SHIELD THERAPEUTICS PLC

Improving Lives Together

Interim results for the six months ended 30 June 2020

September 2020

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Operational Highlights (including post-period end)

- Licence agreement signed for Feraccru®/Accrufer® with Jiangsu Aosaikang Pharmaceutical Co. Ltd ("ASK Pharm") covering China, Hong Kong, Macau and Taiwan

- Net sales of Feraccru® in Europe for first 6 months of 2020 up 50% over previous 6 months

- Re-analysis of the AEGIS-H2H study data demonstrates that Feraccru®/Accrufer® is a credible alternative to IV iron therapy and offers economic advantages

- Continued progress being made to secure a US commercialisation partner

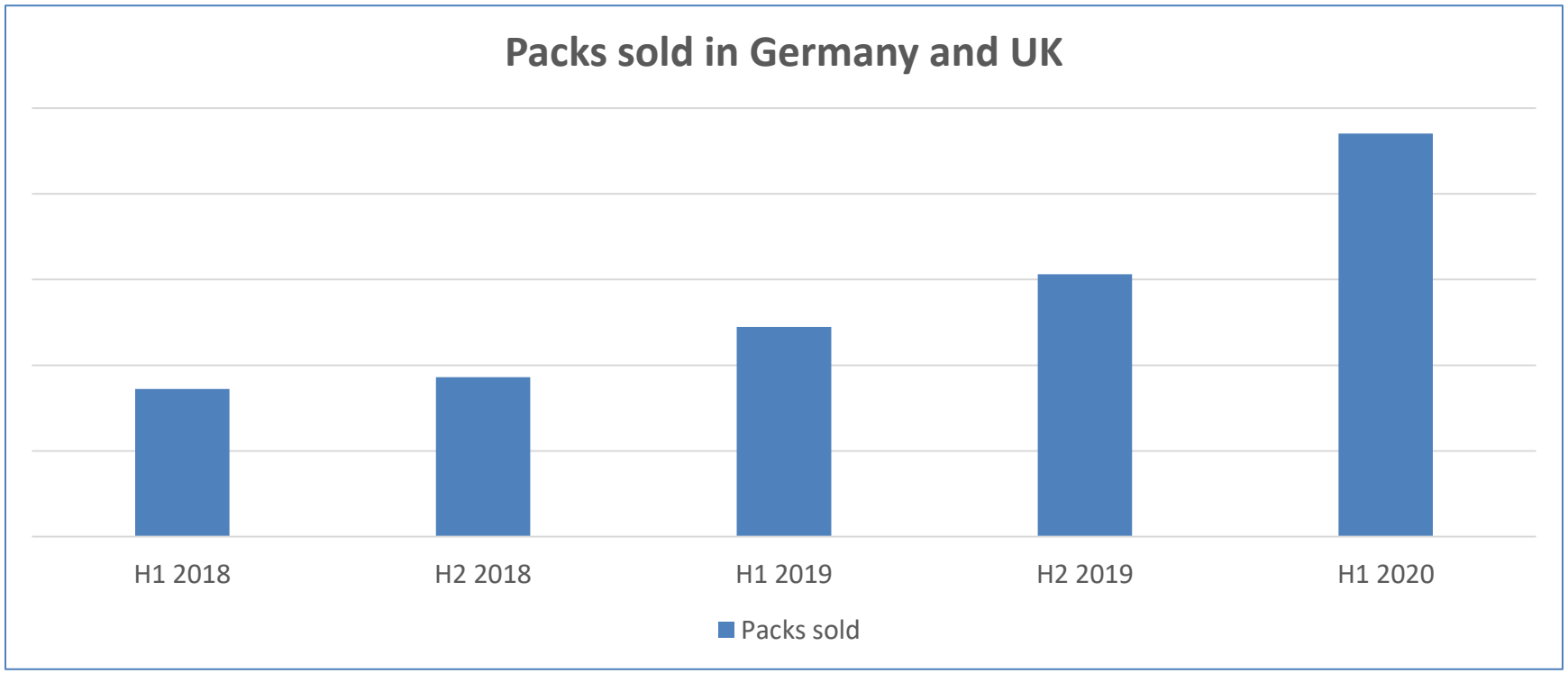
China commercialisation – ASK Pharm*

- Exclusive licence to develop and commercialise Feraccru® in China, Hong Kong, Macau and Taiwan
  - $11.4 million upfront licence payment
  - $11.4 million development milestone on regulatory approval
  - Up to $40 million in sales milestones
  - Tiered royalties of 10% or 15% depending on level of sales

- ASK Pharm have been working with CDE (Chinese regulator) to define the development programme required
- CDE have indicated it may require only a Phase III study in inflammatory bowel disease and that neither a pharmacokinetic study nor a Phase III study in chronic kidney disease (CKD) will be required
- If confirmed, this could lead to a NDA submission in H1 2022 and potential launch in H2 2023

Europe commercialisation

Net sales of Feraccru® in Europe for first 6 months of 2020 up 50% over previous 6 months

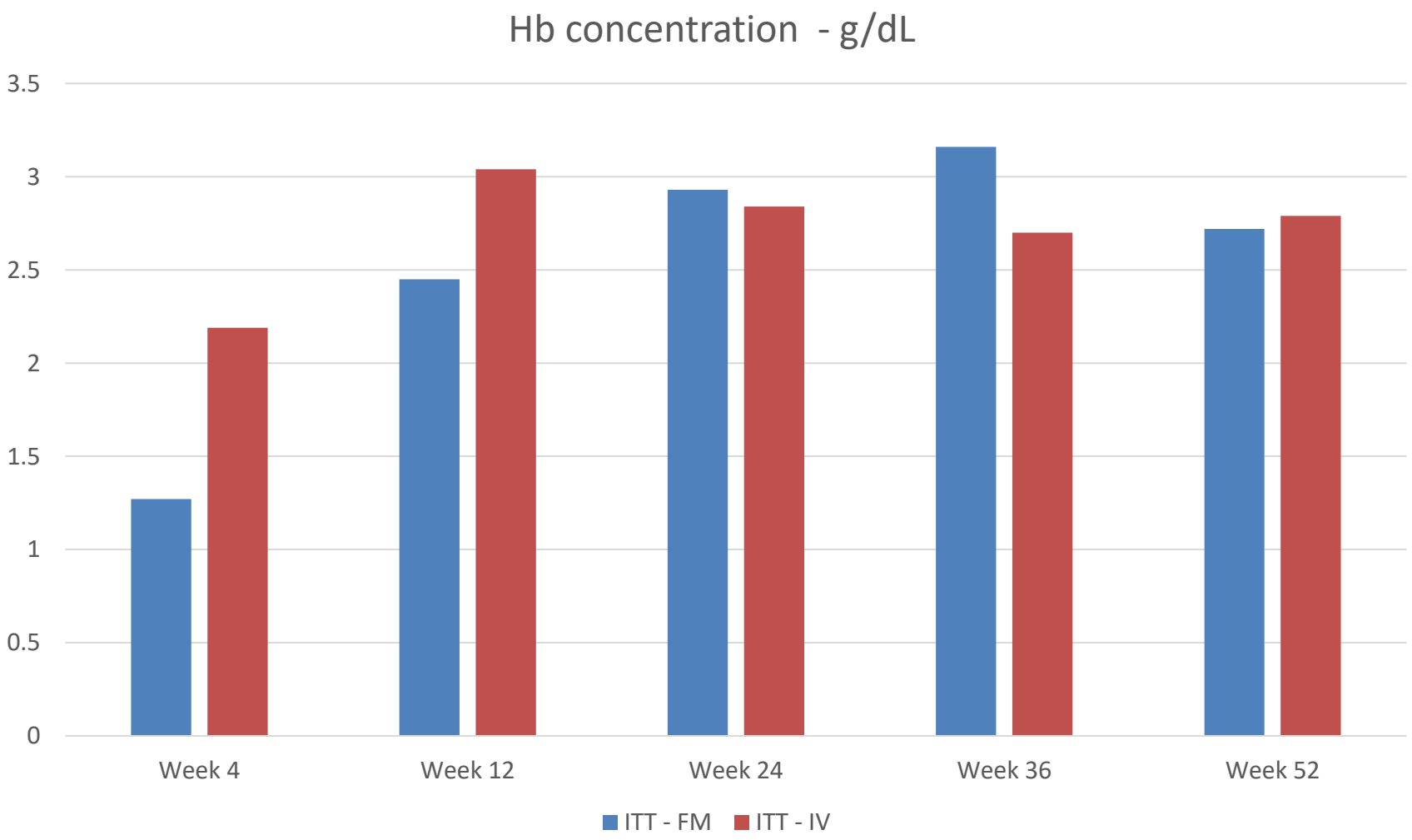


Pricing & reimbursement submissions in France, Italy, Spain and other EU markets will re-start as soon as amended H2H Clinical Study Report is available, expected October 2020. Launches in these countries expected from late 2021 onwards.

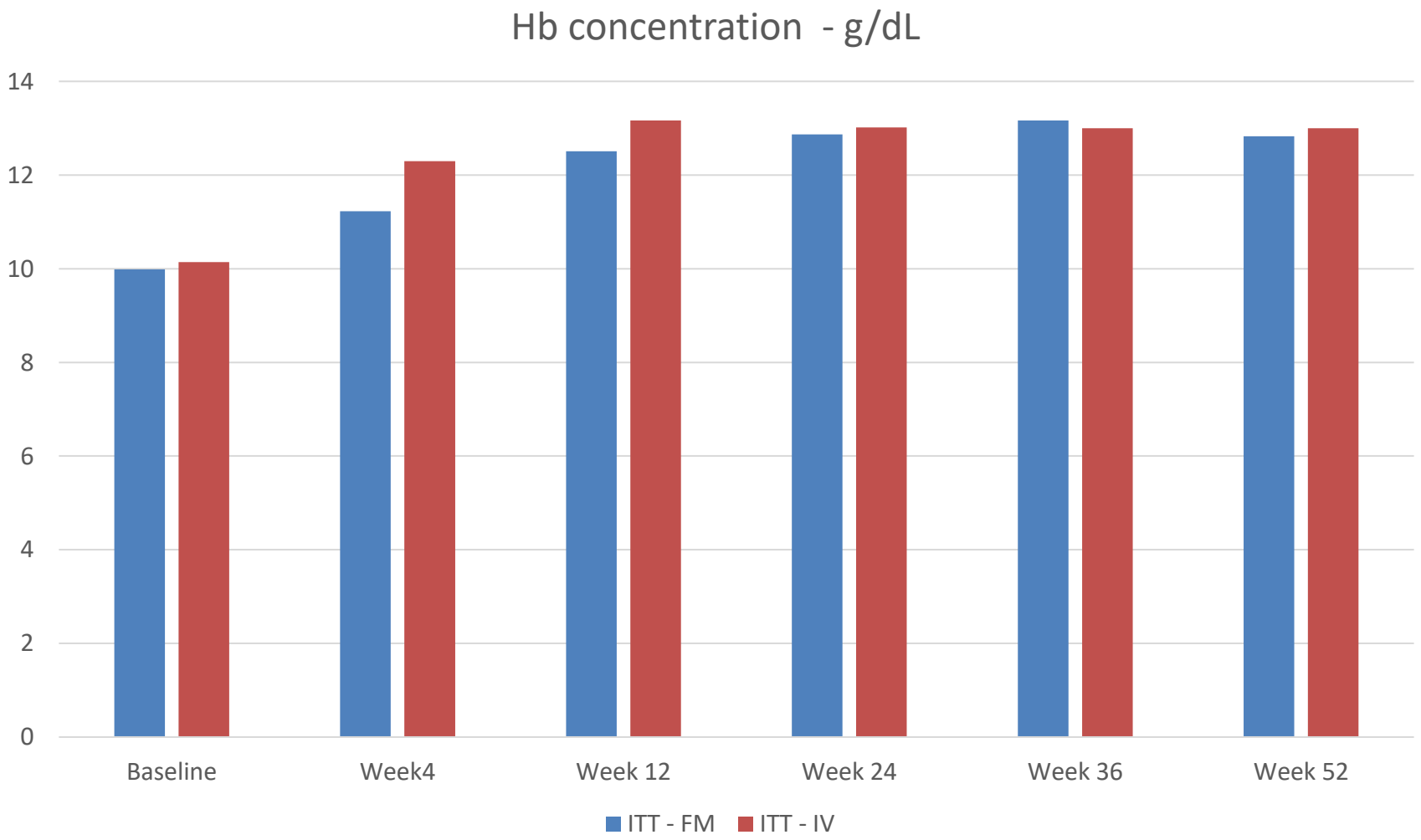
AEGIS-H2H (Head-to-Head)

- Comparison of patients treated with Feraccru® compared with intravenous (IV) iron therapy
- Study intended for health economics, pricing and reimbursement (not a regulatory study)
- Primary “non-inferiority” endpoint defined as % of “responders” at 12 weeks but patients were followed over 52 weeks
  - Response defined as ≥ 2g/dL increase in Hb or normalisation of Hb (women ≥12g/dL; men ≥13g/dL
- Protocol primary endpoint required both ITT and PP populations to demonstrate non-inferiority at 12 weeks
- Re-analysis of data showed
  - primary non-inferiority endpoint at 12 weeks was not achieved in either ITT or PP populations
  - But secondary endpoints and health economic analyses remain positive

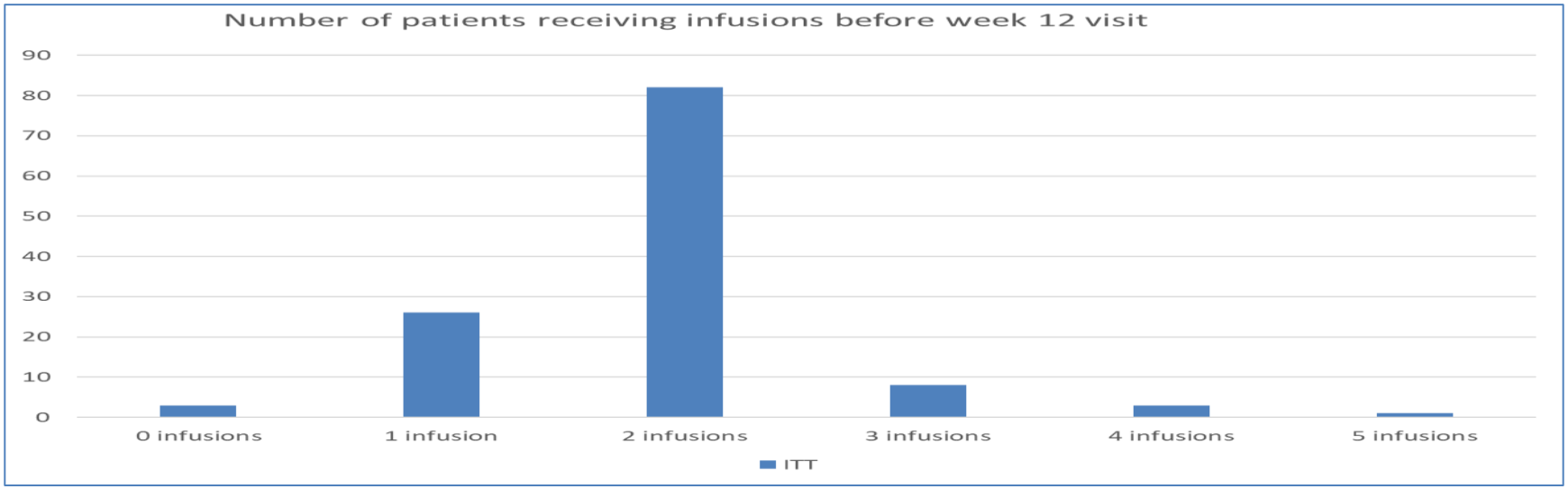
H2H - Hb concentration – average change from baseline by visit (ITT)

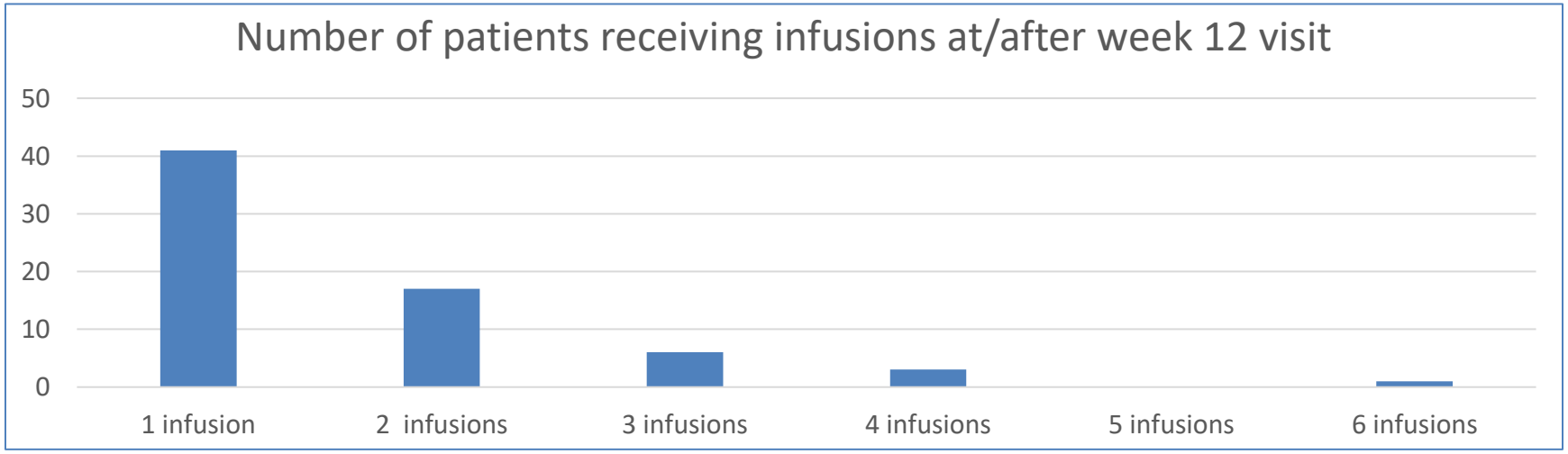


H2H - Average Hb concentration by visit (ITT)



H2H - IV infusions (ITT population)





US update

- Top priority for 2020
- Need to achieve
  - Optimal financial terms
  - Partner that can exploit Accrufer® across the full range of therapy areas where ID is prevalent
- Engaged with multiple companies, many signed confidentiality agreements
- Several submitted non-binding offers
- More detailed discussions with a number of these

- US launch stocks ordered from manufacturer for availability around end-2020

Paediatric Programme

- Liquid formulation developed, manufactured, released and now in USA
- First phase – crossover study to confirm liquid formulation equivalent to capsules
  - 32 healthy adult volunteers
  - Recruitment starting imminently
  - Expected to complete by end 2020
- Main study
  - Will start H1 2021 assuming first phase successful

Financial headlines

Financial position

- Revenues of £8.9 million (H1 2019: £0.4 million)
  - $11.4m (£8.7m) China upfront
- Profit for the period of £3.1 million (H1 2019 loss: £4.2 million)
  - SG&A £4.8m includes China transaction costs and costs related to US process
  - R&D £0.7m is low due to delayed start to paediatric study
- Net cash inflow from operations £2.0 million (H1 2019 outflow: £1.9 million)
- Cash of £6.5 million (31 December 2019: £4.1 million)

Outlook for H2/Full Year 2020

- Feraccru® royalties from Norgine sales in UK and Germany expected to continue to grow
  - Launches in France, Italy & Spain subject to pricing and reimbursement negotiations and not expected until late 2021 at earliest
- H2 2020 SG&A cost base to continue at levels seen in 2019 and H1 2020
- R&D expenditure will accelerate in H2 2020 as paediatric study gets under way
- Cash runway extends into Q1 2021
  - Excluding potential upfront receipts from potential out-licensing deals

Newsflow and summary

Anticipated newsflow

Indicative timing	Event
H2 2020	Potential out-licensing agreement for Accrufer® in USA
H2 2020	Potential start of formulation work for PT20[1]
End 2020	Conclusion of first stage of paediatric study
Q1 2021	Further update on European sales

(1) Subject to funding

Summary

- Licence agreement signed for Feraccru®/Accrufer® covering China, Hong Kong, Macau and Taiwan
  - may require only a Phase III study in IBD
- Strong Feraccru® sales growth in Germany and England
  - Other major EU markets from late 2021 onwards
- H2H reanalysis completed
  - Confirms that Feraccru®/Accrufer® is a credible alternative to IV therapy
- Continued progress being made to secure a US commercialisation partner
  - US packs ordered for delivery end-2020
- Cash runway extends to Q1 2021
  - excluding any upfronts
- Valuation upside potential
  - Market waiting for confirmation of US commercialisation

SHIELD
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Results: P&L (unaudited)

£'000	H1 2020	H1 2019 (restated)[1]
Revenue	8,919	430
Gross profit	7,908	119
Selling, general & administration	(4,834)	(3,575)
Research and development	(681)	(1,273)
Operating profit/(loss)	2,393	(4,729)
Financial income	355	47
Profit/(loss) before tax	2,748	(4,682)
Taxation	376	500
Profit/(loss) for the period	**3,124**	**(4,182)**

(1) restated to reflect the impact of the requirement to repay Norgine the €2.5 million milestone payment originally received in April 2019 relating to the AEGIS-H2H clinical study. This milestone was subsequently found to be invalid and was excluded from the audited full year financial statements for 2019. The restatement has resulted in revenue and profits for the six months to 30 June 2019 decreasing by £2.2 million.

Results: Balance sheet

£'000	30 Jun 2020 (unaudited)	31 Dec 2019 (audited)
Intangible assets & PPE	28,646	29,924
Inventory & receivables	3,080	2,254
Cash	6,515	4,141
Total assets	**38,241**	**36,319**
Current liabilities	(2,774)	(4,174)
Net Assets	**35,467**	**32,145**

Results: Cashflow (unaudited)

£'000	H1 2020	H1 2019 (restated)[1]
Cashflow from operating activities	2,041	(1,943)
Cashflow from investing activities (includes capitalised R&D)	356	(1,148)
Cashflow from financing activities	(23)	(77)
Net increase/(decrease) in cash	2,374	(3,168)
Cash at start of period	4,141	9,776
Cash at period end	6,515	6,608

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