

A photograph of three young adults (two men and one woman) sitting on a rocky cliff overlooking the ocean. They are all smiling and looking at a smartphone held by one of the men, as if taking a selfie. The woman is in the center, wearing a floral crop top. The man on the left has curly hair and sunglasses. The man on the right has glasses and a beard. The background shows a clear blue sky and the ocean. A teal and dark blue geometric graphic is overlaid on the right side of the image.

# **SHIELD THERAPEUTICS**

## **Investor Presentation**

December 2021

A Potential Best in Class Oral Iron Replacement Therapy

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# Investment Highlights

## Significant Unmet Need

for effective, well-tolerated iron replacement therapy for iron deficiency, a 15MM patients & 13.4MM annual prescriptions opportunity

## Potential Best in Class

approved product, Accrufer<sup>®</sup>, designed to treat iron deficiency with minimal gastrointestinal adverse events which drive treatment discontinuation & failures

## Experienced New Executive Team

to build the business and drive market adoption and revenue growth in the US & Rest of World

## Near Term Value inflection Catalysts

from expanded reimbursement, increasing sales & commercial partnerships





## Market Cap<sup>1</sup>

~\$100MM as of 12/03/21 provides an attractive entry point

## Cash and Accrufer<sup>®</sup> Market Potential

\$31.3MM cash as of 06/30/21  
\$2.2B U.S. market opportunity  
Patent coverage thru 2035

# Shield Team

<b>Greg Madison</b> CEO	Experienced leader with a track record of building organizations and launching specialty pharmaceuticals with brands including Renvela®, Feraheme®, and Auryxia®. Prior Exec roles at Melt Pharmaceuticals, Keryx Biopharmaceuticals, AMAG, Genzyme	
<b>José Menoyo</b> CMO	Responsible for establishing and executing Clinical Development and Medical Affairs Strategies Supported launched products like Renvela®, Sensipar®, Soliris®, Ultomiris® Leadership roles at Alexion, ZS Pharma/AstraZeneca, Sanofi, Genzyme, Amgen	
<b>Hans-Peter Rudolf</b> CFO	US CPA with 30-years experience in audit, international finance and as a CFO Prior Life Science finance experience at Vicarius Pharma Prior finance roles at Deloitte, Ernst & Young, Crowe and COFRA Group	
<b>Jackie Mitchell</b> VP, Regulatory	Responsible for Shield's Regulatory Affairs and Quality, based on 30 years field experience Regulatory lead for MAA/NDA applications for Kaletra®, Lazanda and Humira® Prior roles at Boehringer Ingelheim, Abbott, J&J, Archimedes	



# 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



Fatigue, tachycardia, cardiac murmur, angina, dyspnea  
Increased hospitalizations



Headache, vertigo, syncope  
Cognitive impairment  
Restless legs syndrome



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

# Current ID Treatment Options: 90% of Prescriptions are Oral

## Oral



- ✓ Convenient, readily available
- ✗ Less efficient absorption
- ✗ **Poor tolerability**
- ✗ Slower iron repletion
- ✗ Exacerbation of IBD
- ✗ **Poor compliance often due to adverse events**
- ✗ Risk of iron overload due to overdose

## IV



- ✓ Fast iron repletion
- ✓ Better bioavailability and absorption
- ✓ No compliance issues
- ✗ **Inconvenient**
- ✗ **Infusion required**
- ✗ Risk of anaphylaxis
- ✗ Risk of iron overload due to overdose

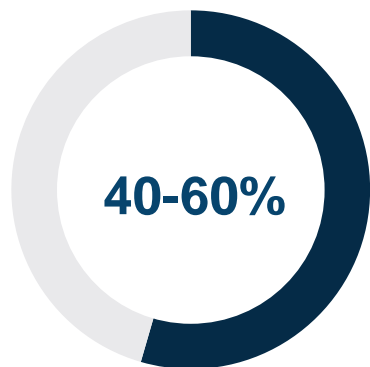
Poor Tolerability/Inconvenience Drives Poor Adherence



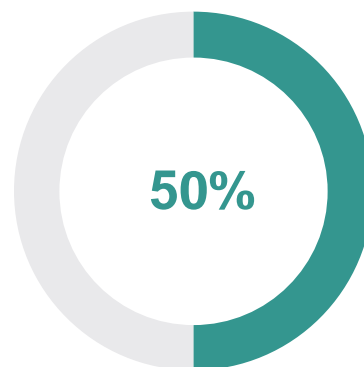
SHIELD  
THERAPEUTICS PLC

IBD, inflammatory bowel disease

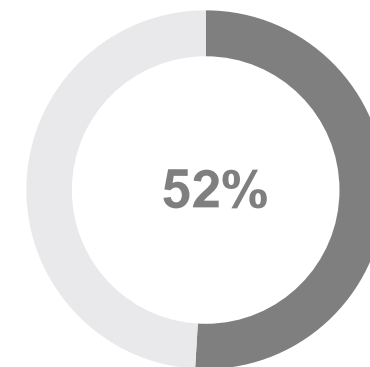
# Adverse Events Associated with Current Oral Iron Treatments Can Limit Patient Adherence



Estimated overall adherence with oral iron for IDA due to *all* AEs<sup>1</sup>



Estimated overall adherence with oral iron for IDA due to GI AEs<sup>2</sup>



Of IBD patients with IDA reduce or withdraw oral iron dose due to AEs<sup>3</sup>

**Non-adherence Can Lead to Substantial Treatment Failures<sup>2</sup>**

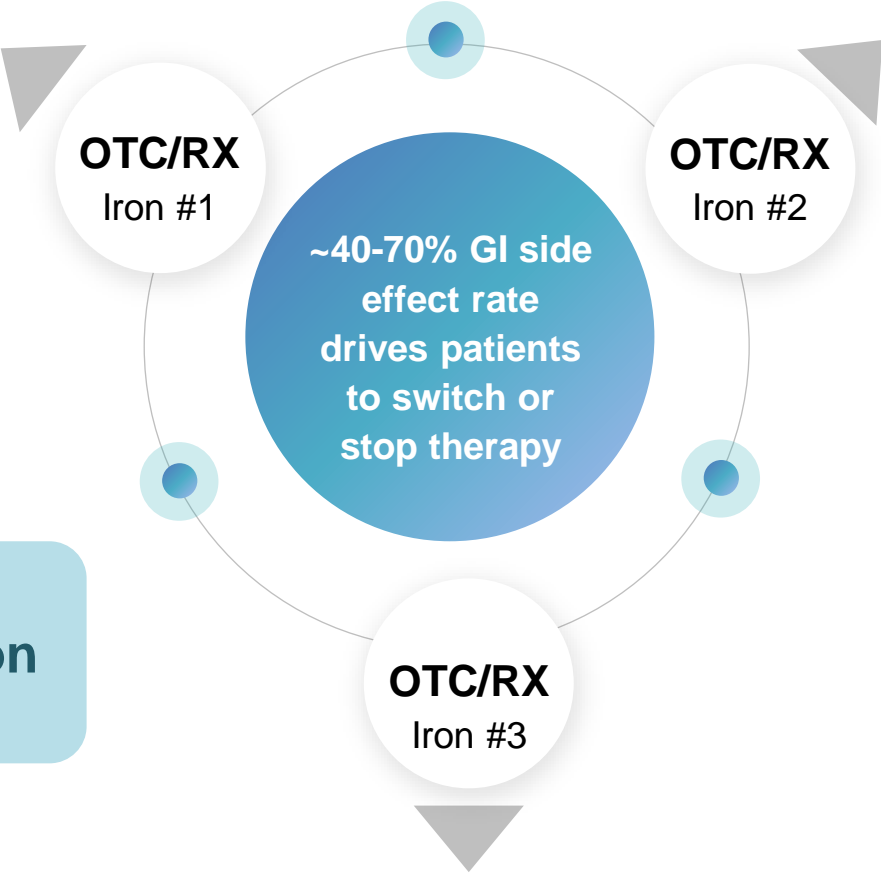
# Iron Deficiency Treatment Algorithm

An Unsatisfactory Cycle of Switches and Discontinuations



OTC/Generic RX Oral Iron

 = Stop Treatment

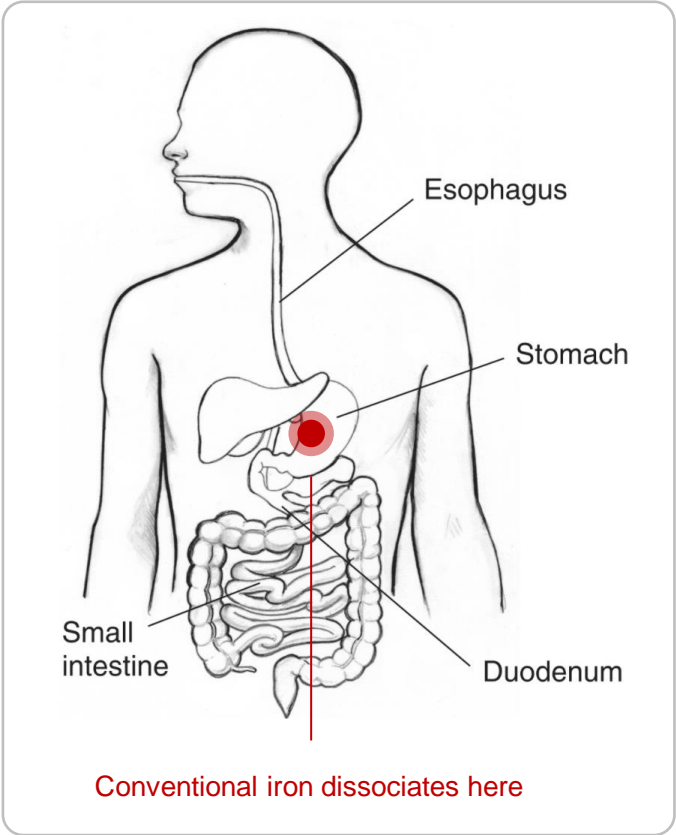


Patients and Health Care Providers (HCPs) are Seeking a Well-Tolerated and Effective Oral Iron Replacement Therapy



# Design of Conventional Ferrous Iron Products Require High Doses of Iron

Conventional Iron	Formulated as a ferrous salt taken 1-3X/day
Dose	~300 mg daily dose of elemental iron required to achieve therapeutic hemoglobin increase
The Problem	(1) Ferrous salts dissociate prior to intestinal uptake <sup>1</sup> (2) Inefficient absorption results in residual free iron in the gastro-intestinal tract <sup>2</sup>
The Conventional Solution	Increase the dose of elemental iron
Impact	(1) Higher doses of elemental iron generate reactive oxygen species (2) This damages the gastric mucosa & increases the risk of GI adverse events <sup>3</sup>



## The Math on Conventional Oral Iron Supplements

The Product	Elemental Iron per Tablet	Daily Dosing Frequency	Elemental Iron Delivered
Ferrous Salts	~106 mg	1-3X	~300mg

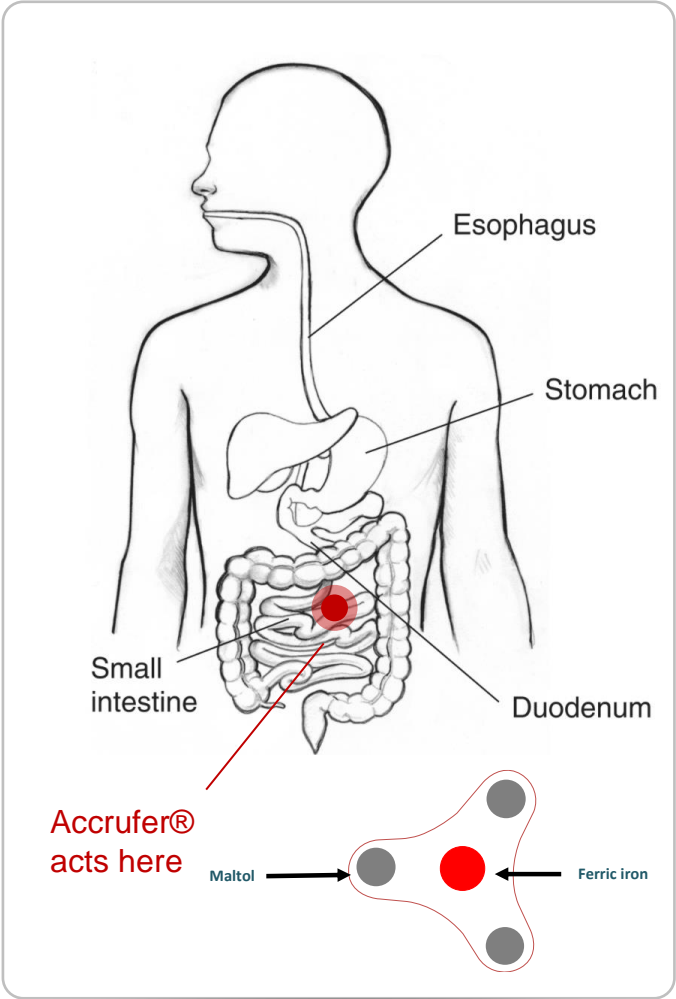
# Accrufer® is a Novel Formulation of Oral Iron

Accrufer®	Proprietary maltol formulation, dosed 2X/day <sup>1</sup>
Dose	Daily doses of ~60 mg of elemental iron significantly increased hemoglobin levels over 12 weeks, maintained over 52 and 64 weeks across studies <sup>1</sup>
Well Tolerated	Good tolerability, bioavailability and absorption <sup>1</sup> <5% adverse event & discontinuation rate <sup>1</sup> , well below published 40-60% discontinuation rate for conventional oral iron therapy
Safety	Neither short- nor long-term treatment led to iron overload <sup>1</sup>
Accrufer®	Effective at One-Fifth the Dose of Conventional Oral Iron

The Product	Elemental Iron per Tablet	Daily Dosing Frequency	Elemental Iron Delivered
Ferric maltol <sup>1</sup>	30 mg	2X	60mg
Ferrous salt	~106mg	1-3X	~300 mg

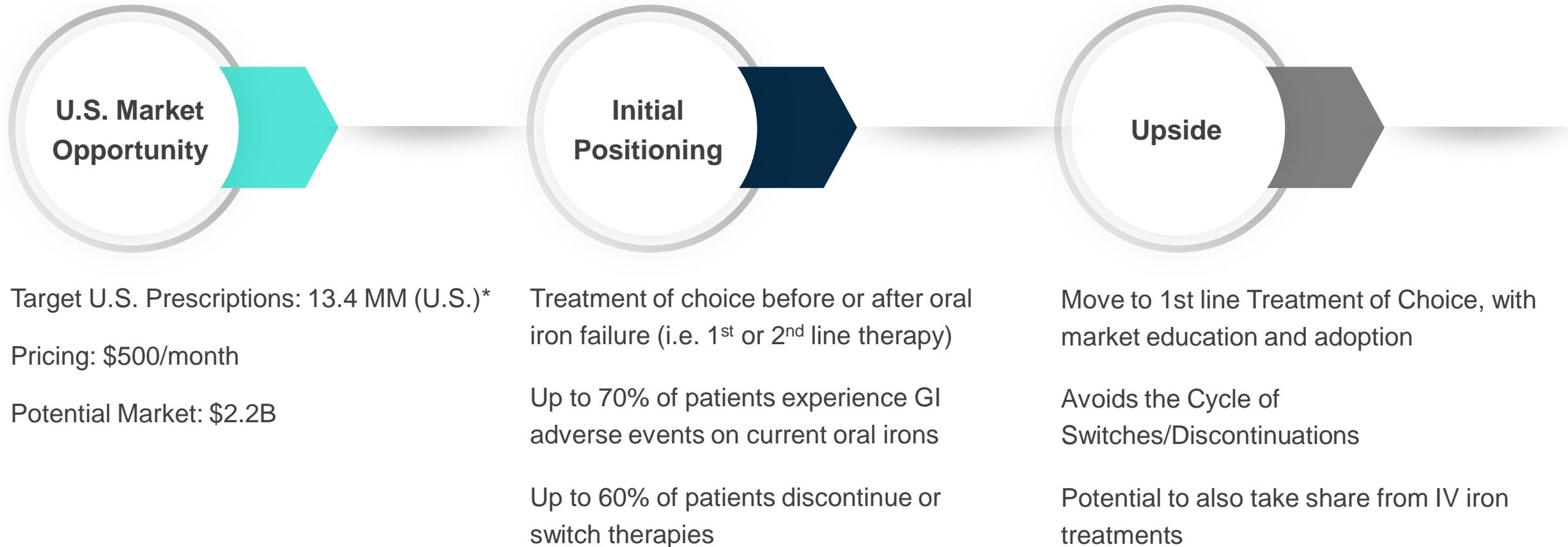


Source: <https://www.niddk.nih.gov/news/media-library/8269>:  
 1. Accrufer® (ferric maltol) [Prescribing Information]. Austin, TX: Shield Therapeutics, 2019.



# The Accrufer® Opportunity

To Become the Oral Iron Treatment of Choice



# Accrufer<sup>®</sup>'s Peak Net U.S. Sales Potential<sup>1</sup>: \$500MM+



## Oral Iron Therapy:

13.4MM Rx (2021, US)

## Initial Accrufer<sup>®</sup> Target:

WAC Price = \$500/mo

Est. GTN<sup>2</sup> = 50%

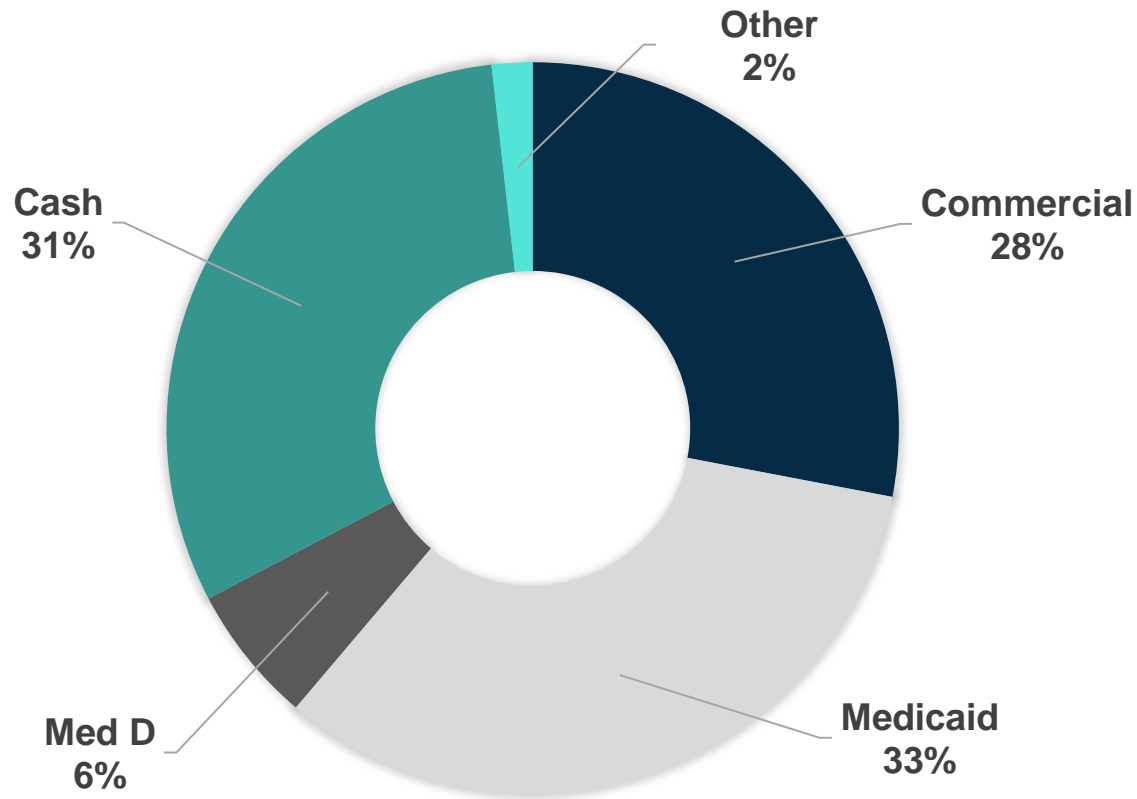
Est. Covered payor market = 66%

Est. Total Available Market = \$2.2B

Market Share	Number of Rx's	Net Price/Month per Rx	Est. Peak Net US Sales
<b>40%</b> High Case	3.5MM	\$250	\$875MM
<b>25%</b> Base Case	2.2MM	\$250	\$550MM
<b>15%</b> Low Case	1.3MM	\$250	\$325MM

1 pt of Market Share = ~\$22MM in Potential Net US Sales<sup>1</sup>

# Commercial and Medicaid Represent 2/3<sup>rd</sup>s of Reimbursement for Oral Irons



## Initial Focus on Commercial Segment

For covered patients, out-of-pocket costs are expected to be \$10/month

## And Medicaid Drug Rebate Program

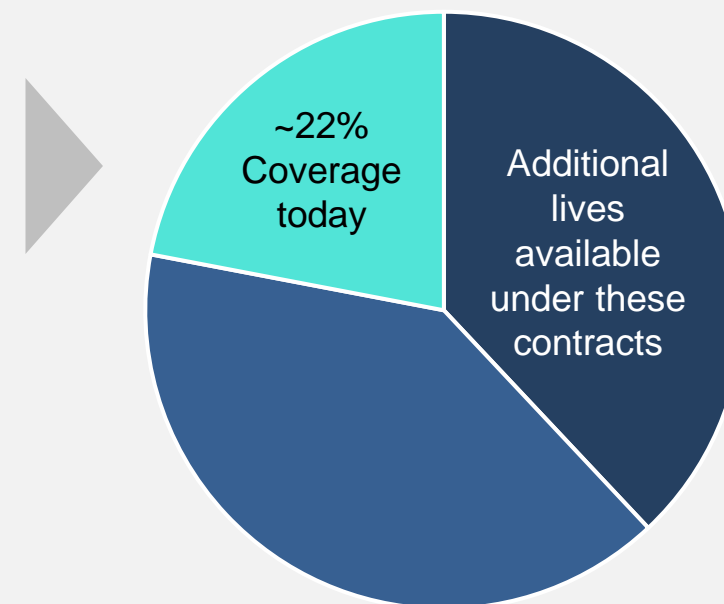
Will begin additional focus on key states in H2: 2022

# Significant Progress with Commercial Payers – 40M+ Lives Covered

Expect Additional Increases in 2022

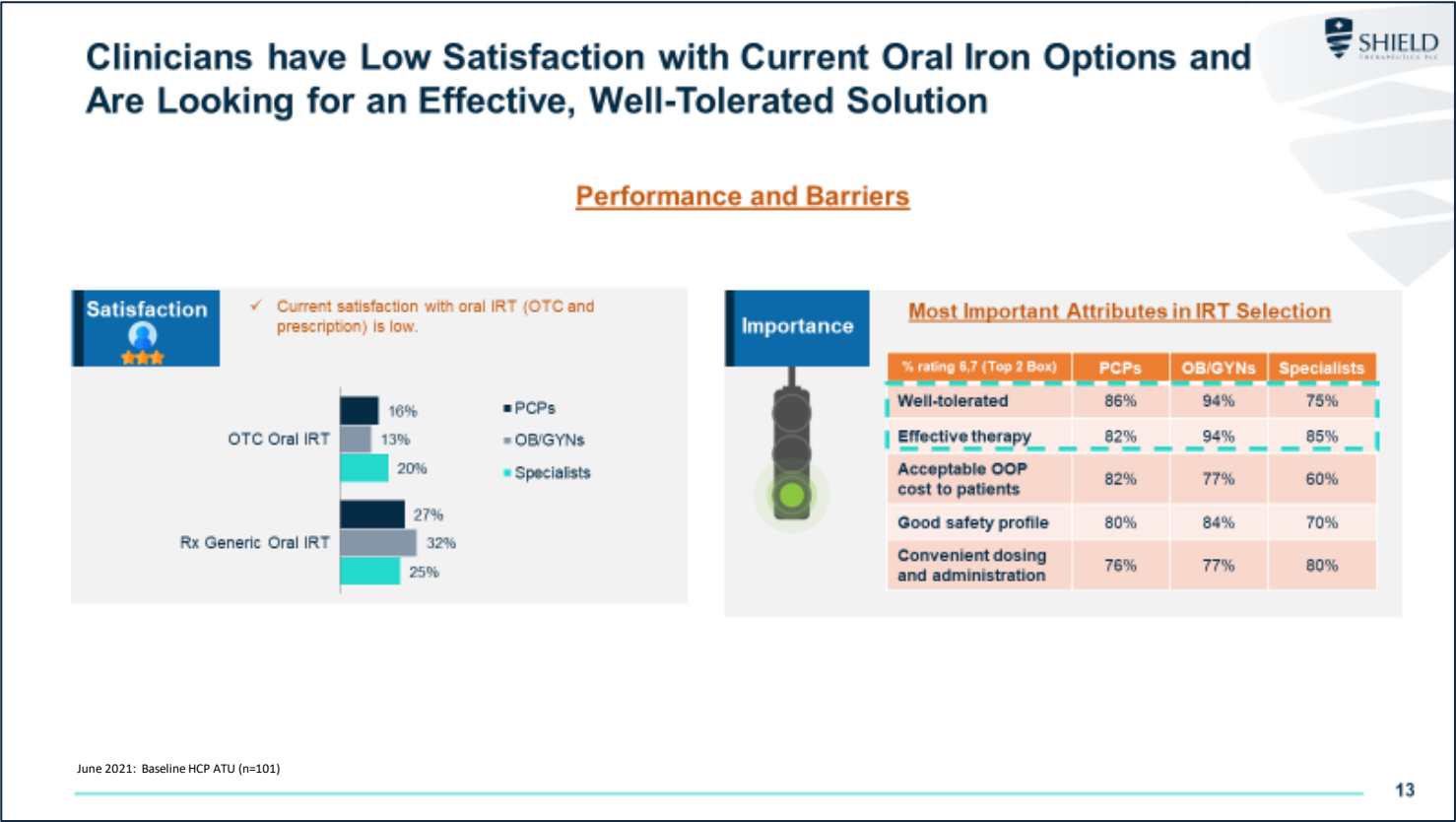
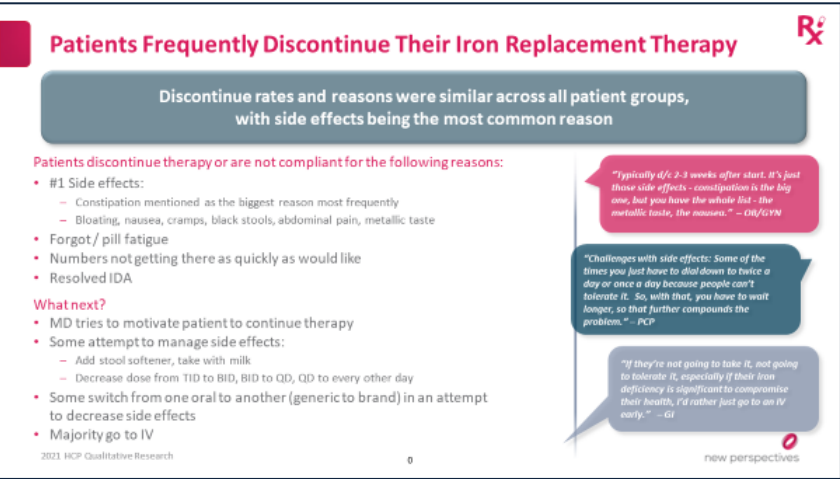
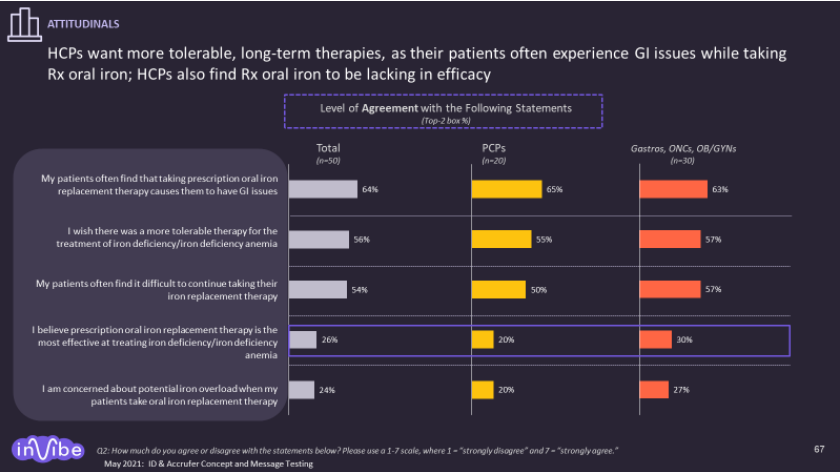


Commercial Payers, % Covered Lives





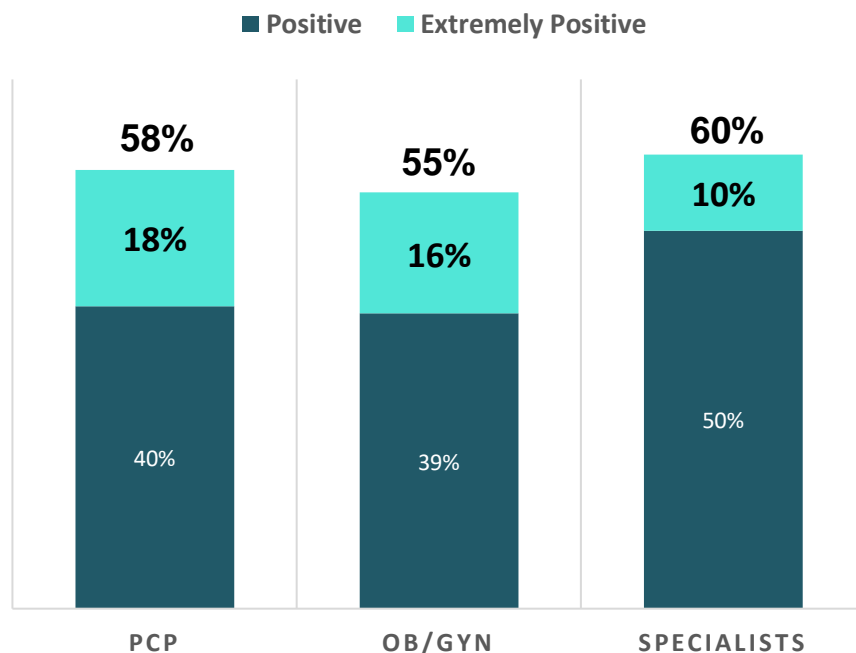
# Multiple Market Research Studies Confirm Clinicians are Looking for an Effective, Well-Tolerated Oral Iron Solution



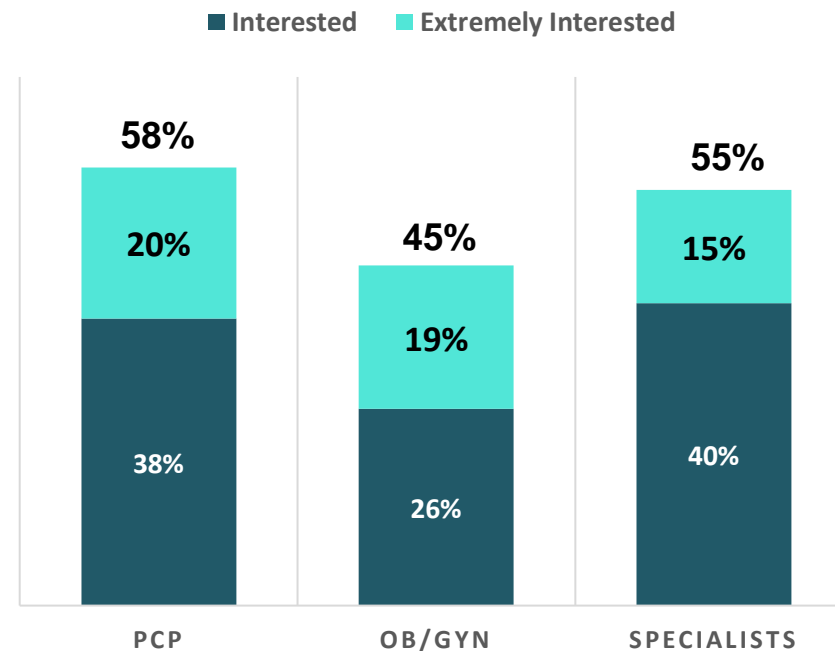
# HCP Response to Accrufer® is Positive

HCPs have a Positive Overall Reaction to the Product and are Interested to Learn More

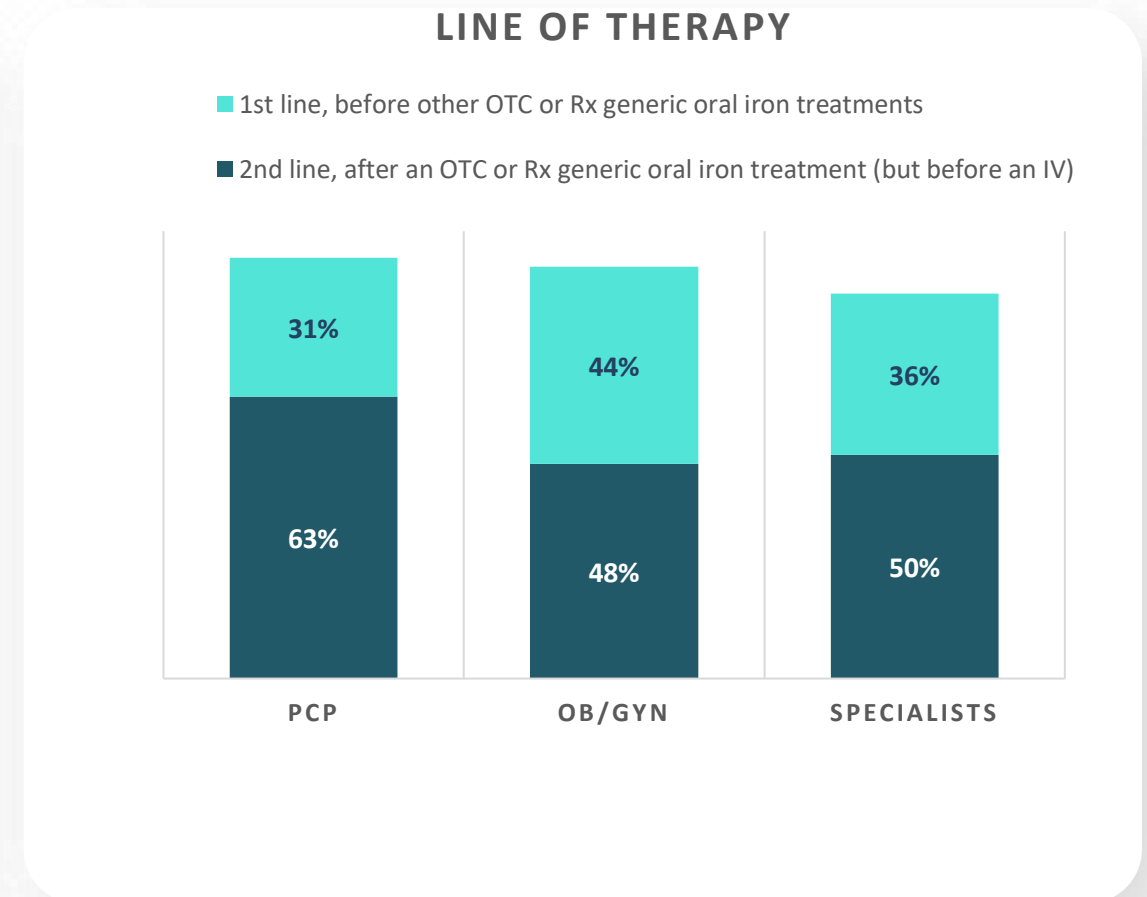
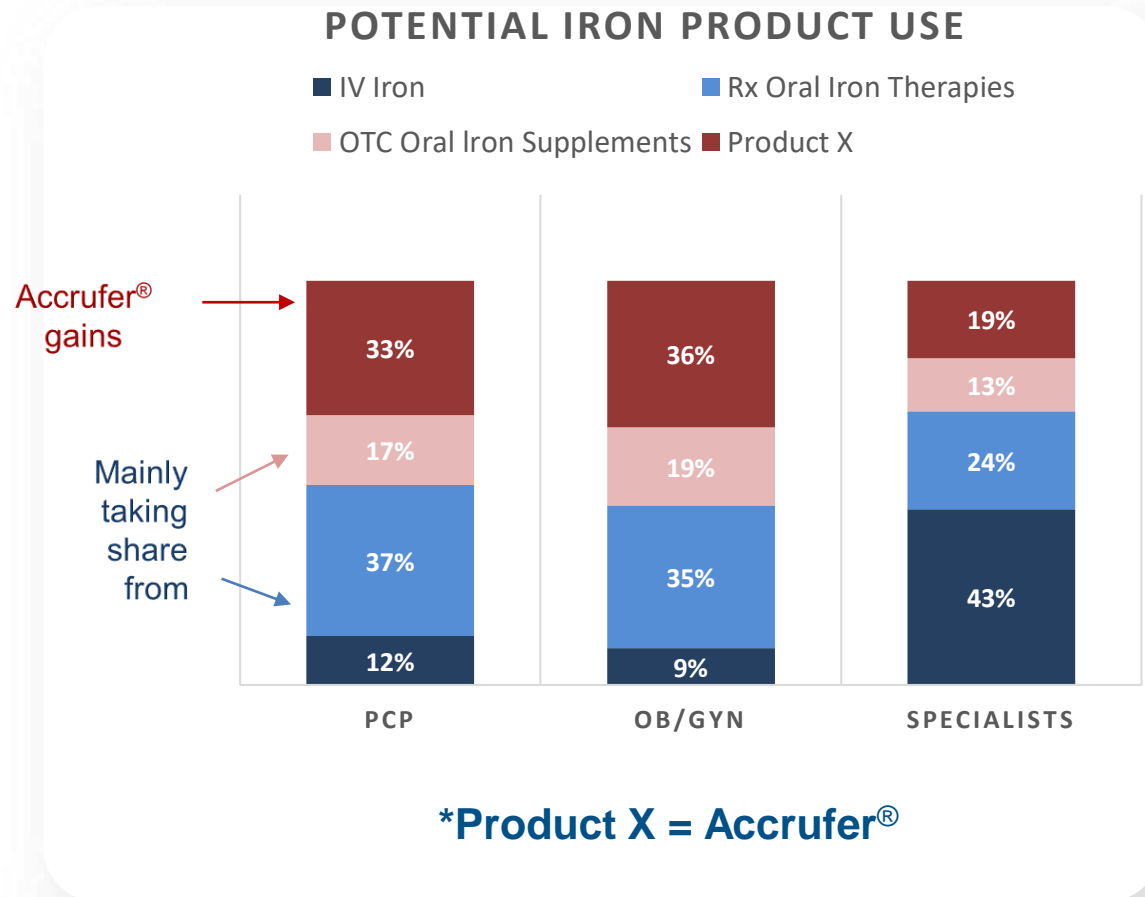
## Overall Reaction



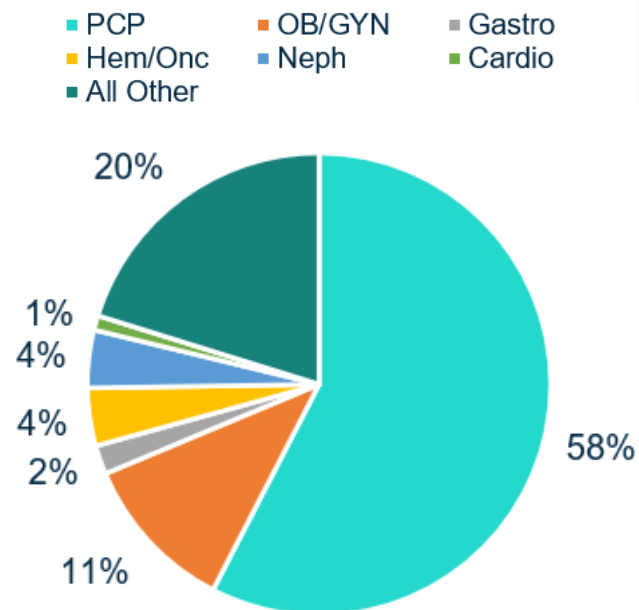
## Interest in Learning More



# HCP's Anticipate Robust Initial Use of Accrufer® Instead of Conventional Oral Irons in 1st or 2nd Line Position



# HCP Targeting Launch Strategy



**~70% of volume is driven by PCPs & OB/GYNs**

**~4K HCPs**  
~11% TRx Oral Market Volume  
30 sales reps in field in H2:2021 covering 4,000 high prescribing HCPs

**~61K HCPs**  
~55% TRx Oral Market Volume  
Additional reps to be phased in coinciding with increased payer coverage

Oral TRx Volume by Specialty

**550K HCP Universe**  
13.4MM (100%) TRx Oral Market Volume

# Accrufer® Strategic Map



**Long Term Future:** Brand Leader in Oral Iron Therapy

# HCP Multi-Channel Engagement

## Media & Digital Platforms

Objective: drive brand awareness & education

Utilize media mix to reach clinicians

- Targeted Display
- Search
- Newsletters
- Endemic Site Placements
- Content Sponsorships
- EMR/EHR

Full media plan began 10/1/2021



Medscape

doximity

epocrates®



AD+PRIME

Google

NEJM  
GROUP

SKIPTA  
OUR SPECIALTY IS CONNECTING YOURS

TI Health  
TARGETING INTELLIGENCE

BulletinHealthcare

RXNT

JAMA The Journal of the  
American Medical Association

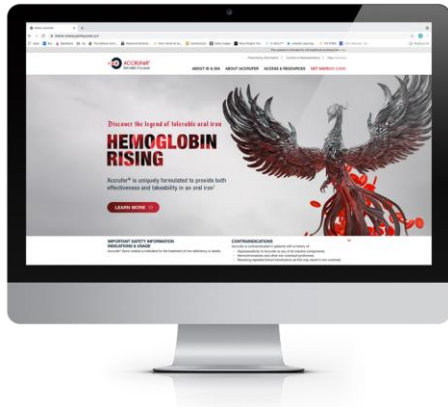


# HCP Promotion Snapshot

Leverage Current Creative Campaign with Segmented Message Platform to Drive Immediate Sales of Accrufer®

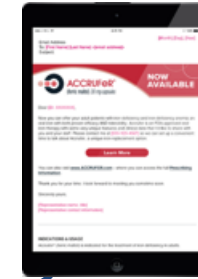
## Accrufer.com

Build upon existing website framework for engaging and informative experience



## CRM

Unify data, optimize engagement & access via direct mail, email, fax blasts, etc.



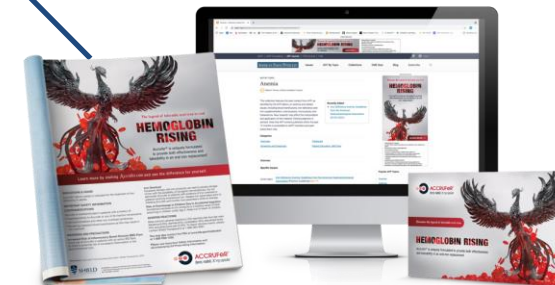
## Office Support

Keep Accrufer® top-of-mind with in-office reminder tools



## Non-Personal Surround Sound

Amplify the sales story with targeted media



## Digital Sales Tools

Development of suite of tools building upon 2021 approved assets for personalized sales call

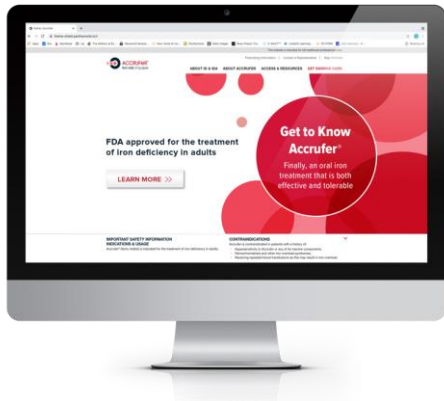


# Patient Launch Snapshot

Introduce Accrufer® as the Preferred Oral Iron Tx for Patients with ID and IDA

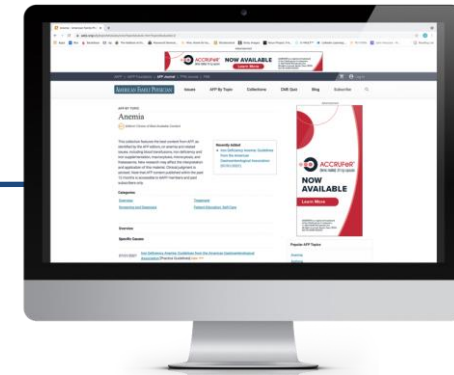
## Website Development

Development and launch of patient site including education materials, copay assistance and testimonial accounts.



## Media

Targeted digital and traditional media placements to drive brand awareness



## In-Office Patient Education Program

Empower patients to request samples and learn more about Accrufer® with compelling and strategically placed materials throughout PCP, GI, and OB/GYN offices



## Access Support

Minimize barriers to Rx fulfillment with customized, region-specific approach in messaging and materials available to patients



# Accrufer®: A \$2.2B U.S. Market Opportunity for Iron Deficiency

## Iron deficiency with or without anemia

- 15MM patients
- A major source of morbidity and mortality

## Adverse events associated with conventional oral iron are

driving an unsatisfactory cycle of switches and discontinuations

Accrufer® is an effective, well tolerated low-dose oral iron with an adverse event and discontinuation rate well below published 40-60% rate for conventional oral iron therapy.

## Estimated Peak Net U.S. Sales of \$500MM+ supported by:

- **Payor Coverage:** Expected to grow beyond 40MM+ covered lives
- **Positive Market Feedback:** HCPs are interested in using Accrufer® for 1<sup>st</sup> and 2<sup>nd</sup> line therapy
- **Commercial Plan:** Focused on the top 65K prescribers, mainly PCPs and OB/GYNs




## Ex-US Launch Adds Upside Attracting Key Partners to Drive Adoption and Revenue

International Brands: Feraccru®/Accrufer®

Target Geographies: EU, China, Korea,  
Japan, Canada



# Attractive Ex-US Deals Provide Upfronts, Milestones & Royalties

Partner	Geography	Upfront	Approval Milestone	Royalty on Net Sales	Sales Milestones	Status
	China, Hong Kong, Macau and Taiwan	\$11.4MM	\$11.4MM*	10-15%	Up to \$40MM	Phase 3
	Europe, Australia and New Zealand	\$14.5MM	N/A***	25-40%**	Up to \$58MM	Nominal royalty Updated commercial strategy to drive growth
	Republic of Korea	\$0.7MM	\$2.0MM*	15%	Up to \$5.5MM	Phase 3

# Near Term Value Inflection Points





# Investment Highlights

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for effective, well-tolerated iron replacement therapy for iron deficiency, a 15MM patients & 13.4MM annual prescriptions opportunity

## Potential Best in Class

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\$2.2B U.S. market opportunity  
Patent coverage thru 2035

# SHIELD THERAPEUTICS

**A Potential Best in Case Oral Iron Replacement Therapy**

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