Acacia Pharma Group plc

Results for the year ended 31 December 2019

Cambridge, UK and Indianapolis, US – 2 March 2020: 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 2019. The full Annual Report and Financial Statements will be available on the Group's website later today.

Operating Highlights

- US Food and Drug Administration (FDA) approved the New Drug Application (NDA) for BARHEMSYS® (intravenous amisulpride) for the prevention and treatment of postoperative nausea & vomiting (PONV) in adult patients on 26 February 2020
    - US launch planned in H2 2020
- Core US commercial infrastructure established, and key sales representatives identified
    - Minimum 30 field managers planned to be in place prior to launch
- Product portfolio expanded through in-licensing of Byfavo™ (remimazolam), an ultra-short-acting and reversible sedative/anesthetic designed for use during invasive medical procedures, from Cosmo Pharmaceutical N.V. in January 2020
    - PDUFA date for Byfavo of 5 April 2020
- Planned management changes
    - Mike Bolinder appointed as Chief Executive Officer on 1 August 2019 upon Julian Gilbert stepping down
    - Gary Gemignani appointed as Chief Financial Officer on 29 February 2020 succeeding Christine Soden, who also stepped down from the Board of Directors

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 2019 $22.8m (2018: $20.7m):
    - R&D expenses $3.9m (2018: $5.0m) with the reduction reflecting lower R&D activities on completion of BARHEMSYS clinical program
    - Sales and marketing expenses $14.0m (2018: $9.3m) reflecting increased activities leading up to the planned launch of BARHEMSYS
    - General and administrative expenses $4.4m (2018 $5.7m) with 2018 costs higher as a result of the Euronext IPO and fundraising activities
- Cash and cash equivalents as at 31 December 2019 $17.0m (2018: $37.4m)
    - Balance sheet strengthened post-year end with €10m ($11.2m) equity investment in January and €10m ($11.2m) loan facility, which became available following BARHEMSYS approval, each from Cosmo Pharmaceuticals

Summary and outlook for 2020

The Directors of Acacia Pharma are pleased with the progress made in the year in bringing BARHEMSYS to US regulatory approval and in building an effective US commercial operation. Detailed work undertaken over the last two years has only enhanced the Directors' belief in the commercial and medical value of delivering a new solution to better manage PONV and of the commercial prospects for BARHEMSYS. The addition of the rights to Byfavo, equity investment and debt availability has significantly enhanced the Group's resources and ability to deliver long-term value for shareholders.

Commenting on the results, Mike Bolinder, Chief Executive Officer, said: "Our vision is to become a leading US hospital pharmaceutical company and with the approval of BARHEMSYS and in-licensing of Byfavo, we now believe we are well positioned to achieve this aim in the medium term. Receiving a second complete response letter for BARHEMSYS from the FDA last year was clearly disappointing, but we have now successfully completed this critical step. I am truly grateful to our employees for their dedication and loyalty during what was a challenging year and to our shareholders for their continued support."

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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 pipeline aims to address.

Acacia Pharma's lead product, BARHEMSYS® (intravenous amisulpride) for postoperative nausea & vomiting (PONV), has been approved by the US FDA, with US launch planned for H2 2020.

Byfavo™ (intravenous remimazolam), an ultra-short-acting and reversible sedative/anesthetic for use during invasive medical procedures, such as colonoscopy and bronchoscopy, is in-licensed from Cosmo Pharmaceuticals for the US market. The NDA for Byfavo has been filed with the US FDA and the target PDUFA action date is 5 April 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

About BARHEMSYS®

BARHEMSYS is a low dose intravenous formulation of the selective dopamine D_2 and D_3 antagonist amisulpride, which Acacia Pharma has developed and patent-protected for the management of PONV.

BARHEMSYS is indicated in adults for:

- treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or who have not received prophylaxis; and
- prevention of postoperative nausea and vomiting (PONV), either alone or in combination with an antiemetic of a different class.

www.BARHEMSYS.com

About PONV

PONV is a common complication of surgery, occurring in approximately 30% of surgical patients and up to 80% of high-risk patients. It is associated with the use of anaesthetic gases and opioid painkillers and is particularly common following gynecological, abdominal, breast, eye and ear operations, especially those lasting an hour or more. PONV has been ranked as the most undesirable of all surgical complications in some patient surveys, even worse than pain.

Acacia Pharma estimates that approximately 65 million surgical procedures are conducted in the US each year that are eligible for antiemetic use to prevent PONV. Based on market research, Acacia Pharma estimates that the total market in the US for high risk prophylactic and rescue treatment comprises an estimated 34 million patients annually.

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

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

Mobilizing patients as quickly as possible can improve the rate at which they recover, reduce the incidence of secondary complications and hospital readmittances and improve healthcare economics. Our products and product candidates are well-placed to meet the needs of hospitals and healthcare professionals in achieving better patient outcomes and enhancing their recovery.

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

Our newly in-licensed product, Byfavo (intravenous remimazolam), an ultra-short-acting and reversible intravenous sedative/anesthetic offers the potential for patients to recover more rapidly from sedation used during invasive medical procedures, such as bronchoscopies and colonoscopies, than with current sedatives.

Our strategy

We believe we can deliver effective new treatments to improve the outcomes and recovery for surgical patients in the US through a targeted specialist sales and marketing organization. Our initial focus has been on better management of PONV and we are now following that with a product geared at improving procedural sedation and then looking to expand our product base with APD403 in CINV.

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 moderate to high-risk patients are likely to receive a backbone of a $5HT_3$ antagonist (e.g. ondansetron) and possibly a steroid (e.g. dexamethasone). Despite this prophylaxis, approximately one third of patients still suffer PONV. It is not effective to treat these patients with a drug class they have previously received before surgery and currently other well characterized, safe and effective options are limited.

The Group sees an opportunity to add an important treatment to the armamentarium of anesthetists and surgeons, delivering an effective dopamine antagonist, BARHEMSYS. BARHEMSYS has been shown, in an extensive and robust Phase 3 clinical trial program, to treat patients who suffer PONV despite having received prophylaxis treatment with antiemetic drugs from other classes and can also be used in combination with these other antiemetics to prevent PONV in higher-risk patients and procedures.

Byfavo is an ultra-short-acting and reversible IV sedative/anesthetic designed for use during invasive medical procedures, such as during colonoscopy and bronchoscopy, and developed to improve patient recovery times after procedural sedation. Rapid onset and offset are seen as important attributes to products in this area, as is a good safety profile and lack of post-sedation drowsiness. Moving patients through these procedures as effectively as possible can improve patient outcomes and hospital efficiencies.

Once our first two products are established, and once we complete the remaining development work, we intend to further exploit our sales and marketing channel in the US to promote APD403 for the management of CINV, where delayed-phase nausea is a real unmet medical need.

A scalable platform

During 2018 and 2019, we built the capabilities and infrastructure to support a targeted hospital sales force and US launch of a PONV product in the US. The work we undertook has given us the confidence to believe we can launch effectively with an initial field force of 30 representatives, targeting the major surgical centers. We plan to expand this field force to 60 or 80 as demand justifies. Once in place, this platform can support the sale of other products in the hospital, such as Byfavo, if approved, and eventually APD403, which has already successfully completed two Phase 2 studies for CINV. We will continue to look to add additional complementary products to our portfolio as opportunities arise and finances allow.

Operational progress

In May 2019, the US FDA issued a second Complete Response Letter (CRL) to the Company for BARHEMSYS. The CRL indicated that the NDA could not yet be approved until deficiencies reported during a pre-approval FDA inspection of the contract manufacturer supplying amisulpride, the active pharmaceutical ingredient of BARHEMSYS, had been resolved. As with the first CRL received in October 2018, no inadequacies were noted regarding the purity or stability of the active ingredient, or the manufacturing process or quality of the finished product, and no concerns were raised by the FDA on any of the clinical or non-clinical data in the application and no further studies or data analyses were required for approval.

The Group worked closely with the contract manufacturer in the preparation of a Corrective and Preventive Action (CAPA) plan to address the deficiencies at the facility and the manufacturer subsequently submitted the CAPA to the FDA, whereupon the Group resubmitted its NDA application.

On 26 February, the FDA approved the NDA for BARHEMSYS.

The BARHEMSYS product label achieved by the Group is for the:

(i) treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or who have not received prophylaxis (at a dose of 10 mg); and
(ii) prevention of PONV, either alone or in combination with an antiemetic of a different class (at a dose of 5 mg).

The label includes rescue treatment in patients who have failed prior prophylaxis, and combination prophylaxis with other antiemetics in higher-risk patients, the two key commercial unmet needs. Initially, we will focus our commercial efforts on patients who have failed prior prophylaxis and are in need of “rescue” treatment. The Directors believe this label for BARHEMSYS provides it with a strong competitive position that addresses the key unmet medical needs in PONV and provides compelling pharmacoeconomic benefits to hospitals.

On 10 January 2020, we announced we had entered into a strategic in-licensing transaction with Cosmo Pharmaceuticals. The transaction granted to the Group exclusive US commercialization rights to Byfavo as well as an equity investment and debt facility provided by Cosmo to finance the commercialization efforts of both BARHEMSYS and Byfavo.

The NDA for Byfavo is currently under review by FDA with a target review (“PDUFA”) date of 5 April 2020.

Under the principal terms of the in-license agreement, Cosmo became eligible for:

- an upfront payment of €10 million satisfied through the issue of 4,646,841 new ordinary shares of 2p in the Company at €2.152 per share, being the 15-day volume weighted average share price up to 8 January 2020
- a €30 million payment upon US approval of Byfavo, consisting of €15 million payable in cash and €15 million payable in new ordinary shares
- a €5 million payment upon first commercial sale of Byfavo in the US payable in new ordinary shares
- sales-related milestones of up to €105 million, payable in cash upon achieving pre-specified annual sales targets, and
- tiered double-digit royalties on US sales.

Under the terms of the agreement, Cosmo has also made a strategic equity investment in the Company of €10 million by agreeing to subscribe for 4,347,826 new ordinary shares at a price of €2.30 per share, based on the closing price on 8 January 2020. Following this investment, together with the shares issued in respect of the licensing agreement, Cosmo owns 8,994,667 ordinary shares of 2p in the Company, representing 14.08% of its enlarged share capital.

In addition, Cosmo has made available to Acacia Pharma a new loan facility of up to €35 million, conditional on the achievement of certain specified milestones and in two tranches:

- €10 million became available on the US approval of BARHEMSYS, and
- €25 million will become available upon the US approval of Byfavo.

- The loans will be interest-only until January 2023 and repayable over the ensuing 24 months. Until such time as the Group's existing loan facility with Hercules Growth Capital is repaid in full, the Cosmo facility will be unsecured and bear interest at 11% per annum. Thereafter, the loan will be secured upon assets of the Group and bear interest at 9%.

Cosmo is entitled to appoint one director to the Acacia Pharma Board of Directors.

Byfavo is an ultra-short-acting and reversible intravenous benzodiazepine sedative/anesthetic designed for use during invasive medical procedures, such as during colonoscopy and bronchoscopy. Approximately 24.5 million such procedures take place annually in the US, of which around 90% use moderate sedation. Byfavo has demonstrated efficacy and safety in an extensive clinical trial programme involving around 2,400 volunteers and patients. Data so far indicate that 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. Cosmo in-licensed the US rights to Byfavo from Paion AG in 2016 and together they have progressed the product candidate through to registration. The NDA for Byfavo, was submitted to the US FDA in April 2019 and has a target review (PDUFA) date of 5 April 2020.

The Group expanded rapidly during 2018, rising from six full-time employees at IPO to 40 by the year-end, including building its US commercialization and administration team to approximately 35 full-time employees. In 2019, despite the delays in launch due to the previously mentioned CRLs received, we were able to maintain the core of our US team, which includes highly experienced sales, marketing, regulatory and operations professionals. We expect to add the needed headcount to the team in order to effectively launch BARHEMSYS and Byfavo (upon FDA approval) and currently anticipate initially adding 30 hospital territory managers to the Group and then adding additional territory managers as demand and resources dictate.

Future drivers of growth

As we near our launch of BARHEMSYS and expected launch of Byfavo, we have built a solid commercial platform capable of supporting a specialist hospital salesforce and driving forward to meet the large opportunity we see in the treatment of PONV, procedural sedation, CINV and related areas.

Priorities for 2020

Our key objectives for 2020 are:

Recruit a 30-strong, highly skilled and experienced US hospital salesforce

Now we have the NDA approval we will focus on delivering final packaged product to the market to support a full launch at the beginning of H2 2020. To the extent product is available earlier, we may see early sales from certain key customers and sites. We have identified many of the sales representatives we wish to recruit. We plan to bring the full team on board in July 2020 to support a full launch of the products in H2 2020. We will assess the need to supplement this team as we gain more knowledge of the Byfavo opportunity and as demand for our products and available resources dictate.

Secure additional debt or equity finance

The approval of BARHEMSYS means we can now draw the first, €10million, tranche of the Cosmo debt facility. Gaining approval of Byfavo would further strengthen cash resources by a net €10m. However, in order to finance the full launches of BARHEMSYS and Byfavo we will need to secure additional debt or equity capital during 2020.

Gain FDA approval of the NDA for Byfavo with the required prescribing label and launch in H2 2020

The current PDUFA date for the approval of the NDA for Byfavo is 5 April 2020 and we aim to secure approval on, or no later than three months after, that date. We will work closely with Cosmo Pharmaceuticals and Paion AG, the original licensor of Byfavo to transfer all relevant knowledge in order to secure an effective launch.

Secure acceptance of BARHEMSYS and Byfavo on as many hospital pharmacy formulary lists as possible and deliver product sales

The products will typically be paid for by hospitals through the fixed DRG payments received in respect of any single surgery or invasive medical procedure.
The success of a hospital product is geared to gaining acceptance on the relevant hospital's formulary and embedding its use into "standing orders" relating to management of the procedure within that institution. Typically, access to formulary is managed through the pharmacy and therapeutics (P&T) committee comprised of representatives from various departments including pharmacy (responsible for managing the cost of delivering optimal patient treatments), subject matter experts (in this case, anaesthetists) and specialist advocates (surgeons, theatre and post-surgery nurses and invasive proceduralists).

Once BARHEMSYS is launched we will measure progress against the number of P&T committees for which BARHEMSYS is up for review, the number of formulary approvals we receive and, eventually product sales. We will establish similar metrics for the success of the Byfavo launch.

We will continue to build additional pharmaco-economic data and evidence to support our arguments to gain formulary access.

Financial Review

Presentation in US Dollars (USD)

With effect from 1 January 2019, the Group's presentation currency changed from Pounds Sterling to US Dollars, given that a significant majority of Group expenses are denominated in US Dollars. Future revenues and costs are expected to arise predominantly in US Dollars, and the Directors believe that the presentation currency change will give investors and other stakeholders a clearer understanding of the Group's performance over time.

Operating loss

The operating loss increased by $2.3m to $22.4m (2018: $20.1m), reflecting the costs of building and running our US commercial infrastructure and launch preparations.

R&D expenditure was $3.9m (2018: $5.0m), down $1.1m, reflecting a reduction in activities surrounding the management of the NDA submission and product development.

Sales and marketing expenses were $14.0m (2018: $9.3m) in the year, driven by the costs of recruiting and running our new commercial team and significant pre-launch marketing, education, training, distribution, regulatory and other activities.

General and administrative costs fell $1.3m to $4.4m (2018: $5.7m), largely as a result of the non-repeated costs incurred in 2018 in conducting the IPO and listing on Euronext Brussels.

Following the receipt of the complete response letter from the FDA in May 2019, sales and marketing activities were curtailed and costs significantly reduced although costs are now expected to increase from March 2020 with the approval of BARHEMSYS.

Finance income and expense

Finance income fell to $0.4m, reflecting the lower cash balances held and a foreign exchange loss of $0.1m in comparison to a gain of $0.9m in 2018.

Finance expense fell $1.3m in the year to $1.5m (2018: $2.8m) primarily as a result of the conversion of the preferred shares and the convertible loan note into ordinary shares upon the IPO, and therefore incurring no finance expense in relation to these in 2019, but offset by loan interest and foreign exchange losses in 2019.

Taxation

The tax credit for 2018 was $0.7m (2018: $0.9m) 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 2019 was $22.8m (2018: $20.7m) largely as a result of the increase of $2.3m in the operating loss, offset by reduced net finance expense. The loss per share was $0.43 (2018: $0.47) mainly as a result of the increase in the weighted average number of shares, following the IPO part way through 2018.

Balance sheet

Current assets

Current assets decreased by $20.4m to $18.3m, dominated by the decrease in cash and cash equivalents to $17.0m (2018: $37.4m) as a result of funding the Group's operations in the year.

Liabilities

Non-current liabilities of $4.7m 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, plus $0.3m in respect of the long-term lease liability now held on balance sheet under IFRS16. The loan was interest only until January 2020.

Current liabilities increased significantly to $9.6m (2018: $5.2m), primarily amounts due under the Hercules loan facility in 2020, offset by a reduction in trade and other payables of $0.5m to $4.2m.

Share capital and total equity

Total equity at 31 December 2019 was $4.3m compared to $24.7m at the previous year end, reflecting the loss in the year.

1,558,993 ordinary shares were issued upon the exercise of share options, raising proceeds of $0.2m. Share-based payments charges of $2.4m further enhanced total equity, being offset by the losses for the year of $22.8m.

In-licensing transaction

On 10 January 2020, the Group announced a strategic in-licensing, investment and loan transaction with Cosmo Pharmaceuticals N.V., bringing to the Group the US rights to Byfavo, the NDA for which has a target PDUFA review date of 5 April 2020. The Directors believe that having a second product which shares the same attractive commercial message as BARHEMSYS will allow for significant synergies in sales and marketing operations and more efficient investment in commercial operations. The concomitant debt and equity funding strengthens the Group's balance sheet.

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 the first half of 2021.

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 2 to 14 of the financial statements. The Directors have carried out a robust assessment of the principal 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 summarized in the risk management and principal risks section on pages 30 to 31 of the financial statements.

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 gaining US regulatory approval for Byfavo, obtaining sufficient additional debt or equity capital to take the Group through to cashflow positivity and the timing of both of these events. The Directors have a reasonable expectation that the Group will obtain regulatory approval for Byfavo, while BARHEMSYS was approved on 26 February 2020, meaning the business owns valuable assets. The ability to raise capital in the near term will depend on wider financial market influences, and cannot be certain, and could adversely influence the ability to launch BARHEMSYS and Byfavo in the time frame and in the manner anticipated. The Group has significant cash reserves as at the date of this report, and the Directors believe they can manage resources such that value can be delivered from BARHEMSYS and Byfavo through its planned commercialization strategy, thus ensuring the Group's viability.

Summary and outlook for 2020

Acacia Pharma is pleased with the progress made in the year towards bringing BARHEMSYS to US regulatory approval and in building an effective US commercial operation. Detailed work undertaken over the last year has only enhanced the Directors' belief in the commercial and medical value of delivering a new solution to better manage PONV and of the commercial prospects for BARHEMSYS. The addition of the rights to Byfavo, related equity investment and debt availability has significantly enhanced the Group's resources and ability to deliver significant long-term value for shareholders, however, as was made clear at our IPO in 2018, the Group will need to secure additional debt or equity finance in order to meet its planned operations from H1 2021 forward.

Consolidated Income Statement for the year ended 31 December 2019

	2019 $'000	2018 $'000
Research and development expenses	**(3,928)**	(5,031)
Sales and marketing expenses	**(14,019)**	(9,336)
General and administrative expenses	**(4,447)**	(5,679)
Operating loss	**(22,394)**	(20,046)
Finance income	**432**	1,237
Finance expense	**(1,545)**	(2,764)
Loss before income tax	**(23,507)**	(21,573)
Taxation credit	**668**	881
Loss for the financial year	**(22,839)**	(20,692)
Basic and diluted losses per Ordinary Share	**(0.43)**	(0.47)

Consolidated statement of comprehensive income for the year ended 31 December 2019

	2019 $'000	2018 $'000
Loss for the financial year	**(22,839)**	(20,692)
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	**(78)**	(2,023)
Other comprehensive expense for the financial year	**(78)**	(2,023)
Total comprehensive expense for the financial year	**(22,917)**	(22,715)

Consolidated Statement of Financial Position as at 31 December 2019

	2019 $'000	2018 $'000	2017 $'000
Assets			
Non-Current Assets			
Right-of-use asset	**372**	-	-
Total Non-Current Assets	**372**	-	-
Current Assets			
Other receivables	**609**	397	208
Current income tax assets	**679**	874	471
Cash and cash equivalents	**17,009**	37,443	4,142
Total Current Assets	**18,297**	38,714	4,821
Total Assets	**18,669**	38,714	4,821
Equity and Liabilities			
Equity attributable to equity holders			
Called up share capital	**1,619**	1,581	1,074
Share premium account	**75,588**	75,454	5,575
Profit and loss account	**31,225**	54,078	74,770
Share based payment reserve	**3,791**	1,354	358
Merger reserve	**(106,625)**	(106,625)	(106,625)
Foreign currency translation reserve	**(1,250)**	(1,172)	851
Total Equity	**4,348**	24,670	(23,997)
Liabilities			
Non-current liabilities			
Loans and other borrowings	**4,701**	8,867	-
Current liabilities			
Trade and other payables	**4,167**	4,727	1,354
Loans and other borrowings	**5,453**	450	27,464
	9,620	5,177	28,818
Total Liabilities	**14,321**	14,044	28,818
Total Equity and Liabilities	**18,669**	38,714	4,821

Consolidated Cash Flow Statement for the year ended 31 December 2019

	2019 $'000	2018 $'000
Cash flows from operating activities:		
Cash used in operations	**(20,665)**	(15,863)
Income tax credit received	**834**	432
Net cash used in operating activities	**(19,831)**	(15,431)
Cash flows from investing activities:		
Interest received	**432**	246
Net cash generated from investing activities	**432**	246
Cash flows from financing activities:		
Proceeds of issuance of Ordinary Shares	**180**	49,379
Issue costs of Ordinary Shares	**(8)**	(2,296)
Repayments of lease liabilities – principal and interest	**(101)**	-
Loan proceeds	**-**	10,000
Costs of securing term loan	**-**	(644)
Loan repayments	**-**	(6,215)
Interest and fees paid on loans	**(998)**	(1,324)
Net cash (used in) / generated from financing activities	**(927)**	48,900
Net (decrease) / increase in cash and cash equivalents	**(20,326)**	33,715
Cash and cash equivalents at beginning of the period	**37,443**	4,142
Effect of exchange rate movements on cash held	**(108)**	(414)
Cash and cash equivalents at end of the period	**17,009**	37,443

Consolidated Statement of Changes in Equity

Consolidated Statement of Changes in Equity for the year ended 31 December 2019

	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 2018	**1,074**	**5,575**	**74,770**	**(106,625)**	**358**	**851**	**(23,997)**
Loss for the period	-	-	(20,692)	-	-	-	(20,692)
Exchange differences	-	-	-	-	-	(2,023)	(2,023)
Total comprehensive expense for the period	-	-	(20,692)	-	-	(2,023)	(22,715)
Warrants issued	-	-	-	-	327	-	327
Transactions with Owners							
Issue of Ordinary Shares	507	72,175	-	-	-	-	72,682
Costs of issue of Ordinary Shares	-	(2,296)	-	-	-	-	(2,296)
Employee share option scheme	-	-	-	-	669	-	669
Balance at 31 December 2018	**1,581**	**75,454**	**54,078**	**(106,625)**	**1,354**	**(1,172)**	**24,670**
Balance at 1 January 2019 as previously stated	**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	-	-	(22,839)	-	-	-	(22,839)
Exchange differences	-	-	-	-	-	(78)	(78)
Total comprehensive expense for the period	-	-	(22,839)	-	-	(78)	(22,917)
Transactions with Owners							
Issue of Ordinary Shares	38	142	-	-	-	-	180
Costs of issue of Ordinary Shares	-	(8)	-	-	-	-	(8)
Employee share option scheme	-	-	-	-	2,437	-	2,437
Balance at 31 December 2019	**1,619**	**75,588**	**31,225**	**(106,625)**	**3,791**	**(1,250)**	**4,348**

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 commercializes lower-risk pharmaceutical product opportunities within its therapeutic areas of interest.

The Group's Consolidated Financial Information is presented as at and for the year ended 31 December 2019 and 31 December 2018.

Acacia Pharma's 2019 Annual Report will be posted to shareholders in March and will be available on the Company's website, www.acaciapharma.com from today. The financial information set out herein does not constitute the Company's statutory accounts for the years ended 31 December 2019 or 2018 but is derived from those accounts. Statutory accounts for 2018 have been delivered to the Registrar of Companies, and those for 2019 will be delivered to the Registrar of Companies following the Company's Annual General Meeting, which will be held at 11.00 am on 7 April 2020. 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 Consolidated Financial Information has been prepared in accordance with the requirements of the International Financial Reporting Standards as endorsed by the EU (IFRSs), the IFRS Interpretations Committee (formerly the International Financial Reporting Interpretations Committee (IFRIC)) interpretations 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 note on Going Concern below, the Consolidated Financial Information has been prepared on a going concern basis and under the historical cost convention. The principal accounting policies set out in the 2018 Annual Report have been consistently applied to all periods presented with the exception of IFRS 9, discussed below.

Changes in accounting policy and disclosures

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

IFRS 16 'Leases' was issued by the IASB in January 2016 and was implemented by the Group from 1 January 2019. It resulted in almost all leases being recognized on the statement of financial position, as the distinction between operating and finance leases is removed. Under the new standard, an asset (the right to use the leased item) and a financial liability to pay rentals are recognized. The only exceptions are short-term and low-value leases.

- IFRS 16 'Leases' was issued by the IASB in January 2016 and was implemented by the Group from 1 January 2019. The impact is set out in note 23 in the financial statements.
- IFRIC 23 'Uncertainty over income tax treatments' was issued by the IASB in July 2017 and was implemented by the Group from 1 January 2019. The effect was immaterial.

The Group applied the simplified transition approach and has not restated comparative amounts for the year prior to first adoption. Right-of-use assets for property leases were measured on transition as if the new rules had always been applied. All other right-of-use assets were measured at the amount of the lease liability on adoption (adjusted for any prepaid or accrued lease expenses).

Change in the Group's presentation currency

With effect from 1 January 2019, the Group's presentation currency changed from Pounds Sterling to US Dollars, given that a significant majority of Group expenses are denominated in US Dollars. Future revenues and costs are expected to arise predominantly in US dollars, and the Directors believe that the presentation currency change will give investors and other stakeholders a clearer understanding of the Group's performance over time.

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.

Based on the Directors' current forecasts and plans, which assumes the recruitment of a salesforce and the successful commercialisation of BARHEMSYS and Byfavo (upon FDA approval) and, considering the existing cash and debt facilities, the Group and Company have sufficient funding to continue their operations until the first half of 2021, such that during the first half of 2021, the Group and Company will need to raise additional funding in order to meet their cash requirements for the subsequent months.

The Directors are confident that it is 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

	2019 $'000	2018 $'000
Bank account interest	**6**	6
Interest on short-term deposits	**426**	239
Foreign exchange gains	**-**	992
	432	1,237

4. Finance expense

	2019 $'000	2018 $'000
Foreign exchange losses	**57**	-
Finance charges on convertible instruments	**-**	1,817
Finance charges on term loan	**1,446**	947
Interest expense on lease liabilities	**42**	-
	1,545	2,764

5. Income tax

	2019 $'000	2018 $'000
Current tax		
Current year tax credit	**666**	916
Prior year adjustments	**2**	(35)
Total tax credit	**668**	881

As at 31 December 2019, the unrecognized deferred tax assets relating to operating losses amounted to $7,885,000 (2018: $4,977,000). 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:

	2019	2018
Losses per Ordinary Share		
Loss for the financial year ($'000)	**(22,839)**	(20,692)
Weighted average number of Ordinary Shares (basic) (thousands)	**53,680**	44,094
Losses per Ordinary Share basic ($)	**(0.43)**	(0.47)

Share options and convertible instruments are anti-dilutive in both 2019 and 2018 for the purposes of the losses per share calculation and their effect is therefore not considered. For the avoidance of doubt, this calculation is based on Ordinary Shares only.

8. Cash and cash equivalents

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

	2019 $'000	2018 $'000	2017 $'000
Sterling accounts	**918**	359	3,803
Euro accounts	**229**	377	4
US Dollar accounts	**15,862**	36,707	335
	17,009	37,443	4,142

9. Share capital and premium

Share capital and premium	**Ordinary shares** Number	**Preference shares** Number	**Ordinary shares** $'000	**Preference shares** $'000	**Share premium** $'000
At 1 January 2018	**2,664,662**	**40,948,964**	**82**	**992**	**5,575**
Issue of Ordinary Shares in settlement of liabilities and anti-dilution and preference rights on A, B, C & D shares	5,171,495	-	143	-	15,612
Conversion of S, A, B, C & D shares to Ordinary shares	32,337,899	(32,337,899)	992	(992)	-
Cancellation of P shares	-	(8,611,065)	-	-	-
Issue of Ordinary Shares to holders of P shares on consolidation and conversion	270	-	-	-	-
Issue of Ordinary Shares on conversion of loan notes	1,633,624	-	45	-	7,148
Issue of Ordinary Shares for cash	11,111,111	-	308	-	49,271
Issue of Ordinary Shares upon exercise of share options	410,144	-	11	-	144
Issue costs	-	-	-	-	(2,296)
At 31 December 2018 and 1 January 2019	**53,329,205**	**-**	**1,581**	**-**	**75,454**
Issue of Ordinary Shares upon exercise of share options	1,558,993		38		142
Issue costs					(8)
At 31 December 2019	**54,888,198**		**1,619**		**75,588**

On 6 March 2018 the Company completed an IPO and was admitted to trading on Euronext Brussels. Immediately before the completion of the IPO, all of the existing S ordinary, A ordinary, B preferred, C preferred and D preferred shares were converted into Ordinary Shares on a one-for-one basis. In addition, Ordinary Shares were issued upon the conversion of the Convertible Loan Notes and in settlement of the accrued finance charges on the A, B, C and D shares and the loan notes. The P shares were converted into 270 Ordinary shares. Upon the completion of the IPO, 11,111,111 Ordinary Shares were issued for cash at €3.60 per share, raising gross proceeds of €40 million or $49,579,000. Costs directly associated with the issue of shares of $2,296,000 were incurred.

10. Loans and other borrowings

	31 Dec 2019 $'000	31 Dec 2018 $'000	31 Dec 2017 $'000
Loans and other borrowings payable within one year			
Term bank loan, amounts payable within one year	**5,337**	450	6,995
Convertible loan notes	**-**	-	5,439
Liability component of convertible shares	**-**	-	15,030
Lease liability, amounts payable within one year	**116**	-	-
Total Loans and other borrowings payable within one year	**5,453**	450	27,464
Loans and other borrowings payable after one year			
Term bank loan, amounts payable after one year	**4,428**	8,867	-
Lease liability, amounts payable after one year	**273**	-	-
Total Loans and other borrowings payable after one year	**4,701**	8,867	-

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

	2019 $'000	2018 $'000	2017 $'000
UK pound		-	20,468
US dollar	**10,154**	9,765	6,995
	10,154	9,765	27,464

The term bank loan with Silicon Valley Bank was repaid in full on 27 June 2018.

A new 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 is interest only until January 2020. Thereafter the principal and interest on the loan will be repayable in 25 equal 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.

11. Cash used in operations

	2019 $'000	2018 $'000
Loss before income tax	**(23,507)**	(21,572)
Adjustments for:		
Share-based payments	**2,437**	647
Foreign exchange (gain)/loss	**57**	(910)
Finance expense	**1,488**	2,764
Finance income	**(432)**	(328)
Depreciation	**95**	-
Changes in working capital		
- (Increase) in other receivables	**(369)**	(199)
- (Decrease) in trade and other payables	**(434)**	(3,735)

Cash used in operations	**(20,665)**	(15,863)

12. Commitments and contingencies

a) Commitments on expenditure

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

	2019 $'000	2018 $'000	2017 $'000
Inventory	**166**	211	-
Research and development expenditure	**230**	293	-
Total	**396**	504	-

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:

	2019 $'000	**2018 $'000**	2017 $'000
Payments under operating leases which fall due:			
Within 1 year	28	**27**	18
Total	28	**27**	18