SHIELD THERAPEUTICS PLC

Improving Lives Together

Proactive Investor 1-2-1 Forum

8 April 2021

Tim Watts, CEO

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Company Overview
&
Investment Highlights

Overview of Shield Therapeutics:

Revenue Generating Pharmaceutical Company Focused on the Treatment of Iron Deficiency

- **AIM-listed biotech company (STX.L)**
- **Primary focus is on developing and commercializing Feraccru®/Accrufer®**
  - A novel oral treatment for treating iron deficiency (ID) in adults
  - Approved in the USA and EU
  - £29m raised March 2021 to launch Accrufer® in the US
  - Commercialization out-licensed to:
    - Norgine (Q4 2018) – Europe, Australia and New Zealand - £11m upfront received
    - ASK Pharma (Q1 2020) – China, Taiwan, Hong Kong and Macau - $11.4m upfront received
  - Patent protection until 2035
- **Development pipeline**
  - Late state asset - PT20 (phosphate binder to treat hyperphosphatemia)
  - Requires one phase 3 study to submit a MAA in Europe and NDA in the USA
- **Organisation**
  - Small but experienced management team in UK
    - Corporate, non-US business development/alliance management, manufacturing & supply, clinical studies & regulatory affairs, IP
  - US commercial team established to launch Accrufer

Investment Highlights (1/2)

- Iron deficiency is a large, diverse and undertreated market
  - Prevalent in multiple therapy areas – IBD, CKD, oncology, cardiology, women's health
  - Existing oral and IV therapies have significant drawbacks of poor tolerability/effectiveness (oral) and cost/ inconvenience/risk of iron overload (IV)
  - US market size
    - ~10 million ID patients; ~5 million patients treated annually for IDA
    - >11 million US prescriptions annually

- There is a clear need for an effective, well-tolerated oral iron option

- Feraccru®/Accrufer® is a novel, oral, iron replacement therapy with patent protection to 2035

- Sales estimates generated internally and by management consultants/3rd parties support the potential for Accrufer® US sales to exceed $100m from the third year following launch and to reach $300m-$400m by years 5-6
  - $100m sales @90% gross margin and US costs $40m-$45m => $45m free cash flow
  - $300m sales @90% gross margin and US costs $40m-$45m => $225m free cash flow

Investment Highlights (2/2)

Current market capitalisation (~£100m) very significantly below analyst valuations

Analyst NPVs £m	USA £m	Europe/ China £m	Costs £m	Total £m	Comments
Hardman (January)	246[1]				Hardman assessed US NPV from 2021-2026 only in January
finnCap (March)	484	70		554	
Edison (March)				471	
Peel Hunt (March)	>>168[2]	116	(30)	>>254	Peel Hunt noted stated that they would update forecasts onto Shield launch basis after 2020 results announcement but that will be significant upside to previous £254m valuation based on out-licence assumption

(1) US NPV from 2021-2026 only
(2) US NPV on out-licence basis. To be updated to Shield-launch basis after 2020 results released

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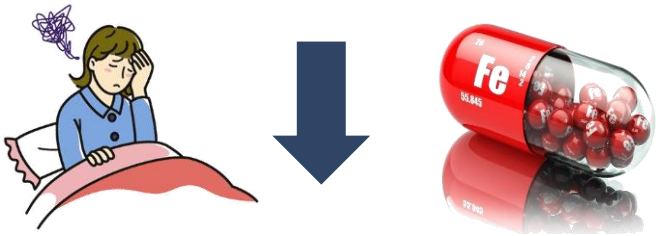
Feraccru ® /Accrufer®

Attributes & positioning

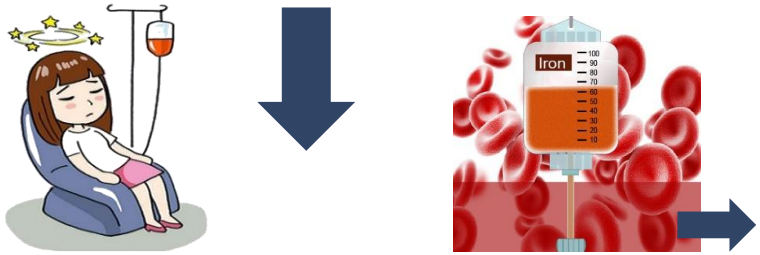
Current Iron Deficiency Treatment Paradigm: Significant Unmet Needs

Patient diagnosed with iron deficiency

1st line treatment – oral iron salts



2nd line treatment – hospital/clinic-based IV infusion



Unmet Need

- **Oral:**
- Mostly salt-based iron compounds
  - \+ Inexpensive generics
  - \+ Convenient to take
  - – Poor tolerability in the gut
  - – Less efficient absorption
  - – Slower efficacy
  - – Poor compliance

- **Intravenous (IV):**
- Used mainly in patients intolerant of oral therapies
  - \+ Increases iron levels quickly
  - \+ Better bioavailability/absorption
  - \+ No compliance issue
  - – Requires hospital administration
  - – Inconvenient
  - – Risk of iron overload
  - – Risk of allergic reaction
  - – Risk of infection
  - – Expensive

Three Phase III studies have demonstrated Feraccru®/Accrufer®'s effectiveness, tolerability and convenience

Studies in IBD and CKD patients compared Feraccru®/Accrufer® against placebo. These showed effectiveness, safety and tolerability and were the basis of the product's approval in Europe and the US

AEGIS H2H (head-to-head) compared Feraccru®/Accrufer® against IV iron:

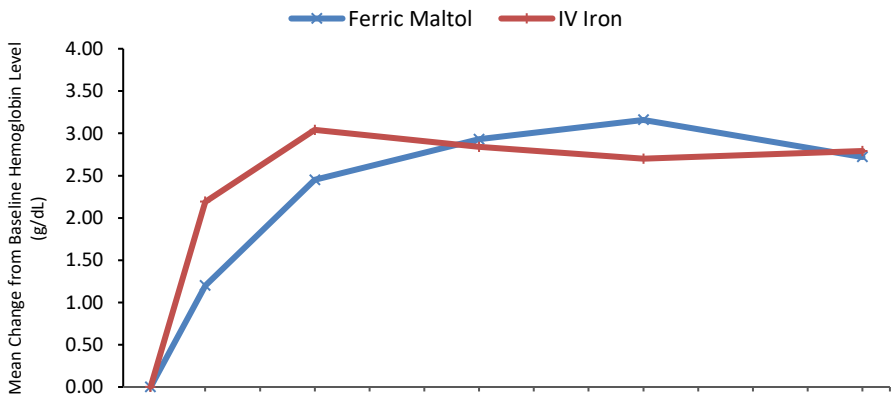
By week 12 (first phase):

- Mean increase in Hb levels:
  - Accrufer: 2.45 g/dL; Injectafer: 3.04 g/dL
- % of patients who had responded to treatment (as defined in protocol) by week 12:
  - Accrufer: 67%; Injectafer: 84%
- 82% of IV patients received more than one infusion during the first 12-weeks of the study

Long term phase:

- At weeks 24, 36 and 52, the mean increases in Hb levels in those patients still being monitored :
  - Accrufer: 2.93 g/dL, 3.16 g/dL and 2.72 g/dL
  - Injectafer: 2.84 g/dL, 2.70 g/dL and 2.79 g/dL
- 58% of the Injectafer patients who were monitored from the week 12 visit required at least one further IV infusion

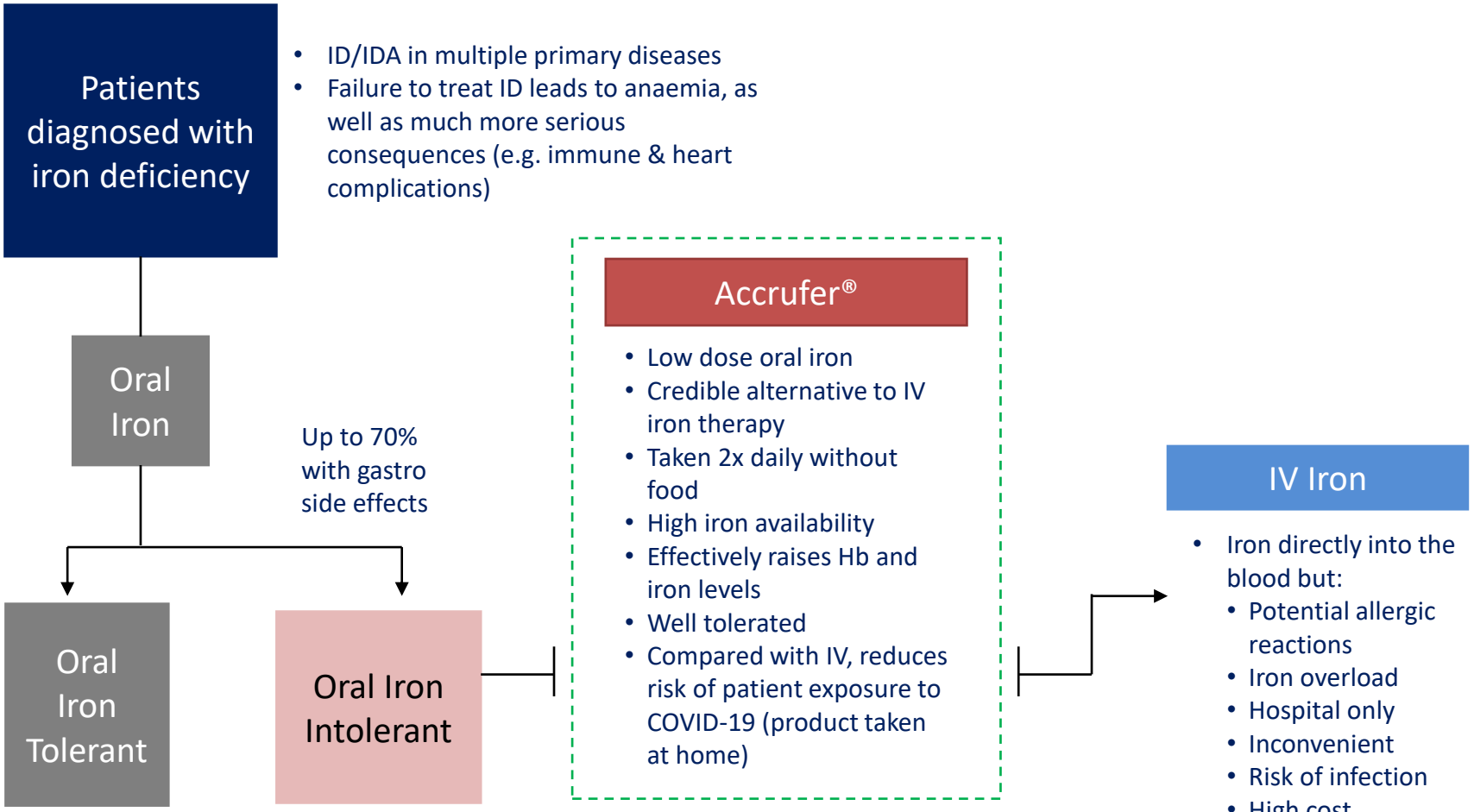
Mean Change from Baseline Hb Concentration rise seen in the ITT population



Number of eligible patients:	Day 0	Week 4	Week 12	Week 24	Week 36	Week 52
Ferric maltol	125	123	115	92	72	61
IV FCM	125	121	118	91	67	56

Although the H2H study did not demonstrate non-inferiority of Feraccru®/Accrufer® to IV iron at the 12 week visit, the mean increase in Hb of 2.45g/dL is clinically meaningful. And from weeks 12-52, Feraccru®/Accrufer® maintained Hb levels effectively and conveniently

Feraccru®/Accrufer® positioning - can address both oral and IV segments of the market



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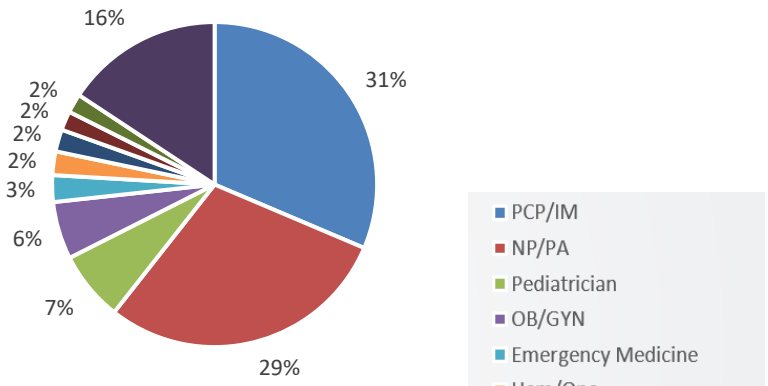
US Market Opportunity

Accrufer® Market Opportunity Overview

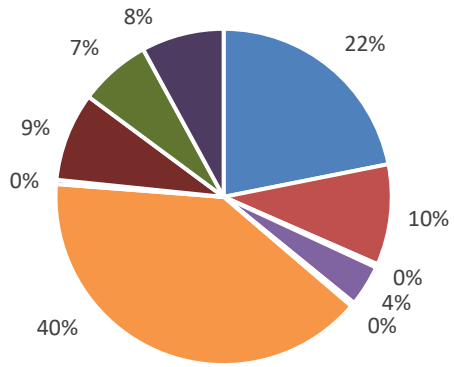
- **Iron deficiency is a large, diverse and undertreated market**
  - ~10 million ID patients in US: ~5 million patients treated annually for IDA
  - Existing 1st line therapies are poorly tolerated iron salts: ~10-11 million TRx annually
  - 2nd line therapy is intravenous (IV) iron which is inconvenient for patients with expensive administration costs
    - ~ 2.3 million doses yearly
    - Annual IV iron sales ~$1.2 billion
- **Prescriber market research highlights the need for an effective, well-tolerated oral iron option**
- **Payer market research indicates that Accrufer should have few restrictions at WAC (gross price) of ~$500/pack (1 month's supply containing 60 capsules)**
- **COVID-19 is changing healthcare delivery and recommendations for the care of at-risk patients**
  - Increased use of telemedicine
  - Recommendations to consider home treatments and/or switching patients from IV to oral therapies to minimize exposure

Large Number of HCPS Writing for Oral Iron but a Much Smaller Number Writing for IV Iron

Total Number of HCPs Writing Oral Iron by Specialty (n=~460,000)



Total Number of HCPs Writing IV Iron by Specialty (n=~11,500)



Target the Highest Rx Writers and Most Productive Specialties* for Oral Iron (D8-D10)

- ~11,000 Rx writers account for 30% of TRx (D8-D10)
  - Represent only ~3% of total target writers
  - Average 252 TRx per year per writer
    - D1-D7 writers average only 15 TRx
  - Almost 100 “super writers”
    - 1,000+ TRx annually
- **Therefore, ~ 60 sales reps can cover 80%+ of the target list**

* Target HCP Specialties Defined as: Gastroenterologists, Hematologists/Oncologists, OB/GYNs, Nurse Practitioners & Physician Assistants and PCPs (including FPs, GPs, PCPs and IMs)

Accrufer® US sales potential

Sales estimates generated by management consultants/3rd parties support the potential for Accrufer® sales to exceed $100m from the third year following launch and to reach $300m-$400m by years 5-6

- At approximately $1,000 per patient per year (assuming 4 packs per year, $250 net price per pack[1])…
- …net sales of $100m pa equate to 100,000 patients treated or 400,000 prescriptions
  - only 2% of 5 million US IDA patients treated annually

Substantial cash generation potential

- 90% gross margin, after manufacturing costs and Vitra[2] 5% royalty
- Year 3 US SG&A costs forecast to be ~$40m-$45m
- Implied cash generation
  - $100m net sales => ~$45m free cash
  - $300m net sales => ~$225m free cash
- Expect to take 15-18 months from launch to breakeven on monthly basis

1. Net sales expressed after assumed 50% gross to net deductions
2. Vitra Ltd was original owner of ferric maltol IP and is entitled to a 5% royalty on net sales under terms of 2010 agreement

US launch preparation

- Shield Therapeutics Inc. (STI) legal entity established with bank account, payroll provider, etc
- Brian Groch and his three original consultant colleagues (covering marketing, medical affairs and operations) are now STI employees
- Further recruitment underway, and some appointments already made, for key positions in marketing, medical science liaison (MSLs), market access, and operations (e.g. logistics, data management)
- Sales force and National Account Managers likely to be outsourced initially – contract discussions with providers are reaching conclusion
- Master Service Agreements and Work Orders being negotiated and concluded with suppliers covering activities such as advertising, medical communications, logistics, supply chain reporting, digital marketing platform, etc
- US launch packs likely to be QC released imminently by manufacturer and shipped to US by end-April
- Planning to launch by end Q2 2021

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Summary

Summary

- There is a clear need for an effective, well-tolerated oral iron option
- Feraccru®/Accrufer® is a novel, oral, iron replacement therapy with patent protection to 2035
- Large market opportunity, especially in US
- Shield's current market capitalization underpinned by licence deals covering Europe and China
- Very substantial upside from US opportunity

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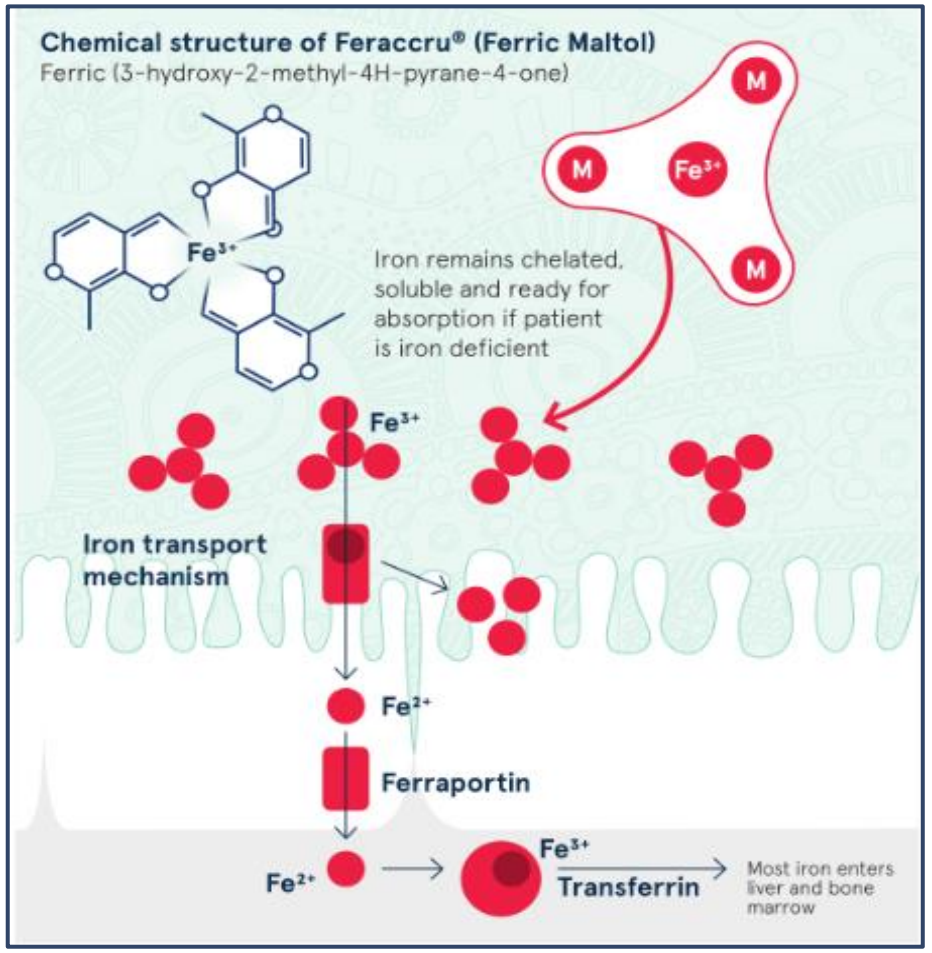
Back Up

Accrufer® (Ferric Maltol) is Uniquely Positioned to Address Unmet Needs in Iron Deficiency Patients

- **Accrufer® is a low dose (30mg BID) oral formulation of a non-salt complex of Fe^{3+}, which is stable in the GI tract:**
  - Other oral irons are salts, and require the Fe to dissociate to be absorbed
  - This leads to formation of insoluble products in the GI tract, causing intolerance in patients, which is one of the main reasons behind discontinuation/dissatisfaction with oral therapy
- **The Fe^{3+} in Accrufer® remains in complex with maltol until absorbed and iron is delivered into the bloodstream where it binds to transferrin:**
  - Maltol is metabolised and excreted in urine
  - Unabsorbed Accrufer® passes through the digestive system in the benign complex and is excreted in feces
- **Accrufer® is a well tolerated, oral iron replacement therapy, with its long-term efficacy profile comparable to that of IV iron replacement therapy**
- **An Accrufer® pack contains 1 month's supply**

Accrufer® Mechanism of Action



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Europe/China

Paediatric study

Intellectual Property

Feraccru® in Europe & China

Europe

Licensed to Norgine (September 2018)

- £11m upfront received
- Sales royalties 25%-40% (Shield pays cost of goods)
- Sales milestones – up to €50m
- On market in Germany, UK, Scandinavia and Belgium
- 2020 sales volumes in Germany/UK up 70% vs 2019 - £0.7m royalties
- Norgine using Head-to-Head Phase III study results to reconfirm pricing & reimbursement strategy in France, Italy and Spain

China

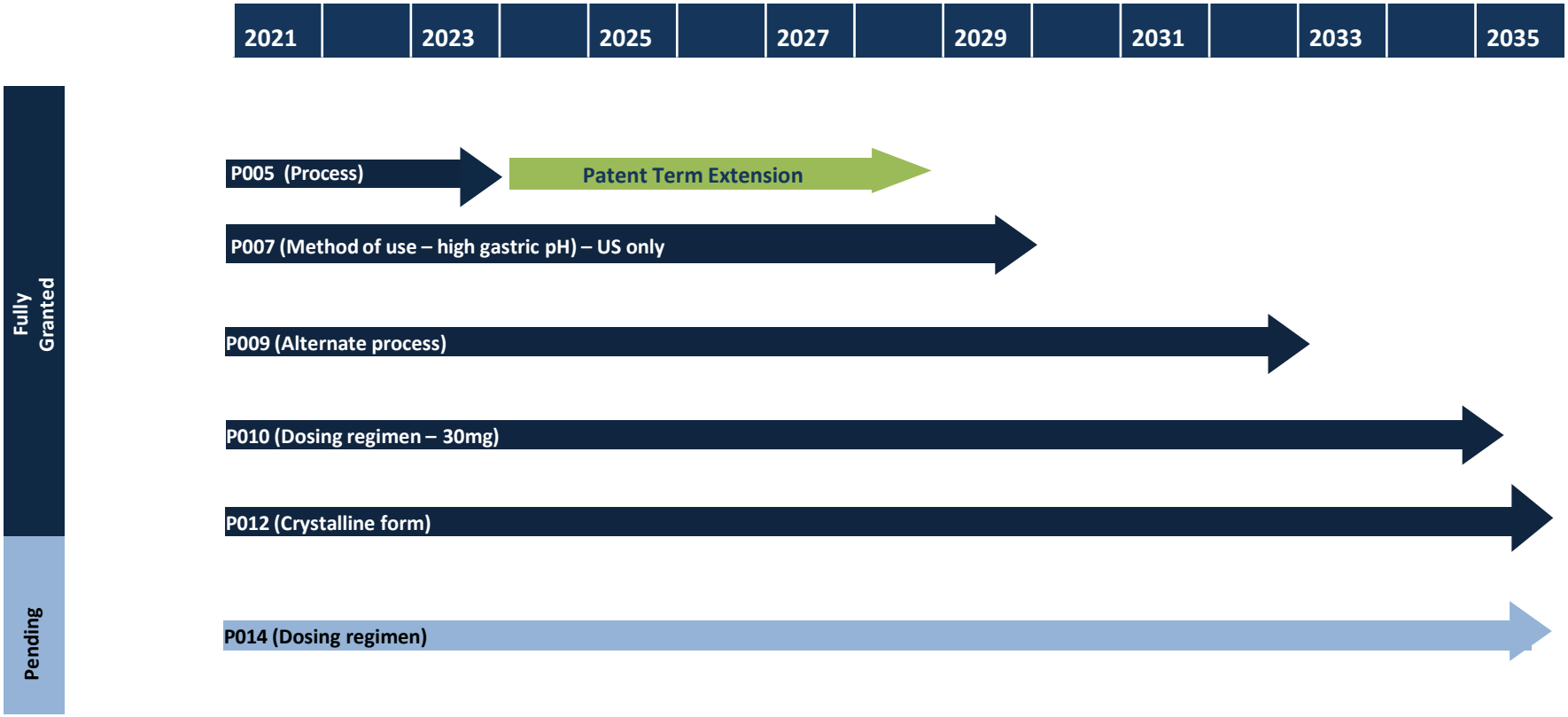
Licensed to ASK Pharm (January 2020)

- $11.4m upfront received
- IND application submitted - likely to require only one Phase III 12-week study in 120 IBD patients
- Potential approval & launch in 2023
- $11.4m milestone due on approval
- Sales royalties 10%-15% (ASK pays cost of goods)
- Sales milestones – up to $40m

Paediatric study

- A post-approval requirement of both EMA and FDA is to evaluate safety and tolerability (primary end points) of Feraccru®/Accrufer® in infants, children and adolescents
  - Secondary endpoints include change in Hb concentration and achieving Hb concentration within normal range by Week 12
- A liquid formulation has been developed and been successfully tested in healthy adult volunteers for equivalence with the capsule (Stage 1)
- The main study (Stage 2) is expected to start recruiting 110 subjects in Summer 2021
- Stage 2 forecast to cost around £4.5m and take 2- 2½ years
- Successful outcome expected to lead to label expansion to include children

Accrufer® / Feraccru® Patent portfolio



- Orange Book listed patents are P007, P010, P012.
- Patent Term Extensions have been applied for patents P005, P007, P009, P010, P012, Shield would elect to extend patent P005 if PTE granted.

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