# Interim Results for the six months ended 30 June 2021

*August 2021*

SHIELD THERAPEUTICS PLC

Improving Lives Together

# Disclaimer

These slides have been prepared by Shield Therapeutics plc (the "Company") solely for your information and for use at a presentation for the purpose of providing background information on the Company, its business and the industry in which it operates. For the purposes of this notice, "presentation" means these slides, any oral presentation, any question and answer session and any written or oral material discussed or distributed during the presentation meeting.

This presentation has not been approved by the United Kingdom Listing Authority under the Prospectus Rules (made under Part VI of the Financial Services and Markets Act 2000, as amended) or otherwise, or by the London Stock Exchange plc. This presentation has not been independently verified and no representation or warranty, express or implied, is made or given by or on behalf of the Company or any of its subsidiaries or subsidiary undertakings, or any of such person's respective directors, officers, partners, employees, agents, affiliates or advisers, as to, and no reliance may be placed for any purpose whatsoever on the information or opinions contained in this presentation or on the completeness, accuracy or fairness thereof.

This presentation does not constitute or form part of, and should not be construed as, any offer, invitation or recommendation to purchase, sell or subscribe for any securities of the Company in any jurisdiction and neither the issue of this presentation nor anything contained herein shall form the basis of or be relied upon in connection with, or act as an inducement to enter into, any investment activity. This presentation does not purport to contain all of the information that may be required to evaluate any investment in the Company or any of its securities and should not be relied upon to form the basis of, or be relied on in connection with, any contract or commitment or investment decision whatsoever. This presentation is intended to present background information on the Company, its business and the industry in which it operates and is not intended to provide complete disclosure upon which an investment decision could be made. The merit and suitability of an investment in the Company should be independently evaluated and any person considering such an investment in the Company is advised to obtain independent advice as to the legal, tax, accounting, financial, credit and other related advice prior to making an investment.

No undertaking, representation, warranty or other assurance, express or implied, is or will be made or given by or on behalf of the Company or any of its subsidiary or subsidiary undertakings, or any of such person's respective directors, officers, partners, employees, agents, affiliates or advisers or any other person as to the accuracy or completeness of the information or opinions contained in this presentation and no responsibility or liability is accepted by any such person for any such information or opinions or for any errors, omissions or misstatements, negligent or otherwise, nor for any other communication written or otherwise. All information in this presentation is subject to verification, correction, completion and change without notice. None of the Company or any of its subsidiary or subsidiary undertakings, or any of such person's respective directors, officers, partners, employees, agents, affiliates or advisers, undertakes any obligation to amend, correct or update this presentation or to provide the recipient with access to any additional information that may arise in connection with it.

The statements contained in this presentation may include "forward-looking statements" that express expectations as to future events or results. Forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes", "estimates", "anticipates", "projects", "expects", "intends", "may", "will", "seeks" or "should" or, in each case, their negative or other variations or comparable terminology, or by discussions of strategy, plans, objectives, goals, future events or intentions. These statements are based on current expectations and involve risk and uncertainty because they relate to events and depend upon circumstances that may or may not occur in the future. There are a number of factors which could cause actual results or developments to differ materially from those expressed or implied by such forward-looking statements. Any of the assumptions underlying forward-looking statements could prove inaccurate or incorrect and therefore any results contemplated in forward-looking statements may not actually be achieved. Nothing contained in this presentation should be construed as a profit forecast or profit estimate. Investors and any other recipients of such communications are cautioned not to place reliance on any forward-looking statements. The Company undertakes no obligation to update or revise (publicly or otherwise) any forward-looking statement, whether as a result of new information, future events or other circumstances.

To the extent available, the data contained in this presentation has come from official or third party sources. Third party industry publications, studies and surveys generally state that the data contained therein have been obtained from sources believed to be reliable, but that there is no guarantee of the accuracy or completeness of such data. While the Company believes that each of these publications, studies and surveys has been prepared by a reputable source, the Company has not independently verified the data contained therein. In addition, certain of the data contained in this presentation come from the Company's own internal research and estimates based on the knowledge and experience of the Company's management in the market in which the Company operates. While the Company believes that such research and estimates are reasonable and reliable, they, and their underlying methodology and assumptions, have not been verified by any independent source for accuracy or completeness and are subject to change without notice. Accordingly, undue reliance should not be placed on any of the data contained in this presentation.

This presentation should not be copied or distributed by recipients and, in particular, should not be distributed by any means, including electronic transmission, to persons with addresses in the United States of America, Canada, Australia, South Africa or Japan, their possessions or territories or to any citizens thereof, or to any corporation, partnership or such entity created or organised under the laws thereof, or any other jurisdiction, where such distribution is unlawful. Any such distribution contrary to the above could result in a violation of the laws of such jurisdictions.

This presentation is confidential and is being supplied to you solely for your information and may not be reproduced, re-distributed or passed on, directly or indirectly, to any other person or published in whole or in part for any purpose. By attending the meeting where this presentation is made or by accepting a copy of this presentation, you agree to be bound by the limitations and restrictions set out above.

SHIELD THERAPEUTICS PLC

SHIELD THERAPEUTICS PLC

Improving Lives Together

# Operational Highlights

## Results for Six Months Ended 30 June 2021

# Operational Highlights
## (including post-period end)

- Accrufer® launched in USA effective 1 July 2021
- 51% growth in Feraccru® sales volumes in Europe
- Chinese authorities confirm regulatory approval pathway for Feraccru® in China
- First stage of Feraccru® / Accrufer® paediatric study completed
- License deal for development and commercialisation of Accrufer® in Republic of Korea secured (August 2021)

# US Launch of Accrufer®

- Recruitment and training of 30 sales rep's during Q2 2021, followed by launch effective 1 July 2021
- Recent market research confirms positioning and opportunity; initial feedback from field indicates 'high' level of interest in Accrufer®
- Face-to-face contact with physicians limited due to COVID pandemic restrictions
- Ongoing discussion with payers on formulary placement to increase patient access of Accrufer®

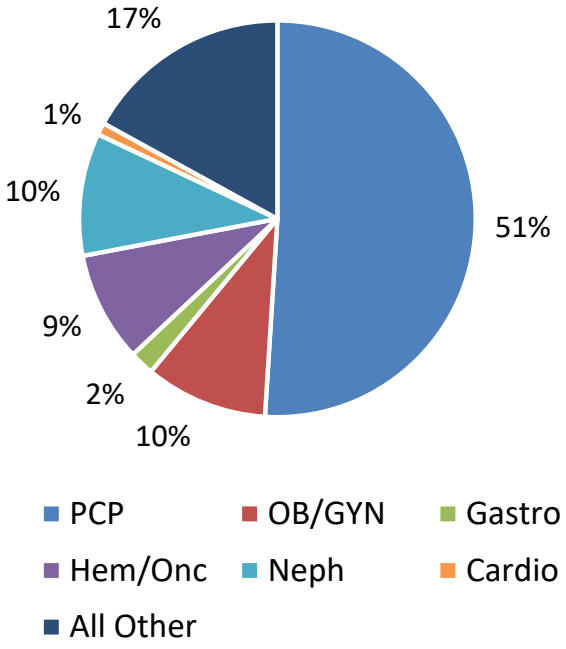
# US Market Opportunity

*Iron Replacement Market is Large with PCPs Writing 50% of the Rx and Oral Therapies Making Up 90% of the Volume*

~550K clinicians writing for oral and/or IV iron yearly
PCPs make up over 50% of the volume

~10 million Rx's per year for oral iron
Generics and OTC

65,000 physicians drive >60% or oral iron volume
PCP's, OB/GYN majority of volume




Note: All specialty groups include any associated NPPAs i.e. OBGYN specialty group includes board certified OBGYNs and any mid-levels that practice with them. PCPs here include Family Practice, General Practice, and Internal Medicine specialties, and their associated NPPAs
Source: Medical Claims and Xponent data, 12 month time period ending Dec 2019



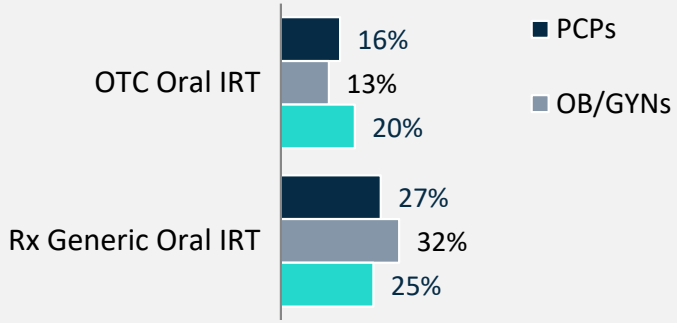
SHIELD THERAPEUTICS PLC

# Clinicians Feedback – 1 of 3

*Clinicians are seeking a well tolerated and effective oral iron*

**Satisfaction**

✓ Current satisfaction with oral IRT (OTC and prescription) is low.




**Importance**

**Most Important Attributes in IRT Selection**

| % rating 6,7 (Top 2 Box) | PCPs | OB/GYNs | Specialists |
|---|---|---|---|
| **Well-tolerated** | 86% | 94% | 75% |
| **Effective therapy** | 82% | 94% | 85% |
| **Acceptable OOP cost to patients** | 82% | 77% | 60% |
| **Good safety profile** | 80% | 84% | 70% |
| **Convenient dosing and administration** | 76% | 77% | 80% |



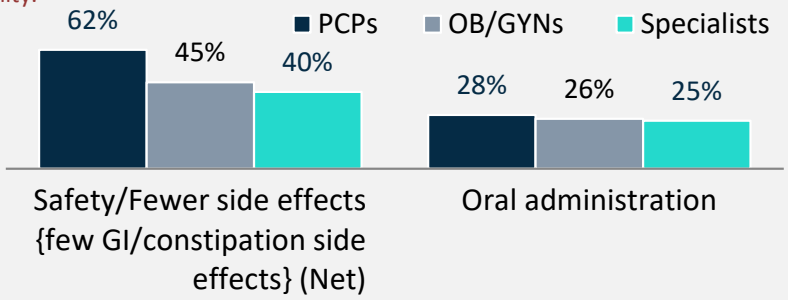
SHIELD THERAPEUTICS PLC

# Clinicians Feedback – 2 of 3

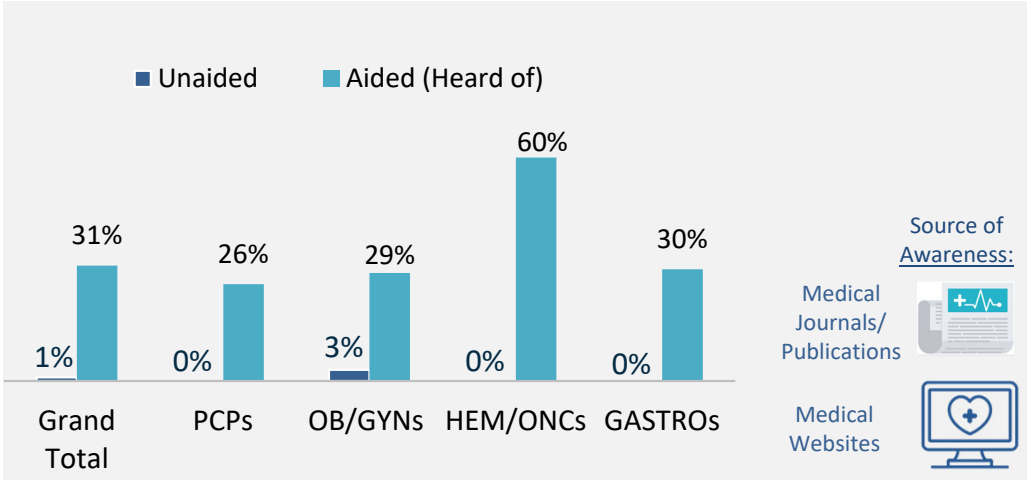
*Clinicians want more from their oral iron, however awareness of Accrufer® is low*

## Unmet Needs

✓ Physicians want more oral ID/IDA treatments with fewer side effects and better tolerability.

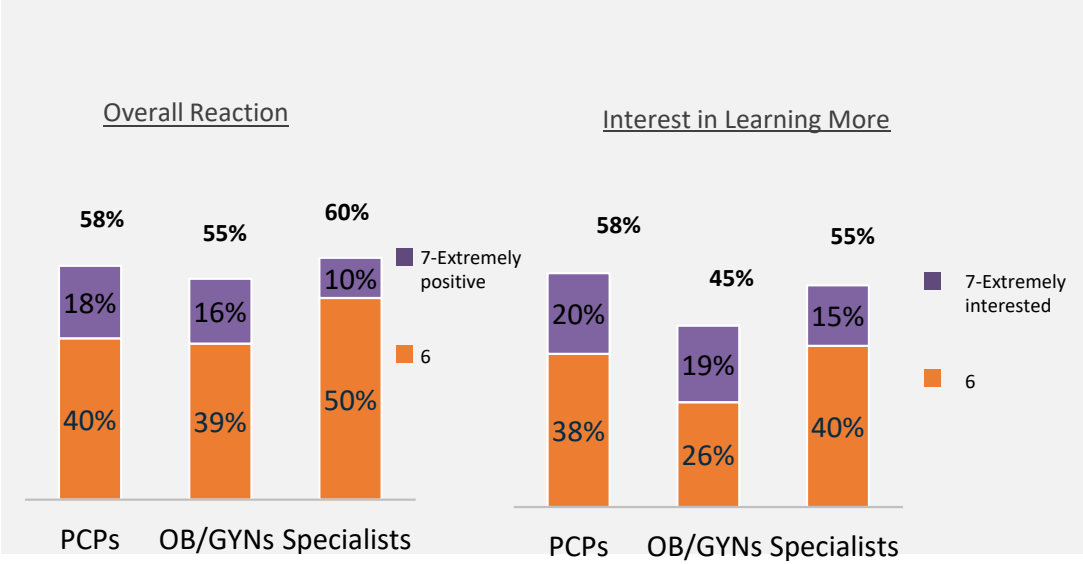


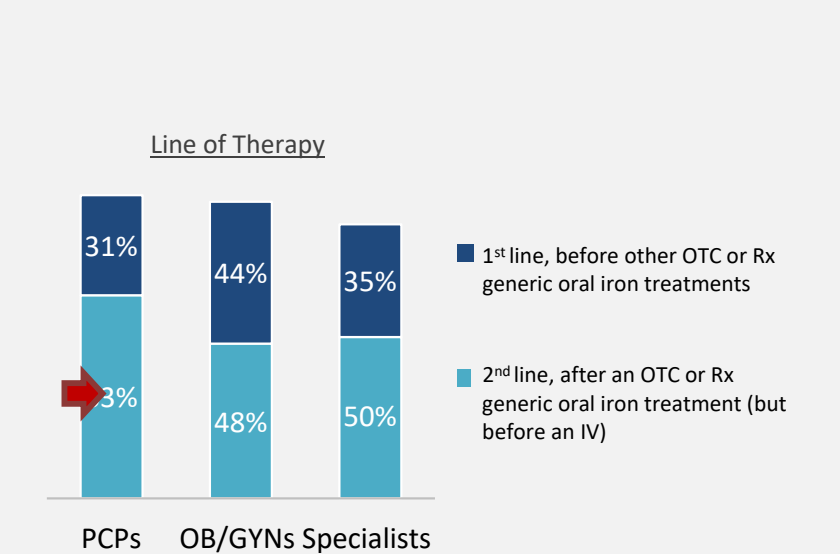

## Treatment Awareness and Usage: Accrufer®



# Clinicians Feedback – 3 of 3

*Clinicians respond favorably to Accrufer® profile*



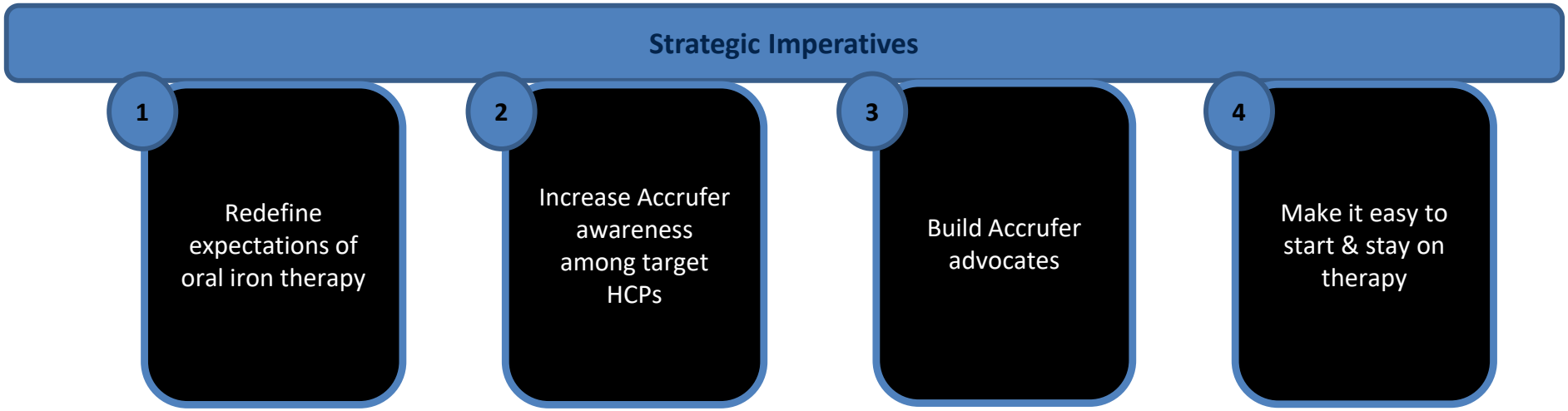




N= 101 (49 PCPs, 31 OB/GYNs, 10 Gastros and 10 Hem/Oncs) Specialists = Gastros + Hem/Oncs



SHIELD THERAPEUTICS PLC

# Critical Success Factors






SHIELD THERAPEUTICS PLC

# US Launch of Accrufer®

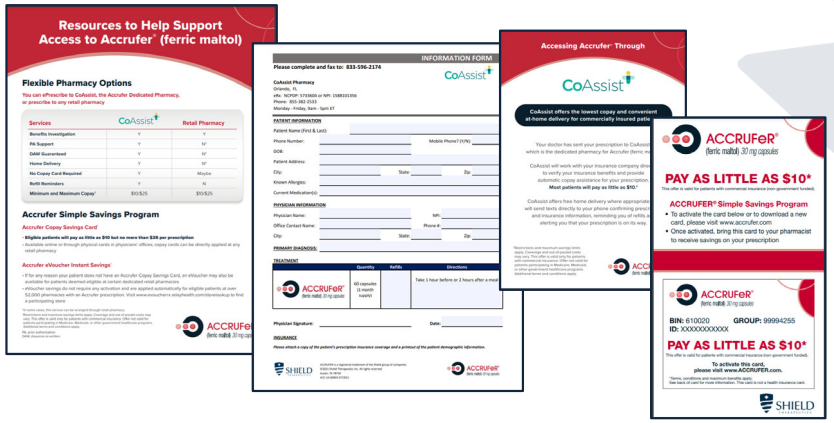



SHIELD THERAPEUTICS PLC

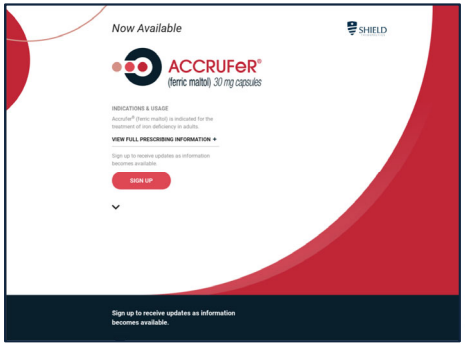
# Key Tactical Assets

## HCP Promotional Tools

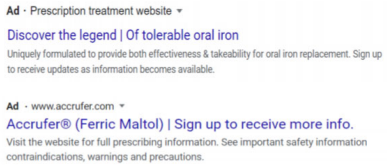

## Patient Access Materials




## Digital Tactics








SHIELD THERAPEUTICS PLC

# US Launch of Accrufer®

- Market research confirms need for well tolerated and effective oral iron
- Low awareness of Accrufer® at launch, however…
- Interest level is ‘high’ for Accrufer® profile
- Payer discussions ongoing

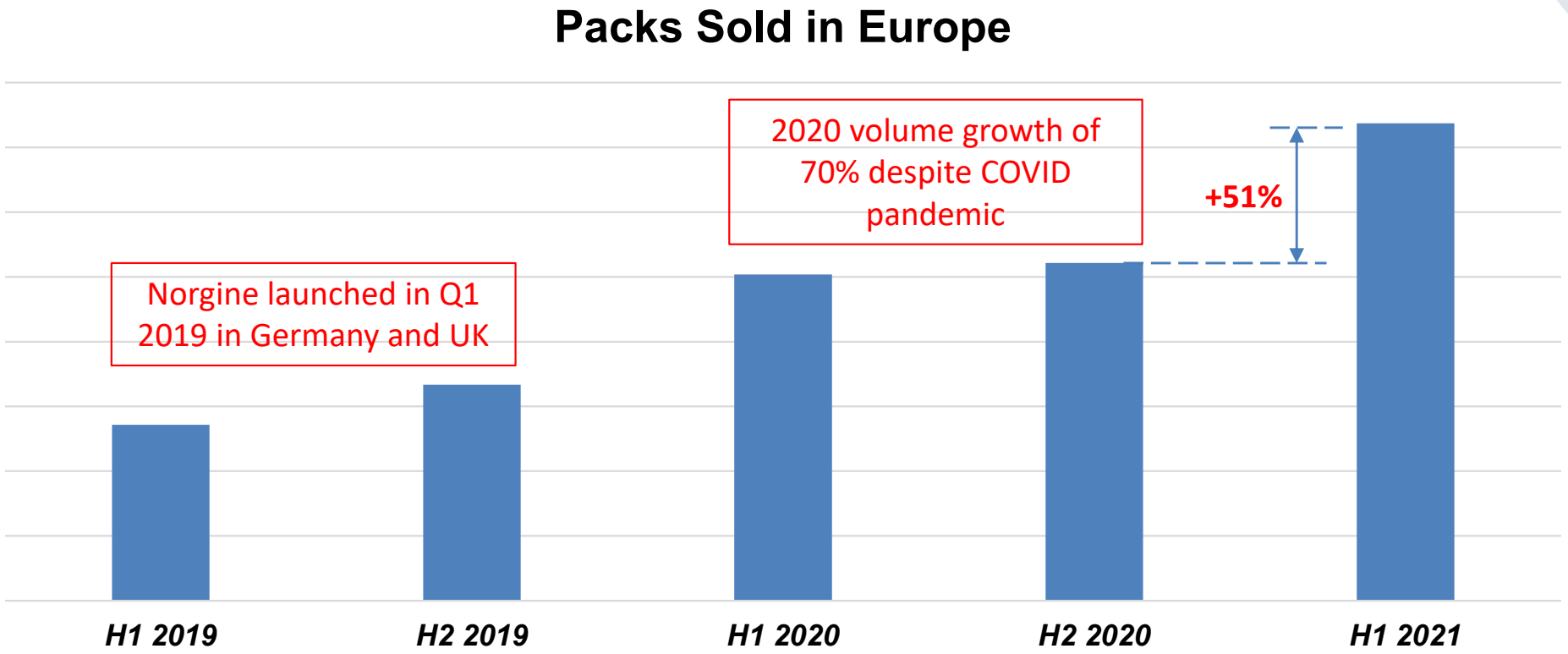
**Key focus areas:**

***Increase awareness of Accrufer®***

***Generate clinical experience with patient access programmes***

***Establish payer coverage***

# European Sales of Feraccru®




- Number of Feraccru® packs sold in Europe increased by 51% in H1 2021 compared to H2 2020
- UK and Germany account for 87% of packs sold (H2 2020: 93%)
- Norgine (European license partner) continues to seek commercial adoption in other major European markets (e.g., Scandinavia, Benelux, France, Italy, and Spain)

# Regulatory Approval Pathway in China

- Chinese regulatory authority (CDE) approved Investigational New Drug (IND) application for Feraccru® to conduct two studies:
  - Phase III study in 120 IBD patients for 12 weeks, and in parallel
  - Pharmacokinetic / pharmacodynamic study
- ASK Pharm (license partner) started screening patients for study
- Estimated time of study completion by end of 2022, followed by marketing approval and product launch in late 2023
- Financial deal terms:
  - Milestone payment of USD 11.4 million on drug approval
  - Additional milestone payments of up to USD 40.0 million upon achievement of specified cumulative sales targets
  - Tiered royalties of 10% or 15% on net sales

# Product Development

**Paediatric Study Update**

- Agreement with EMA/FDA for Feraccru® / Accrufer® Paediatric Investigational Plan (PIP) / Pediatric Development Plan (PDP)
- Single Phase III protocol covering ages 1 month to 17 years, plus suspension / capsule crossover in healthy volunteers, including fed/fasted comparison
- Cross-over study satisfactorily completed in H1 2021; main study planned to commence with recruiting patients in H2 2021

**Formulation Work on PT20**

- New formulation work of PT20 (development stage phosphate binder) has commenced in H1 2021

# Korea License Deal for Accrufer®
## (August 2021)

- Exclusive license agreement for Accrufer with Korea Pharma in Republic of Korea
- Korea Pharma will undertake and pay for all activities to achieve marketing authorisation and commercialise Accrufer® in Korea
- Korea Pharma responsible for all clinical and regulatory costs and activities, plus manufacturing and distributions costs
- Financial deal terms:
  - Upfront payment of GBP 0.5 million at signing
  - Milestone payment of GBP 1.5 million upon first commercial sale of Accrufer®
  - Additional milestone payments of up to GBP 4.0 million upon achievement of specified cumulative sales targets
  - Royalties of 15% of net sales of Accrufer® in Korea

SHIELD THERAPEUTICS PLC

Improving Lives Together

# Financial Review

## Results for Six Months Ended 30 June 2021

# Financial Highlights

- Revenue of GBP 0.5 million (H1 2020: GBP 8.9 million)
- Loss for period of GBP 7.3 million (H1 2020 Profit: GBP 3.1 million)
- Net cash outflow from operating activities of GPB 8.0 million (H1 2020 inflow: GBP 2.0 million)
- Net proceeds from share placing in March 2021 of GBP 27.7 million
- Cash balance of GBP 22.6 million (31 Dec 2020: GBP 2.9 million)

# Outlook

- Ramp-up of revenue from Accrufer sales in USA:
  - Increase in sales volumes, plus
  - Increase of payer coverage by signing reimbursement agreements with various providers
- Continuing increase in expenditures related to build-out of commercial activities in USA, plus recruitment for paediatric study
- Steady growth in revenues from Norgine royalties on European sales of Feraccru
- Recognition of GBP 0.5 million upfront payment from license transaction with Korea Pharma

SHIELD
THERAPEUTICS PLC
Improving Lives Together

Contact:
Greg Madison, CEO
Hans-Peter Rudolf, CFO
Tel: +44 (0)191 511 8500
info@shieldtx.com
www.shieldtherapeutics.com

To be kept up to date with Shield Therapeutics plc news and to receive relevant investor communications on the Company going forward, please email Walbrook PR at shield@walbrookpr.com to subscribe

# Interim Results 2021

## Consolidated Statement of Profit and Loss

| **For six-month period ended**<br>*In GBP thousands* | **30 June 2021**<br>*(unaudited)* | **30 June 2020**<br>*(unaudited)* |
|---|---|---|
| Revenue | 481 | 8’919 |
| Cost of sales | -411 | -1’011 |
| **Gross profit** | **70** | **7’908** |
| Selling, general & administration | -6’121 | -4’834 |
| Research and development | -1’592 | -681 |
| **Operating (loss) / profit** | **-7’643** | **2’393** |
| Financial income, net | 60 | 355 |
| **Profit / (loss) before tax** | **-7’583** | **2’748** |
| Taxation | 300 | 376 |
| **(Loss) / profit for the period** | **-7’283** | **3’124** |



SHIELD THERAPEUTICS PLC

# Interim Results 2021

## Consolidated Balance Sheet

| **Balance at**<br>*In GBP thousands* | **30 June 2021**<br>*(unaudited)* | **31 Dec 2020**<br>*(audited)* |
|---|---|---|
| Non-current assets | 26’075 | 27’298 |
| Inventories & receivables | 3’731 | 2’290 |
| Cash and cash equivalents | 22’602 | 2’940 |
| **Total assets** | **52’408** | **32’528** |
| Current liabilities | -1’394 | -2’252 |
| **Net assets / Total equity** | **51’014** | **30’276** |



SHIELD THERAPEUTICS PLC

# Interim Results 2021

## Consolidated Statement of Cash Flows

| **For six-month period ended**<br>*In GBP thousands* | **30 June 2021**<br>*(unaudited)* | **30 June 2020**<br>*(unaudited)* |
|---|---|---|
| Cash flows from operating activities | -8'037 | 2'041 |
| Cash flows from investing activities | -64 | 356 |
| Cash flows from financing activities | 27'702 | -23 |
| **Net increase / (decrease) in cash** | **19'601** | **2'374** |
| Effect of exchange rate differences | 61 | - |
| Cash balance at start of period | 2'940 | 4'141 |
| **Cash balance at end of period** | **22'602** | **6'515** |



SHIELD THERAPEUTICS PLC