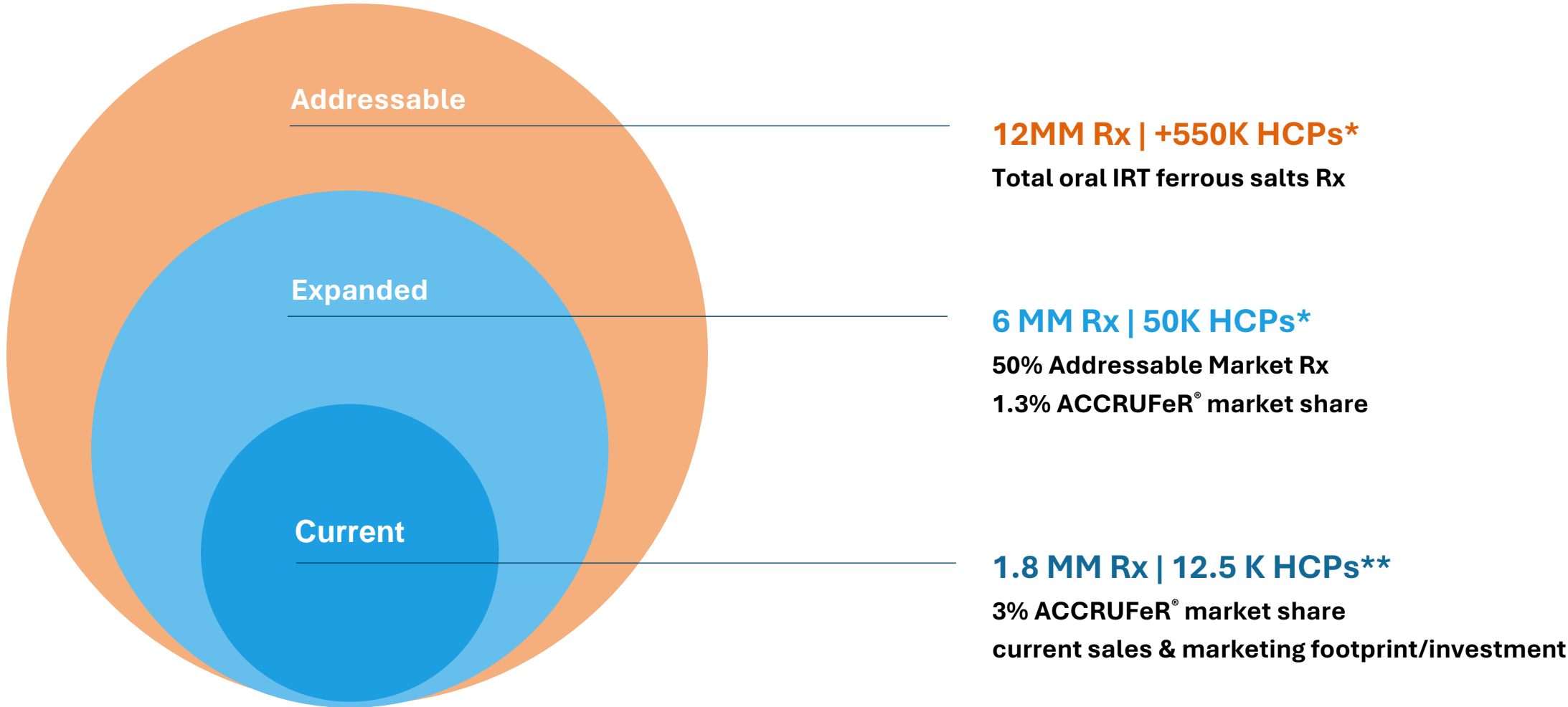
Large, defined market:

- ✓ ~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**

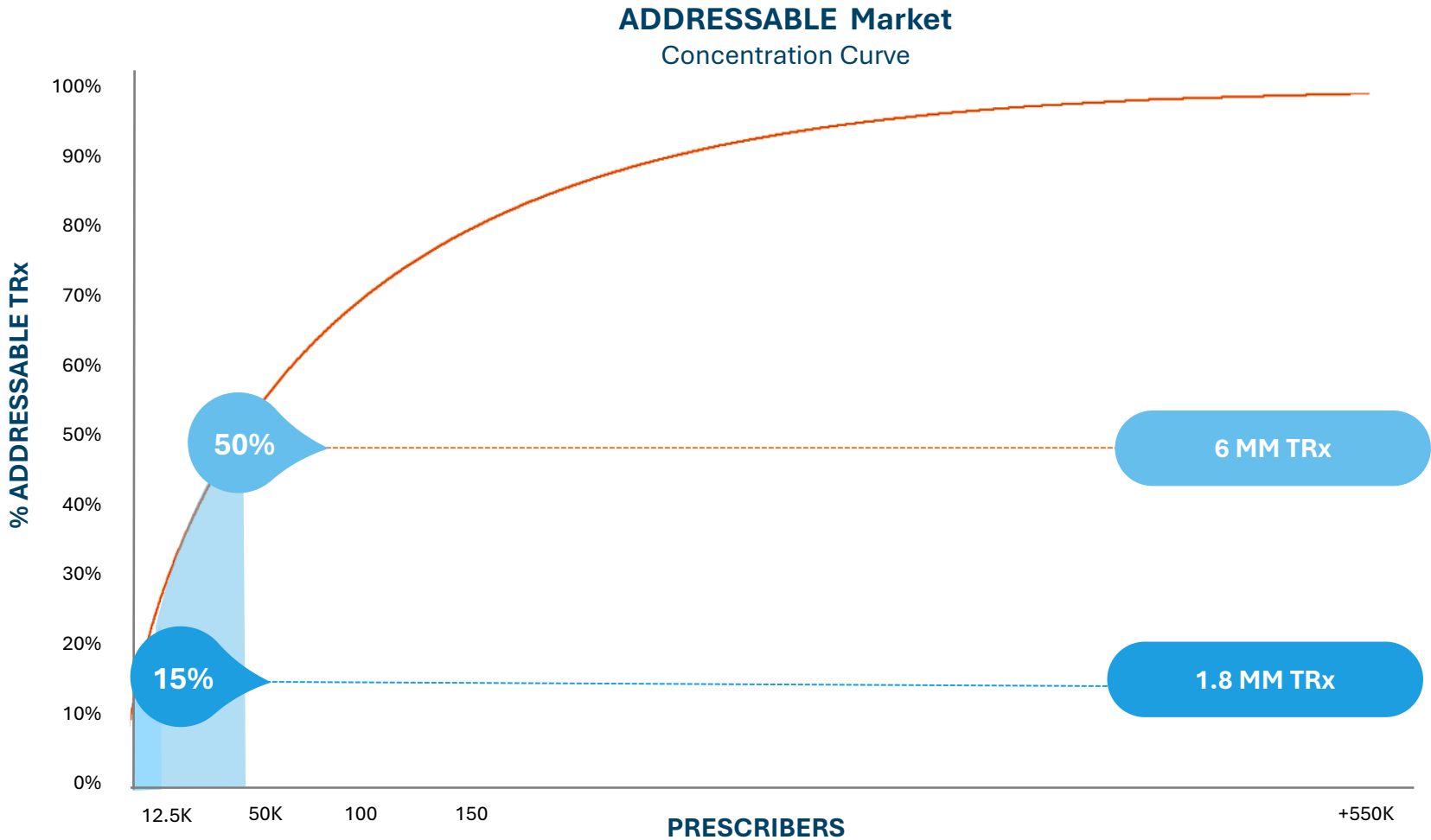
Total prescription oral iron replacement therapy (IRT) market



*2023 Rx Data IQVIA Xponent PlanTrak + consignment

**Q3 2024 ACCRUFeR® targets FY 2023 Rx (ACCRUFeR®, ferrous sulfate, integra, ferralet, proferrin, irospan, slow Fe+, iron combo product, other ferrous elemental irons)

Concentrated prescriber base creates a broader opportunity for ACCRUFeR[®] 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[®]

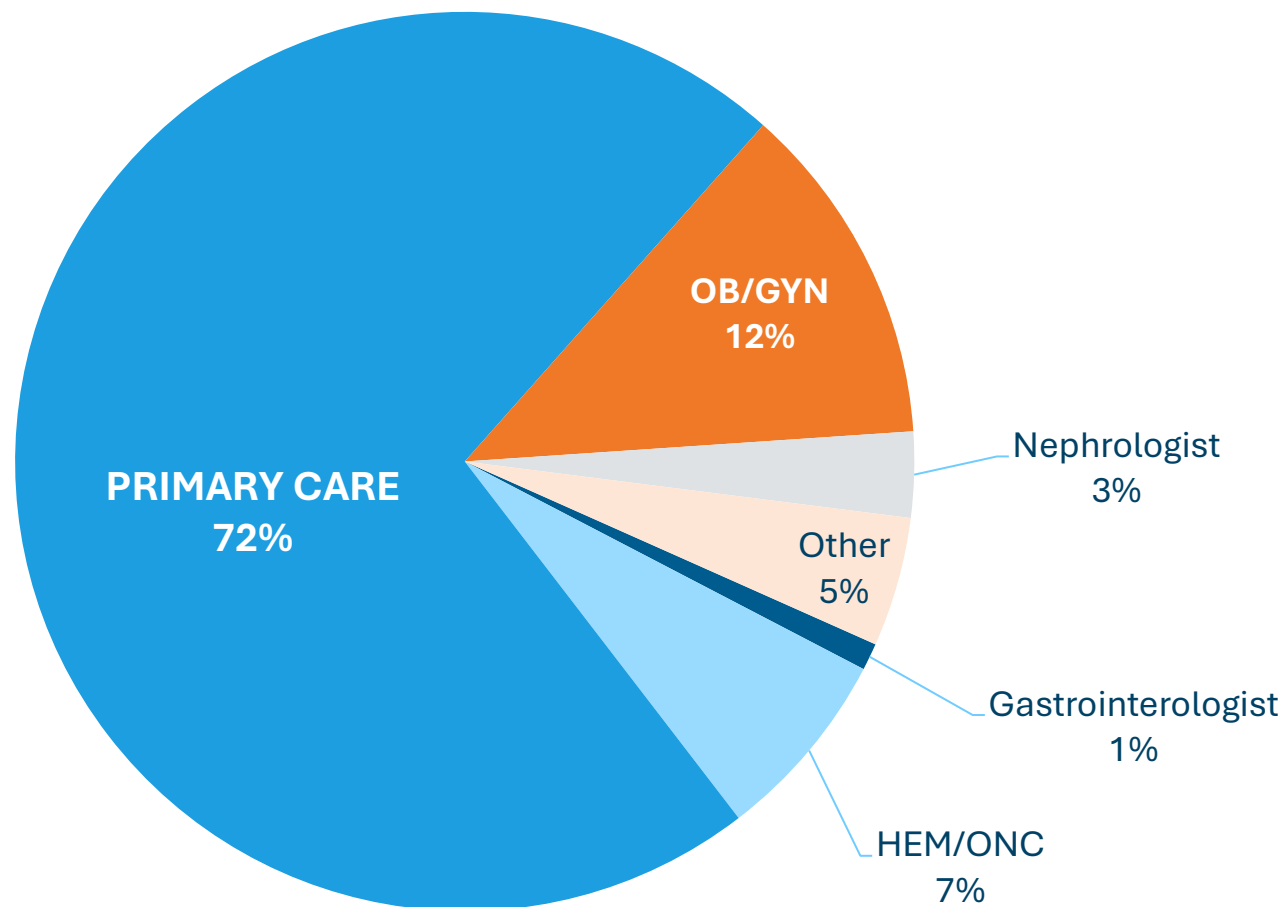
ID/IDA Market Dynamics as Viewed by Shield and Viatrix



- **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

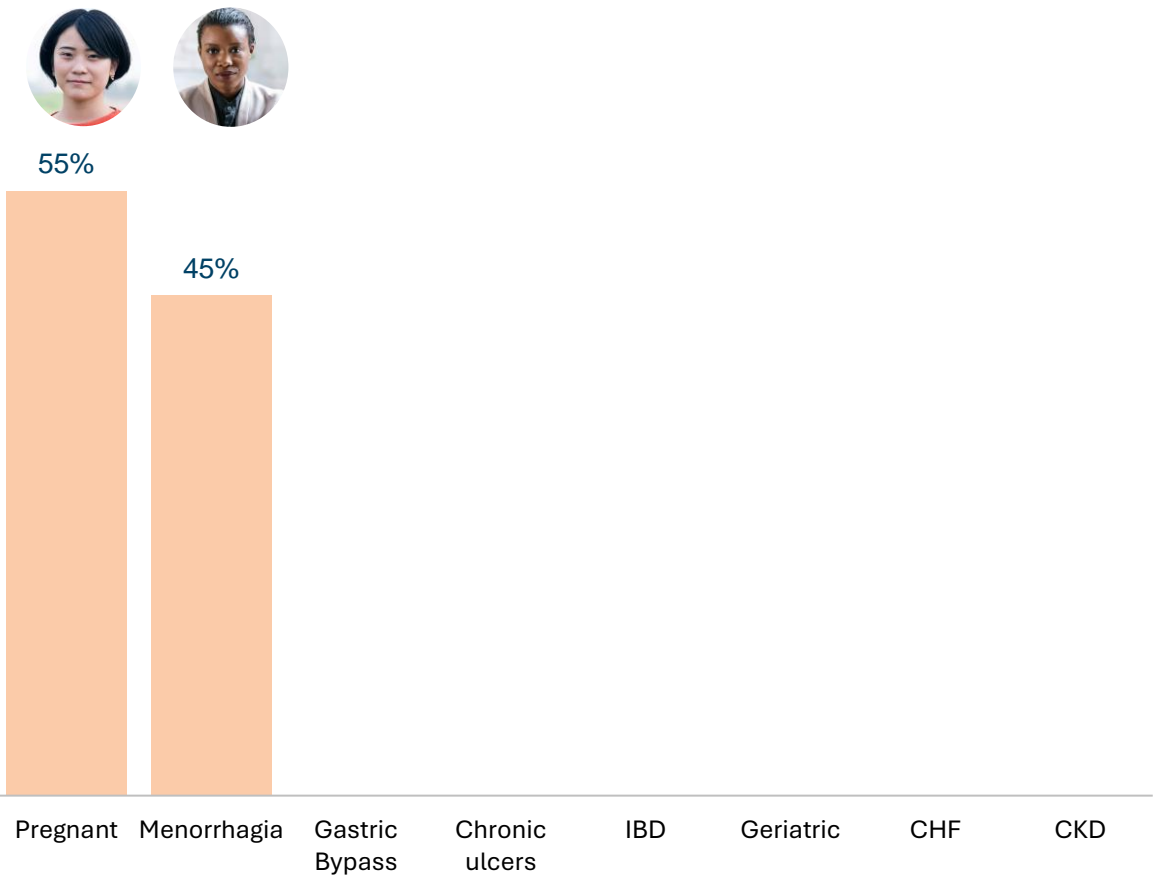
Expanded Market By Specialty*
6MM | 50K HCPs



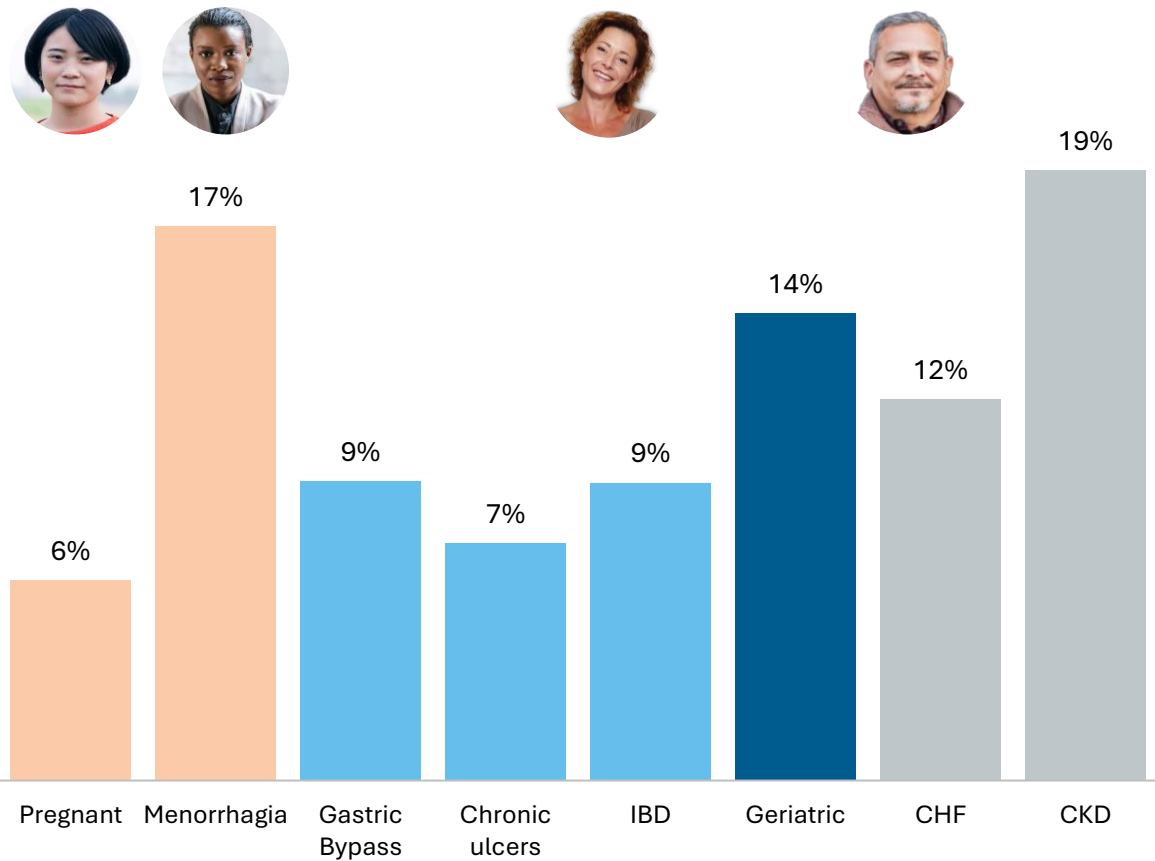
*2023 TRx Data IQVIA Xponent PlanTrak + consignment

OB/GYN and PCP ID/IDA Patients

OB/GYN



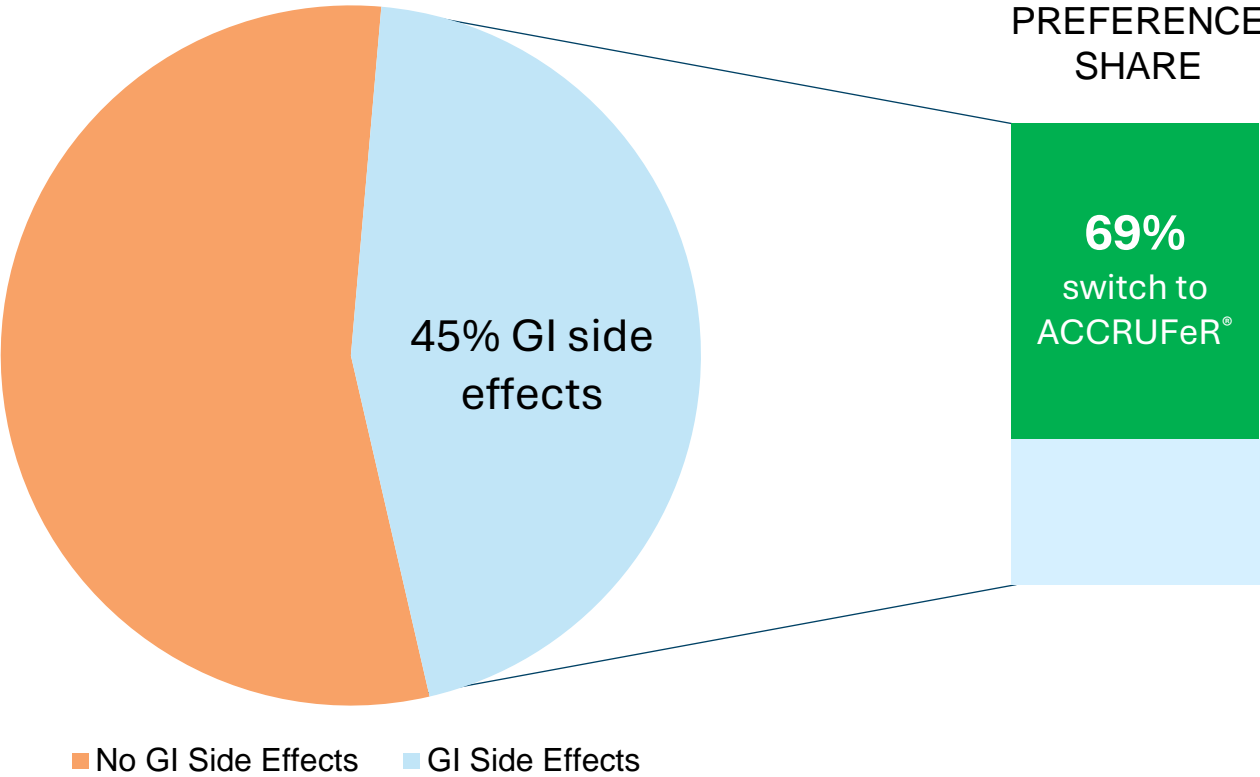
PCP



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

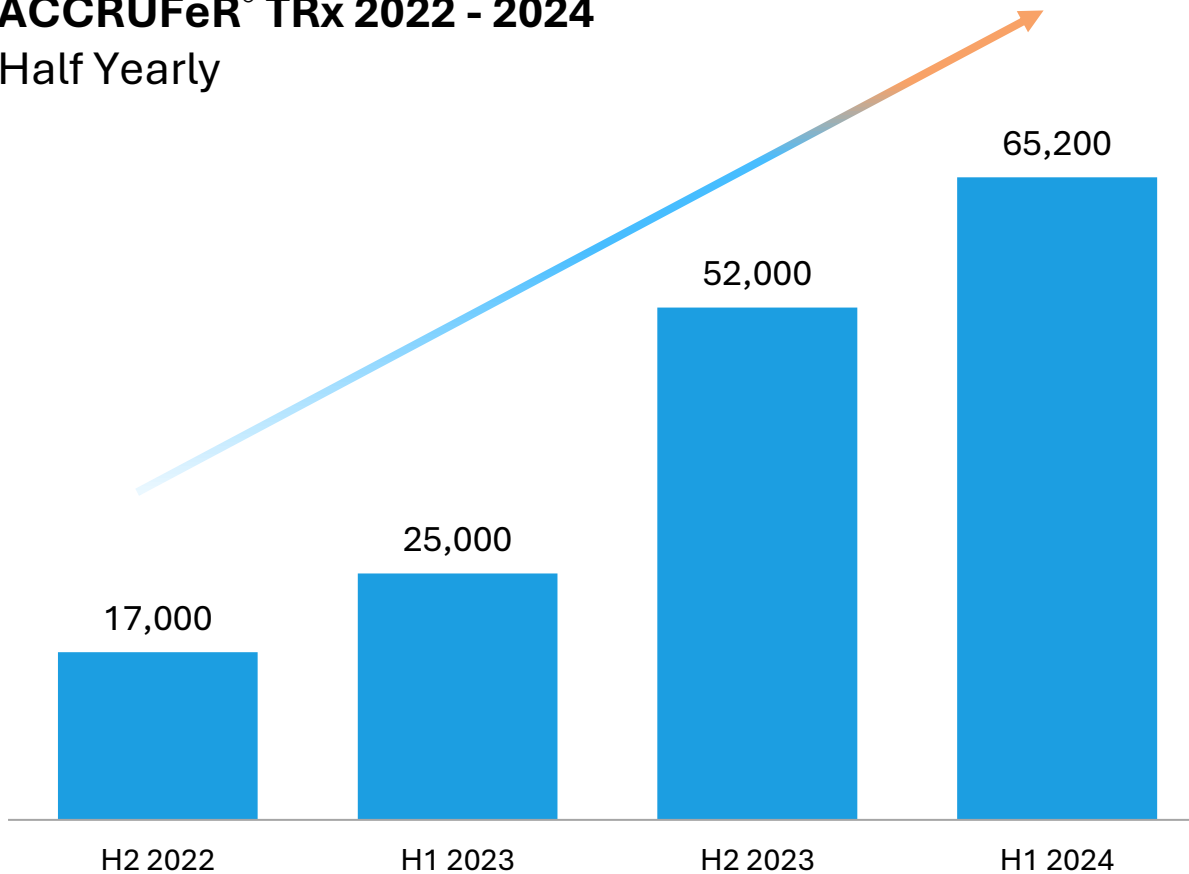


LOW unaided awareness of ACCRUFer®		
	PCPs N = 170	OBGYN N = 30
ACCRUFer®	19%	10%
Benchmark	29%	59%

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

Positive ACCRUFer® growth trajectory following 2023 sales expansion

ACCRUFer® TRx 2022 - 2024
Half Yearly



100 sales reps shared between Shield and Viatrix

Averaging 25% quarter over quarter growth following field expansions with Viatrix (five quarters)

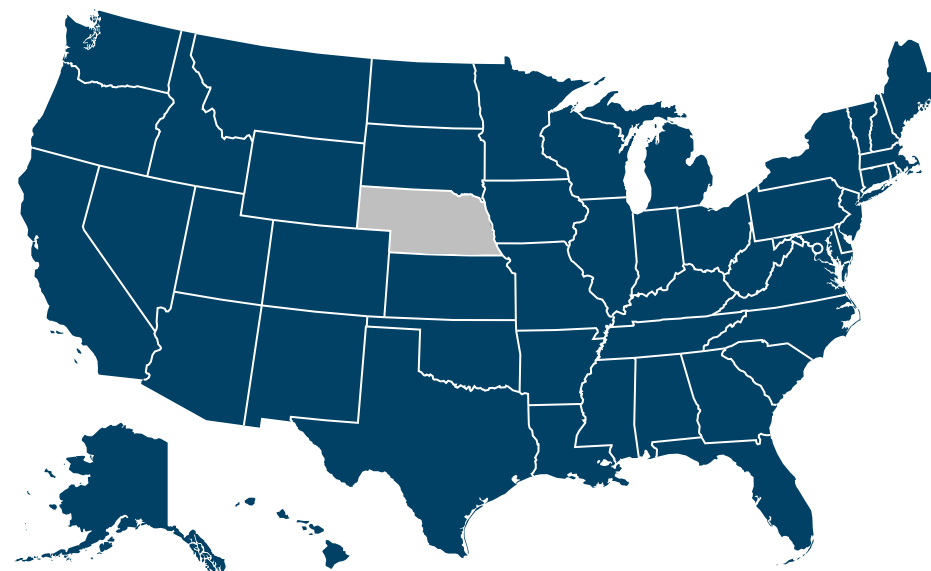
26% Increase in 2nd Quarter 2024

Broad access to ACCRUFer® for HCP's and patients

Commercial Plans and PBM's:



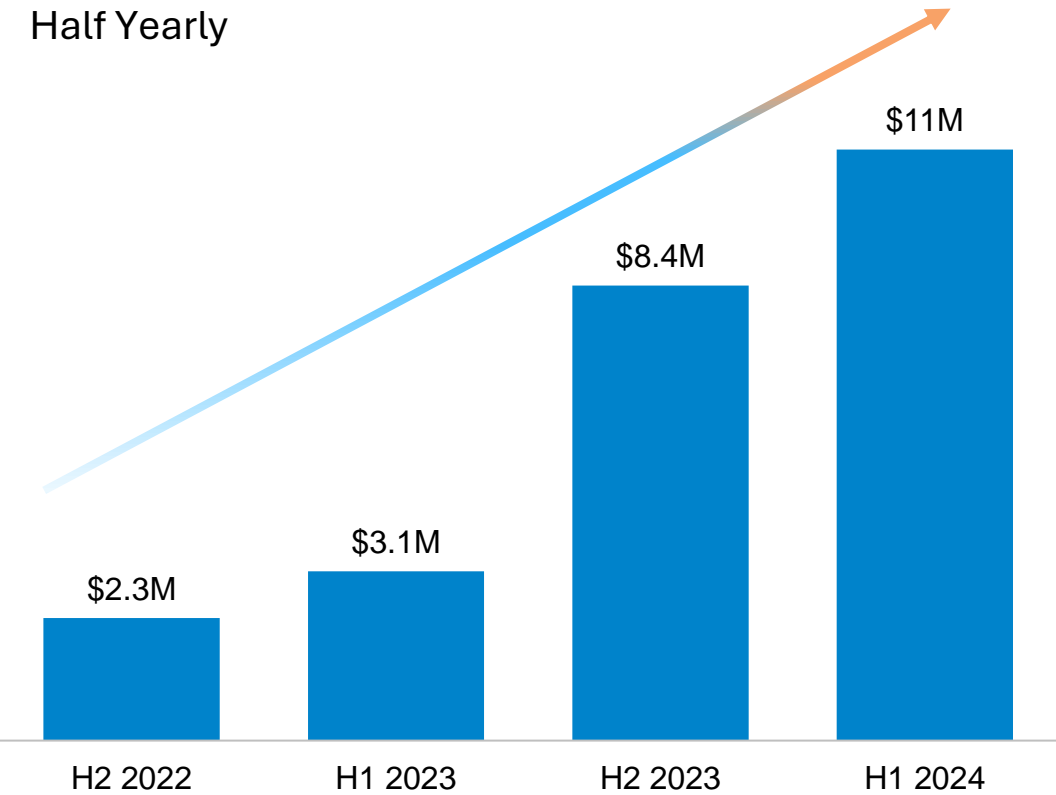
State Medicaid Programs



Positive ACCRUFer® growth trajectory following 2023 sales expansion

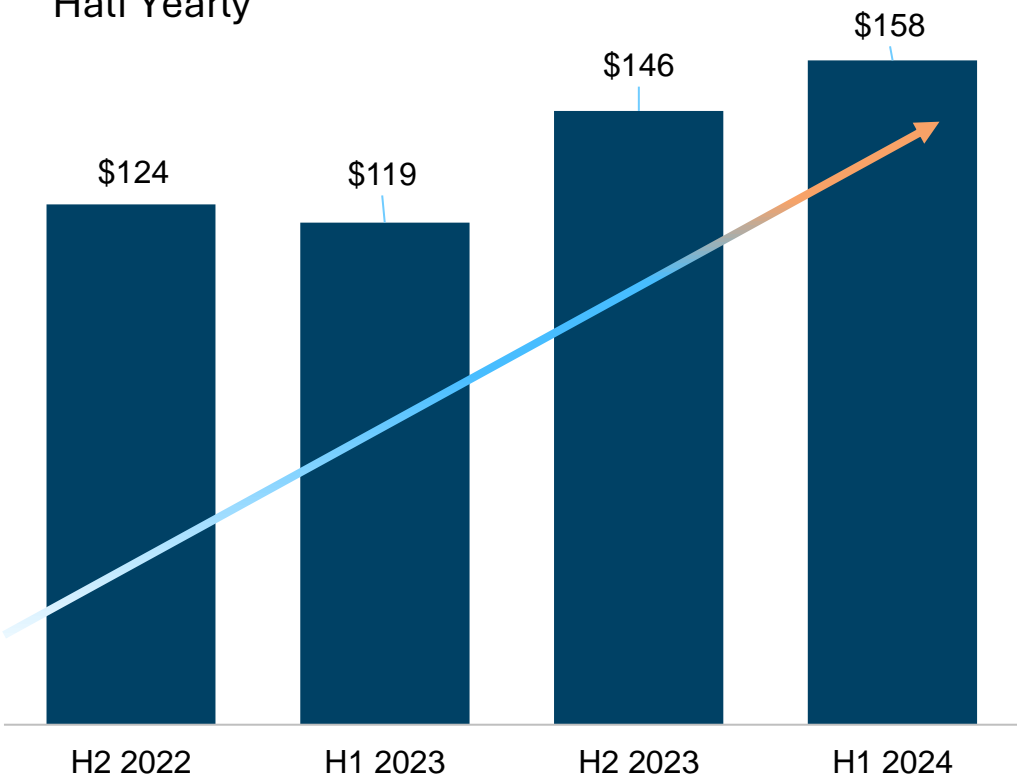
ACCRUFer® Net Revenues 2022 - 2024

Half Yearly



ACCRUFer® Net Price Per Script 2022 - 2024

Half Yearly



Note: 2024 ACCRUFer® WAC price of \$562.28 for 30-day supply

2024 business priorities

**Growth in
ACCRUFer®
Revenues, TRx &
Gross to Net
Q2 2024**

\$6.9M ACCRUFer® Net Revenues
69% increase vs. Q1 24

>36,400 TRx
26% increase vs. Q1 24

\$171 avg. net selling price / Rx
increase vs. \$139 in Q1 24

**Increased balance
sheet and
operational flexibility
Q2 2024**

\$8.1M cash on hand

Continued impact of
Accounts Receivable
Financing

Added \$5.7M from the China
milestone monetization in Q3 24

**Expand global
patient access of
ferric maltol
Q2 2024**

KP Pharma (Korea) filing for
approval H2 '24

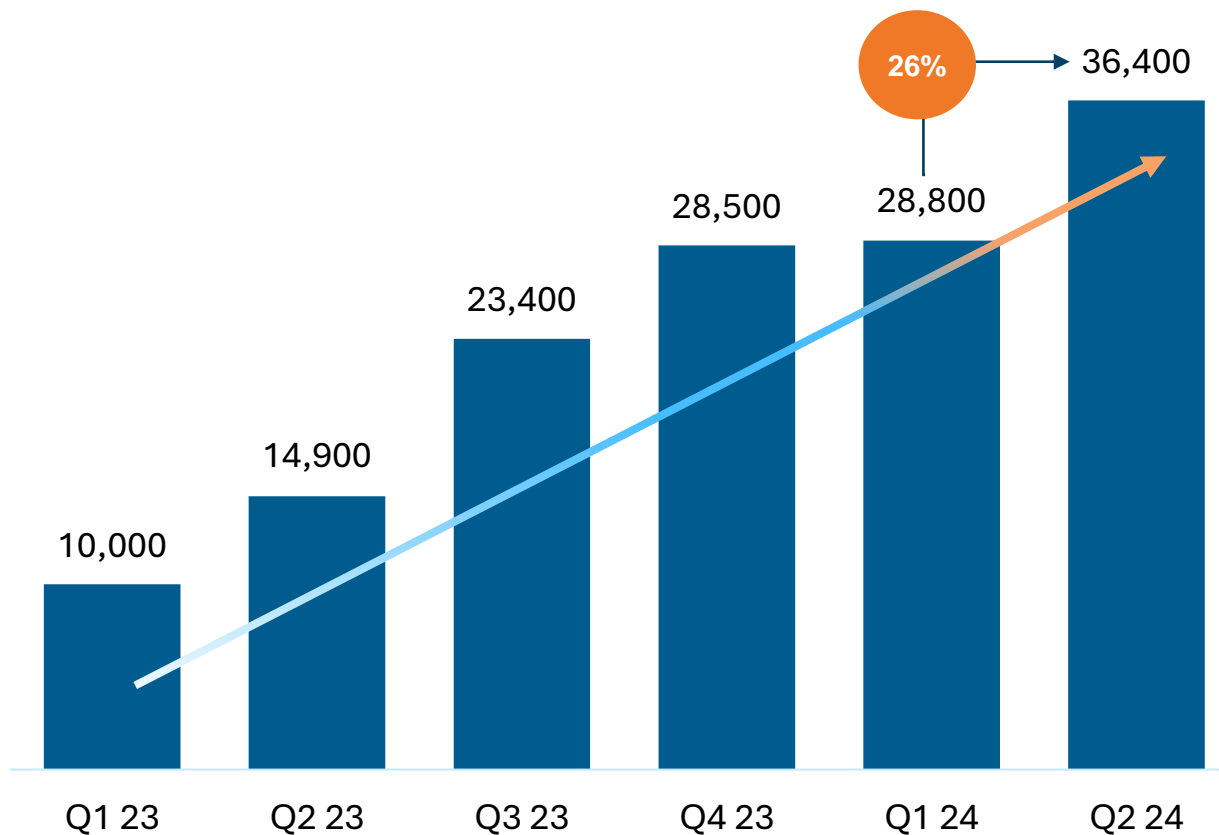
Kye Pharmaceuticals (Canada)
Health Canada decision
expected in 2024

Pediatric study expected
completion in 2024

Robust increase in ACCRUFER[®] prescriptions in Q2 2024

ACCRUFER[®] TRx 2023 - 2024

Quarterly



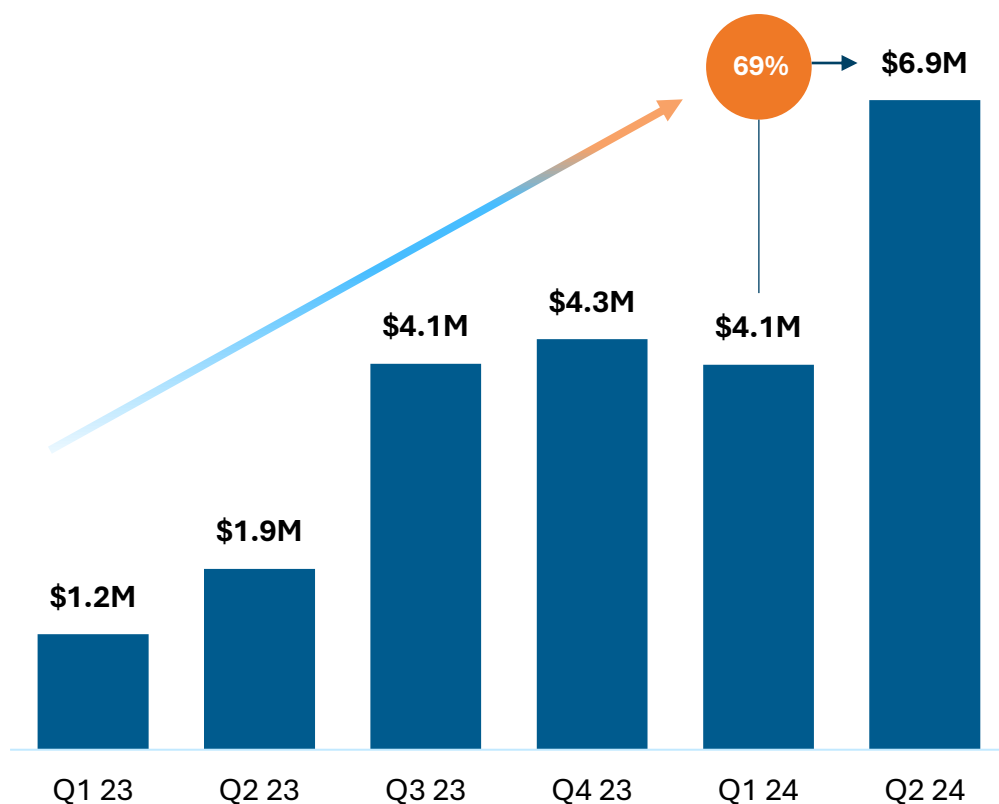
Continued focused execution by the combined Shield-Viatris field sales teams

Large states such as California, New York, and Florida continue to drive increase in prescriptions

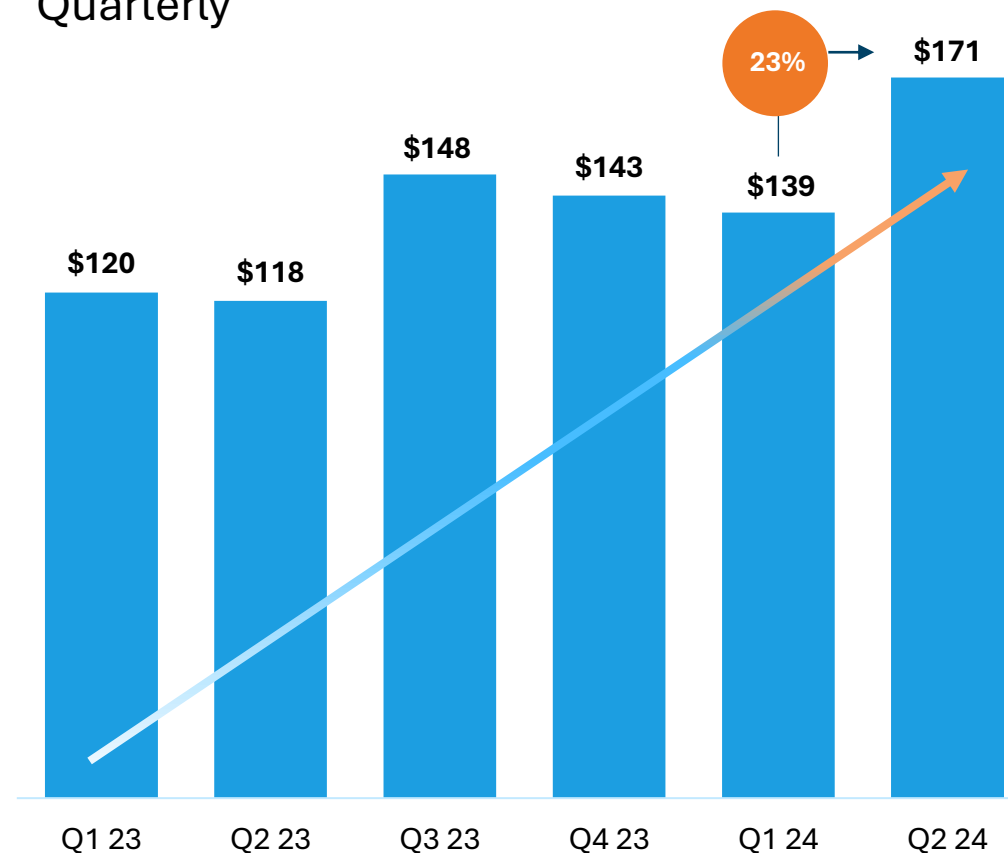
Texas starting to rebound from Q1

69% sequential Q2 24 ACCRUFeR[®] revenue growth driven by robust increases in prescriptions and average net selling price per Rx

ACCRUFeR[®] Net Revenues 2023 - 2024
Quarterly



ACCRUFeR[®] Net Price Per Script 2023 - 2024
Quarterly



\$8.1M Cash Balance at H1 2024 excluding \$5.7M from milestone monetization



\$20M Term Loan

- Sept. 2028 maturity
- Interest rate SOFR + 9.25%
- 9 quarters interest only periods
- 6.5% final payment fee
- Secured by all assets
- Minimum liquidity and minimum revenue targets¹ covenants



\$10M AR Factoring

- Through Apr '25, extendable to 2026
- Advance rate on eligible ACCRUFer[®] receivables
- Interest rate of 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

¹ 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

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2. Shield management estimate

Thank You!

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

www.shieldtherapeutics.com

