SHIELD THERAPEUTICS PLC

Improving Lives Together

Preliminary results for the year ending

31 December 2020

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2020 operational highlights (including post-period end)

During 2020

- Feraccru® licensed to ASK Pharm in China
- AEGIS-H2H re-analysis confirms Feraccru®/Accrufer® is a credible alternative to IV therapy for iron deficiency anaemia
- Teva withdraw all oppositions to Shield's European patents
- 2020 sales of Feraccru® packs increase by 70% in Germany and UK compared with 2019
- First stage of paediatric study conducted successfully

Post period end

- £29 million gross proceeds raised by means of placing, subscription and open offer
- Decision made for Shield to launch Accrufer® in US

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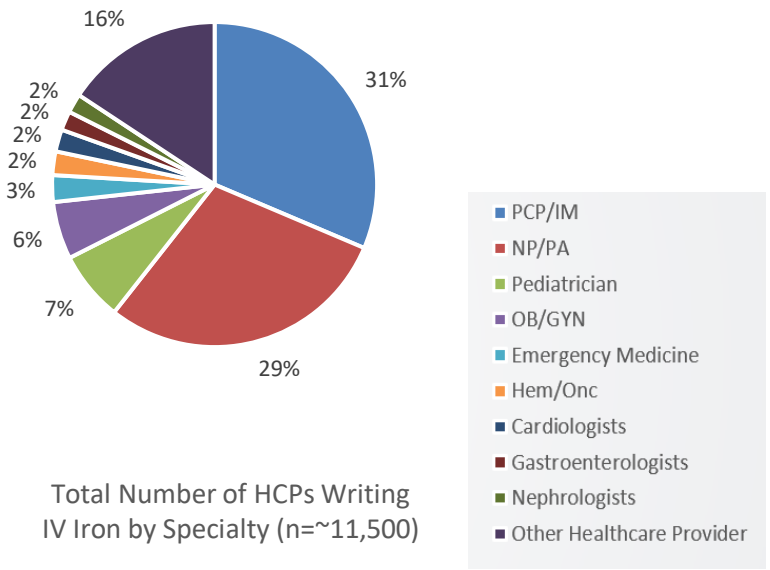
US opportunity

Accrufer® Market Opportunity Overview

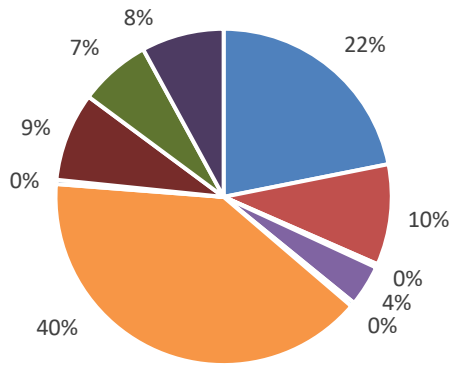
- **Iron deficiency is a large, diverse and undertreated market**
  - ~10 million ID patients in US: ~5 million patients treated annually for IDA
  - Existing 1st line therapies are poorly tolerated iron salts: ~10-11 million TRx annually
  - 2nd line therapy is intravenous (IV) iron which is inconvenient 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 minimise exposure

Large Number of Healthcare Professionals ('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)

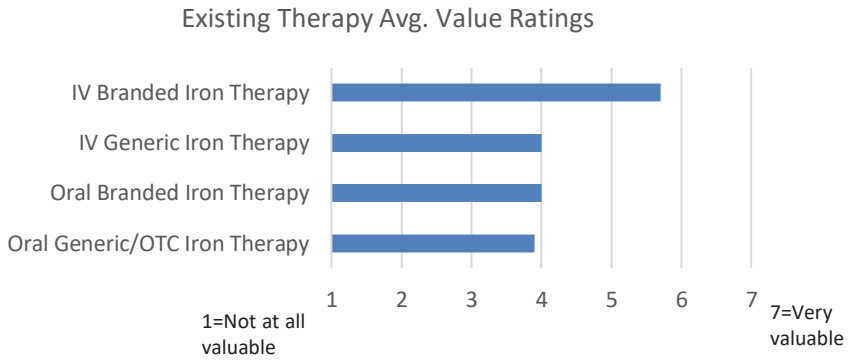
- ~11,000 Rx writers account for 30% of TRx (D8-D10)
  - Represent only ~3% of total target writers
  - Average 252 TRx per year per writer
    - D1-D7 writers average only 15 TRx
  - Almost 100 "super writers"
    - 1,000+ TRx annually
- **Therefore, ~ 60 sales reps can cover 80%+ of the target list**

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

Market Research[1] & Competitor Data[2] Confirm the Unmet Need

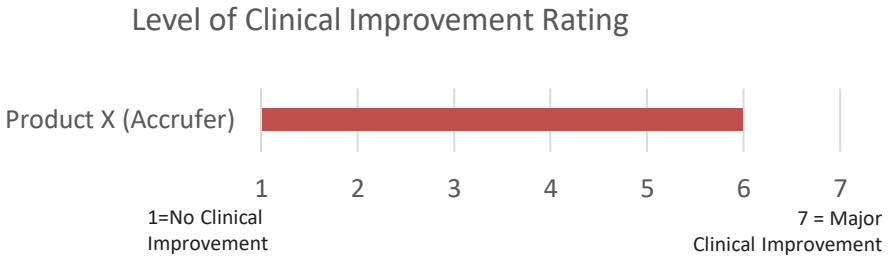
Physicians believe there is an unmet need in the market…..

- Iron replacement therapy is generally considered an area of unmet need
- Key needs are effectiveness and GI tolerability



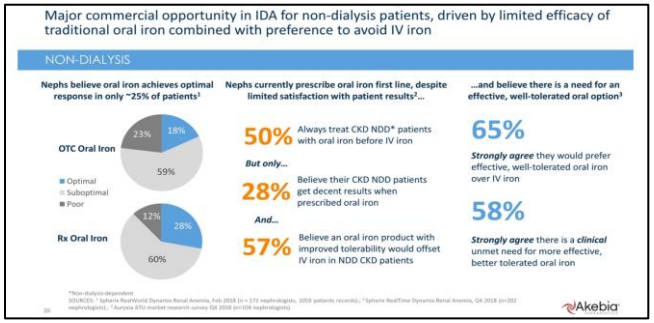
….and see Accrufer® as delivering a high level of clinical improvement over existing therapies

- Accrufer® was viewed favorably as a clinically meaningful improvement
  - Good **tolerability** profile and **efficacy** data are key benefits
  - Potential first line use if allowed by insurance plans



Competitors have also outlined the need for an effective, well tolerated oral option

- Auryxia® (Akebia) tablets, completed market research for IDA in non-dialysis CKD patients, demonstrated a clear unmet need for a better oral iron



1. MME: Accrufer PRMA Opportunity for United States. June 2020. 8 physicians (3 Nephrologists, 3 Gastroenterologists, 2 OB/GYN and 2 Hematology/Oncology)
2. Akebia Therapeutics 2019 Current Report 8-K dated January 7, 2019

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

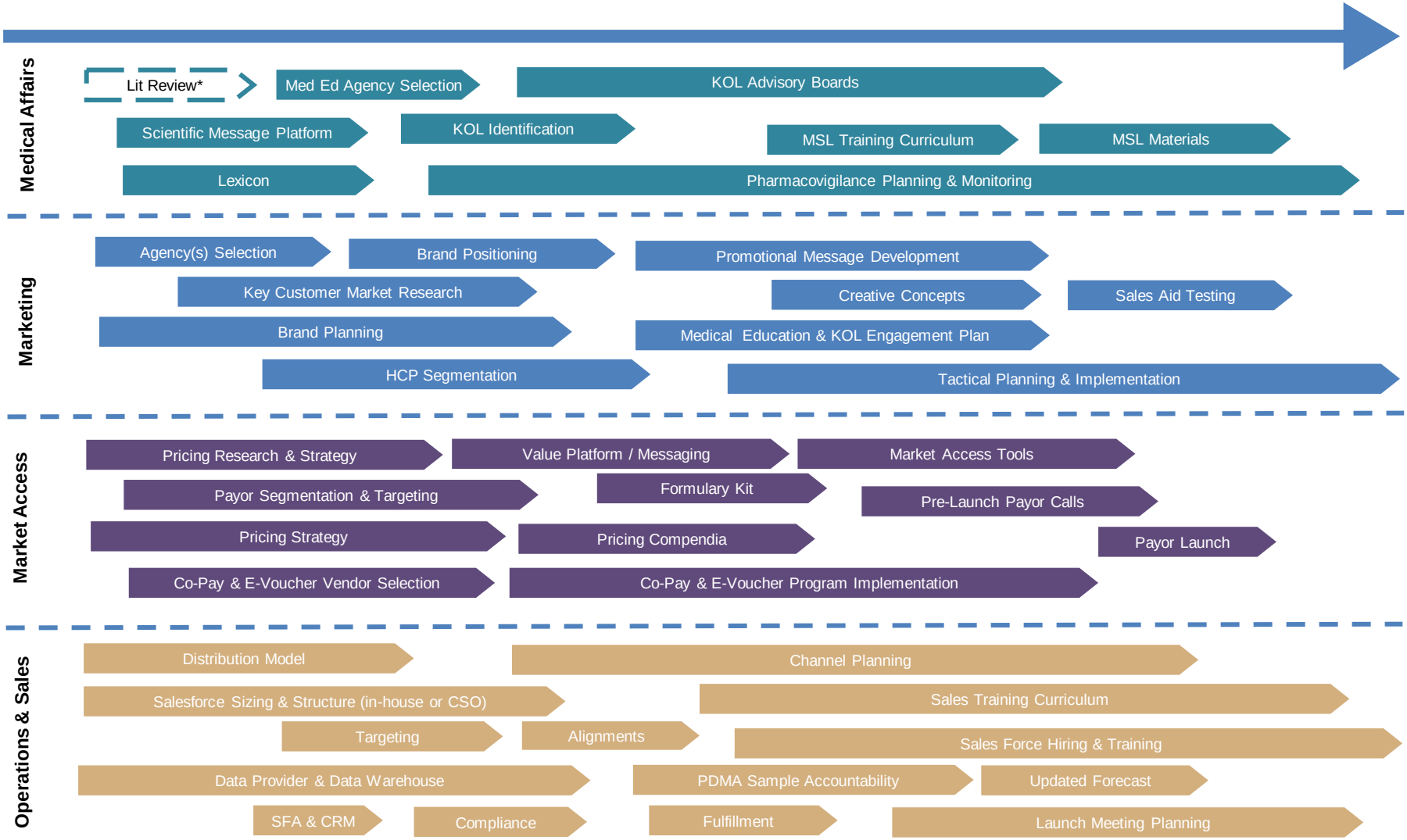
- At approximately $1,000 per patient per year (assuming 4 packs per year, $250 net price per pack[1])…
- …net sales of $100m pa equate to 100,000 patients treated or 400,000 prescriptions
  - only 2% of 5 million US IDA patients treated annually

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

Planning for a Successful US Launch of Accrufer®:
Major Work Streams in Process



Representative of major work streams for overall launch. It is not meant to provide an exact timing of project initiation or completion.

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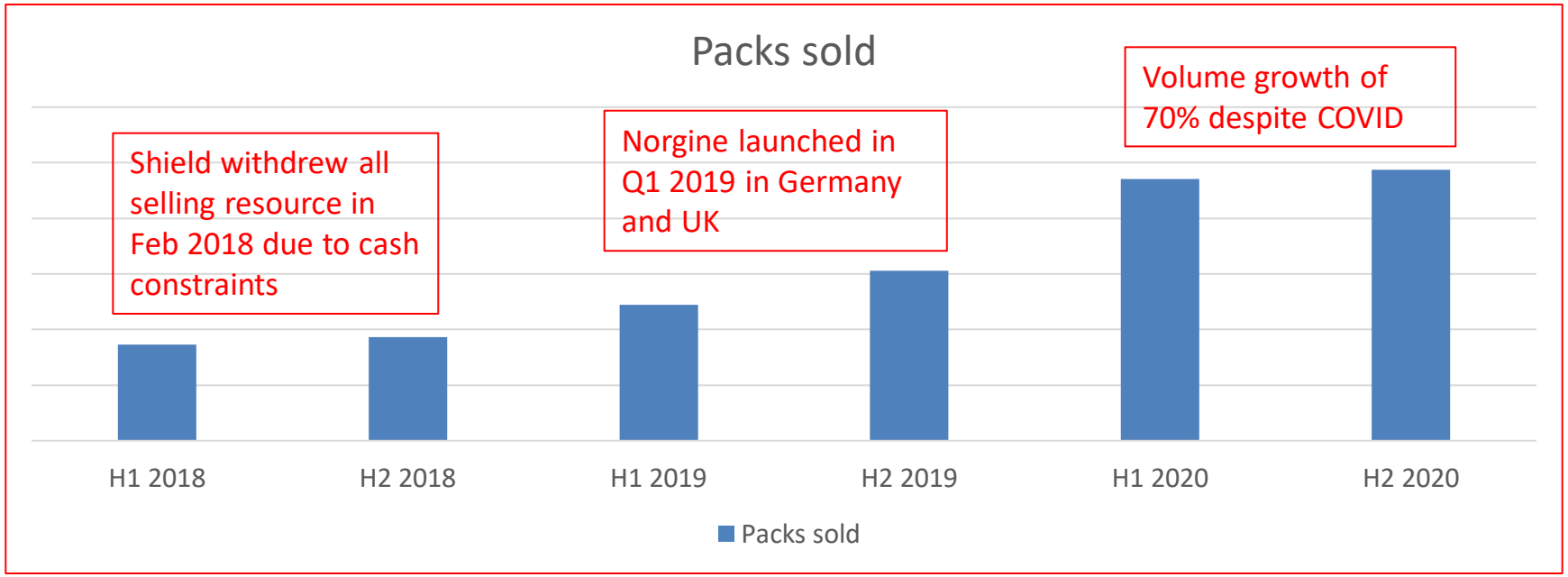
Feraccru® outside USA

Europe

- Feraccru® is now marketed by Norgine in Germany, UK, Scandinavia (since Q4 2020, previously AOP) and Belgium (since January 2021)



- Norgine and Shield are working together to evaluate the optimal way to use the AEGIS-H2H study data to support pricing and reimbursement applications in France, Italy and Spain

Australia, China and other markets

Australia

- Norgine also have commercialisation rights in Australia and New Zealand
- In March 2021 Feraccru® became listed in the Australia Register of Therapeutic Goods. Pricing negotiations will take place during 2021

China

- ASK Pharm will complete development and commercialise in China, Taiwan, Hong Kong and Macau
- $11.4m upfront received on signing (Jan 2020)
- ASK have submitted NDA to CDE (Chinese regulatory authority)
  - Ongoing discussions with CDE suggest that one Phase III study will be required in ~120 IBD patients
  - Potential marketing approval by end-2023
  - $11.4m development milestone due to Shield on approval
- Clinical study supplies of Feraccru® have been shipped to China
- Chinese patent office have allowed our composition of matter patent providing protection until 2035

Other markets

- Currently in active discussions with potential licence partners in three separate countries
- One potential transaction is at licence documentation stage, the other two are at earlier stages

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R&D

AEGIS H2H study results

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

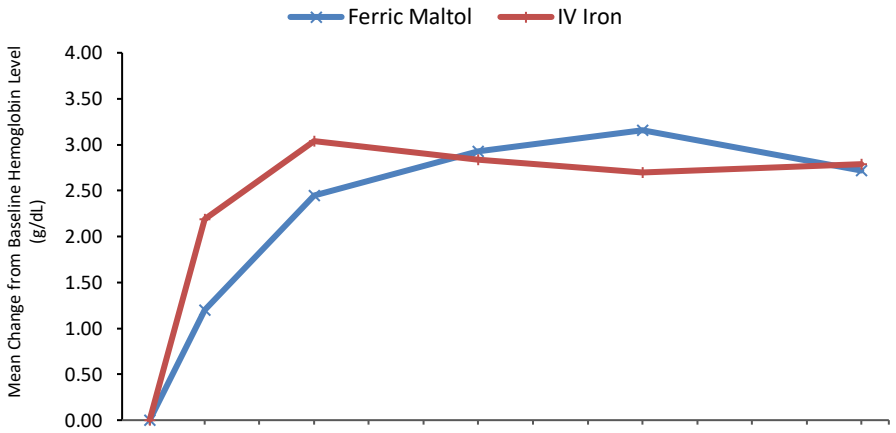
By week 12 (first phase):

- Accrufer demonstrated a clinically meaningful increase in Hb levels:
  - Mean increase in Hb levels:
    - Accrufer: 2.45 g/dL & Injectafer: 3.04 g/dL
- Percent of patients who had responded to treatment (as previously defined) 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 (using the ITT results):

- 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

"Total per patient drug costs were approximately 1.6 times higher for treatment with IV than ferric maltol" – quote from paper published in Journal of Crohn's and Colitis based on treatment in German healthcare setting

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
- An age-appropriate suspension 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

PT20 – a treatment for hyperphosphatemia

- Elevated phosphate levels in the blood is a ubiquitous complication of moderately and severely reduced kidney function
- Standard of care for phosphate control remains the prescription of phosphate binders. Older phosphate binders suffer from side effects, poor tolerance and lack of effectiveness.
- Latest generation products are iron-based
  - Velphoro ~$480m global 2020 in-market sales
  - Auryxia ~$129m US 2020 sales

  but older polymer-based products Renvela and Renagel still sold ~$282m globally in 2020
- PT20 is a novel formulation iron-based phosphate binder which enhances phosphate binding and reduces side effects compared with Velphoro and Auryxia
- PT20 has completed one Phase II pivotal study and now requires one further Phase III pivotal study to allow a NDA to be filed
- CRO identified to develop a commercially-suitable formulation of PT20 which will be used in the Phase III study – anticipated cost ~£500k over 12-18 months

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Financial Highlights

2020 financial highlights

- Revenues of £10.4 million (2019: £0.7 million)
  - £9.7m from ASK Pharm
    - $11.4m (£8.7m) licence upfront received grossed up by £1m re withholding tax borne by ASK Pharm (added to tax charge so no net impact)
  - £0.7m from Norgine re European sales
- Loss for the year of £2.6 million (2019: £8.8 million)
- Net cash of £2.9 million (2019: £4.1 million)

March 2021

- £29.2 million gross proceeds (£27.8 million net of expenses) raised by means of placing, subscription and open offer

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Outlook & Newsflow

Outlook & Newsflow

Commercial

- US launch of Accrufer® planned for June 2021
- Further country launches of Feraccru® in Europe towards end 2021/early 2022
- Potential further commercialisation out-license transactions during 2021

Development

- Start of paediatric Stage 2 in summer 2021
- Start of PT20 formulation work during 2021

Financial

- US sales to start growing during H2 2021
- Significant US cost ramp-up during 2021
- R&D costs in 2021 of £2.5m-£3m as paediatric study and PT20 formulation work get underway
- Steady growth in Europe royalties

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Appendix

Results: P&L

£'000	2020	2019
Revenue	10,387	719
Gross Profit	9,033	234
Selling, General & Admin*	(8,608)	(6,773)
Research and development	(2,579)	(2,496)
Operating loss	(2,154)	(9,035)
Financial income/(expense)	268	(31)
Loss before tax	(1,886)	(9,066)
Taxation	(744)	266
Loss for the year	**(2,630)**	**(8,800)**

* includes £2,705k depreciation and amortisation (2019: £2,621k)

Results: Balance sheet

£'000	31 Dec 2020	31 Dec 2019
Intangible assets & PPE	27,298	29,924
Inventory & receivables	2,290	2,254
Cash	2,940	4,141
Total assets	**32,528**	**36,319**
Current liabilities	(2,252)	(4,174)
Net Assets	**30,276**	**32,145**

Results: Cashflow

£'000	2020	2019
Cashflow from operating activities	(1,400)	(4,066)
Cashflow from investing activities	(20)	(1,366)*
Cashflow from financing activities	(47)	(203)
Net decrease in cash	(1,467)	(5,635)
Cash at start of period	4,141	9,776
Currency gains	266	-
Cash at period end	2,940	4,141

* mainly capitalised R&D