



*This announcement contains inside information for the purposes of Article 7 of the Market Abuse Regulation (EU) No 596/2014.*

## **Acacia Pharma Group plc**

### **Results for the year ended 31 December 2020**

**Cambridge, UK and Indianapolis, US – 29 March 2021:** Acacia Pharma Group plc (“Acacia Pharma”, the “Group” or the “Company”) (EURONEXT: ACPH), a hospital pharmaceutical company focused on the development and commercialization of new products aimed at improving the care of patients undergoing significant treatments such as surgery, other invasive procedures or cancer chemotherapy, announces its results for the year ended 31 December 2020 and provides an update on progress with the commercialization of BARHEMSYS® and BYFAVO™ in the United States.

A presentation by Acacia Pharma’s senior management team will be webcast live today at 14.30 CEST (08.30 EST) and participants can register by [clicking here](#) or from [www.acaciapharma.com](http://www.acaciapharma.com). A replay will be available after the event at the same link.

International conference call dial-in details are noted below.

The results report and presentation will be available at [www.acaciapharma.com](http://www.acaciapharma.com) in the Investors section from 07.00 CEST today.

The full Annual Report and Financial Statements will be available on the Group’s website by 31 March.

**Commenting on the results, Mike Bolinder, Chief Executive Officer, said:** “Our vision to become a leading US hospital pharmaceutical company is on the road to being realized. The US approval and launch in the last year of two major new products in BARHEMSYS and BYFAVO is a tremendous achievement, practically unprecedented for a company of our size.

“Our early progress on formulary adoption for BARHEMSYS reflects the unmet need that exists in PONV and strong underlying demand for our product, our outstanding and extremely experienced commercial team and salesforce, as well as our well-constructed, well-executed launch plans. During 2021, we aim to continue gaining formulary access in our initial targeted accounts, as this will lay the strong foundation for significant revenue pull-through from 2022 onwards.

“Acacia Pharma is now at an exciting stage in its path to long-term commercial success, and we intend to continue to resolutely execute our plans as we bring these important new treatments to patients and at the same time build further significant value for our shareholders. I am once again truly grateful to our employees for their dedication and remarkable efforts during this year of outstanding progress against the challenging backdrop of the COVID-19 pandemic, and to our shareholders for their continued support.”

### **Operating Highlights for 2020 and Significant Post-period Updates**

- US commercial infrastructure successfully built and fully operational
  - Highly experienced sales, marketing, medical affairs, commercial operations teams in place
  - Nationwide salesforce deployed against ~900 initial targeted hospital accounts since mid-October 2020
- Two high-potential products approved by the US Food and Drug Administration (FDA) in 2020
  - **BARHEMSYS** (amisulpride injection)
    - Approved February 2020 in the US with a broad label for the treatment and prevention of postoperative nausea & vomiting (PONV)
    - First and only antiemetic approved for the rescue treatment of PONV in patients who have failed prior prophylaxis

- Approximately 16m surgical patients each year in the US suffer from PONV despite receiving prophylaxis<sup>1</sup>
    - Estimated \$2.7 billion annual total addressable market<sup>2</sup>
  - **BYFAVO** (remimazolam injection)
    - US commercial rights in-licensed from Cosmo Pharmaceuticals NV (“Cosmo”) in January 2020
    - Approved July 2020 for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less
    - Key target: 40m procedures a year in US, including 25m gastro-intestinal procedures<sup>3</sup>
    - Estimated >\$1.5 billion annual total addressable market<sup>4</sup>
- Commercialization off to excellent start, with strong early formulary uptake
  - After deploying our sales team in mid-October, to date BARHEMSYS has been added to formulary at 120 institutions – Pharmacy & Therapeutics (P&T) Committee review success > 85%
  - Strong appreciation of clinical and health economic benefits of BARHEMSYS
  - BYFAVO launched at end of January 2021 and in eight weeks of launch is already approved on formulary in seven accounts
  - High level of enthusiasm from healthcare professionals for first major sedative launch in two decades
- Management and Board Changes
  - Gary Gemignani appointed new CFO following planned succession succeeding Christine Soden who retired as CFO and from the Board in February 2020
  - Patrick Vink (Chairman), Pieter van der Meer and Johan Kördel stepped down from the Board of Directors at the 2020 AGM
  - Scott Byrd, a non-executive director of Acacia Pharma, was elected as Chairman at the AGM and Alessandro Della Chá, CEO of Cosmo Pharmaceuticals N.V. was appointed as a non-executive director
- Named BEL Small Cap Company of the Year for the second consecutive year

## Financial Highlights

Results are presented in US\$, reflecting the currency of the majority of expected costs and revenues

- Loss after tax for the year ended 31 December 2020 of \$33.5m (2019: \$22.8m):
  - The operating loss increased by \$8.5m to \$30.9m (2019: \$22.4m), reflecting the investment in our US commercial infrastructure and product launch preparations
  - R&D expenses \$0.1m (2019: \$3.9m) with the reduction reflecting lower R&D activities on completion of BARHEMSYS clinical program, together with a \$1.4m credit on reversing certain inventory provisions on the approval of BARHEMSYS
  - Sales and marketing expenses \$19.4m (2019: \$14.0m) reflecting increased activities leading up to the planned launch of BARHEMSYS and BYFAVO
  - General and administrative expenses \$11.6m (2019: \$4.4m) with 2020 costs higher as a result of fundraising activities, staff costs and amortisation of intangibles
- Cash and cash equivalents as at 31 December 2020 of \$46.7m (2019: \$17.0m)
- Balance sheet strengthened through €20m equity investment from Cosmo, €25m loan from Cosmo, together with €25m equity financing in August 2020
  - Additional equity financing undertaken in February 2021 with gross proceeds of €27m

## Summary and Outlook for 2021

The Directors of Acacia Pharma are pleased with the excellent progress made since the beginning of 2020 in bringing two products forward to approval and now launch in the important US market. BARHEMSYS and BYFAVO are highly complementary products that together can efficiently utilize the commercial infrastructure that the Company has now built in the US.

The addition of the rights to BYFAVO along with the accompanying equity investment and debt facility from Cosmo as well as the recent equity raises have enhanced the Group's ability to facilitate a successful launch and roll out of these products.

The early success with hospital formulary access for BARHEMSYS has confirmed the Directors' belief in the strong product profile and compelling health economic arguments in favour of its adoption and use. This is an important first step to building a solid and growing sales platform for the product.

While it remains early days in the launch of BYFAVO, the Directors believe that it too offers significant medical and commercial value that will be viewed favorably by formulary committees and payors, as well as doctors and patients.

### **Conference call dial-in details**

To join the conference call by telephone, please dial-in 5-10 minutes prior to the start using the password **Acacia Pharma** and any of the phone numbers provided below.

UK/Standard International dial-in: +44 (0) 33 0551 0200

UK Toll Free: 0808 109 0700

Belgium Toll Free: 0800 746 68

Netherlands Toll Free: 0800 022 9132

US New York: +1 212 999 6659

USA Toll Free: +1 866 966 5335

### **References**

1. Calculations based on available procedural data, applied Compound Annual Growth Rate and quantitative market research responses as follows: National Hospital Discharge Survey, 2006; National Survey of Ambulatory Surgery, 2006 (as revised in 2009); Source Healthcare; NCHS 2005; Life Science Strategy Group, LLC Market Research; Apfel et al., 2004.
2. Based on the calculations in (1) multiplied by the number of doses per patient at a WAC price of \$85 per 10mg dose.
3. iData Research, US Market Report Procedure Numbers for Gastrointestinal Endoscopic Devices February 2019; American Society of Anesthesiologists, Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018; and Quantitative Market Research prepared by The Link Group for Cosmo Technologies (March 2019).
4. Based on the calculation in (4) multiplied by the number of doses per patient at a WAC price of \$39 per dose.

### **Contacts**

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### **About Acacia Pharma**

Acacia Pharma is a hospital pharmaceutical company focused on the development and commercialization of new products aimed at improving the care of patients undergoing significant treatments such as surgery, other invasive procedures, or cancer chemotherapy. The Company has identified important and commercially attractive unmet needs in these areas that its product portfolio aims to address.

Acacia Pharma's first product, BARHEMSYS<sup>®</sup> (amisulpride injection) is available in the US for the management of postoperative nausea & vomiting (PONV).

BYFAVO™ (remimazolam) for injection, a very rapid onset/offset IV benzodiazepine sedative is approved and launched in the US for use during invasive medical procedures in adults lasting 30 minutes or less, such as colonoscopy and bronchoscopy. BYFAVO is in-licensed from Paion UK Limited for the US market.

APD403 (intravenous and oral amisulpride), a selective dopamine antagonist for chemotherapy induced nausea & vomiting (CINV) has successfully completed one proof-of-concept and one Phase 2 dose-ranging study in patients receiving highly emetogenic chemotherapy.

Acacia Pharma has its US headquarters in Indianapolis, IN and its R&D operations are centred in Cambridge, UK. The Company is listed on the Euronext Brussels exchange under the ISIN code GB00BYWF9Y76 and ticker symbol ACPH.

[www.acaciapharma.com](http://www.acaciapharma.com)

### **Forward looking statements**

*This announcement includes forward-looking statements, which are based on current expectations and projections about future events. These statements may include, without limitation, any statements preceded by, followed by or including words such as "believe", "expect", "intend", "may", "plan", "will", "should", "could" and other words and terms of similar meaning or the negative thereof. Forward-looking statements may and often do differ materially from actual results. These forward-looking statements are subject to risks, uncertainties and assumptions about the Company and its subsidiaries and investments, including, among other things, the development of its business, trends in its operating industry, and future capital expenditures and acquisitions. By their nature, forward-looking statements involve risk and uncertainty because they relate to future events and circumstances. Any forward-looking statements reflect the Company's current view with respect to future events and are subject to risks relating to future events and other risks, uncertainties and assumptions relating to the Group's business, results of operations, financial position, prospects, growth or strategies and the industry in which it operates. Save as required by law or applicable regulation, the Company and its affiliates expressly disclaim any obligation or undertaking to update, review or revise any forward-looking statement contained in this announcement whether as a result of new information, future developments or otherwise. Forward-looking statements speak only as of the date they are made.*

## **Operating Review**

### **Responding to a changing world**

#### **A year of disruption and resilience**

On 11 March 2020, the World Health Organisation announced that the outbreak of coronavirus (commonly referred to as COVID-19) had been declared a global pandemic. The long-term impacts of the outbreak are unknown and continue to evolve rapidly. Like other healthcare businesses throughout the world, Acacia Pharma had to adjust its commercialisation plans for both BARHEMSYS and BYFAVO to accommodate for travel restrictions, reduced elective surgeries, the shift in priorities for healthcare institutions and restricted access to healthcare settings.

Whilst the situation has created certain challenges in accessing decision makers in hospitals and ambiguity around the timing of their formulary committee meetings, the COVID-19 situation has led to increased interest in our products BARHEMSYS and BYFAVO, which are designed to deliver better patient outcomes and enhance recovery post-surgery. This interest has been further elevated by the drug shortages of the most commonly used antiemetics like ondansetron and dexamethasone as well as procedural sedatives like midazolam and propofol, all of which currently remain on the FDA drug shortages list. The COVID-19 situation has also created procedural backlogs and pent-up demand for products that can help improve procedural throughput as hospitals and surgical centres now need to significantly increase their patient throughput, which we believe has further heightened the value proposition for both drugs as customers seek to rebuild revenues and regain lost profits.

#### **Working with customers to deliver solutions that meet their needs**

##### **Healthcare systems around the world are focusing on patient outcomes and enhancing recovery after surgery**

Our products are well-placed to meet the needs of hospitals and healthcare professionals in achieving better patient outcomes and enhancing their recovery.

Mobilising patients as quickly as possible after surgery can help improve recovery, reducing the incidence of secondary complications and hospital readmission and improving healthcare economics.

We believe BARHEMSYS will prove an effective tool in the improved management of PONV which is a key factor in achieving these goals, since PONV can prevent patients from moving through the hospital or day-surgery centres to home and can impair the clinical progress post-surgery in certain procedures, including for example bariatric surgery, upper GI surgery or wired-jaw surgeries.

BYFAVO, an ultra-short-acting and reversible intravenous sedative benzodiazepine intentionally designed for rapid onset and offset for use during invasive medical procedures (such as bronchoscopies and colonoscopies) in order to offer clinicians a predictable level of sedation and procedural efficiency.

While, as detailed above, the COVID-19 pandemic has led to drug shortages and procedural backlogs in the US hospital market, we believe our product portfolio offers a significant value proposition to hospitals and enables improved patient throughput. We are closely monitoring the return to normal operations at hospitals and surgical centres as we emerge from the crisis caused by the pandemic. The situation has caused the Group to adjust its commercialization strategy to accommodate more virtual engagements with clinical staff which has proved an effective means of communication during the pandemic. Fortunately, we were able to successfully recruit a team of very experienced sales representatives with longstanding key customer relationships to facilitate dialogue even with restricted physical access to medical facilities. Additionally, due to the increasing virtual engagement with hospital accounts, the field teams have been able to increase their customer reach beyond what had been previously planned.

#### **Our strategy**

We believe we can deliver our effective new treatments to improve the outcomes and recovery for surgical patients in the US through our targeted specialist sales and marketing organisation. Our initial focus has been on promoting BARHEMSYS for better management of PONV and we are now following that with BYFAVO, a product geared at improving procedural sedation that we in-licensed from Cosmo Pharmaceuticals N.V. ("Cosmo") in January 2020. .

PONV remains poorly managed in many patients. It is caused by the stimulation of one or more biological pathways. The prevention of PONV is, therefore, managed by prescribing one or more antiemetics from different mechanistic classes that can inhibit this stimulation. Current practice in the US is that most surgical patients are likely to receive PONV prophylaxis involving a backbone of a 5HT<sub>3</sub> antagonist (e.g. ondansetron), often supplemented by a corticosteroid (e.g. dexamethasone). Despite the prophylaxis given to almost 50 million surgical patients a year in the US, approximately one third still suffer PONV. Treating these patients is a major challenge. Currently, most are re-dosed with one of the drugs they have already received as prophylaxis, a strategy that has repeatedly been shown to be ineffective. Other drugs used for rescue treatment of these patients have not been shown to be effective in prospective, randomized controlled trials and many have safety concerns. The Group therefore sees an opportunity to address a major unmet need by adding an important treatment to the armamentarium of anaesthetologists and surgeons, delivering an effective dopamine antagonist, BARHEMSYS (intravenous amisulpride). BARHEMSYS is the first product to show a benefit in a well-controlled trial in treating patients suffering with PONV after failing standard prophylaxis and is the first product specifically approved by FDA for that indication. In an extensive and robust Phase 3 clinical trial program, BARHEMSYS was also shown to be safe and effective for prophylaxis, including when given in combination with other antiemetics of different classes.

The Group added to its pipeline of hospital products through the strategic in-licensing of exclusive US rights to BYFAVO (intravenous remimazolam). BYFAVO is a fast on / fast off, reversible IV sedative designed for use during invasive medical procedures, such as colonoscopy and bronchoscopy, which may help to improve patient recovery times after such procedures. Rapid onset and offset are seen as important attributes for products in this area, as is a good safety-profile and lack of post-sedation drowsiness, all of which are features of BYFAVO. Quick recovery and early mobilization after these procedures are likely to be beneficial to patients and can provide economic benefits for healthcare providers and institutions.

The Directors believe that having a second product that shares the same attractive commercial message as BARHEMSYS will allow for significant synergies in sales and marketing operations and allow for more efficient investment in commercial infrastructure. Moreover, the concomitant debt and equity funding provided by Cosmo under the terms of the US licensing deal for BYFAVO strengthened the Group's financial position in support of the ongoing product launches. In July, Acacia Pharma was assigned the US license to BYFAVO from PAION AG, the original developer of remimazolam, from whom Cosmo first licensed the drug.

## **Operational progress**

On 26 February 2020 the FDA approved the NDA for BARHEMSYS. The received label makes BARHEMSYS the first and only approved agent for "rescue" treatment in patients who have failed prior prophylaxis. It is also approved for combination prophylaxis with other antiemetics in higher risk patients, thus addressing the two key commercial unmet needs in the PONV setting. The Directors believe the label for BARHEMSYS provides it with a strong competitive position and provides compelling pharmacoeconomic benefits to hospitals. Initially, we will focus our commercial efforts on patients who have failed prior prophylaxis and are in need of "rescue" treatment.

The NDA for BYFAVO was approved on 2 July 2020 and the required DEA scheduling was received on 6 October 2020. BYFAVO is the first new sedative approved in the US in 20 years and is designed for use during invasive medical procedures, such as during colonoscopy and bronchoscopy. It is estimated there are approximately 25 million such procedures performed annually in the US. The broad label granted for BYFAVO, covering all adult patient procedures lasting less than 30 minutes, makes it applicable for use in a range of other settings such as interventional radiology, ophthalmic and plastic surgery procedures, bringing the total number of procedures for which BYFAVO is suitable to approximately 40 million. BYFAVO has demonstrated efficacy and safety in an extensive clinical trial program involving around 2,400 volunteers and patients. Data from clinical trials show that remimazolam (BYFAVO) has a rapid onset and offset of action combined with a good cardio-respiratory safety profile. BYFAVO is designed to act more quickly than the available alternatives of the same pharmaceutical class for the same indication (e.g. midazolam) and can be reversed with flumazenil to rapidly terminate sedation or anaesthesia if necessary, an important safety feature.

In preparing for the launches of BARHEMSYS and BYFAVO, the Group established strong sales, marketing, medical affairs, and commercial operations teams. Our priority is to gain acceptance for both products on hospital formularies, which in time is expected to drive sales through the volume of procedures undertaken rather than individual clinician decisions.

We are pleased with the progress on BARHEMSYS, especially considering how challenging the launch environment has been. Early market reception by healthcare professionals has been very positive. Our experienced sales team has been deployed against ~900 initial targeted hospital accounts in the US since mid-October 2020. We believe we have had an excellent start in terms of the commercial launch of the product.

BYFAVO was successfully launched in January 2021 and shares commercial synergy with BARHEMSYS, which is being recognized in our discussions with P&T Committee reviews.

## **Management and Board changes**

Strong corporate governance and leadership is an essential part of Acacia Pharma's strategy. Christine Soden, our CFO for the last 5 years, stepped down on 29 February 2020 with Gary Gemignani taking the role of CFO as our business becomes more heavily weighted to US operations. Patrick Vink, our Chairman, Pieter van der Meer and Johan Kördel all stepped down from the Board of Directors at the 2020 AGM. Scott Byrd, a non-executive director of Acacia Pharma, was elected as Chairman at the AGM. Alessandro Della Chá, CEO of Cosmo Pharmaceuticals N.V. was appointed to our Board as its representative in April 2020 as a non-executive director and we will continue to assess the effectiveness and make-up of the Board to support the changes in or needs of our business.

## **Priorities for 2021**

Our key objectives for 2021 are:

### **Successfully commercialise BARHEMSYS and BYFAVO in the US by gaining extensive formulary access to facilitate and grow product use within hospital accounts**

The first step to a successful hospital launch involves gaining approval by the Pharmacy and Therapeutics (P&T) committee to add the product to their formulary. We will closely monitor formulary "wins" for the products and the number of accounts where we have gained access for the drugs to be used, as this is the key leading indicator for sales in this environment.

### **Raise sufficient capital to fund the product launches and support the current business plan**

It is necessary for the Group to raise additional capital in order to fully fund the product launches through to cash-flow positivity.

### **Deliver revenues and manage OPEX to plan/budget for 2021**

It is imperative that we deliver on our operational plans with regard to revenues and operating expense in order to continue to successfully operate in this environment, grow and provide returns for our Shareholders.

### **Meet all FDA timelines for post-marketing requirement/commitment studies for both products**

We need to perform all required post-marketing commitments for both products, which include further investigational studies in order to maintain the marketing authorization granted by the FDA for commercialization of the products in the US.

## Financial review

### Operating loss

The operating loss increased by \$8.5m to \$30.9m (2019: \$22.4m), reflecting the investment in our US commercial infrastructure and product launch preparations.

R&D expenditure was \$0.1m (2019: \$3.9m), down \$3.8m, reflecting a reduction in activities surrounding the management of the NDA submission and product development, together with the reversal of \$1.4m of inventory provisions on BARHEMSYS, following FDA approval.

Sales and marketing expenses were \$19.4m (2019: \$14.0m) in the year, driven by the costs of recruiting and running our commercial team and significant pre-launch marketing, education, training, distribution, regulatory and other activities.

General and administrative costs increased \$7.2m to \$11.6m (2019: \$4.4m), largely as a result of the costs incurred by amortisation of the Byfavo license (\$3.1m), increased payroll costs (\$2.5m including the IFRS2 charge) and financing transactions (\$0.5m).

### Finance income and expense

Finance income fell to \$0.04m (2019: \$0.43m), reflecting the lower cash balances at the beginning of the year together with the reduction in interest rates implemented by banks in response to the financial volatility caused by the pandemic.

Finance expense increased \$1.7m in the year to \$3.2m (2019: \$1.5m) primarily as a result of the interest incurred on the Cosmo loans which were drawn down in the year.

### Taxation

The tax credit for 2020 was \$0.6m (2019: \$0.7m) relating to R&D credits to be claimed on certain R&D activities.

### Loss for the financial year and loss per share

The post-tax loss for 2020 was \$33.5m (2019: \$22.8m) largely as a result of the increase of \$8.5m in the operating loss together with the increase in finance costs incurred in relation to the Cosmo loan. The loss per share was \$0.46 (2019: \$0.43) mainly as a result of the increase in losses in the year, offset by the increase in the number of Ordinary shares as a result of the Cosmo transaction and the August equity financing.

## Balance sheet

### Current assets

Current assets increased by \$32.1m to \$50.4m, dominated by the increase in cash and cash equivalents to \$46.7m (2019: \$17.0m) as a result of the August equity financing and the Cosmo transaction.

In February 2021, after year end, the Group raised gross proceeds of €27 million (\$31 million), further extending its cash runway to support its commercialization activities.

### Liabilities

Non-current liabilities of \$31.3m represent the long-term proportion of the debt facility entered into with Hercules Technology Growth Capital of which \$10m was drawn down on 30 June 2018; the long-term proportion of the loans entered into with Cosmo, of which €15m was drawn down on 27 July 2020 and a further €10m was drawn down on 27 September 2020; and \$0.3m in respect of the long-term lease liability now held on balance sheet under IFRS16.

Current liabilities increased to \$11.1m (2019: \$9.6m), primarily amounts due under the Hercules loan facility in 2020, together with an increase in trade and other payables of \$1.5m to \$5.7m.



## Share capital and total equity

Total equity at 31 December 2020 was \$60.5m compared to \$4.3m at the previous year end, reflecting the financing transactions undertaken in the year (\$83.7m), offset by the loss in the year (\$33.5m).

## Viability statement

The Directors have assessed the prospects of the Group. The Directors confirm that they have a reasonable expectation that the Group will continue to operate and meet its liabilities, as they fall due, and continue its planned activities through to Q2 of 2022.

The activities of the Group, together with factors likely to affect its future development and performance, its financial position, its cash flows, liquidity position and borrowing facilities are described in this Strategic Report on pages 3 to 17. The Directors have carried out a robust assessment of the principal and emerging risks facing the Group, including those that would threaten its business model, future performance, solvency or liquidity. These risks and the manner in which they are mitigated are summarised in the risk management and principal risks section on pages 34 to 35.

Taking account of the Group's financial position and principal risks, the Directors assess the prospects of the Group by reviewing at least annually the annual budget, quarterly reforecasts, the three-year strategic plan and the Group's risk framework. The Directors review the potential impact of each principal risk as well as the risk impact of any major events or transactions.

The major risks facing Acacia Pharma are those surrounding the successful launch of BARHEMSYS and BYFAVO, the impact of the ongoing COVID-19 pandemic and obtaining sufficient additional debt or equity capital to continue to meet the Group's obligations as they fall due. The ability to continue to raise capital to fund commercialisation will depend on wider financial market influences, and cannot be certain, and could adversely influence the ability to fully commercialise BARHEMSYS and BYFAVO in the time frame and in the manner anticipated. The Group has sufficient cash reserves as at the date of this report for the next twelve months, and the Directors believe they can continue to manage resources such that value can be delivered from BARHEMSYS and BYFAVO through its planned commercialisation strategy, thus ensuring the Group's viability. However, under the strategic plan, there is a need for additional financing to continue commercialisation.

## Summary and outlook for 2021

The Directors of Acacia Pharma are pleased with the excellent progress made since the beginning of 2020 in bringing two products forward to approval and now launch in the important US market. BARHEMSYS and BYFAVO are highly complementary products that together can efficiently utilize the commercial infrastructure that the Company has now built in the US.

The addition of the rights to BYFAVO along with the accompanying equity investment and debt facility from Cosmo as well as the recent equity raises have enhanced the Group's ability to facilitate a successful launch and roll out of these products.

The early success with hospital formulary access for BARHEMSYS has confirmed the Directors' belief in the strong product profile and compelling health economic arguments in favor of its adoption and use. This is an important first step to building a solid and growing sales platform for the product.

While it remains early days in the launch of BYFAVO, the Directors believe that it too offers significant medical and commercial value that will be viewed favorably by formulary committees and payors, as well as doctors and patients.

## Consolidated Income Statement for the year ended 31 December 2020

	Note	2020 \$'000	2019 \$'000
Revenue		211	-
Cost of Sales		(29)	-
<b>Gross profit</b>		<b>182</b>	<b>-</b>
Research and development expenses		(99)	(3,928)
Sales and marketing expenses		(19,438)	(14,019)
General and administrative expenses		(11,566)	(4,447)
<b>Operating loss</b>		<b>(30,921)</b>	<b>(22,394)</b>
Finance income	3	41	432
Finance expense	4	(3,212)	(1,545)
<b>Loss before income tax</b>	5	<b>(34,092)</b>	<b>(23,507)</b>
Taxation credit	8	614	668
<b>Loss for the financial year</b>		<b>(33,478)</b>	<b>(22,839)</b>
Basic and diluted losses per Ordinary Share (\$)	9	(0.46)	(0.43)

## Consolidated statement of comprehensive income for the year ended 31 December 2020

	2020 \$'000	2019 \$'000
<b>Loss for the financial year</b>	<b>(33,478)</b>	<b>(22,839)</b>
<i>Items that may be reclassified to profit or loss</i>		
Exchange differences on translation of foreign operations	3,218	(78)
<b>Other comprehensive income / (expense) for the financial year</b>	<b>3,218</b>	<b>(78)</b>
<b>Total comprehensive expense for the financial year</b>	<b>(30,260)</b>	<b>(22,917)</b>

## Consolidated Statement of Financial Position as at 31 December 2020

	Note	2020 \$'000	2019 \$'000
<b>Assets</b>			
<b>Non-Current Assets</b>			
Intangibles	11	52,168	-
Right-of-use asset	12	277	372
<b>Total Non-Current Assets</b>		<b>52,445</b>	<b>372</b>
<b>Current Assets</b>			
Trade and other receivables	13	461	609
Current income tax assets		574	679
Inventories	14	2,662	-
Cash and cash equivalents	15	46,693	17,009
<b>Total Current Assets</b>		<b>50,390</b>	<b>18,297</b>
<b>Total Assets</b>		<b>102,835</b>	<b>18,669</b>
<b>Equity and Liabilities</b>			
<b>Equity attributable to equity holders</b>			
Called up share capital	16	2,518	1,619
Share premium account	16	158,449	75,588
Profit and loss account		(2,269)	31,225
Share based payment reserve		6,485	3,791
Merger reserve		(106,625)	(106,625)
Foreign currency translation reserve		1,968	(1,250)
Treasury shares		(41)	-
<b>Total Equity</b>		<b>60,485</b>	<b>4,348</b>
<b>Liabilities</b>			
<b>Non-current liabilities</b>			
Loans and other borrowings	18	31,276	4,701
<b>Current liabilities</b>			
Trade and other payables	17	5,657	4,167
Loans and other borrowings	18	5,417	5,453
		<b>11,074</b>	<b>9,620</b>
<b>Total Liabilities</b>		<b>42,350</b>	<b>14,321</b>
<b>Total Equity and Liabilities</b>		<b>102,835</b>	<b>18,669</b>

**Consolidated Cash Flow Statement for the year ended 31 December 2020**

	Note	2020 \$'000	2019 \$'000
<b>Cash flows from operating activities:</b>			
Cash used in operations	20	(26,104)	(20,665)
Income tax credit received		740	834
<b>Net cash used in operating activities</b>		<b>(25,364)</b>	<b>(19,831)</b>
<b>Cash flows from investing activities:</b>			
Interest received		41	432
<b>Net cash generated from investing activities</b>		<b>41</b>	<b>432</b>
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of Ordinary Shares	16	51,933	180
Issue costs of Ordinary Shares	16	(3,533)	(8)
Repayments of lease liabilities – principal and interest		(115)	(101)
Loan proceeds	19	13,910	-
Loan repayments	19	(4,621)	-
Interest and fees paid on loans	19	(1,586)	(998)
<b>Net cash generated from / (used in) financing activities</b>		<b>55,988</b>	<b>(927)</b>
<b>Net increase / (decrease) in cash and cash equivalents</b>		<b>30,665</b>	<b>(20,326)</b>
Cash and cash equivalents at beginning of the period		17,009	37,443
Effect of exchange rate movements on cash held		(981)	(108)
<b>Cash and cash equivalents at end of the period</b>	15	<b>46,693</b>	<b>17,009</b>

## Consolidated Statement of Changes in Equity for the year ended 31 December 2020

	Issued Share Capital	Share Premium	Profit and Loss account	Merger reserve	Share based payment reserve	Foreign currency translation reserve	Treasury Shares	Total Equity
	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000
<b>Balance at 1 January 2019</b>	<b>1,581</b>	<b>75,454</b>	<b>54,064</b>	<b>(106,625)</b>	<b>1,354</b>	<b>(1,172)</b>	<b>-</b>	<b>24,656</b>
Loss for the period	-	-	(22,839)	-	-	-	-	(22,839)
Exchange differences	-	-	-	-	-	(78)	-	(78)
Total comprehensive expense for the period	-	-	(22,839)	-	-	(78)	-	(22,917)
Warrants issued	-	-	-	-	-	-	-	-
<b>Transactions with Owners</b>								
Issue of Ordinary Shares	38	142	-	-	-	-	-	180
Costs of issue of Ordinary Shares	-	(8)	-	-	-	-	-	(8)
Employee share option scheme	-	-	-	-	2,437	-	-	2,437
<b>Balance at 31 December 2019</b>	<b>1,619</b>	<b>75,588</b>	<b>31,225</b>	<b>(106,625)</b>	<b>3,791</b>	<b>(1,250)</b>	<b>-</b>	<b>4,348</b>
<b>Balance at 1 January 2020</b>	<b>1,619</b>	<b>75,588</b>	<b>31,225</b>	<b>(106,625)</b>	<b>3,791</b>	<b>(1,250)</b>	<b>-</b>	<b>4,348</b>
Loss for the period	-	-	(33,478)	-	-	-	-	(33,478)
Exchange differences	-	-	-	-	-	3,218	-	3,218
Total comprehensive expense for the period	-	-	(33,478)	-	-	3,218	-	(30,260)
<b>Transactions with Owners</b>								
Issue of Ordinary Shares	832	86,394	-	-	-	-	-	87,226
Costs of issue of Ordinary Shares	-	(3,533)	-	-	-	-	-	(3,533)
Issue of Ordinary Shares to the EBT	57	-	-	-	-	-	(57)	-
Transfer of Treasury Shares to employees	-	-	(16)	-	-	-	16	-
Issue of shares on exercise of options	10	-	-	-	-	-	-	10
Employee share option scheme	-	-	-	-	2,694	-	-	2,694
<b>Balance at 31 December 2020</b>	<b>2,518</b>	<b>158,449</b>	<b>(2,269)</b>	<b>(106,625)</b>	<b>6,485</b>	<b>1,968</b>	<b>(41)</b>	<b>60,485</b>

## 1. General information

Acacia Pharma Group plc is a public limited company incorporated and domiciled in England and Wales with registered number 09759376. The Company's registered office is The Officers' Mess, Royston Road, Duxford, Cambridge CB22 4QH.

The principal activity of the Company and its subsidiaries (together "the Group") is that of a pharmaceutical business which discovers, develops and commercialises lower risk pharmaceutical product opportunities within its therapeutic areas of interest.

The Group's Financial Statements are presented as at and for the year ended 31 December 2020.

Acacia Pharma's 2020 Annual Report will be posted to shareholders and will be available on the Company's website, [www.acaciapharma.com](http://www.acaciapharma.com). The financial information set out herein does not constitute the Company's statutory accounts for the years ended 31 December 2020 or 2019 but is derived from those accounts. Statutory accounts for 2019 have been delivered to the Registrar of Companies, and those for 2020 will be delivered to the Registrar of Companies following the Company's Annual General Meeting. The auditor has reported on those accounts; their reports were unqualified and did not contain a statement under section 498 (2) or (3) of the Companies Act 2006 but did include an emphasis of matter in relation to going concern.

### Basis of preparation

The Group Financial Statements have been prepared in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006, international financial reporting standards adopted pursuant to Regulation (EC) No 1606/2002 as it applies in the European Union and those parts of the Companies Act 2006 applicable to companies reporting under IFRS.

Following careful consideration by the directors, as set out in the Going Concern section of note 1 below, the Group Financial Statements have been prepared on a going concern basis and under the historical cost convention. The principal accounting policies set out in the 2020 Annual Report have been consistently applied to all periods presented with the exception of IFRS15, discussed below.

### Changes in accounting policy and disclosures

#### *(a) New standards, amendments and interpretations adopted by the group*

IFRS 15 'Revenue from contracts' was issued by the IASB in January 2016, and was implemented by the Group once revenue started to be generated. There are therefore no changes in accounting policies to disclose, a new policy has however been adopted below.

#### *(b) Standards, amendments and interpretations that are not yet effective and have not been early adopted*

There are no standards that are not yet effective and that would be expected to have a material impact on the Group in the current or future reporting periods and on foreseeable future transactions.

### Intangibles

The separately acquired licence to BYFAVO is shown at historical cost, under the cost accumulation model, whereby contingent consideration, comprising development and sales milestones, is not considered upon initial recognition of the asset, but is added to the cost of the asset initially recorded when incurred. The license has a finite useful life, and is subsequently carried at cost less accumulated amortisation and impairment losses. Amortisation is calculated on a straight-line basis over the patent life, being 7 years from FDA approval on 2 July 2020. Amortisation is charged to general and administrative expenses in the income statement. Amortisation on future sales milestones will be charged over the remaining patent life from the point of recognition.

## Revenue

The Group generates all of its revenue from Product Sales. Revenue is recognised in accordance with IFRS15 'Revenue from Contracts with Customers'. Revenue on the sales of products to the customer is recognised when a contractual promise to a customer (performance obligation) has been fulfilled by transferring control over the promised goods to the customer (typically upon delivery, which is also when transfer of title occurs). The amount of revenue recognised is based on the consideration Acacia expects to receive in exchange for its goods, when it is highly probable that a significant reversal will not occur.

The consideration Acacia receives in exchange for its goods may be fixed or variable. The most common elements of variable consideration are commercial and government rebates, fee for service agreements, prompt pay discounts, returns and allowances, and chargebacks. Given the levels of revenue in the current year, these estimates are not considered significant.

The methodology and assumptions used to estimate rebates, discounts and returns are monitored and adjusted regularly in the light of contractual and legal obligations, management experience, projected market conditions, and other information that is reasonably available to us.

Provisions for revenue deductions are adjusted to actual amounts as rebates, discounts and returns are processed. The provision represents estimates of the related obligations, requiring the use of judgment when estimating the effect of these revenue deductions.

## Going concern

The financial statements have been prepared on a going concern basis which assumes that the Group and Company will continue in operational existence for the foreseeable future. The Directors have considered a period of 18 months in making their going concern assessment.

The Directors' base case forecast and plans assume the successful commercialisation of BARHEMSYS and BYFAVO. The downside scenario assumes that revenue remains consistent with that earned in Q1 of 2021. Based on both the Directors' base case scenario and severe but plausible downside scenario assessments, and considering the existing cash and debt facilities, the Group and Company have sufficient funding to commercialise BARHEMSYS and BYFAVO until the end of Q2 of 2022. These forecasts are dependent on revenues which are not certain, and there is a need for additional financing to continue commercialisation and for the group to continue as a going concern.

Based on prior fundraising experience, the Directors are confident that they will be able to secure additional financing by the end of Q2 of 2022 and therefore consider it appropriate to prepare these financial statements on the going concern basis. However, there is no guarantee that attempts to raise adequate additional financing on a timely basis will be successful and therefore this represents a material uncertainty, which may cast significant doubt about the Group's and Company's ability to continue as a going concern. These financial statements do not include the adjustments that would result if the Group or Company were unable to continue as a going concern.

## 2. Segmental reporting

The Group has adopted IFRS 8, "Operating Segments". IFRS 8 defines operating segments as those activities of an entity about which separate financial information is available and which are evaluated by the Chief Operating Decision Maker to assess performance and determine the allocation of resources. The Chief Operating Decision Maker has been identified as the Board of Directors.

The Directors are of the opinion that under IFRS 8 the Group has only one operating segment, being the development and commercialisation of intellectual property through direct sale of the protected products in the US and long-term licensing income elsewhere. The Board of Directors assess the performance of the operating segment using financial information which is measured and presented in a manner consistent with that in the financial information. The Group has no reportable operating segments separate from the Income Statement presented in this Financial Information.

### 3. Finance income

	2020 \$'000	2019 \$'000
Bank account interest	-	6
Interest on short-term deposits	41	426
	<b>41</b>	<b>432</b>

### 4. Finance expense

	2020 \$'000	2019 \$'000
Foreign exchange losses	234	57
Finance charges on term loan	2,156	1,446
Finance charge on Cosmo debt-equity swap	788	-
Interest expense on lease liabilities	34	42
	<b>3,212</b>	<b>1,545</b>

### 5. Income tax

	2020 \$'000	2019 \$'000
<b>Current tax</b>		
Current year tax credit	560	666
Prior year adjustments	54	2
<b>Total tax credit</b>	<b>614</b>	<b>668</b>

As at 31 December 2020, the unrecognised deferred tax assets relating to operating losses amounted to \$14,123,000 (2019: \$7,885,000). These have not been recognized due to the uncertainty over the utilisation of the losses.

### 6. Basic and diluted losses per Ordinary Share

Basic and diluted losses per Ordinary Share is calculated by dividing the loss for the financial year by the weighted average number of Ordinary Shares in issue during the year. The losses and weighted average number of shares used in the calculations are set out below:

	2020	2019
Losses per Ordinary Share		
Loss for the financial year (\$'000)	<b>(33,478)</b>	(22,839)
Weighted average number of Ordinary Shares (basic) (thousands)	<b>73,580</b>	53,680
Losses per Ordinary Share basic (\$)	<b>(0.46)</b>	(0.43)

Share options and convertible instruments are anti-dilutive in both 2020 and 2019 for the purposes of the losses per share calculation and their effect is therefore not considered.



## 7. Cash and cash equivalents

The Group retains all cash on instant access accounts in Sterling, Euros and US dollars.

	<b>2020</b>	2019
	<b>\$'000</b>	\$'000
Sterling accounts	<b>663</b>	918
Euro accounts	<b>29,516</b>	229
US Dollar accounts	<b>16,514</b>	15,862
	<b>46,693</b>	17,009

## 8. Intangibles

	<b>BYFAVO licence</b>
	\$'000
<b>Year ended 31 December 2020</b>	
<b>Opening net book amount</b>	-
Additions	51,359
Amortisation	(3,051)
Foreign exchange differences	3,860
<b>Closing net book amount</b>	<b>52,168</b>
<b>At 31 December 2020</b>	
Cost or fair value	55,219
Accumulated amortisation	(3,051)
<b>Net book amount</b>	<b>52,168</b>

The intangible asset acquired in the period represents amounts paid to Cosmo for the BYFAVO license. Amortisation is included within general and administrative expenses in the income statement. Under the terms of the agreement, a number of milestones became payable during the year as set out below.

<b>Date</b>	<b>Number of shares issued</b>	<b>Milestone</b>	<b>Fair value</b>
			\$'000
January 2020	4,646,841	€15 million on contract inception	11,959
July 2020	4,923,811	€15 million on BYFAVO approval	16,421
July 2020	-	€15 million on BYFAVO approval – cash payment	16,844
December 2020	2,099,958	€5 million on BYFAVO commercial milestone	6,134
<b>As at 31 December 2020</b>			<b>51,358</b>

The remaining useful economic life at the year end date is 6.5 years. Additional commercial milestones will become payable on sales above certain levels.

## 9. Share capital and premium

Share capital and premium	Ordinary shares of £0.02	Ordinary shares of £0.02	Share premium
	Number	\$'000	\$'000
<b>At 1 January 2019</b>	<b>53,329,205</b>	<b>1,581</b>	<b>75,454</b>
Issue of Ordinary Shares upon exercise of share options	1,558,993	38	142
Issue costs			(8)
<b>At 31 December 2019 and 1 January 2020</b>	<b>54,888,198</b>	<b>1,619</b>	<b>75,588</b>
Issue of Ordinary Shares	34,709,753	899	86,394
Issue costs			(3,533)
<b>At 31 December 2020</b>	<b>89,597,951</b>	<b>2,518</b>	<b>158,449</b>

## 10. Loans and other borrowings

	2020 \$'000	2019 \$'000
<b>Loans and other borrowings payable within one year</b>		
Term loans, amounts payable within one year	5,298	5,337
Lease liability, amounts payable within one year	119	116
<b>Total Loans and other borrowings payable within one year</b>	<b>5,417</b>	<b>5,453</b>
<b>Loans and other borrowings payable after one year</b>		
Term loans, amounts payable after one year	31,087	4,428
Lease liability, amounts payable after one year	189	273
<b>Total Loans and other borrowings payable after one year</b>	<b>31,276</b>	<b>4,701</b>

The carrying amount of the Group's borrowings are denominated in the following currencies:

	2020 \$'000	2019 \$'000
Euro	30,753	-
US dollar	5,940	10,154
	<b>36,693</b>	<b>10,154</b>

The fair value of non-current borrowings is \$31.3 million, based on cash flows discounted using a rate based on the borrowing rate of each loan. The fair values of current borrowings are considered to equal their carrying value, as the impact of discounting is not significant.

## 11. Cash used in operations

	2020 \$'000	2019 \$'000
Loss before income tax	(33,974)	(23,507)
Adjustments for:		
Share-based payments	2,582	2,437
Foreign exchange (gain)/loss	234	57
Finance expense	2,977	1,488
Finance income	(41)	(432)
Depreciation and amortisation	3,146	95
Changes in working capital		
- Decrease / (Increase) in trade and other receivables	150	(369)
- (Increase) in inventory	(2,662)	-
- Increase / (Decrease) in trade and other payables	1,484	(434)
<b>Cash used in operations</b>	<b>(26,104)</b>	<b>(20,665)</b>

## 12. Commitments and contingencies

### a) Commitments on expenditure

Expenditure contracted for at the year end but not yet incurred is as follows:

	2020 \$'000	2019 \$'000
Inventory	1,548	166
Research and development expenditure	736	230
Total	2,284	396

### b) Short-term lease commitments

Lease payments represent amounts payable by the Group for its office property held under short-term (< 1 year) leases. The future aggregate minimum lease payments under non-cancellable short-term operating leases at the balance sheet date were as follows:

	2020 \$'000	2019 \$'000
Payments under operating leases which fall due:		
Within 1 year	25	28
Total	25	28

### **13. Post period events**

On 23 February 2021, the Company completed a capital raise by way of a Placing of new ordinary shares. The capital raise had gross proceeds of €27 million (\$33m), providing the Group with additional financial resources to support the continued launch and roll out of BARHEMSYS and BYFAVO in the US.

Following the end of the United Kingdom's transition period for leaving the European Union on 31 December 2020, the United Kingdom can no longer be the home Member State of Acacia Pharma for the purposes of Directive 2004/109/EC of 15 December 2004 on the harmonisation of transparency requirements in relation to information about issuers whose securities are admitted to trading on a regulated market and amending Directive 2001/34/EC (the EU Transparency Directive).

The Group chose Belgium as its home Member State in accordance with article 10, §3, of the Belgian Act of 2 August 2002 regarding financial supervision and financial services. The Company has given due notice of this change to the Belgian Financial Services and Markets Authority (the "Belgian FSMA").