



Evgen Pharma plc

("Evgen Pharma", "the Group" or "the Company")

Interim results for the six months ended 30 September 2016

Lead product SFX-01 successfully enters two Phase II trials

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 2016.

Highlights in the year to date:

- First patient dosed (April 2016) in the Company's Phase II clinical trial SAS (SFX-01 after subarachnoid haemorrhage) and patient recruitment rates in-line with expectations
- US Food & Drug Administration ("FDA") granted the Company orphan drug designation (August 2016) for the use of stabilised sulforaphane in subarachnoid haemorrhage ("SAH")
- First clinical site is now open for patient recruitment for the Company's Phase II clinical trial STEM (SFX-01 in the Treatment and Evaluation of Metastatic Breast Cancer), with further sites due to open across Europe in H1 CY 2017
- Further preclinical data to be presented at the San Antonio Breast Cancer Symposium (December 2016) entitled *SFX-01 targets Wnt signalling to inhibit stem-like cells in breast cancer patient-derived xenograft tumours*
- Positive data from preclinical studies of SFX-01 in various models of the relapsing remitting form of multiple sclerosis ("MS") presented (September 2016) at leading MS conference
- Dr Bob Holland and Dr Tom Morris appointed as Medical Advisers, in neurology and oncology respectively (September 2016)
- The total comprehensive loss for the period was £1.7m (30 September 2015: total comprehensive loss £1.2m)
- The cash position (including short-term deposits) at 30 September 2016 was £5.5m (30 September 2015: £1.8m); the IPO placing in October 2015 raised £7.0m (gross), fully funding the Company to complete two Phase II studies and to support further preclinical work

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

"We are pleased with the significant progress made this year. The SAS trial is recruiting patients as planned and the STEM trial has now opened for recruitment at the first site in Europe. Both trials are projected to report in-line with expectations in the first half of calendar year 2018. Furthermore, we have secured orphan designation for our lead product in the treatment of subarachnoid haemorrhage, a type of stroke for which there has been no material advance in treatment for over 20 years.

"In addition to the clinical programmes, we were delighted to present positive preclinical data for SFX-01 at this year'sECTRIMS (European Committee for Treatment and Research in Multiple Sclerosis), the largest annual conference

dedicated to basic and clinical research in MS. The data demonstrated that SFX-01 was superior to the active principle in Biogen's Tecfidera®, particularly in the way that it improved neurological recovery in the chronic stage after relapse. As part of an ongoing strategic review, the Company continues to assess all options for a potential third clinical programme."

Analyst meeting

A meeting for analysts will be held at 11am this morning, 5 December 2016, at the offices of Buchanan, 107 Cheapside, London EC2V 6DN. Please contact Buchanan on 020 7466 5000 for further information.

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Notes for editors:

About Evgen Pharma plc

Evgen Pharma is a clinical stage drug development company whose lead programmes are in breast cancer and subarachnoid haemorrhage, a type of stroke. It also has a clinical interest in multiple sclerosis and prostate cancer. 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.

Evgen Pharma commenced operations in January 2008 and is based in Liverpool, UK, at the Liverpool Science Park. 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.

CHAIRMAN'S AND CHIEF EXECUTIVE'S STATEMENT

We are pleased to present the financial results of Evgen Pharma for the six months ended 30 September 2016 and to provide an update on the significant progress made by the Company during the period.

INTRODUCTION

Evgen Pharma's core technology seeks to unlock the therapeutic potential of sulforaphane, a compound first isolated from the brassica family of plants. The Company's patent-protected Sulforadex® technology enables the scalable manufacturing of a stabilised, synthetic sulforaphane. The stabilised composition is a solid powder, which can easily be formulated into pills and other medicinal formats. The Sulforadex® technology is also applicable to novel compounds based upon the core sulforaphane structure, giving the Company the opportunity to develop a broad clinical pipeline and to become the world leader in sulforaphane and sulforaphane-like pharmaceuticals.

The initial product to use the Sulforadex® technology is code-named SFX-01, which is a synthetic copy of sulforaphane stabilised within an alpha-cyclodextrin complex. SFX-01 has been advanced through preclinical and Phase I clinical trials and is now in Phase II trials in two separate indications: metastatic breast cancer and subarachnoid haemorrhage.

PIPELINE

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 Pharma has worked with the Cancer Research UK Manchester Institute and together they 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. This data was first presented at the American Association of Cancer Research annual conference in Philadelphia in April 2015. We are delighted to be able to announce that this week, on 7 December 2016, further preclinical data will be presented at the San Antonio Breast Cancer Symposium entitled *SFX-01 targets Wnt signalling to inhibit stem-like cells in breast cancer patient-derived xenograft tumours*.

STEM (SFX-01 in the Treatment and Evaluation of Metastatic Breast Cancer) is a multi-centre, Phase IIa clinical trial that is now open for recruitment at the first European site, in Belgium, with a minimum of nine further sites due to open in early H1 CY 2017.

The trial, led by Principal Investigator Dr Sacha Howell of the Christie Hospital in Manchester, will recruit 60 patients from multiple sites in the UK, Belgium, Spain, France and the Czech Republic. All patients will have ER+ metastatic breast cancer and will have been on treatment with either tamoxifen, aromatase inhibitors (AI) or fulvestrant. These patients will have responded to their current therapy for at least six months but then present with documented progressive disease. Patients will be assigned to one of three arms (20 in each arm) in the study (tamoxifen, AI or fulvestrant) and will continue to receive their hormone therapy but in addition to SFX-01. Patients will be dosed for up to 24 weeks with regular scans. The primary endpoints are safety / tolerability and clinical benefit rate (CBR) as measured by RECIST (Response Evaluation Criteria In Solid Tumors). After 24 weeks, for responding patients, there will be a continued access programme and a follow-up for safety.

The trial is now registered at ClinicalTrials.gov and can be viewed at this link:

<https://clinicaltrials.gov/ct2/show/NCT02970682?term=SFX-01&rank=2>

The trial is projected to report in H1 CY 2018. As the trial is not blinded, it is likely that there will be sequential read-outs from the three arms of the study.

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 around the outside of the brain. It is a relatively rare condition, accounting for around 5% of all strokes. It is fatal in approximately 40% 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.

SFX-01 is being aimed at reducing the neurological damage associated with the DCI via the up-regulation of the Nrf2–ARE (nuclear factor erythroid 2-related factor 2–antioxidant response element) pathway. Sulforaphane, the active principle 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 cerebral vasospasm following SAH.

On 30 April 2016, the first patient was dosed in the Company's Phase II clinical trial entitled SAS: SFX-01 After Subarachnoid haemorrhage. The trial is a double-blind, placebo-controlled study of 90 patients; 45 receiving nimodipine and 45 received nimodipine with 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 cerebral vasospasm), safety and pharmacokinetics.

The trial is registered at ClinicalTrials.gov and can be viewed at this link:
<https://clinicaltrials.gov/ct2/show/NCT02614742?term=evgen&rank=1>.

The trial is projected to report in H1 CY 2018.

In August 2016, the US Food & Drug Administration ("FDA") granted the Company orphan drug designation for the use of stabilised sulforaphane for the treatment of subarachnoid haemorrhage.

SFX-01 in multiple sclerosis

The principal mechanism of action of SFX-01 in SAH is via sulforaphane's ability to upregulate the Nrf2 pathway, resulting in a wide range of antioxidant and anti-inflammatory effects. It is this pathway that is implicated in Biogen IDEC's treatment for multiple sclerosis, Tecfidera®. In-vitro studies have shown that sulforaphane is a more potent activator of Nrf2 than dimethyl fumarate, the active ingredient in Tecfidera®.

In September 2016, the Company presented a late-breaking abstract and poster at the 32nd Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in London. The poster was entitled *Efficacy of SFX-01, a sulforaphane-based drug in experimental autoimmune encephalomyelitis* and its authors were Dr Ian Galea (Associate Professor in Experimental Neurology, Faculty of Medicine, University of Southampton), Dr Ian Copple (Lecturer, Institute of Translational Medicine, University of Liverpool) and Dr David Howat (Evgen's Chief Development Officer). The study concluded that: "SFX-01 appears to be superior to BG-12 in the therapeutic EAE model. SFX-01 appears to exert maximum effects later in the course of the disease by enabling superior neurological recovery in the chronic stage after relapse. SFX-01 is a promising drug candidate in MS, and warrants further investigation."

Early stage pipeline

As mentioned earlier, SFX-01 is a synthetic and stable sulforaphane, which has been shown to have excellent pharmacokinetics and a bioavailability of around 80%. When the synthetic sulforaphane is released from its sugar lattice in the gastrointestinal tract it has the same half-life in the body as naturally occurring sulforaphane and has been shown to be equipotent.

Medicinal chemists at the University of Seville have gone on to create a range of novel compounds based upon the sulforaphane core structure. As previously announced, Evgen Pharma has in-licensed the Seville intellectual property presenting the Company with multiple new chemical entities based upon sulforaphane. Patent protection for these compounds is pending in Europe, United States, China, Japan, Australia, and Canada and is already granted in Spain.

We are delighted to be able to report that the first batch of novel analogues have been manufactured in Spain and shipped to the UK where they will be assayed in due course as part of a research contract with the University of Liverpool.

PEOPLE

We would like to take this opportunity to welcome to the team Dr Bob Holland and Dr Tom Morris who became Medical Advisers (in neurology and oncology respectively) to the Company in September 2016. Dr Bob Holland had a long career at AstraZeneca having been their VP and Head of Personalised Healthcare & Biomarkers and prior to that their VP and Head of Neuroscience Therapeutic Area. Dr Tom Morris has held various medical roles in oncology at AstraZeneca including Senior Medical Director for Oncology, Executive Director of Clinical Programs and Medical Science Director for the Oncology Therapy Area.

Barry Clare became Executive Chairman of the Company at IPO to help oversee the first year as a public company. With our plans advancing as expected, Barry will, with immediate effect, revert to his position of Non-Executive Chairman.

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

FINANCIAL REVIEW

The financial performance for the six-month period to 30 September 2016 was in line with expectations. The total comprehensive loss for the period was £1.7m (30 September 2015: £1.2m).

The cash position (including short-term deposits) at 30 September 2016 increased to £5.5m (30 September 2015: £1.8m), reflecting the admission of the Company to trading on AIM in October 2015 after raising £7.0m (£6.3m after expenses) in an oversubscribed placing.

OUTLOOK

We are pleased with the significant progress made this year. Both Phase II trials are underway and are projected to report in-line with expectations in H1 CY 2018. Furthermore, we have secured orphan designation for our lead product in the treatment of subarachnoid haemorrhage, a type of stroke for which there has been no material advance in treatment for over 20 years.

In addition to the clinical programmes, we were delighted to present positive preclinical data for SFX-01 at this year's ECTRIMS, the largest annual conference dedicated to basic and clinical research in multiple sclerosis. The data demonstrated that SFX-01 was superior to the active principle in Biogen's Tecfidera®, particularly in the way that it improved neurological recovery in the chronic stage after relapse.

As part of an ongoing strategic review, the Company continues to assess all options (including MS and a number of orphan indications within neurology) for a potential third clinical programme based on SFX-01.

Barry Clare
Chairman

Stephen Franklin
CEO

5 December 2016

**Consolidated Statement of Comprehensive Income
for the six months ended 30 September 2016 - unaudited**

	Six months ended 30 September 2016 £'000 unaudited	Six months ended 30 September 2015 £'000 unaudited	Year ended 31 March 2016 £'000 audited
Operating expenses			
Operating expenses	(1,595)	(367)	(1,232)
Share based compensation	(98)	(141)	(519)
Non-recurring administrative expenses	-	-	(683)
Total operating expenses	(1,693)	(508)	(2,434)
Operating loss	(1,693)	(508)	(2,434)
Finance income	12	-	8
Finance expense	(3)	(682)	(791)
Loss on ordinary activities before taxation	(1,684)	(1,190)	(3,217)
Taxation	1	-	85
Loss and total comprehensive expense attributable to equity holders for the period	(1,683)	(1,190)	(3,132)
Loss earnings per share (pence)			
Basic loss per share	(2.30)	(3.88)	(6.29)
Diluted loss per share	(2.30)	(3.88)	(6.29)

**Consolidated Statement of Financial Position
as at 30 September 2016 - unaudited**

	As at 30 September 2016 £'000 unaudited	As at 30 September 2015 £'000 unaudited	As at 31 March 2016 £'000 audited
ASSETS			
Non-current assets			
Property, plant and equipment	6	1	6
Intangible assets	135	42	74
Total non-current assets	141	43	80
Current assets			
Trade and other receivables	105	164	79
Current tax receivable	85	30	115
Short-term investments and cash on deposit	2,006	-	2,006
Cash and cash equivalents	3,542	1,776	5,120
Total current assets	5,738	1,970	7,320
Total assets	5,879	2,013	7,400
LIABILITIES AND EQUITY			
Current liabilities			
Trade and other payables	377	722	313
Loans	-	3	-
Total current liabilities	377	725	313
Non-current liabilities			
Loans	-	1,646	-
Total non-current liabilities	-	1,646	-
Equity			
Share capital	183	92	183
Share premium	10,495	1,859	10,495
Merger reserve	2,067	2,067	2,067
Shares to be issued	-	1,750	-
Share based compensation	1,365	607	1,267
Accumulated losses	(8,608)	(6,733)	(6,925)
Total equity	5,502	(358)	7,087
Total liabilities and equity	5,879	2,013	7,400

Consolidated Statement of Changes in Equity
for the six months ended 30 September 2016 - unaudited

	Share capital £'000	Share premium £'000	Merger reserve £'000	Share based compensation £'000	Accumulated losses £'000	Total £'000
Balance at 1 April 2016	183	10,495	2,067	1,267	(6,925)	7,087
Total comprehensive expense for the period	-	-	-	-	(1,683)	(1,683)
Transactions with owners						
Share based compensation – share options	-	-	-	98	-	98
Total transactions with owners	-	-	-	98	(1,683)	(1,585)
Balance at 30 September 2016	183	10,495	2,067	1,365	(8,608)	5,502

	Share capital £'000	Share premium £'000	Merger reserve £'000	Shares to be issued £'000	Share based compensation £'000	Accumulated losses £'000	Total £'000
Balance at 1 April 2015	73	—	2,067	1,750	466	(5,543)	(1,187)
Total comprehensive expense for the period	—	—	—	—	—	(1,190)	(1,190)
Transactions with owners							
Share based compensation – share options	—	—	—	—	141	—	141
Share issue	19	1,859	—	—	—	—	1,878
Total transactions with owners	19	1,859	—	—	141	(1,190)	829
Balance at 30 September 2015	92	1,859	2,067	1,750	607	(6,733)	(358)

	Share capital £'000	Share premium £'000	Merger reserve £'000	Shares to be issued £'000	Share based compensation £'000	Accumulated losses £'000	Total £'000
Balance at 1 April 2015	73	—	2,067	1,750	466	(5,543)	(1,187)
Total comprehensive expense for the period	—	—	—	—	—	(3,132)	(3,132)
Transactions with owners							
Equity element of loan note	—	—	—	(1,750)	—	1,750	—
Share based compensation – share options	—	—	—	—	519	—	519
Share based compensation - warrants	—	—	—	—	282	—	282
Share issue - cash	19	1,840	—	—	—	—	1,859
Share issue – cash	47	6,645	—	—	—	—	6,692

Share issue – loan note conversion	23	2,017	—	—	—	—	2,040
Share issue – bonus issue	20	(20)	—	—	—	—	—
Share issue – options exercised	1	13	—	—	—	—	14
Total transactions with owners	110	10,495	—	(1,750)	801	1,750	11,406
Balance at 31 March 2016	183	10,495	2,067	—	1,267	(6,925)	7,087

Consolidated Statement of Cash Flows
for the six months ended 30 September 2016 - unaudited

	Six months ended 30 September 2016 £'000 unaudited	Six months ended 30 September 2015 £'000 unaudited	Year ended 31 March 2016 £'000 audited
Cash flows from operating activities			
Loss before taxation for the period	(1,684)	(1,190)	(3,217)
Finance (income)/expense	(9)	682	791
Depreciation and amortisation	9	3	8
Share based compensation	98	141	801
	(1,586)	(364)	(1,617)
Changes in working capital			
Increase in trade and other receivables	(26)	(47)	(47)
Increase in trade and other payables	64	146	104
Cash generated from changes in working capital	38	99	57
Taxation received	31	-	-
Net cash used in operating activities	(1,517)	(265)	(1,560)
Cash flows from investing activities			
Acquisition of intangible assets	(67)	-	(36)
Purchase of property, plant and equipment	(2)	-	(6)
Short-term investments and cash on deposit	-	-	(2,006)
Net cash used in investing activities	(69)	-	(2,048)
Cash flows from financing activities			
Issue of shares	-	2,000	9,014
Cost of share issue	-	(122)	(449)
Interest received	8	-	-
Net cash generated from financing activities	8	1,878	8,565
Movements in cash and cash equivalents in the period	(1,578)	1,613	4,957
Cash and cash equivalents at start of period	5,120	163	163
Cash and cash equivalents at end of period	3,542	1,776	5,120

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 Company 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 2016. 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 2015 and 30 September 2016 is unaudited.

Full audited financial statements of the Group in respect of the period ended 31 March 2016, which received an unqualified audit opinion and did not contain a statement under section 498(2) or (3) of the Companies Act 2006, 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 2016 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 2017.

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 the time of approving the condensed consolidated interim financial information, and based on a review of the group’s forecasts and business plan, the directors have a reasonable expectation that the Group have adequate resources to continue in operational existence for the foreseeable future. Thus they have adopted the going concern basis of accounting in preparing the condensed consolidated interim financial information.

Significant management judgement in applying accounting policies and estimation uncertainty

When preparing the condensed consolidated interim financial information, the Directors make a number of judgements, estimates and assumptions about the recognition and measurement of assets, liabilities, income and expenses.

Significant management judgements

The following are significant management judgements in applying the accounting policies of the Group that have the most significant effect on the condensed consolidated interim financial information.

Estimation uncertainty

Information about estimates and assumptions that have the most significant effect on recognition and measurement of assets, liabilities, income and expenses is provided below. 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.

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 2016 £'000 Unaudited	Six months ended 30 September 2015 £'000 unaudited	Year ended 31 March 2016 £'000 audited
Loss for the period attributable to equity holders	(1,683)	(1,190)	(3,132)
	As at 30 September 2016 Number Unaudited	As at 30 September 2015 Number unaudited	As at 31 March 2016 Number audited
Weighted average number of ordinary shares	73,142,862	30,675,541	49,797,654
Weighted average number of ordinary shares adjusted for the effects of dilution	73,142,862	30,675,541	49,797,654
	Pence (2.30)	Pence (3.88)	Pence (6.29)

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 2016	
	Number	WAEP
Outstanding at 1 April 2016	8,473,251	£0.03
Granted during the period	53,473	-
Exercised during the period	-	-
Lapsed/cancelled during the period	-	-
Outstanding at 30 September 2016	8,526,724	£0.03

During the six month period ended 30 September 2016, a share-based payment charged of £98,000 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.