**For immediate release** **12 December 2018**

**Evgen Pharma plc**
("Evgen" or "the Company")

## Interim results for the six months ended 30 September 2018

***Moving close to value inflection points***

**Evgen Pharma plc** (AIM: EVG), the clinical stage drug development company focused on cancer and neurological conditions, announces its unaudited interim results for the six months ended 30 September 2018.

**Highlights in the year to date:**

- Positive interim data released from ongoing STEM (SFX-01 in the Treatment and Evaluation of Metastatic Breast Cancer) Phase IIa clinical study
- Recruitment in STEM study concluded early as the main aims of the trial, being a favourable safety and tolerability profile and evidence of clinical benefit, had been met
- Poster presentation of STEM programme given at 2018 San Antonio Breast Cancer Symposium
- Financial performance in line with expectations:
    - Total comprehensive loss of £1.8m (2017: loss of £1.7m)
    - Net cash outflow of £1.5m (2017: outflow of £1.7m)
    - Cash and short-term investments at 30 September 2018 of £2.2m (30 September 2017: £2.2m)
- Ongoing SAS (SFX-01 after subarachnoid haemorrhage) Phase IIb clinical study is proceeding well with patient recruitment almost complete; but below trend recruitment rate through October and November means the primary endpoint readout is now expected in Q2 calendar year 2019
- Encouraging data in recent preliminary reports from preclinical programmes in triple negative breast cancer, glioblastoma and ischaemic stroke
- Co-authorship of a major review on the therapeutic targeting of the Nrf2 pathway by sulforaphane and other molecules to be published in Nature Reviews Drug Discovery (in press)
- Key process patent grant in Europe concerning the manufacture of lead compound, SFX-01
- Fundraising in October 2018 raised £0.75m before expenses

**Stephen Franklin, Chief Executive Officer of Evgen Pharma, said:**

"We were delighted with the positive breast cancer interim data showing good tolerability and efficacy in this very difficult to treat patient population and are hopeful that these trends will be maintained in the final analysis. With final read-outs of the STEM and SAS clinical trials due in Q1 and Q2 2019 respectively we are excited about the near-term prospects of the Company.

"We have also been encouraged by our discussions with leading academics and clinicians who have

access to grant funding, and who wish to use SFX-01 for new investigator-initiated trials in non-core indications such as NASH (non-alcoholic steatohepatitis), a subset of non-alcoholic fatty liver disease. These new clinical opportunities have the potential to broaden the use of SFX-01 and thereby build shareholder value."

*This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014.*

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**Notes for editors:**

**About Evgen Pharma plc**

Evgen is a clinical stage drug development company whose lead programmes are in breast cancer and subarachnoid haemorrhage, a type of stroke. The Company's core technology is Sulforadex®, a method for synthesising and stabilising the naturally occurring compound sulforaphane and novel proprietary analogues based on sulforaphane. The lead product, SFX-01, is a patented composition of synthetic sulforaphane and alpha-cyclodextrin.

The Group commenced operations in January 2008 and has its headquarters at The Colony, Wilmslow, Cheshire, and its registered office is at the Liverpool Science Park, Liverpool. It joined the AIM market of the London Stock Exchange in October 2015 and trades under the ticker symbol EVG.

For further information, please visit: www.evgen.com

For commissioned research on the Company, please visit: http://evgen.com/investors/analyst-coverage/

## CHAIRMAN'S AND CHIEF EXECUTIVE'S STATEMENT

We are pleased to present the financial results of Evgen for the six months ended 30 September 2018 and to provide an update on the significant progress made by the Group during the period.

### INTRODUCTION

Evgen is a clinical stage drug development company focused on the development of a new class of pharmaceuticals based upon the small molecule, sulforaphane. Evgen has built a substantive intellectual property package covering novel compositions and processes in order to secure a stronghold around the therapeutic development and use of sulforaphane and related analogues. Our pipeline exploits sulforaphane's activity in two separate biochemical pathways: inhibition of STAT3, of importance in cancer, and up-regulation of Nrf2, a target for reducing neurodegeneration.

Our lead product, SFX-01, is coming to the end of Phase II trials in the two separate indications of metastatic breast cancer and subarachnoid haemorrhage.

### CLINICAL TRIAL PROGRESS

#### SFX-01 in metastatic breast cancer

Breast cancer is the biggest cause of cancer deaths in women worldwide. In around 75% of breast cancers, the hormone oestrogen plays a key part in tumour growth. Such tumours express the oestrogen receptor (ER+) and, if the cancer is metastatic, endocrine therapy is the main treatment. It is thought that hormone independent cancer stem cells are implicated in the development of resistance to hormone therapy and the spread of the disease by metastases. Since 2012, Evgen has worked with University of Manchester scientists at the Cancer Research UK Manchester Institute and together we have generated promising data showing SFX-01 reduces the number of cancer stem cells in patient-derived breast cancer tissue in xenograft models. The xenograft studies used a combination of hormone therapy and SFX-01, with the role of SFX-01 being to target the cancer stem cell population. Crucially, the data also showed that SFX-01 is unique in deactivating phosphorylated STAT3, a key agent in cancer proliferation and resistance to current standards of care.

STEM ('SFX-01 in the Treatment and Evaluation of Metastatic Breast Cancer') is a multi-centre, Phase IIa clinical trial. Led by Principal Investigator Dr Sacha Howell of the Christie Hospital in Manchester, it was initially designed to recruit 60 patients from 14 sites in the UK, France, Spain and Belgium.

All STEM patients had ER+ metastatic breast cancer and had been on treatment with either tamoxifen, aromatase inhibitors or fulvestrant. Prior to entry to the STEM trial, all patients had previously responded to their current hormone therapy for at least six months but then presented with progressive disease, thereby demonstrating the start of resistance to the hormone therapy. Once entered into the trial, patients continue to receive their failing hormone therapy in addition to SFX-01 and have regular scans through to week 24. Patients discontinue the trial when one of the scans shows disease progression or at week 24.

The primary endpoints are safety/tolerability and clinical benefit rate (CBR) as measured by RECIST (Response Evaluation Criteria In Solid Tumours). After 24 weeks, for responding patients, a compassionate use programme provides continued access to SFX-01 with follow-up for safety.

In June 2018 we announced an interim update on the first 20 patients to have completed the trial. In the opinion of the Chief Investigator, Dr Sacha Howell, and of the Company's Chief Medical Advisor the interim observations were:

- SFX-01 was proving to be well tolerated with no safety concerns arising; and

- SFX-01 had shown encouraging early signs of anti-tumour activity.

Specifically, four patients had their disease stabilised (that is, having come on to the trial with progressive disease, their tumours stopped progressing) for the full duration of the study through to, and including, a favourable final scan result at week 24. Of these four patients, one also had a partial response, which is a reduction in tumour size of at least 30% on one scan. In addition to these four patients, a further two patients had their disease stabilised through to, and including, the week 18 scan but then showed disease progression at the final week 24 scan. One of these two patients also demonstrated a partial response on one scan before disease progression was recorded at the final scan.

All patients that had a favourable week 18 scan are registered in the compassionate use programme to ensure continuity of drug between the final week 24 scan and the scan result, which can be some time later.

In July 2018, we announced that, following the positive interim read-out, the Chief Investigator and the Company's medical adviser had concluded that the main aims of the trial, being a favourable safety and tolerability profile and evidence of clinical benefit, had been successfully met. Accordingly, we halted recruitment early on the basis that there was no merit in recruiting the full number of patients allowed under the protocol. In total, there will be 46 evaluable patients treated with SFX-01, compared with the initial target of 60, of whom one remained in the trial (i.e. pre-week 24) as at 7 December 2018. The final readout will occur in February or March 2019. This will include details of the safety, tolerability and the clinical benefit rate observed across all patients.

**SFX-01 in subarachnoid haemorrhage (SAH)**

Aneurysmal SAH is a form of stroke, caused by a ruptured aneurysm which leads to a bleed in the subarachnoid space of the brain. It is a relatively rare condition, accounting for around 5% of all strokes. It is fatal in approximately 50% of cases with approximately 15% dying before they reach hospital. A delayed cerebral ischaemia (DCI), which happens 3-14 days after the initial haemorrhage, remains the single most important cause of morbidity and mortality in those patients that survive the initial bleed. Over 60% of surviving patients suffer some permanent neurological deficit.

Nimodipine, the current standard of care, is a generic and has been used for more than 20 years, during which time there have been no significant clinical advances in the treatment of SAH. Whilst SAH is relatively rare, the market potential for this devastating condition, with its high unmet clinical need, is significant. In October 2015, Credit Suisse estimated potential peak sales of $1.7bn by 2032 for a Phase III development product based on the intraventricular delivery of a nimodipine-based formulation.

SFX-01 is aimed at reducing the neurological damage associated with the DCI via the up-regulation of the Nrf2-ARE (nuclear factor erythroid2-related factor 2–antioxidant response element) pathway. Sulforaphane, the active principal in SFX-01, is a well-known activator of the Nrf2–ARE pathway which plays a protective role in many physiological stress processes such as inflammatory damage, oxidative stress, and the accumulation of toxic metabolites, which are all involved in the DCI following SAH. The trial is a double-blind, placebo-controlled study of 90 patients; 45 patients receive nimodipine and placebo and 45 patients receive nimodipine and SFX-01. The primary endpoints are Transcranial Doppler (essentially blood flow as measured by ultrasound through the brain’s blood vessels and a measure of the DCI), safety and pharmacokinetics.

Importantly, secondary endpoints include a cognitive measurement of clinical improvement (“the modified Rankin Scale”) assessed at 7, 28, 90 and 180 days post haemorrhage. Potential follow-on studies would almost certainly have primary clinical endpoints based on such clinical outcomes.

To date, 84 evaluable patients have been recruited from three UK centres; University Hospital Southampton, St Bartholomew's Hospital in London and the Western General Hospital in Edinburgh. A further 6 evaluable patients are required to achieve the 90 patient target. Patient recruitment in the past two months has been materially below the trend (due to fewer eligible patients presenting with subarachnoid haemorrhage) and accordingly we now anticipate the read out of the primary endpoints in Q2 calendar year 2019; with the secondary endpoints reading out in late summer 2019.

**INVESTIGATOR-LED CLINICAL TRIALS**

Academic interest and publication of scientific papers around sulforaphane continues to be high. This has prompted an escalating number of well-respected academics to contact us with a view to supporting their pre-clinical and clinical activities. In particular, and subject to grant funding being procured, there are opportunities to support Phase II trials in fatty liver disease (NASH), autism spectrum disorder (ASD) and intra-cerebral haemorrhage (ICH). In each case Evgen would supply SFX-01 and retain commercial rights.

**PRE-CLINICAL PIPELINE**

We have seen encouraging early results from our collaboration with Dr Sacha Howell and Dr Rob Clarke at the Manchester Cancer Research Centre, University of Manchester, in which SFX-01 is being tested in in-vivo models of triple negative breast cancer (TNBC). Notably the data showed that SFX-01 monotherapy induced a significant inhibition of tumour growth and mammosphere formation (a measure of cancer stem cells). As a consequence of this data the Shine Bright Foundation, which is the TNBC-focused charity funding the work, will provide further funding to extend the collaboration.

In a collaboration with Dr Claudio Festuccia at the Department of Applied Clinical Sciences and Biotechnologies, University of L'Aquila, Italy, SFX-01 is being tested in animal models of glioblastoma. Preliminary data shows improved survival after treatment with SFX-01 alone when compared with radiotherapy alone, but with a much superior effect when SFX-01 is delivered in combination with radiotherapy.

In our collaboration with Professor Giovanni E. Mann at King's BHF Centre of Research Excellence, King's College London, we have also been investigating the effects of SFX-01 in an in-vivo model of ischaemic stroke. The studies include Laser Speckle Blood Flow Imaging, a technology that shows real-time blood flow around the brain, before, during and after an experimental stroke. Whilst still ongoing, the study has shown that preconditioning with SFX-01 (i.e. three days dosing prior to stroke) improves the blood flow to the site of the stroke and this results in improved measures of functional and motor deficit. Notably, both pre-treatment and acute treatment with SFX-01 after ischaemic stroke rescued blood flow on reperfusion, suggesting that SFX-01 is protective if given before a stroke. This is promising with regard to our SAS clinical trial, where SFX-01 is administered days in advance of the ischaemia that follows the initial haemorrhage. The study also revealed an unexpected neuropsychiatric benefit after 30 days dosing of SFX-01; details will be disclosed after patent protection has been assessed and the data has been published.

We continue to investigate the use of SFX-01 in an animal model of relevance to autism (ASD), working with a separate group at Kings College London. This study is ongoing with results expected next year.

Finally, we are co-authors on a comprehensive review paper entitled "Transcription Factor NRF2 as a Therapeutic Target for Chronic Diseases: A Systems Medicine Approach''. This authoritative review, to be published shortly in Nature Reviews Drug Discovery, reviews all NRF2-modulating drugs in clinical

development, including SFX-01. The paper validates the opportunity for such drugs in a wide range of disease areas.

**Intellectual property update**

In May we announced the grant of a key European patent ascribing intellectual property rights to the Company for a method of stabilising sulforaphane, the naturally occurring compound on which SFX-01, the Company's lead product, is based. The Company has granted process patents in Australia, China, Europe, United States and Japan, with patents pending in Brazil, Canada and India. These patents have an expiry no later than 2033 (without patent extensions).

The core composition of matter patent family, entitled "Stabilized Sulforaphane", with expiry no later than 2028 (without patent extensions), now has patents granted in Europe, United States, Canada and Australia and pending in Japan and Hong Kong.

The novel sulforaphane analogues composition of matter patent family is now granted in Australia, China, Europe, Japan and United States; with a pending application in Canada. This patent family has an expiry no later than 2033 (without patent extensions).

Further patent protection associated with product formulation and dosing regimens remain under review.

**FINANCIAL REVIEW**

The financial performance for the six-month period to 30 September 2018 was in line with expectations. The total comprehensive loss for the period was £1.8m (30 September 2017: £1.7m). The net cash outflow for the period was £1.5m (30 September 2017: £1.7m).

The cash position at 30 September 2018 stood at £2.2m (30 September 2017: £2.2m), reflecting continued research and development and administrative costs. Since the period end the Group has received £436k in cash from R&D tax credits.

In October 2018 Evgen raised £0.75m before expenses through the placing of 5,555,558 new ordinary shares at an issue price of 13.5p per share.

**OUTLOOK**

Our focus in the year to date has been on completing the two ongoing trials and refining the next stages of clinical development. We have also been working with academic clinicians to support investigator-initiated trials in non-core indications which would potentially broaden the clinical use of SFX-01 and reduce shareholder risk.

We are very excited by the potential for positive read-outs during the first half of 2019 from our two Phase II trials and the opportunities these would present for the further development of Evgen.

We would like to thank all our shareholders for their support.

| | |
|---|---|
| **Barry Clare** | **Stephen Franklin** |
| Chairman | CEO |
| 12 December 2018 | |

**Consolidated Statement of Comprehensive Income**
**for the six months ended 30 September 2018 - unaudited**

| | Notes | **Six months ended 30 September 2018 £'000 unaudited** | Six months ended 30 September 2017 £'000 unaudited | Year ended 31 March 2018 £'000 audited |
|---|---|---|---|---|
| **Operating expenses** | | | | |
| Operating expenses | | **(1,727)** | (1,633) | (2,915) |
| Share-based compensation | **4** | **(60)** | (48) | (111) |
| **Total operating expenses** | | **(1,787)** | (1,681) | (3,026) |
| **Operating loss** | | **(1,787)** | (1,681) | (3,026) |
| **Loss on ordinary activities before taxation** | | **(1,787)** | (1,681) | (3,026) |
| Taxation | | **-** | 4 | 443 |
| **Loss and total comprehensive expense attributable to equity holders for the period** | | **(1,787)** | (1,677) | (2,583) |
| **Loss earnings per share (pence)** | | | | |
| Basic loss per share | **3** | **(1.91)** | (2.28) | (3.28) |
| Diluted loss per share | **3** | **(1.91)** | (2.28) | (3.28) |

**Consolidated Statement of Financial Position**
**as at 30 September 2018 - unaudited**

| | Notes | **As at 30 September 2018 £'000 unaudited** | As at 30 September 2017 £'000 unaudited | As at 31 March 2018 £'000 audited |
|---|---|---|---|---|
| **ASSETS** | | | | |
| **Non-current assets** | | | | |
| Property, plant and equipment | | **10** | 15 | 12 |
| Intangible assets | | **105** | 120 | 113 |
| **Total non-current assets** | | **115** | 135 | 125 |
| **Current assets** | | | | |
| Trade and other receivables | | **126** | 74 | 77 |
| Current tax receivable | | **432** | 575 | 432 |
| Cash and cash equivalents | | **2,158** | 2,207 | 3,626 |
| **Total current assets** | | **2,716** | 2,856 | 4,135 |
| **Total assets** | | **2,831** | 2,991 | 4,260 |
| **LIABILITIES AND EQUITY** | | | | |
| **Current liabilities** | | | | |
| Trade and other payables | | **682** | 358 | 389 |
| **Total current liabilities** | | **682** | 358 | 389 |
| **Equity** | | | | |
| Share capital | **5** | **233** | 185 | 233 |
| Share premium | | **12,565** | 10,527 | 12,560 |
| Merger reserve | | **2,067** | 2,067 | 2,067 |
| Share-based compensation | | **1,647** | 1,524 | 1,587 |
| Accumulated losses | | **(14,363)** | (11,670) | (12,576) |
| **Total equity** | | **2,149** | 2,633 | 3,871 |
| **Total liabilities and equity** | | **2,831** | 2,991 | 4,260 |

The registered number of Evgen Pharma plc is 09246681.

**Consolidated Statement of Changes in Equity**
**for the six months ended 30 September 2018 – unaudited**

| | Share capital £'000 | Share premium £'000 | Merger reserve £'000 | Share-based compensation £'000 | Accumulated losses £'000 | Total £'000 |
|---|---|---|---|---|---|---|
| **Balance at 1 April 2018** | **233** | **12,560** | **2,067** | **1,587** | **(12,576)** | **3,871** |
| Total comprehensive expense for the period | - | - | - | - | (1,787) | (1,787) |
| **Transactions with owners** | | | | | | |
| Share issue | - | 5 | - | - | - | 5 |
| Share-based compensation – share options | - | - | - | 60 | - | 60 |
| **Total transactions with owners** | **-** | **5** | **-** | **60** | **-** | **65** |
| **Balance at 30 September 2018** | **233** | **12,565** | **2,067** | **1,647** | **(14,363)** | **2,149** |

| | Share capital £'000 | Share premium £'000 | Merger reserve £'000 | Share-based compensation £'000 | Accumulated losses £'000 | Total £'000 |
|---|---|---|---|---|---|---|
| **Balance at 1 April 2017** | **183** | **10,495** | **2,067** | **1,476** | **(9,993)** | **4,228** |
| Total comprehensive expense for the period | - | - | - | - | (1,677) | (1,677) |
| **Transactions with owners** | | | | | | |
| Share issue | 2 | 32 | - | - | - | 34 |
| Share-based compensation – share options | - | - | - | 48 | - | 48 |
| **Total transactions with owners** | **2** | **32** | **-** | **48** | **-** | **82** |
| **Balance at 30 September 2017** | **185** | **10,527** | **2,067** | **1,524** | **(11,670)** | **2,633** |

| | Share capital £'000 | Share premium £'000 | Merger reserve £'000 | Share-based compensation £'000 | Accumulated losses £'000 | Total £'000 |
|---|---|---|---|---|---|---|
| **Balance at 1 April 2017** | **183** | **10,495** | **2,067** | **1,476** | **(9,993)** | **4,228** |
| Total comprehensive expense for the period | - | - | - | - | (2,583) | (2,583) |
| **Transactions with owners** | | | | | | |
| Share issue - cash | 48 | 2,034 | - | - | - | 2,082 |
| Share issue – options exercised | 2 | 31 | - | - | - | 33 |
| Share-based compensation – share options | - | - | - | 111 | - | 111 |
| **Total transactions with owners** | **50** | **2,065** | **-** | **111** | **-** | **2,226** |
| **Balance at 31 March 2018** | **233** | **12,560** | **2,067** | **1,587** | **(12,576)** | **3,871** |

**Consolidated Statement of Cash Flows**
**for the six months ended 30 September 2018 - unaudited**

| | **Six months ended 30 September 2018 £'000 unaudited** | Six months ended 30 September 2017 £'000 unaudited | Year ended 31 March 2018 £'000 audited |
|---|---|---|---|
| **Cash flows from operating activities** | | | |
| Loss before taxation for the period | **(1,787)** | (1,681) | (3,026) |
| Depreciation and amortisation | **11** | 10 | 21 |
| Share-based compensation | **60** | 48 | 111 |
| | **(1,716)** | (1,623) | (2,894) |
| **Changes in working capital** | | | |
| (Increase)/decrease in trade and other receivables | **(49)** | 10 | 7 |
| Increase/(decrease) in trade and other payables | **292** | (153) | (125) |
| **Cash used in operations** | **243** | (143) | (118) |
| Taxation received | **-** | 85 | 671 |
| **Net cash used in operating activities** | **(1,473)** | (1,681) | (2,341) |
| | | | |
| **Cash flows from investing activities** | | | |
| Purchase of property, plant and equipment | **-** | (5) | (7) |
| **Net cash used in investing activities** | **-** | (5) | (7) |
| | | | |
| **Cash flows from financing activities** | | | |
| Issue of shares | **5** | 34 | 2,115 |
| **Net cash generated from financing activities** | **5** | 34 | 2,115 |
| | | | |
| **Movements in cash and cash equivalents in the period** | **(1,468)** | (1,652) | (233) |
| Cash and cash equivalents at start of period | **3,626** | 3,859 | 3,859 |
| **Cash and cash equivalents at end of period** | **2,158** | 2,207 | 3,626 |

## 1. GENERAL INFORMATION

Evgen Pharma plc ("Evgen", "the Group" or "the Company") is a public limited company incorporated in England & Wales and is admitted to trading on the AIM market of the London Stock Exchange under the symbol EVG.

The address of its registered office is Liverpool Science Park Innovation Centre 2, 146 Brownlow Hill, Liverpool, Merseyside L3 5RF. The principal activity of the Group is clinical stage drug development.

## 2. BASIS OF PREPARATION AND SIGNIFICANT ACCOUNTING POLICIES

### Basis of preparation

The Group's half-yearly financial information, which is unaudited, consolidates the results of Evgen Pharma plc and its subsidiary undertaking up to 30 September 2018. The Group's accounting reference date is 31 March. Evgen Pharma plc's shares are quoted on the AIM Market of the London Stock Exchange (AIM).

The Company is a public limited liability company incorporated and domiciled in the UK. The consolidated financial information is presented in round thousands of Pounds Sterling (£'000).

The financial information contained in this half-yearly financial report does not constitute statutory accounts as defined in section 434 of the Companies Act 2006. It does not therefore include all of the information and disclosures required in the annual financial statements. The financial information for the six months ended 30 September 2017 and 30 September 2018 is unaudited.

The results for the year ended 31 March 2018 are in abbreviated form and have been extracted from the full audited financial statements of the Group in respect of the period ended 31 March 2018, which received an unqualified audit opinion and did not contain a statement under section 498(2) or (3) of the Companies Act 2006. The audit report included a material uncertainty related to going concern.

The audited financial statements of the Group for the year ended 31 March 2018 have been delivered to the Registrar of Companies.

The accounting policies used in the preparation of the financial information for the six months ended 30 September 2018 are in accordance with the recognition and measurement criteria of International Financial Reporting Standards as adopted by the European Union ('IFRS') and are consistent with those which will be adopted in the annual financial statements for the year ending 31 March 2019.

Whilst the financial information included has been prepared in accordance with the recognition and measurement criteria of IFRS, the financial information does not contain sufficient information to comply with IFRS.

The Group has not applied IAS 34, Interim Financial Reporting, which is not mandatory for UK AIM listed Groups, in the preparation of this interim financial report.

### Going concern

At 30 September 2018, the Group had cash and cash equivalents, including short-term investments and cash on deposit, of £2.2 million.

The Directors have prepared detailed financial forecasts and cash flows looking beyond 12 months from the date of the approval of these financial statements. In developing these forecasts, the Directors have made assumptions based upon their view of the current and future economic conditions that will prevail over the forecast period. These projections take account of the fundraising completed in October 2018 which raised £0.75m before expenses.

The Directors estimate that the cash held by the Group together with known receivables will be sufficient to support the current level of activities to the end of September 2019. The Directors are continuing to explore sources of finance available to the Group and have confidence that they will be able to secure sufficient cash inflows for the Group to continue its activities for not less than 12 months from the date of approval of these financial statements; they have therefore prepared the half-yearly financial report on a going concern basis. Because the additional finance is not committed at the date of approval of this half-yearly financial report, these circumstances represent an uncertainty as to the Group's ability to continue as a going concern. Should the Group be unable to obtain further finance such that the going concern basis of preparation were no longer appropriate, adjustments would be required including to reduce balance sheet values of assets to their recoverable amounts, to provide for further liabilities that might arise and to reclassify fixed assets as current assets.

**Significant management judgement in applying accounting policies and estimation uncertainty**
When preparing the half-yearly financial report, the Directors make a number of judgements, estimates and assumptions about the recognition and measurement of assets, liabilities, income and expenses.

The following are significant management judgements and estimates in applying the accounting policies of the Group that have the most significant effect on the half-yearly financial report. Actual results may be substantially different.

**Share-based payments**
The Group measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. The fair value of the options granted is determined using the Black-Scholes model, taking into consideration the best estimate of the expected life of the option and the estimated number of shares that will eventually vest.

**Research and development expenditure**
All research and development costs, whether funded by third parties under licence and development agreements or not, are included within operating expenses and classified as such. Research and development costs relating to clinical trials are recognised over the period of the clinical trial based on information provided by clinical research organisations. All other expenditure on research and development is recognised as the work is completed.

All ongoing development expenditure is currently expensed in the period in which it is incurred. Due to the regulatory and other uncertainties inherent in the development of the Group's programmes, the criteria for development costs to be recognised as an asset, as prescribed by IAS 38, 'Intangible assets', are not met until the product has been submitted for regulatory approval, such approval has been received and it is probable that future economic benefits will flow to the Group. The Group does not currently have any such internal development costs that qualify for capitalisation as intangible assets.

**3. LOSS PER SHARE**

Basic loss per share is calculated by dividing the loss for the period attributable to equity holders by the weighted average number of ordinary shares outstanding during the period.

For diluted loss per share, the loss for the period attributable to equity holders and the weighted average number of ordinary shares outstanding during the period is adjusted to assume conversion of all dilutive potential ordinary shares. As the effect of the share options would be to reduce the loss per share, the diluted loss per share is the same as the basic loss per share.

The calculation of the Group's basic and diluted loss per share is based on the following data:

| | **Six months ended 30 September 2018 £'000 unaudited** | Six months ended 30 September 2017 £'000 unaudited | Year ended 31 March 2018 £'000 audited |
|---|---|---|---|
| Loss for the period attributable to equity holders | **(1,787)** | (1,677) | (2,583) |

| | **As at 30 September 2018 Number unaudited** | As at 30 September 2017 Number unaudited | As at 31 March 2018 Number audited |
|---|---|---|---|
| Weighted average number of ordinary shares | **93,313,143** | 73,410,657 | 78,697,455 |
| Weighted average number of ordinary shares adjusted for the effects of dilution | **93,313,143** | 73,410,657 | 78,697,455 |

| | **Pence** | Pence | Pence |
|---|---|---|---|
| Loss per share – basic and diluted | **(1.91)** | (2.28) | (3.28) |

**4. SHARE-BASED PAYMENTS**

As at the end of the current period, the reconciliation of share option scheme movements is as follows:

| | **As at 30 September 2018** | |
|---|---|---|
| | **Number** | **WAEP** |
| Outstanding at 1 April 2018 | 8,665,255 | £0.02 |
| Granted during the period | 368,304 | - |
| Exercised during the period | (80,000) | (£0.01) |
| Lapsed/cancelled during the period | (145,370) | - |
| **Outstanding at 30 September 2018** | **8,808,189** | **£0.02** |

During the six month period ended 30 September 2018, a share-based payment charge of £60,374 (six months ended 30 September 2017: £47,715) was expensed to the Consolidated Statement of Comprehensive Income.

The fair values of the options granted have been calculated using a Black-Scholes model.

Assumptions used were an option life of 5 years, a risk-free rate of 2 per cent., a volatility of 60 per cent. and no dividend yield.

**5. ISSUED CAPITAL AND RESERVES**

**Ordinary shares**

| | | Company | |
|---|---|---|---|
| | | **Number** | **Share Capital £'000** |
| **At 31 March 2018** | | **93,276,858** | **233** |
| Issued on exercise of options | | **80,000** | **-** |
| **At 30 September 2018** | | **93,356,858** | **233** |

On 10 July 2018 80,000 ordinary shares were issued in connection with the exercise of share options.

On 18 October 2018 the Company announced the placing of 5,555,558 new Ordinary shares at 13.5p per share to raise £0.75m before expenses.