Acacia Pharma Group plc
Results
For the year ended 31 December 2018

Cambridge, UK and Indianapolis, US – 27 February 2019: Acacia Pharma Group plc ("Acacia Pharma", the "Group" or the "Company") (EURONEXT: ACPH), a hospital pharmaceutical company focused on the development and commercialisation of new nausea & vomiting treatments for surgical and cancer patients, announces its results for the year ended 31 December 2018. A conference call will take place at 3:00pm CET today (details below) and the presentation will be available on the Group's website in the Investors section (Financial Reports and Presentations) shortly before.

Operating Highlights

- IPO and listing on Euronext Brussels completed in March
- US infrastructure established in preparation for commercialising BARHEMSYS™, pending regulatory approval
- Revised target PDUFA date of 5 May 2019 for review of BARHEMSYS NDA by US FDA
    - Complete Response Letter from FDA received 5 October 2018 - no issues cited over safety or efficacy of BARHEMSYS
    - Rapid re-submission and acceptance of NDA
- Publication of positive Phase 3 clinical study results of BARHEMSYS in post-operative nausea & vomiting (PONV) in leading peer-reviewed publications focused on surgical care and anaesthesiology
- Positive outcomes from additional safety study with BARHEMSYS enhance earlier clinical results (announced January 2019)
- Board strengthened with appointments of Dr John Brown and Edward Borkowski as Non-Executive Directors

Financial Highlights

- Loss after tax of £15.5m (2017: £6.2m) with increases reflecting costs relating to Euronext listing and preparations for the commercialisation of BARHEMSYS in the US:
    - R&D expenses (£2.3m higher at £3.8m)
    - G&A expenses (£2.8m higher at £4.3m)
    - Sales and marketing costs (£6.9m higher at £6.9m)
- IPO raised net proceeds of £34.1m in March 2018
- New $30m term loan facility secured with Hercules Technology Growth Capital
    - $10m drawn in June 2018 and existing Silicon Valley Bank loan (£5.2m) repaid
- Strong cash position at year end of £29.4m (2017: £3.1m)

Commenting on the results, Dr Julian Gilbert, Chief Executive Officer, said: "Our vision is to become a leading US hospital pharmaceutical company. Healthcare systems around the world increasingly are focusing on patient outcomes and enhancing recovery after surgery. Improved management of nausea and vomiting in the post-operative and chemotherapy settings can add significantly to patient well-being as well as potentially reducing the overall costs of care. We are building a scalable commercial platform in the US and we look forward to being able to bring BARHEMSYS to market to address the unmet needs in PONV. Receiving a complete response letter from the FDA in October was clearly disappointing, but the speed with which our team addressed this and resubmitted our NDA application was pleasing. I would like to thank our employees for their hard work and loyalty and our shareholders for their support."

Conference call details

To join the conference call, please dial in 5-10 minutes prior to the start using phone numbers and password provided below.

Standard International Access	+44 (0) 20 3003 2666
UK Toll Free	0808 109 0700
Belgium	0800 746 68
USA Toll Free	1 866 966 5335
Conference password	acacia pharma

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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 pain-killers and is particularly common following gynaecological, abdominal, breast, eye and ear operations, especially those lasting an hour or more.

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

PONV has been ranked as the most undesirable of all surgical complications by patients and contributes significantly to patient anxiety and distress. PONV can delay hospital discharge; result in re-admission after in-patient procedures; and lead to day-case patients being admitted to hospital, all of which can result in significantly increased healthcare costs.

About Acacia Pharma

Acacia Pharma is a hospital pharmaceutical company focused on the development and commercialisation of new nausea & vomiting treatments for surgical and cancer patients. The Group has identified important and commercially attractive unmet needs in nausea & vomiting and has discovered two product candidates based on the same active ingredient, amisulpride, to meet those needs.

The Group's lead project, BARHEMSYS™ for post-operative nausea & vomiting (PONV), has generated positive results in four Phase 3 clinical studies. A New Drug Application (NDA) for BARHEMSYS is under review by the US Food and Drug Administration (FDA). Its sister project, APD403 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 under 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

Overview

Our initial strategy is to develop and sell new nausea & vomiting treatments directly in the US. The key elements of this strategy are:

- Complete the registration of our lead product BARHEMSYS™ (amisulpride injection) for the prophylaxis and treatment of post-operative nausea & vomiting (PONV)
- Directly commercialise BARHEMSYS in the US through our own sales channel, seeking strategic partners where commercially viable for ex-US markets
- Complete the development of APD403 for the management of chemotherapy induced nausea & vomiting (CINV) and leverage our commercial infrastructure to sell APD403 to hospital and office-based oncologists
- Review opportunities to identify, acquire or in-license complementary products.

We took important steps towards achieving our vision in 2018. In March, we successfully completed the IPO of the Group on Euronext Brussels, raising €40m before costs. Subsequently we began the rapid growth of our US commercial and medical infrastructure, recruiting some 35 highly experienced industry professionals, and undertaking multiple pre-launch activities and building processes and resources to support our future growth plans.

While we continue to develop and embed a strong governance framework across the culture of our organisation, we also take a balanced approach to ensure that our processes are efficient and support our growth strategy. We invest in the development of our people to ensure we have the capabilities to succeed. Our business standards and ways of working are guided by our Code of Conduct and are embodied in day-to-day behaviours.

The Group's risk management framework is based on the UK Corporate Governance Code. Our internal processes and controls provide us with a clear understanding of the principal risks inherent in our business operations and strategy, and give us confidence in the appropriateness of the actions we take to mitigate them. Strong corporate governance and leadership is an essential part of Acacia Pharma's strategy. We brought two highly experienced industry professionals onto our Board in 2018, John Brown and Edward Borkowski, and continue to assess the effectiveness and make-up of the Board as the Group evolves.

In the year ahead we anticipate launching BARHEMSYS onto the US market and delivering first revenues. We are working closely with our suppliers and believe them capable of delivering the GMP compliant product we need. We are highly encouraged by the interest shown by healthcare professionals in better managing PONV and patient outcomes.

Post-operative nausea & vomiting (PONV)

Mobilising patients as quickly as possible improves the rate at which they recover, reduces the incidence of secondary complications and hospital readmittances and improves healthcare economics. Effective management of PONV is a key factor in achieving these goals, since PONV prevents patients moving through the hospital or day-surgery centres to home and can impair the clinical progress post-surgery in certain procedures, including for example bariatric surgery, upper GI surgery or wired-jaws.

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, many patients (around one third) still suffer PONV. It is not possible to treat these patients with a drug class they have previously received before surgery and that has proved not to be effective and other well characterised safe and effective options are limited.

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

Operating Progress

During 2018, we built the capabilities and infrastructure to support a targeted hospital sales force and US launch of a PONV product in the US. We believe this infrastructure will support a planned field force of an initial 60 representatives, sufficient to launch BARHEMSYS once approved, and to expand to 100 as demand justifies. Once in place, this platform could support the sale of other products in the hospital, such as APD403, which has already successfully completed two Phase 2 studies for CINV. We will also look to add additional products if and when opportunities arise.

The Group submitted the BARHEMSYS New Drug Application (NDA) to the US Food and Drug Administration (FDA) in October 2017. On 5 October 2018, the FDA issued a Complete Response Letter (CRL) to the Company, indicating that the NDA could not yet be approved until deficiencies reported during a recent pre-approval FDA inspection of the contract manufacturer supplying amisulpride, the active pharmaceutical ingredient of BARHEMSYS, had been resolved. No inadequacies were noted regarding the purity or stability of the active ingredient, or the manufacturing process or quality of the finished product.

Importantly, no concerns were raised by FDA on any of the clinical or non-clinical data in the application and no further studies or data analyses will be 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 5 December 2018, the FDA confirmed it had accepted the Group's resubmission of the NDA for BARHEMSYS as a complete response, addressing the deficiencies identified in the CRL issued by the FDA. The resubmission was classified as Class 2 and the FDA has given a Prescription Drug User Fee Act (PDUFA) goal of reviewing and acting on it no later than 5 May 2019.

The BARHEMSYS product label sought 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 planned label would include 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. The Directors believe that such a label for BARHEMSYS would provide it with a strong competitive position once approved by the FDA.

The Group expanded significantly during 2018, rising from six full-time employees at IPO to 40 by the year-end, including building its US commercialisation and administration team to approximately 35 full-time employees. This US team, which includes highly experienced sales, marketing, regulatory and operations professionals, is expected to rise to around 40 as BARHEMSYS nears or reaches approval and by a further 60 once the Group is in a position to bring on its direct field staff.

As we near our expected launch of BARHEMSYS, 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, CINV and related areas.

Financial review

The operating loss increased by £12.0m to £15.0m (2017: £3.0m), reflecting increased R&D activities surrounding the NDA and product development, the costs of building and running our US commercial infrastructure and launch preparations, and the costs of the IPO.

R&D expenditure was £3.8m (2017: £1.5m), up £2.3m, reflecting activities surrounding the management of the NDA submission, product development and study DP10022, which delivered additional data with respect to the cardiac safety of BARHEMSYS. Sales and marketing expenses were £6.9m (2017: £nil) 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 rose £2.8m to £4.3m (2017: £1.5m), reflecting the costs of conducting its IPO and listing on Euronext Brussels and the additional costs of being a public company.

Finance income rose to £0.9m, comprising the interest earned on the proceeds of the IPO and exchange gains on cash and other balances held. Finance expense fell £1.4m in the year to £2.1m (2017: £3.5m) primarily as a result of the conversion of the preferred shares and the convertible loan note into ordinary shares upon the IPO.

The tax credit for 2018 was £0.7m (2017: £0.3m) relating to R&D credits to be claimed on certain R&D activities. The post-tax loss for 2018 was £15.6m (2017: £6.2m) with the increase of £12.0m in the operating loss offset by reduced net finance expense and the increased tax credit. The loss per share was 35p (2017: 232p) with the increase in losses offset by the increase in the number of ordinary shares following the conversion of the preferred shares and convertible loan notes to ordinary shares and the issue of 11.1m new ordinary shares upon the IPO.

Current assets increased by £26.8m to £30.4m, dominated by the increase in cash and cash equivalents to £29.4m (2017: £3.1m). Non-current liabilities of £7.0m represent the long-term proportion of the new debt facility of up to $30m entered into with Hercules Technology Growth Capital of which $10m was drawn down on 30 June 2018. The loan is interest only until January 2020 at the earliest, and a further $10m can be drawn upon the approval of the NDA for BARHEMSYS when the interest-only period will extend by three months.

Current liabilities reduced significantly to £4.1m (2017: £21.4m) with an increase in trade and other payables of £2.7m to £3.7m offset by the reduction of £11.1m in the liability component of convertible shares and £4.0m in convertible loan notes, each upon their conversion into ordinary shares upon the IPO. Furthermore, the debt facility with Silicon Valley Bank (2017: £5.2m) was repaid in full in June 2018.

Total equity at the 31 December 2018 was £19.0m compared to a deficit of £17.8m at the previous year end. The Company issued 11,111,111 new ordinary shares for €3.60 per share in cash at its IPO on Euronext Brussels on 6 March 2018, raising proceeds of £35.7m gross and delivering net proceeds of £34.1m after payment of issue costs of £1.6m. In addition, the Company issued 39,143,288 ordinary shares in satisfaction of liabilities upon the conversion of S ordinary, P shares, A ordinary and B, C and D preferred shares and of the convertible loan notes into ordinary shares, enhancing equity by £16.5m.

A further 410,144 ordinary shares were issued upon the exercise of share options, raising proceeds of £0.1m. Share-based payments charges of £0.7m and unrealised exchange gains on translation of the balance sheet of Acacia Pharma Inc of £1.2m further enhanced total equity, being offset by the losses for the year of £15.5m.

Presentation in US Dollars (USD)

Acacia Pharma's activities will be predominantly delivered in US dollars and as such the Group will in future present in US dollars, starting with its Interim Results for the six months ending 30 June 2019.

Summary and outlook for 2019

Acacia Pharma is pleased with the progress made in the year towards bringing BARHEMSYS to US regulatory approval and in building its core 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 Directors believe this should enable the business to deliver significant long-term value for shareholders.

Consolidated Income Statement

	Note	**2018 £'000**	2017 £'000
Research and development expenses		**(3,766)**	(1,479)
Sales and marketing expenses		**(6,943)**	-
General and administrative expenses		**(4,326)**	(1,534)
Operating loss		**(15,035)**	(3,013)
Finance income	3	**926**	2
Finance expense	4	**(2,069)**	(3,510)
Loss before income tax		**(16,178)**	(6,521)
Taxation credit	5	**660**	349
Loss for the financial year		**(15,518)**	(6,172)
Basic and diluted losses per Ordinary Share		**(35)p**	(232)p

Consolidated statement of comprehensive income

	2018 £'000	2017 £'000
Loss for the financial year	**(15,518)**	(6,172)
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	**1,169**	17
Other comprehensive expense for the financial year	**1,169**	17
Total comprehensive expense for the financial year	**(14,349)**	(6,155)

Consolidated Statement of Financial Position

	Note	2018 £'000	2017 £'000
Assets			
Current Assets			
Other receivables		**312**	154
Current income tax assets		**686**	349
Cash and cash equivalents	8	**29,353**	3,070
Total Current Assets		**30,351**	3,573
Total Assets		**30,351**	3,573
Equity and Liabilities			
Equity attributable to equity holders			
Share capital	9	**1,067**	701
Share premium	9	**54,858**	4,513
Profit and loss account		**31,537**	45,886
Share-based payments reserve		**997**	253
Merger reserve		**(69,136)**	(69,136)
Total Equity		**19,323**	(17,783)
Liabilities			
Non-current liabilities			
Term bank loan, amounts payable after one year	10	**6,968**	-
		6,968	-
Current liabilities			
Trade and other payables		**3,726**	1,000
Liability component of convertible shares		**-**	11,140
Term loans, amounts payable within one year	10	**334**	5,185
Convertible loan notes		**-**	4,031
		4,060	21,356
Total Liabilities		**11,028**	21,356
Total Equity and Liabilities		**30,351**	3,573

Consolidated Cash Flow Statement

	Note	2018 £'000	2017 £'000
Cash flows from operating activities:			
Cash used in operations	11	**(11,972)**	(6,542)
Income tax credit received		**323**	2,793
Net cash used in operating activities		**(11,649)**	(3,749)
Cash flows from investing activities:			
Interest received		**202**	2
Net cash generated from investing activities		**202**	2
Cash flows from financing activities:			
Proceeds of issuance of convertible loan		**-**	3,400
Proceeds of issuance of Ordinary Shares	9	**35,832**	-
Issue costs of Ordinary Shares	9	**(1,652)**	-
Amounts borrowed under term loan	10	**7,671**	-
Costs of securing term loan	10	**(494)**	-
Principal repaid under term loan	10	**(4,500)**	(3,000)
Interest and fees paid on loans	10	**(1,193)**	(368)
Net cash generated from financing activities		**35,664**	32
Net increase / (decrease) in cash and cash equivalents		**24,217**	(3,715)
Cash and cash equivalents at beginning of the year		**3,070**	6,884
Effect of exchange rate movements on cash held		**2,066**	(99)
Cash and cash equivalents at end of the year	8	**29,353**	3,070

Consolidated Statement of Changes in Equity

For the year ended 31 December 2018

	Issued Share Capital £'000	Share Premium £'000	Profit and Loss account £'000	Merger reserve £'000	Share based payment reserve £'000	Total Equity £'000
Balance at 1 January 2018	**701**	**4,513**	**45,886**	**(69,136)**	**253**	**(17,783)**
Loss for the year	-	-	(15,518)	-	-	(15,518)
Other comprehensive income	-	-	1,169	-	-	1,169
Total comprehensive expense for the year	-	-	(14,349)	-	-	(14,349)
Warrants issued	-	-	-	-	249	249
Transactions with Owners						
Issue of Ordinary shares	366	51,997	-	-	-	52,363
Costs of issue of Ordinary Shares	-	(1,652)	-	-	-	(1,652)
Employee share option scheme	-	-	-	-	495	495
Balance at 31 December 2018	**1,067**	**54,858**	**31,537**	**(69,136)**	**997**	**19,323**

For the year ended 31 December 2017

	Issued Share Capital £'000	Share Premium £'000	Profit and Loss account £'000	Merger reserve	Share based payment reserve £'000	Total Equity £'000
Balance at 1 January 2017	**701**	**4,513**	**52,041**	**(69,136)**	**144**	**(11,737)**
Loss for the financial year	-	-	(6,172)	-	-	(6,172)
Other comprehensive expense	-	-	17	-	-	17
Total comprehensive expense for the year	-	-	(6,155)	-	-	(6,155)
Transactions with Owners						
Employee share option scheme	-	-	-	-	109	109
Balance at 31 December 2017	**701**	**4,513**	**45,886**	**(69,136)**	**253**	**(17,783)**

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 group which discovers, develops and commercialises 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 2018 and 31 December 2017.

Acacia Pharma's 2018 Annual Report will be posted to shareholders in April 2019. The financial information set out herein does not constitute the Company's statutory accounts for the years ended 31 December 2018 or 2017 but is derived from those accounts. Statutory accounts for 2017 have been delivered to the Registrar of Companies, and those for 2018 will be delivered to the Registrar of Companies following the Company's Annual General Meeting, which will be held at 10.30 am on 3 June 2019. 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 2017 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 15 'Revenue from contracts with customers', was issued by the IASB in May 2014 and has been implemented by the Group from 1 January 2018. The Standard contains a new set of principles on when and how to recognise and measure revenue as well as new requirements related to disclosures. There is no impact of adoption, as the Group is not revenue-generating in the current or prior year.

IFRS 9 'Financial instruments' was issued by the IASB in July 2014, and has been implemented by the Group from 1 January 2018. As disclosed in note 10, the Group's only financial assets are cash and cash equivalents and other receivables, which will continue to be held at amortised cost. There has been no impact on the Group's accounting for financial liabilities, as the new requirements only affect the accounting for financial liabilities that are designated as fair value through profit or loss, and the Group does not have any such liabilities. The impact of adoption is immaterial.

(b) Standards, amendments and interpretations that are not yet effective and have not been early adopted
Below is a list of standards/interpretations that have been issued and are not effective for periods starting on 1 January 2018, but will be effective for later periods:

IFRS 16 'Leases' was issued by the IASB in January 2016, and will be implemented by the Group from 1 January 2019. It will result in almost all leases being recognised 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 recognised. The only exceptions are short-term and low-value leases.

The Group expects to recognise right-of use assets of approximately £228,000, and lease liabilities of approximately £360,000. Net assets will be approximately £11,000 lower, and net current assets will be approximately £66,000 lower due to the presentation of a portion of the liability as a current liability.

Operating cash flows will increase and financing cash flows will decrease by approximately £109,000 as repayment of the principal portion of the lease liabilities will be classified as cash flows from financing activities.

The Group will apply the standard from its mandatory adoption date of 1 January 2019. The group intends to apply the simplified transition approach and will not restate comparative amounts for the year prior to first adoption. Right-of-use assets for property leases will be measured on transition as if the new rules had always been applied. All other right-of-use assets will be measured at the amount of the lease liability on adoption (adjusted for any prepaid or accrued lease expenses).

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

(c) Accounting policies applied until 31 December 2017
The Group applied IFRS 9 retrospectively, but has elected not to restate comparative information. As a result, the comparative information provided continues to be accounted for in accordance with the Group's previous accounting policy. No changes to recognition, measurement or derecognition were caused by the adoption of IFRS9.

Going concern
The financial statements have been prepared on a going concern basis, which assumes that the Group and Company will be able to meet their liabilities as they fall due for the foreseeable future. Based on their current forecasts and plans, and taking into account existing cash and debt facilities, the Group and Company will need to raise additional debt or equity financing in order to have sufficient funds to meet their cash requirements for at least the next 12 months. Planning is well progressed for an additional equity or debt raise but on hold, pending the outcome of the FDA approval for BARHEMSYS. However, FDA approval is not a necessarily a pre-requisite for raising the additional funds. There is a material uncertainty that attempts to raise adequate additional financing on a timely basis will be successful.

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

	2018 £'000	2017 £'000
Bank account interest	**4**	2
Interest on short-term deposits	**241**	-
Foreign exchange gains	**681**	99
	926	2

4. Finance expense

	2018 £'000	2017 £'000
Finance charge on preference shares	**209**	2,006
Finance charge on term loan	**709**	873
Finance charge on convertible loan	**1,151**	631
	2,069	3,510

5. Income tax

	2018 £'000	2017 £'000
Current tax		
Current year tax credit	**686**	349
Prior year adjustments	**(26)**	-
Total tax credit	**660**	349

As at 31 December 2018, the unrecognised deferred tax assets relating to operating losses amounted to £5,435,000 (2017: £2,940,000). These have not been recognised 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:

	2018 £'000	2017 £'000
Losses per Ordinary Share		
Loss for the financial year	**(15,518)**	(6,172)
Weighted average number of Ordinary Shares (basic) (thousands)	**44,094**	2,655
Losses per Ordinary Share basic (pence)	**(35)p**	(232)p

Share option and convertible instruments are anti-dilutive in both 2018 and 2017 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. Other classes of shares, along with preference shares have been excluded in this calculation.

7. Financial instruments and financial risk management

The Group's activities expose it to a variety of risks and uncertainties relating to its business and operating environment, including, but not limited to financial risks including market risk (including currency risk), credit risk, liquidity risk and interest rate cash flow risk. The Group's overall risk management programme focuses on the unpredictability of financial markets and seeks to minimise potential adverse effects on financial performance. The Group does not use derivative financial instruments to hedge risk exposures.

The overall objective of the Board is to set policies that seek to reduce ongoing risk as far as possible without unduly affecting the Group's competitiveness and flexibility.

8. Cash and cash equivalents

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

	2018 £'000	2017 £'000
Sterling accounts	**282**	2,819
Euro accounts	**296**	3
US Dollar accounts	**28,775**	248
	29,353	3,070

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 and 31 December 2017	**2,664,662**	**40,948,964**	**53**	**648**	**4,513**
Issue of Ordinary Shares in settlement of liabilities and anti-dilution and preference rights on A, B, C & D shares	5,171,495	-	103	-	11,246
Conversion of S, A, B, C & D shares to Ordinary shares	32,337,899	(32,337,899)	647	(647)	-
Cancellation of P shares	-	(8,611,065)	-	(1)	-
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	-	34	-	5,149
Issue of Ordinary Shares for cash	11,111,111	-	222	-	35,492
Issue of Ordinary Shares upon exercise of share options	410,144	-	8	-	110
Issue costs	-	-	-	-	(1,652)
At 31 December 2018	**53,329,205**	**-**	**1,067**	**-**	**54,858**

On 6 March 2018, the Company completed an Initial Global Offer and was admitted to trading on Euronext Brussels. Immediately before the completion of the Initial Global Offer, 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. A ordinary shares, B preferred shares, and C preferred shares were compound financial instruments. The equity element of these compound financial instruments was included in other reserves. The liability component of the P shares was immaterial and therefore the P shares were classified as equity in their entirety.

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 £35,714,000. Costs directly associated with the issue of shares of £1,652,000 were incurred. On 29 June 200,000 shares were issued upon the exercise of share options, resulting in proceeds of £38,000. On 2 November 210,144 shares were issued upon the exercise of share options, resulting in proceeds of £79,855.

10. Borrowings

	2018 £'000	2017 £'000
Non-current		
Bank borrowings	**6,968**	-
	6,968	-
Current		
Bank borrowings	**334**	5,185
Convertible loan	**-**	4,031
Convertible preference shares	**-**	11,140
	334	20,356
Total borrowings	**7,302**	20,356

The convertible loan and convertible preferences shares were converted to Ordinary Shares on 6 March 2018, immediately prior to the Initial Global Offer.

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

A new term loan facility with Hercules Technology Growth Capital ("Hercules") was drawn on 29 June 2018. The initial tranche drawn was $10,000,000 (£7,671,000) and costs of $645,000 (£494,000) were incurred. A second tranche of $10,000,000 is available on or before 31 July 2019, upon the receipt of the FDA approval of BARHEMSYS. The loan bears interest which is the higher of 9.5% or 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 (April 2020 if the second tranche is drawn). Thereafter the principal and interest on the loan will be repayable in 25 equal instalments, or 22 equal instalments if the second tranche is drawn down. Warrants over 201,330 Ordinary Shares, exercisable at €3.22 per share, were issued to Hercules as part of the terms of the loan facility. Additional warrants will be issued should further tranches of the loan be drawn. The warrants have been fair valued and are being amortised over the term of the loan.

11. Cash used in operations

	2018 £'000	2017 £'000
Loss before income tax	**(16,178)**	(6,521)
Adjustments for:		
Share-based payments	**495**	109
Foreign exchange (gain)/loss	**(681)**	115
Finance expense	**2,069**	3,510
Finance income	**(245)**	(2)
Changes in working capital		
- (Increase) / decrease in other receivables	**(158)**	385
- Increase / (decrease) in trade and other payables	**2,726**	(4,138)
Cash used in operations	**(11,972)**	(6,542)

12. Commitments and contingencies

a) Commitments on expenditure

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

	2018 £'000	2017 £'000
Inventory	**245**	-
Research and development expenditure	**230**	-
Total	**475**	-

b) Operating lease commitments

Lease payments represent amounts payable by the Group for its office property. The future aggregate minimum lease payments under non–cancellable operating leases at the balance sheet date were as follows:

	2018 £'000	2017 £'000
Payments under operating leases which fall due:		
Within 1 year	**88**	13
Between 1 and 5 years	**368**	-
Total	**456**	13

13. Related party disclosures

The Group's Chief Medical Officer, Gabriel Fox's spouse is a director of Comedica Ltd, which during year to 31 December 2018 provided consulting services to the Group. The cost of these services was £18,500 (2017: £30,000). £2,900 was outstanding at the year-end (2017: £1,000).