

13 August 2020

THIS ANNOUNCEMENT CONTAINS INSIDE INFORMATION FOR THE PURPOSES OF ARTICLE 7 OF EU REGULATION 596/2014.

Acacia Pharma Group plc

Interim Results for the Six Months ended 30 June 2020

- *US approval for BARHEMSYS® for postoperative nausea & vomiting (PONV)*
- *US approval of BYFAVO™ for procedural sedation*
- *Strategic agreement with Cosmo Technologies providing funding for US commercialization*
- *Good progress with preparations for US launch in 2H 2020*

Cambridge, UK and Indianapolis, US – 13 August 2020: Acacia Pharma Group plc (“**Acacia Pharma**” or the “**Company**” and, together with its subsidiaries, the “**Group**”) (EURONEXT: ACPH), a commercial stage biopharmaceutical company focused on developing and commercializing novel products to improve the care of patients undergoing serious medical treatments such as surgery, invasive procedures, or chemotherapy, announces its unaudited interim results for the six-month period ended 30 June 2020.

Mike Bolinder, CEO of Acacia Pharma, said: “The first half of 2020 was truly a transformative period for the Company. We were delighted to gain FDA approval for our first product, BARHEMSYS®, in February. We identified and developed this product through an extensive and successful clinical trials program and it is testament to the founders and employees of the company for achieving this significant milestone.

“The in-licensing and subsequent US approval of BYFAVO™ added a second product to strengthen our portfolio targeting the anesthesiology market. We are now focused on building the optimal commercial organization to launch both products in the US, where we believe there is significant need for our new products.

The coronavirus has created many challenges for the global healthcare system and supply chains. We believe it has also created opportunity for our products, and that we will see strong demand for both products given that they are designed in part to improve procedural throughput to help address the current surgical backlogs in hospitals and surgical centres that exist as a result of the pandemic. We also believe that in making these new products available, we can satisfy the demand for products addressing PONV and procedural sedation owing to shortages of supply that currently exist for the current standard-of-care drugs for these indications.

Our focus is now wholly on executing a successful launch of BARHEMSYS® and BYFAVO™ in 2H 2020, which will further accelerate our transition from an R&D-led company into a commercial business bringing much needed treatments to patients in the US. We look forward to an exciting time ahead and to providing further updates on our progress.”

Operating Highlights (including post-period updates)

- On 26 February 2020, the US Food and Drug Administration (FDA) approved the New Drug Application (NDA) for BARHEMSYS® (amisulpride injection), the Company’s first product approval, allowing its commercialization in the US for the treatment and prevention of postoperative nausea and vomiting (PONV).
 - The label is the first to include rescue treatment in patients who have failed prior prophylaxis, and also includes combination prophylaxis with other antiemetics in higher risk patients, the two key commercial unmet needs.
 - On 27 July 2020, FDA approved a second supplier for the active pharmaceutical ingredient (API) for BARHEMSYS®, supporting the Group’s ability to provide a continuous, high-quality product supply to meet the anticipated ongoing demand.

- On 2 July 2020, FDA approved the NDA for the Group's second product, BYFAVO™ (remimazolam), a rapid onset/offset IV benzodiazepine sedative for injection, for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less, such as colonoscopy and bronchoscopy.
 - BYFAVO™ was in-licensed on 10 January 2020 from Cosmo Technologies Limited (Cosmo) as part of a strategic agreement that also involved Cosmo making an equity investment in Acacia Pharma and providing a debt facility to the Group to finance the US commercialization of BARHEMSYS® and BYFAVO™.
 - On 1 June 2020, the Company announced that €10m of the overall Cosmo debt facility had been replaced by a €10m equity investment.
 - With effect from 7 August 2020, the Group was assigned the US license to BYFAVO™ by Cosmo with the consent of PAION UK Limited, thereby establishing a direct relationship between the originator of remimazolam and the Group as its US commercialization partner.
- US infrastructure established in preparation for launch of BARHEMSYS® and BYFAVO™ in 2H 2020.
 - The Company has assembled a highly experienced commercial leadership team with proven success in commercializing specialty pharmaceutical products to anaesthetists, surgical teams and directors of pharmacy – the target customers for BARHEMSYS® and BYFAVO™.
 - With both products approved, the Company is advancing its plans to build an initial hospital sales force and support staff ahead of launch in the 2H 2020.
 - The Company believes that the procedural backlogs and standard-of-care drug shortages, as a result of the coronavirus situation, have created potential pent-up demand for drugs such as BARHEMSYS® and BYFAVO™.
- The Company announced changes to its senior management team and Board of Directors during 1H 2020 as part of its planned transition into a commercial-stage company.
 - With effect from 1 March 2020, Gary Gemignani was appointed Chief Financial Officer, succeeding Christine Soden who stepped down from the role and retired from the Board of Directors.
 - At the Annual General Meeting (AGM) on 7 April 2020, Scott Byrd was elected Chairman and Alessandro Della Chà, Chief Executive Officer and Director of Cosmo, was elected as a Non-Executive Director.
 - Patrick Vink (former Chairman), Pieter van der Meer and Johan Kördel (both former Non-Executive Directors) previously announced their intentions not to stand for re-election and stepped down from the Board at the AGM.

Financial Highlights

- Cash and cash equivalents were \$24.6m at 30 June 2020 (31 December 2019: \$17.0m, 30 June 2019: \$22.7m).
- Operating loss for the period remained flat at \$12.8m (1H 2019: \$12.8) as the Group transitions from an R&D-led business towards the launch and commercialization of BARHEMSYS® and BYFAVO™.
 - G&A costs increased \$2.2m in 1H 2020 to \$4.4m (1H 2019: \$2.2m) as a result of increased legal and other costs mainly related to the transactions with Cosmo Pharmaceuticals.
 - R&D costs in the 1H 2020 decreased to \$0.6m (1H 2019: \$2.5m) due to costs in the prior year attributed to activities preparing the NDA for BARHEMSYS®.
- Basic loss per share \$0.24 (H1 2019: \$0.25).

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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® (amisulpride injection) for postoperative nausea & vomiting (PONV), has been approved by the US Food and Drug Administration, with US launch planned for 2H 2020.

BYFAVO™ (remimazolam) for injection, a rapid onset/offset IV benzodiazepine sedative is approved in the US for use during invasive medical procedures in adults lasting 30 minutes or less, such as colonoscopy and bronchoscopy. Acacia Pharma's rights to further develop and commercialise BYFAVO™ are in-licensed from Paion UK Limited for the US market, and US launch is planned for 2H 2020.

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 is based in Cambridge, UK and its US operations are centred in Indianapolis, IN. The Company is listed on the Euronext Brussels exchange under the ISIN code GB00BYWF9Y76 and ticker symbol ACPH.

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, prospectus, 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

The first half of the year has been a transformative period for Acacia and we are extremely pleased with the accomplishments our team has achieved during this period. We entered into a strategic relationship with Cosmo Pharmaceuticals whereby Cosmo initially invested €10 million into the Company, we in-licensed BYFAVO, a procedural sedation product that is highly complementary to BARHEMSYS, and we were provided access to additional capital of up to €35 Million upon achieving certain milestones, all of which have been achieved. To date we have received €20 Million of capital, including Cosmo's equity investment. BARHEMSYS was approved for post-operative nausea and vomiting (PONV) in February 2020 and BYFAVO was approved for Procedural Sedation in July 2020.

We expect to be launching both drugs into large target markets, with a primary focus on anaesthesia providers in the second half of the year with a very experienced commercial team. While the COVID pandemic has led to drug shortages and a procedural backlog 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 centers as we emerge from the crisis caused by the pandemic and we are planning to launch BARHEMSYS and BYFAVO in the coming months as the hospitals begin to reconvene their formulary committee meetings and our access to key decision makers improves.

We have made good progress in building our US commercial infrastructure to ensure an expeditious launch for BARHEMSYS and BYFAVO in the second half of 2020. We believe our products demonstrate great portfolio synergy as they are both targeted toward anesthesia with similar value propositions.

We now have an experienced team of 37 full-time employees and they continue to plan for launch, liaising with key group purchasing organisations and integrated delivery networks and understanding large target accounts. While the Group remains on track with its launch readiness plan it has been necessary to restrict activities, due to the outbreak of the global Coronavirus pandemic, which enabled the company to preserve cash resources.

On 11 March 2020, the World Health Organisation announced that the outbreak of COVID-19 (commonly referred to as Coronavirus) had been declared a global pandemic. The long-term impacts of the outbreak are unknown and rapidly evolving. Whilst the FDA approved BARHEMSYS for marketing in the US on 26 February 2020, the Group had to adjust its commercialisation strategy for BARHEMSYS and delay some of the previously planned launch activities as a direct result of COVID-19 owing to restricted access to healthcare settings and the postponement of medical conferences. The commercialisation strategy for BYFAVO has also been adjusted to accommodate the current environment.

Whilst the situation has created certain challenges in accessing decision makers in hospitals and ambiguity around the timing for the resumption of their formulary committee meetings, the COVID-19 situation has created opportunities for the Group as it has led to drug shortages for the most commonly used procedural sedatives like midazolam and propofol as well as antiemetics like ondansetron and dexamethasone, all of which are currently on the FDA drug shortages list. It has also created procedural backlogs and pent up demand for the launch of the Group's products as hospitals and surgical centers now need to significantly increase their patient throughput, which has further heightened the value proposition for both drugs as customers seek to regain lost profits.

The situation has caused the Group to adjust its commercialisation strategy to accommodate more virtual engagements with clinical staff and further reinforces the need for the Group to recruit and retain experienced representatives with longstanding key customer relationships to facilitate dialogue even with restricted physical access to the facility. Furthermore, due to the increasing virtual engagement with hospital accounts, the Directors believe the sales representatives can increase their customer reach, thereby enabling the sales team to become even more productive and able to address a greater number of customers and accounts than previously envisaged.

Mike Bolinder,
Chief Executive Officer

FINANCIAL REVIEW

Sales & marketing costs

As we transition from a research and development led business towards the launch and commercialization of BARHEMSYS and BYFAVO, our expenditures have shifted towards sales and marketing costs. Sales and marketing costs for the first half of 2020 reduced slightly in comparison to prior year at \$7.8m (1H 2019: \$8.1m), mainly due to the decrease in activity, particularly travel and conference costs, occurring as a result of the coronavirus pandemic. We expect the costs associated with the launch and commercialization of BARHEMSYS and BYFAVO to increase in 2H 2020.

General & administrative costs

General and administrative costs increased \$2.2m in 1H to \$4.4m (1H 2019: \$2.2m), largely as a result of legal and other costs in relation to the Cosmo transaction, together with increased staff costs.

Research & development (R&D) expenses

R&D activities have been focused on developing BARHEMSYS for regulatory approval. R&D costs in the first half of 2020 decreased to \$0.6m (1H 2018: \$2.5m) as the development activities wound down.

Operating loss

The operating loss for the period was \$12.8m (1H 2019: \$12.9m).

Financial expense/income

Net finance expense for the first half of 2020 was \$2.5m (1H 2019: \$0.6m). The finance expense in 2020 relates primarily to the break fee payable on the conversion of the €10m loan facility with Cosmo to a €10m cash investment, together with interest payable on the Hercules Capital term loan (\$0.6m) and foreign exchange losses (\$1.0m).

Taxation

The Group has claimed UK R&D tax credits in respect of prior years. The claim for 2019 has been estimated at \$0.7m and for the first half of 2020, \$0.1m. Given the uncertainty surrounding the timing of using tax losses, no deferred tax asset has been recognized.

Loss per share

Basic loss per share the first half of 2020 was \$0.24 (1H 2019: \$0.25), reflecting the significant increase of 10.9 million in the weighted average number of Ordinary Shares (1H 2020: 63.9 million average; 1H 2019: 53.1 million average) following the Cosmo transaction.

Current assets

Current assets in the period increased to \$25.5m as at 30 June 2020 (31 December 2019 : \$18.3m, 30 June 2019: \$24.1m), with higher cash balances driven by the equity investments made by Cosmo Pharmaceuticals N.V.

Non-current assets

Non-current assets as at 30 June 2020 increased to \$11.5m (31 December 2019: \$0.4m, 30 June 2019: \$0.4m) as a result of the in-licensing of BYFAVO.

Non-current liabilities

Non-current liabilities as at 30 June 2020 decreased to \$2.7m (31 December 2019: \$4.7m, 30 June 2019: \$6.3m) due to planned loan repayments made in 1H 2020 reducing the Hercules loan balance.

Current liabilities

Current liabilities increased to \$8.6m as at 30 June 2020 (31 December 2019: \$9.6m, 30 June 2019: \$6.1m) as a result of scheduled loan repayments over the next 12 months.

Cash flow

Cash outflow from operating activities in 1H 2020 decreased to \$11.9m (1H 2019: \$14.5m) as a result of reduced cash spend due to Covid-19. Cash and cash equivalents were \$24.6m at 30 June 2020 (31 December 2019: \$17.0m, 30 June 2019: \$22.7m).

Consolidated Statement of Comprehensive Income

| | Note | Six months ended 30 June 2020 Unaudited \$'000 | Six months ended 30 June 2019 Unaudited \$'000 | Year ended 31 December 2019 Audited \$'000 |
|--------------------------------------|------|--|--|--|
| Continuing operations: | | | | |
| Research and development expenditure | | (623) | (2,511) | (3,928) |
| Sales and marketing expenses | | (7,781) | (8,103) | (14,019) |
| Administrative expenses | | (4,373) | (2,235) | (4,447) |
| Operating loss | | (12,777) | (12,849) | (22,394) |
| Finance income | 3 | 39 | 274 | 432 |
| Finance expenses | 4 | (2,523) | (896) | (1,545) |
| Loss before income tax | | (15,261) | (13,471) | (23,507) |
| Tax on loss | 5 | 65 | 352 | 668 |
| Loss for the period | | (15,196) | (13,119) | (22,839) |

| | | Six months ended 30 June 2020 Unaudited \$'000 | Six months ended 30 June 2019 Unaudited \$'000 | Year ended 31 December 2019 Audited \$'000 |
|---|--|--|--|--|
| Loss for the financial year | | (15,196) | (13,119) | (22,839) |
| <i>Items that may be reclassified to profit or loss</i> | | | | |
| Exchange differences on translation of foreign operations | | 360 | 91 | (78) |
| Other comprehensive expense for the financial year | | 360 | 91 | (78) |
| Total comprehensive expense for the financial year | | (14,836) | (13,028) | (22,917) |

Consolidated Statement of Financial Position

Registration number 05934843

| | Note | 30 June 2020 Unaudited \$'000 | 30 June 2019 Unaudited \$'000 | 31 December 2019 Audited \$'000 |
|--|------|--|--|--|
| Assets | | | | |
| Non-Current Assets | | | | |
| Intangibles | 8 | 11,180 | - | - |
| Right-of-use asset | 9 | 325 | 419 | 372 |
| Total Non-Current Assets | | 11,505 | 419 | 372 |
| Current Assets | | | | |
| Other receivables | | 221 | 186 | 609 |
| Current income tax assets | | 700 | 1,223 | 679 |
| Cash and cash equivalents | 10 | 24,612 | 22,729 | 17,009 |
| Total Current Assets | | 25,533 | 24,138 | 18,297 |
| Total Assets | | 37,038 | 24,557 | 18,669 |
| Equity and Liabilities | | | | |
| Equity attributable to equity holders | | | | |
| Called up share capital | 11 | 1,954 | 1,581 | 1,619 |
| Share premium account | 11 | 110,083 | 75,454 | 75,588 |
| Profit and loss account | | 16,029 | 40,945 | 31,225 |
| Share based payment reserve | | 5,171 | 1,880 | 3,791 |
| Merger reserve | | (106,625) | (106,625) | (106,625) |
| Foreign currency translation reserve | | (890) | (1,081) | (1,250) |
| Total Equity | | 25,722 | 12,154 | 4,348 |
| Liabilities | | | | |
| Non-current liabilities | | | | |
| Loans and borrowings | 12 | 2,719 | 6,260 | 4,701 |
| Current liabilities | | | | |
| Trade and other payables | | 3,184 | 2,445 | 4,167 |
| Loans and other borrowings | 12 | 5,413 | 3,698 | 5,453 |
| | | 8,597 | 6,143 | 9,620 |
| Total Liabilities | | 11,316 | 12,403 | 14,321 |
| Total Equity and Liabilities | | 37,038 | 24,557 | 18,669 |

Consolidated Cash Flow Statement

| | Note | Six months ended 30 June 2020 \$'000 | Six months ended 30 June 2019 \$'000 | Year ended 31 December 2019 \$'000 |
|---|------|---|---|--|
| Cash flows from operating activities: | | | | |
| Cash used in operations | 13 | (11,942) | (14,453) | (20,665) |
| Income tax credit received | | - | - | 834 |
| Net cash used in operating activities | | (11,942) | (14,453) | (19,831) |
| Cash flows from investing activities: | | | | |
| Interest received | | 39 | 271 | 432 |
| Net cash generated from investing activities | | 39 | 271 | 432 |
| Cash flows from financing activities: | | | | |
| Proceeds of issuance of Ordinary Shares | 11 | 22,339 | - | 180 |
| Issue costs of Ordinary Shares | 11 | (255) | - | (8) |
| Repayments of lease liabilities | | (58) | (56) | (101) |
| Loan repayments | 12 | (2,221) | - | - |
| Interest and fees paid on loans | | (427) | (504) | (998) |
| Net cash generated from financing activities | | 19,378 | (560) | (927) |
| Net increase / (decrease) in cash and cash equivalents | | 7,475 | (14,742) | (20,326) |
| Cash and cash equivalents at beginning of the period | | 17,009 | 37,443 | 37,443 |
| Effect of exchange rate movements on cash held | | 128 | 28 | (108) |
| Cash and cash equivalents at end of the period | 10 | 24,612 | 22,729 | 17,009 |

Statement of Changes in Equity

| | Issued Share Capital | Share Premium | Profit and Loss account | Merger reserve | Share based payment reserve | Foreign currency translation reserve | Total Equity |
|--|----------------------------|------------------|-------------------------------|-------------------|--------------------------------------|---|-----------------|
| | \$'000 | \$'000 | \$'000 | \$'000 | \$'000 | \$'000 | \$'000 |
| Balance at 1 January 2019 | 1,581 | 75,454 | 54,078 | (106,625) | 1,354 | (1,172) | 24,670 |
| IFRS16 adjustment | - | - | (14) | - | - | - | (14) |
| Adjusted balance at 1 January 2019 | 1,581 | 75,454 | 54,064 | (106,625) | 1,354 | (1,172) | 24,656 |
| Loss for the period | - | - | (13,119) | - | - | - | (13,119) |
| Exchange differences | - | - | - | - | - | 91 | 91 |
| Total comprehensive expense for the period | - | - | (13,119) | - | - | 91 | (13,028) |
| Transactions with Owners | | | | | | | |
| Issue of Ordinary Shares | - | - | - | - | - | - | - |
| Costs of issue of Ordinary Shares | - | - | - | - | - | - | - |
| Employee share option scheme | - | - | - | - | 526 | - | 526 |
| Balance at 30 June 2019 | 1,581 | 75,454 | 40,945 | (106,625) | 1,880 | (1,081) | 12,154 |
| Balance at 1 July 2019 | 1,581 | 75,454 | 40,945 | (106,625) | 1,880 | (1,081) | 12,154 |
| Loss for the period | - | - | (9,720) | - | - | - | (9,720) |
| Exchange differences | - | - | - | - | - | (169) | (169) |
| Total comprehensive expense for the period | - | - | (9,720) | - | - | (169) | (9,889) |
| Transactions with Owners | | | | | | | |
| Issue of Ordinary Shares | 38 | 142 | - | - | - | - | 180 |
| Costs of issue of Ordinary Shares | - | (8) | - | - | - | - | (8) |
| Employee share option scheme | - | - | - | - | 1,911 | - | 2,437 |
| Balance at 31 December 2019 | 1,619 | 75,588 | 31,225 | (106,625) | 3,791 | (1,250) | 4,348 |
| Balance at 1 January 2020 | 1,619 | 75,588 | 31,225 | (106,625) | 3,791 | (1,250) | 4,348 |
| Loss for the period | - | - | (15,196) | - | - | - | (15,196) |
| Exchange differences | - | - | - | - | - | 360 | 360 |
| Total comprehensive expense for the period | - | - | (15,196) | - | - | 360 | (14,836) |
| Transactions with Owners | | | | | | | |
| Issue of Ordinary Shares | 335 | 34,750 | - | - | - | - | 35,085 |
| Costs of issue of Ordinary Shares | - | (255) | - | - | - | - | (255) |
| Employee share option scheme | - | - | - | - | 1,380 | - | 1,380 |
| Balance at 30 June 2020 | 1,954 | 110,083 | 16,029 | (106,625) | 5,171 | (890) | 25,722 |

Notes

1. Summary of significant accounting policies

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 group which discovers, develops and commercializes lower risk pharmaceutical product opportunities within its therapeutic areas of interest.

Statement of compliance

These condensed consolidated interim financial statements have been prepared in accordance with IAS 34 Interim Financial Reporting. They do not contain all of the information which International Financial Reporting Standards ("IFRS") would require for a complete set of annual financial statements, and should be read in conjunction with the consolidated financial statements of the Group for the year ended 31 December 2019.

Comparative financial information

The comparative figures for the period ended 30 June 2019 do not constitute the Group's statutory accounts for that financial year. Statutory accounts for the year ended 31 December 2019, prepared in accordance with International Financial Reporting Standards as adopted by the EU ("Adopted IFRSs") and as issued by the International Accounting Standards Board, have been reported on by the Group's auditor and delivered to the Registrar of Companies. 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.

Accounting policies

The accounting policies applied by the Group in these condensed consolidated interim financial statements are the same as those applied by the Group in its consolidated financial statements for the year ended 31 December 2019, with the exception of the accounting policy on intangibles, set out below, which was adopted in the year. Prior to 10 January 2020, the Group held no material recognisable intangible assets.

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. Amortization is calculated on a straight-line basis over the patent life, being 7 years from FDA approval.

Going concern

The condensed consolidated interim financial statements have been prepared on a going concern basis, which assumes that the Group will be able to meet its liabilities as they fall due for the foreseeable future.

Whilst the group's current cost base is at a level where the Group has sufficient cash and existing facilities in order to meet its liabilities, as they fall due for at least 12 months from the date of approving these condensed consolidated interim financial statements, such a cost base would not enable the commercialisation of BARHEMSYS and Byfavo, with the addition of 30 sales representatives in addition to the existing field force, as is currently planned. Planning is well progressed for an additional equity raise to fund the launch of the products in the region of \$25m to \$30m (the "Proposed Fund Raising"). Following such a fundraising, it is the directors' intentions to commercialise the products and based on the Directors' current forecasts and plans, and, considering the existing cash and debt facilities following the Proposed Fund raising, the Group would have sufficient funding to continue their operations until Q4 of 2021. By this time, the Group will need to raise capital in addition to the Proposed Fund Raising in order to meet their cash requirements for the subsequent periods.

The Directors are confident that it is appropriate to prepare these condensed consolidated interim 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 ability to continue as a going concern. These condensed consolidated interim financial statements do not include the adjustments that would result if the Group were unable to continue as a going concern.

2. Segmental reporting

The Group applies 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 commercialization 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

| | 6 months ended 30 June 2020 \$'000 | 6 months ended 30 June 2019 \$'000 | Year ended 31 December 2019 \$'000 |
|---------------------------------|---|---|---|
| Bank Account interest | - | - | 6 |
| Interest on short-term deposits | 39 | 274 | 426 |
| | 39 | 274 | 432 |

4. Finance expense

| | 6 months ended 30 June 2020 \$'000 | 6 months ended 30 June 2019 \$'000 | Year ended 31 December 2019 \$'000 |
|---------------------------------------|---|---|---|
| Foreign exchange losses | 1,052 | 153 | 57 |
| Finance charges on term loan | 666 | 721 | 1,446 |
| Other finance expenses | 788 | - | - |
| Interest expense on lease liabilities | 17 | 22 | 42 |
| | 2,523 | 896 | 1,545 |

Foreign exchange losses arise primarily on intercompany balances and cash balances held in Pounds Sterling and Euros. Other finance expenses relate to the break fee paid on conversion of the €10m loan facility with Cosmo to an equity investment.

5. Taxation

Analysis of taxation credit in the period

| | 6 months ended 30 June 2020 \$'000 | 6 months ended 30 June 2019 \$'000 | Year ended 31 December 2019 \$'000 |
|-------------------------------------|---|---|---|
| United Kingdom corporation tax | 65 | 352 | 666 |
| Adjustment relating to prior period | - | - | 2 |
| | 65 | 352 | 668 |

The Company is entitled to claim tax credits in the United Kingdom for certain research and development expenditure. The amount included in the financial statements represents the estimated credit receivable by the Company for the year. The 2019 amounts have not yet been agreed with the relevant tax authorities.

6. Losses per share

| | 6 months ended 30 June 2020 \$'000 | 6 months ended 30 June 2019 \$'000 | Year ended 31 December 2019 \$'000 |
|--|---|---|---|
| Loss for the financial period (\$'000) | (15,196) | (13,119) | (22,839) |
| Weighted average number of Ordinary Shares (thousands) | 63,914 | 53,133 | 53,680 |
| Losses per ordinary share (\$) | (0.24) | (0.25) | (0.43) |

Share options are anti-dilutive in each period for the purposes of the losses per share calculation and their effect is therefore not considered.

7. Share-based payments

Awards made under long-term incentive and other arrangements

Share options are granted to Directors and employees over Ordinary Shares in Acacia Pharma Group plc. Prior to the IPO, options were awarded under the Acacia Pharma EMI Share Option Scheme (the EMI Scheme) and the Acacia Pharma Unapproved Share Option Scheme (the Unapproved Scheme). Following the IPO, new share options schemes were arranged, being the Acacia Pharma Group Performance Share Plan (the 'PSP') and the Company Share Option Plan (the 'CSOP').

Options granted under the Unapproved Scheme, the EMI Scheme and the CSOP have a fixed exercise price based on the market value of shares at the date of grant. Options granted under the PSP have a minimal or nil exercise price.

Options are usually conditional on the employee completing three years' service (the vesting period). The options are exercisable starting three years from the grant date.

The share based payment charge for the period is \$1,380,000 (30 June 2019: \$526,000, 31 December 2019: \$2,437,000)

| | Performance Share Plan | | Company Share Option Plan | | EMI plan | | Unapproved | | Total | |
|--|------------------------|-------------------------------------|---------------------------|-------------------------------------|------------------|-------------------------------------|----------------|-------------------------------------|------------------|-------------------------------------|
| | Options number | Weighted average exercise price (£) | Options number | Weighted average exercise price (£) | Options number | Weighted average exercise price (£) | Options number | Weighted average exercise price (£) | Options number | Weighted average exercise price (£) |
| Outstanding at 1 January 2020 | 3,659,852 | 0.02 | 44,444 | 1.35 | 1,517,476 | 0.07 | 767,500 | 1.58 | 5,989,272 | 0.05 |
| Granted in the period | 603,500 | 0.02 | - | - | - | - | - | - | 603,500 | 0.02 |
| Lapsed in the year | (192,839) | 0.02 | - | - | - | - | - | - | 192,839 | 0.02 |
| Exercised during the year | (154,391) | 0.02 | - | - | (237,000) | 0.02 | - | - | (391,391) | 0.02 |
| Outstanding at 30 June 2020 | 3,916,122 | 0.02 | 44,444 | 1.35 | 1,280,476 | 0.09 | 767,500 | 1.25 | 6,008,542 | 0.39 |
| Exercisable at 30 June 2020 | - | - | - | - | 1,280,476 | 0.09 | 767,500 | 1.25 | 2,047,976 | 0.52 |
| Weighted average life remaining – 30 June 2020 | 9.03 | | 9.48 | | 3.51 | | 5.99 | | 5.72 | |

8. Intangibles

| | Licenses \$'000 |
|--------------------------|--------------------|
| At 1 January 2020 | |
| Opening net book value | - |
| Additions | 11,959 |
| Amortization charge | - |
| Foreign exchange loss | (779) |
| At 30 June 2020 | 11,180 |

Amortization is charged over the patent life from FDA approval. FDA approval was received for BYFAVO on 2 July 2020, accordingly no amortization has been charged in the period.

9. Right of use asset

The Group leases office property in Indianapolis, for which the lease term is 5 years.

| | Buildings \$'000 |
|--|---------------------|
| Net carrying amount | |
| At 30 June 2019 | 419 |
| At 31 December 2019 | 372 |
| At 30 June 2020 | 325 |
| Depreciation expense for the period ended | |
| 30 June 2019 | 40 |
| 31 December 2019 | 95 |
| 30 June 2020 | 47 |

10. Cash and cash equivalents

The Company retains all cash on instant access accounts in Pounds Sterling, US Dollars and Euros.

| | 30 June 2020 \$'000 | 30 June 2019 \$'000 | 31 December 2019 \$'000 |
|--------------------------|---------------------------|---------------------------|-------------------------------|
| Pounds Sterling accounts | 332 | 711 | 918 |
| Euro accounts | 11,562 | 19 | 229 |
| US Dollar accounts | 12,718 | 21,999 | 15,862 |
| | 24,612 | 22,729 | 17,009 |

11. Called up share capital

| Share capital and premium | Ordinary Shares Number | Ordinary Shares \$'000 | Share premium \$'000 |
|---|---------------------------|------------------------------|----------------------------|
| At 1 January 2019 | 53,329,205 | 1,581 | 75,454 |
| Issue of Ordinary Shares upon exercise of share options | 6,215 | - | - |
| At 30 June 2019 | 53,335,420 | 1,581 | 75,454 |
| Issue of Ordinary Shares upon exercise of options | 1,552,778 | 38 | 142 |
| Issue costs | - | - | (8) |
| At 31 December 2019 | 54,888,198 | 1,619 | 75,588 |
| At 1 January 2020 | 54,888,198 | 1,619 | 75,588 |
| Issue of Ordinary Shares | 7,929,488 | 203 | 22,913 |
| Issue of Ordinary Shares in consideration for license | 4,646,841 | 122 | 11,837 |
| Issue of Ordinary Shares upon exercise of options | 391,391 | 10 | - |
| Issue costs | - | - | (255) |
| At 30 June 2020 | 67,855,918 | 1,954 | 110,083 |

12. Loans and other borrowings

Term loans and convertible instruments

A term loan facility with Hercules Capital was drawn on 29 June 2018. The initial tranche drawn was \$10 million and costs of \$644k were incurred. The loan bears interest at the higher of 9.5% or the Wall Street Journal prime rate plus 4.5%, bears a final payment charge of 3.95% of the principal, and was interest only until January 2020. Thereafter the principal and interest on the loan is repayable in 25 equal monthly instalments. Warrants over 201,330 Ordinary Shares, exercisable at €3.22 per share, were issued to Hercules Capital as part of the terms of the loan facility. The later tranches of the \$30 million facility were only automatically available subject to receiving FDA approval for BARHEMSYS by 30 April 2019.

Lease liability

Lease payments represent amounts payable by the Company for its office property.

| | 30 June 2020 \$'000 | 30 June 2019 \$'000 | 31 Dec 2019 \$'000 |
|---|---------------------------|---------------------------|--------------------------|
| Loans and other borrowings payable within one year | | | |
| Term bank loan, amounts payable within one year | 5,296 | 3,622 | 5,337 |
| Lease liability, amounts payable within one year | 117 | 76 | 116 |
| Total Loans and other borrowings payable within one year | 5,413 | 3,698 | 5,453 |
| Loans and other borrowings payable after one year | | | |
| Term bank loan, amounts payable after one year | 2,488 | 5,912 | 4,428 |
| Lease liability, amounts payable after one year | 231 | 348 | 273 |
| Total Loans and other borrowings payable after one year | 2,719 | 6,260 | 4,701 |

13. Cash used in operations

| | 6 months ended 30 June 2020 \$'000 | 6 months ended 30 June 2019 \$'000 | Year ended 31 December 2019 \$'000 |
|---|---|---|---|
| Loss before income tax | (15,261) | (13,471) | (23,507) |
| Adjustments for: | | | |
| Share-based payments | 1,380 | 526 | 2,437 |
| Depreciation | 47 | 40 | 95 |
| Foreign exchange (gain)/loss | 1,052 | 153 | 57 |
| Finance expense | 1,471 | 743 | 1,488 |
| Finance income | (39) | (274) | (432) |
| Changes in working capital | | | |
| - (Increase) / decrease in other receivables | 388 | (13) | (369) |
| - Increase / (decrease) in trade and other payables | (980) | (2,157) | (434) |
| Cash used in operations | (11,942) | (14,453) | (20,665) |

14. Non-cash investing and financing activities

During the year 4,646,841 shares were issued to acquire the ByFavo licence with a fair value at the date of grant of \$11,959,000.

In addition, during the year 367,893 shares, with a fair value of \$1,222,000 were issued in respect of a break fee pursuant to the swap of the €10 million loan facility with Cosmo to a cash investment.

15. Related party disclosures

The Company's Chief Medical Officer, Gabriel Fox, is connected to Linda Bussian, who during the year provided consulting services to the Company. The cost of these services was \$5,000 (30 June 2019: \$5,909; 31 December 2019: \$5,909). The amount outstanding at the period end was \$5,000 (30 June 2019: \$nil; 31 December 2019: \$nil).

16. Principal risks and uncertainties

We have considered the principal risks and uncertainties faced by the Group for the remaining six months of the year and do not consider them to have changed from those set out in the Acacia Pharma Group plc 2019 Annual Report and Accounts, available from the Group's website at www.acaciapharma.com, with the exception of the risks surrounding COVID-19, as set out below.

The widespread health crisis caused by the coronavirus SAR-CoV-2 and COVID-19 has adversely affected the global economy. The future development of the outbreak is highly uncertain and there is no assurance that the outbreak will not have a material adverse impact on the future results of the Company. The extent of the impact will depend on the geographical range of the virus, infection rates, the severity and mortality rates of the virus, the timing and efficacy of a vaccine, the steps taken nationally and globally to prevent the spread of the virus as well as fiscal and monetary stimuli offered by governments globally. Latest evidence suggests that the peak impact of COVID-19 on US healthcare institutions occurred in the second quarter of 2020 and that a return to more normal levels of business activity and healthcare provision is expected through the third and fourth quarters of 2020. If the negative impact from the COVID-19 pandemic extends beyond assumed timelines, the Group's results may be worse than expected. Restricted access to healthcare settings as a result of COVID-19 has already delayed the Group's commercialization plans. The full extent of the impact is currently unknown and will depend on future developments, such as the ultimate duration and the severity of the spread of SAR-CoV-2 in the US and globally, the effectiveness of federal, state, local and foreign governments' mitigation actions, together with the pandemic's impact on the US and global economies.

17. Events after the balance sheet date

On 2 July 2020, the FDA approved BYFAVO for injection for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less. The approval of BYFAVO will help to further strengthen Acacia Pharma's financial resources, as previously announced, the Company will now have access to an additional €25 million debt facility from Cosmo. Pursuant to the sub-licensing agreement with Cosmo, on the approval of BYFAVO, 4,923,811 shares were issued on 16 July 2020; on 27 July 2020 Acacia drew down €15 million on the loan facility and immediately made a milestone payment of €15 million in cash.

The milestone payments will form part of the cost of the license, under Acacia's intangibles accounting policy.

In addition, on 15 July 2020, Acacia entered into an agreement for the assignment of the US license to BYFAVO (remimazolam) for injection by Cosmo Technologies Limited, which will become effective on 7 August 2020. This assignment has the consent of PAION AG, the original developer of remimazolam and results from a mutual release agreement between Cosmo and PAION. In addition, Acacia and Cosmo entered into a wind-up agreement which terminates the BYFAVO Sub-Licence Agreement and specifies which rights and obligations that survive as between Cosmo, the Operating Company and the Company. There are no material changes to Acacia's rights and obligations as compared to the position during the term of the BYFAVO Sub-Licence Agreement, except that many of such rights and obligations are now enforceable against or by PAION instead of Cosmo.

On 27 July 2020, Acacia Pharma announced that the US FDA had approved a second supplier for the active pharmaceutical ingredient (API) for BARHEMSYS. The approval of a second supplier significantly increases the Company's commercial product stock levels ahead of the US launch of BARHEMSYS. The Company anticipates the approval of a second supplier will support its ability to provide a continuous, high-quality product supply to meet the anticipated ongoing demand.

Independent review report to Acacia Pharma Group plc

Report on the condensed consolidated interim financial statements

Our conclusion

We have reviewed Acacia Pharma Group plc's condensed consolidated interim financial statements (the "interim financial statements") in the interim results of Acacia Pharma Group plc for the 6 month period ended 30 June 2020. Based on our review, nothing has come to our attention that causes us to believe that the interim financial statements are not prepared, in all material respects, in accordance with International Accounting Standard 34, 'Interim Financial Reporting', as adopted by the European Union and the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority.

Emphasis of matter – going concern

Without modifying our conclusion on the interim financial statements, we have considered the adequacy of the disclosure made in note 1 to the interim financial statements concerning the group's ability to continue as a going concern. Based on the directors' forecasts and plans following the Proposed Fund Raising set out in note 1, and taking into account existing cash and debt facilities, the group will need to raise additional capital by Q4 2021 in addition to the Proposed Fund Raising in order to meet its cash requirements for the subsequent periods. This condition, along with the other matters explained in note 1 to the interim financial statements, indicates the existence of a material uncertainty which may cast significant doubt about the group's ability to continue as a going concern. The interim financial statements do not include the adjustments that would result if the group were unable to continue as a going concern.

What we have reviewed

The interim financial statements comprise:

- the consolidated statement of financial position as at 30 June 2020;
- the consolidated statement of comprehensive income for the period then ended;
- the consolidated cash flow statement for the period then ended;
- the statement of changes in equity for the period then ended; and
- the explanatory notes to the interim financial statements.

The interim financial statements included in the interim results have been prepared in accordance with International Accounting Standard 34, 'Interim Financial Reporting', as adopted by the European Union and the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority.

As disclosed in note 1 to the interim financial statements, the financial reporting framework that has been applied in the preparation of the full annual financial statements of the Group is applicable law and International Financial Reporting Standards (IFRSs) as adopted by the European Union.

Responsibilities for the interim financial statements and the review

Our responsibilities and those of the directors

The interim results, including the interim financial statements, is the responsibility of, and has been approved by, the directors. The directors are responsible for preparing the interim results in accordance with the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority.

Our responsibility is to express a conclusion on the interim financial statements in the interim results based on our review. This report, including the conclusion, has been prepared for and only for the company for the purpose of complying with the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority and for no other purpose. We do not, in giving this conclusion, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

What a review of interim financial statements involves

We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410, 'Review of Interim Financial Information Performed by the Independent Auditor of the Entity' issued by the Auditing Practices Board for use in the United Kingdom. A review of interim financial information consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures.

A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK) and, consequently, does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

We have read the other information contained in the interim results and considered whether it contains any apparent misstatements or material inconsistencies with the information in the interim financial statements.

PricewaterhouseCoopers LLP
Chartered Accountants
Cambridge
13 August 2020