



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

Half year Report

Evgen Pharma plc (AIM: EVG), the clinical stage drug development company developing sulforaphane-based medicines for the treatment of multiple diseases, announces its unaudited interim results for the six months ended 30 September 2021.

Operational highlights

- Malignant glioma Orphan Drug Designation for SFX-01 granted by FDA
- Encouraging early in vitro data for SFX-01 in Juvenile Myelomonocytic Leukaemia ("JMML") at the MRC Weatherall Institute, University of Oxford
- Final preclinical work in glioblastoma ("GBM") completed and in late-stage preparation for a Phase Ib/II trial
- In vitro pre-clinical work supports SFX-01 use in metastatic breast cancer patients who have become resistant to the widely-used class of CDK4/6 inhibitor drugs
- Publication of positive preclinical in vitro and in vivo data in GBM from two independent groups of collaborators in Italy and New Zealand
- Scale-up of the active ingredient in SFX-01 to commercial scale achieved with a number of process improvements
- New formulation of SFX-01 generated in tablet form enabling scale up to supply late-stage clinical trials and commercial use
- Dr Helen Kuhlman and Dr Glen Clack appointed as Chief Business Officer and Chief Medical Officer respectively, completing the senior management team

Financial highlights

- Financial performance in-line with expectations:
 - Post-tax loss of £1.5m (2020: loss of £1.8m)
 - Cash outflow from operations of £1.5m (2020: outflow of £1.9m)
 - Cash deposits, cash and cash equivalents balance at 30 September 2021 of £10.1m (30 September 2020: £2.3m)

Dr Huw Jones, Chief Executive Officer of Evgen Pharma, said: *"The last six months has yielded further positive preclinical data to support the potential of SFX-01 in a number of cancers and an Orphan Drug Designation in the USA for malignant glioma. With the scale up and refinement of the SFX-01 production process and design of the Phase I and Phase II clinical trials running in parallel, we look forward to commencing further important clinical programmes in H1 2022. With our strengthened senior management team that brings further expertise, we look forward to a successful second half of the year and I would like to extend my thanks to our shareholders for their continued support."*



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About Evgen Pharma plc

Evgen Pharma is a clinical stage drug development company developing sulforaphane based medicines for the treatment of multiple diseases. 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.

Clinical data from the Company's open-label Phase II STEM trial has shown that SFX-01 can halt the growth of progressing tumours in patients with oestrogen-positive (ER+) metastatic breast cancer, and in some cases significantly shrink the tumour, whilst causing very few side effects. It has been used to treat over 200 patients in clinical trials and is well-tolerated with predominately mild side-effects.

The Company has its headquarters at Alderley Park, Cheshire, and its registered office is at the Liverpool Science Park, Liverpool. It is listed on the AIM market of the London Stock Exchange and trades under the ticker symbol EVG.

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

For 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 2021 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 sulforaphane-based compounds, a new class of pharmaceuticals which are synthesised in a proprietary, well-tolerated, stable formulation. We have a comprehensive intellectual property estate covering this technology. Our pipeline exploits sulforaphane's activity in three separate biochemical pathways; inhibition of pSTAT3 and SHP2, both of importance in cancer, and up-regulation of Nrf2, a therapeutic target associated with a broad range of diseases which are characterised by excessive oxidative stress and inflammation. Sulforaphane has attracted huge scientific interest and has been shown to have anti-cancer and anti-inflammatory qualities in a wide range of preclinical and clinical studies. However clinical grade delivery of sulforaphane has proved elusive. Evgen is the only company to be generating such a product for clinical use to the exacting standards of pharmaceutical products.

Our lead product, SFX-01, has demonstrated efficacy in a Phase II trial for advanced metastatic breast cancer. It has been used to treat over 200 patients in clinical trials and is well-tolerated, with a good safety profile and predominantly mild side-effects.

Evgen has exclusive rights to the only technology (Sulforadex®) proven to synthesise this very unstable molecule in a stabilised composition that will satisfy regulatory and medicinal needs for a pharmaceutical and that can be used as a therapeutic. We have a strong balance sheet and robust IP around sulforaphane and Sulforadex®.

PIPELINE

Phase I study of biomarkers including pharmacokinetic and pharmacodynamic ('PK/PD') assessment

An important use of proceeds from the fundraise completed in March this year was to conduct a Phase I study in healthy volunteers to assess PK/PD characteristics of SFX-01, and potentially other biomarkers relevant to our diseases of interest, with our commercial-scale tablet formulation. Whilst an initial Phase 1 study was completed prior to the first efficacy trials conducted by Evgen, as our knowledge of how SFX-01 behaves in the body has developed it has become evident that a further study would be beneficial in informing the design of future efficacy trials, particularly dosing regimens using our new dosage form.

Design of this trial is almost complete and a dialogue with the MHRA has commenced. The intention is to start the trial in Q2 next year as soon as the new tablet formulation of SFX-01 has been finalised and manufactured in sufficient quantities.

Metastatic breast cancer ("mBC")

Since we commenced our phase II trial of SFX-01 in metastatic breast cancer, CDK4/6 inhibitors have grown in acceptance and are becoming standard of care in first line mBC treatment. These drugs provide an extended period of progression free survival, but invariably patients become resistant to them. Accordingly, we are conducting further preclinical work with our collaborators at the Cancer Research UK Manchester Institute to assess the impact of SFX-01 in CDK4/6 resistance models. To date this work has demonstrated encouraging in vitro data and accordingly we are arranging access to in vivo models for experiments that, if successful, would support a trial in



second line mBC treatment of patients who have failed on CDK4/6 inhibitors. This would be designed as a Phase II placebo-controlled study and most likely would be conducted in partnership.

Glioblastoma ("GBM")

Glioma is the most common form of brain tumour affecting around 5 per 100,000 people. The more severe, grade IV classification, glioblastoma, is a very serious form of malignant brain tumour representing 45% of all cases and has a poor prognosis with median survival of around 14 months. The five-year survival of the severe grades is 5%. The therapeutic options for glioma are limited to surgery, radiotherapy and the one drug widely available, temozolomide. There is a clear unmet need for more treatments for use in conjunction with the current standard of care.

A collaboration with Dr Claudio Festuccia and colleagues at the Universities of d'Aquila, Rome and Rieti, Italy has generated highly positive data for SFX-01 in pre-clinical models of glioma and glioblastoma. Using standard in vitro and in vivo pre-clinical models as well as orthotopic models (where glioma cells are implanted in brain tissue representing a more disease-relevant model) both tumour shrinkage and significantly extended survival times were demonstrated. Furthermore, SFX-01 was also found to potentiate (i.e. substantially increase) the therapeutic effect of radiotherapy in these models. The first of two papers relating to this has been published in a peer-reviewed journal and a second paper is being finalised for submission. (Colapietro et al, *Pharmaceuticals*, 2021, 14, 1082.)

Further preclinical work conducted generated by Dr Euphemia Leung and Prof Bruce Baguley of the University of Auckland, New Zealand in GBM cells has been published in the pre-print journal *BioRxIV* (Leung, Wright and Baguley, 2021 <https://www.biorxiv.org/content/10.1101/2021.09.14.459936v1>). This in vitro data is of SFX-01 in GBM cells and 3D spheroids from several patients in New Zealand, together with the more commonly used commercially available cell lines. 3D spheroids are aggregations of tumour cells that more closely reflect the structure of tumours in patients. In these in vitro experiments, SFX-01 demonstrated inhibition of glioblastoma cell growth, supporting the results from the work of Dr Festuccia.

We are now at a late stage in designing a Phase Ib/II clinical study and liaising with potential trial sites in the UK and across Europe. The trial could commence in Q2 2022.

Evgen recently announced the grant of Orphan Drug Designation in the USA for Malignant Glioma, affording the programme additional data protection and other incentives.

SFX-01 in leukaemias

Professor Philip Eaton at Queen Mary University of London has shown that SFX-01 inhibits activity of the non-receptor phosphotyrosine phosphatase, SHP2 (coded by the PTPN11 gene). SHP2 is thought to be a significant factor in many cancers. Professor Eaton's work has recently been submitted for publication.

Following on from this work, an in vitro project was conducted by another world-renowned academic institution, The Wetherall Institute, University of Oxford to study the effect of SFX01 on cell lines from patients with Juvenile Myelomonocytic Leukaemia ('JMML'). SHP2 is a mediator of the cell proliferation seen in JMML patients. Whilst this is preliminary data from a small sample size, we were encouraged to see a statistically significant effect in reducing cell proliferation and increasing apoptosis (cell death).



JMML is an invasive and very rare childhood cancer that may not have sufficient commercial opportunity to be an appropriate programme for Evgen to pursue. Accordingly, we are in dialogue with leading clinicians in this field that may be interested in conducting investigator-led trials.

We are also evaluating other leukaemias which would meet our scientific and commercial criteria for development, and if we conclude there is an opportunity would anticipate starting pre-clinical work in Q1 2022.

ARDS in COVID-19 and other patients

Whilst the STAR Phase IIb/III study conducted at the University of Dundee study provided further data to support the benign safety and tolerability of SFX-01, regrettably the interim analysis did not show efficacy sufficient to justify continuation of the trial. We are awaiting the full data set to analyse biomarker information that will inform our future programmes.

BUSINESS DEVELOPMENT

Juvenescence partnership

Our first commercial out-licensing deal signed, with Juvenescence in September 2020, monetises one element of Evgen's sulforaphane technology platform, being the application of our Sulforadex stabilisation technology in the dietary supplement market. This gives a commercialisation timescale considerably shorter than that typical of pharmaceutical development.

Juvenescence is making good progress with sourcing naturally-derived sulforaphane, production scale-up and regulatory strategy. It is envisaged that product launch will occur in around two years' time at which point milestone payments of over £1m will have been received.

NON-CLINICAL ACTIVITIES

The funds raised in 2019 were allocated in part to completion of long-term toxicology and manufacturing process development work. This is now close to completion and we have achieved the following:

- Six-month toxicology satisfactorily completed with data that supports continued clinical development of SFX-01
- Technology transfer of production process to a UK-based manufacturer of pharmaceutical products and scale-up of both a key intermediate and the active ingredient in SFX-01 achieved, with a number of process improvements
- Good progress with new formulation of SFX-01 in tablet form and commercial scale-up on-going.

The new tablet formulation of SFX-01 will be used in all future clinical trials in place of the prototype capsule that patients have been treated with to date, and which was not suitable for in-market use.

Regarding regulatory matters, we have asked for scientific advice from the MHRA in connection with the Phase 1 PK/PD study and progressed our work on IND submission. We expect to hold a pre-IND meeting with the FDA in Q1/2022.



FINANCIAL REVIEW

The financial performance for the six-month period to 30 September 2021 was in line with expectations. Operating losses decreased in the period by £0.33m from £1.85m to £1.52m; this reflects the long term toxicology programme and manufacturing process development that was concentrated in the prior period, together with some product manufacture for the STAR-Covid-19 trial. Consequently the total comprehensive loss for the period was £1.52m (30 September 2020: £1.84m).

The net cash outflow for the period was £1.54m (30 September 2020: £1.83m) reflecting the lower level of toxicology and manufacturing work noted above.

The cash position (including cash deposits, short term investments and cash equivalents) at 30 September 2021 stood at £10.05m (30 September 2020: £2.31m), reflecting the funding round in March 2021. Since the period end HMRC has remitted R&D tax credits of £0.53m.

The Directors estimate that the cash held by the Group together with known receivables will be sufficient to support the current level of activities into Q3 2023. They have therefore prepared the financial statements on a going concern basis.

OUTLOOK

In the last six months we have broadened our preclinical data sets in mBC, GBM and leukaemia to underpin clinical trials in these diseases and focused on preparing for the next clinical trials. In particular we have developed trial designs for the Phase I PK/PD study, and in collaboration with senior GBM clinicians, the design of the GBM proof of principle study. In parallel we have progressed a new and commercially viable formulation of SFX-01 that will be deployed in these trials. Accordingly, we can look forward to exciting clinical progress in 2022.

We would like to thank all our shareholders for their support and look forward to progressing with our strategy which remains clearly focused on commercialising the undoubted potential of SFX-01.

Barry Clare
Chairman

Huw Jones
CEO

6 December 2021

Consolidated Statement of Comprehensive Income for the six months ended 30 September 2021
- unaudited

		Six months ended 30 September 2021 £'000 Unaudited	Six months ended 30 September 2020 £'000 Unaudited	Year ended 31 March 2021 £'000 Audited
Revenue		-	194	194
Operating expenses				
Operating expenses		(1,443)	(1,965)	(3,519)
Share based compensation	4	(81)	(82)	112
Total operating expenses		(1,524)	(2,047)	(3,407)
Operating loss		(1,524)	(1,853)	(3,213)
Other income		-	10	-
Loss on ordinary activities before taxation		(1,524)	(1,843)	(3,213)
Taxation		-	-	539
Loss and total comprehensive expense attributable to equity holders of the parent for the period		(1,524)	(1,843)	(2,674)
Loss per share attributable to equity holders of the parent (pence)				
Basic loss per share	3	(0.55)	(1.38)	(1.82)
Diluted loss per share	3	(0.55)	(1.38)	(1.82)

Consolidated Statement of Financial Position as at 30 September 2021 - unaudited

	Notes	As at 30 September 2021 £'000 Unaudited	As at 30 September 2020 £'000 Unaudited	As at 31 March 2021 £'000 Audited
ASSETS				
Non-current assets				
Property, plant and equipment		7	1	5
Intangible assets		59	74	66
Total non-current assets		66	75	71
Current assets				
Trade and other receivables		116	161	235
Current tax receivable		519	446	519
Short-term investments and cash on deposit		6,000	-	6,000
Cash and cash equivalents		4,050	2,306	5,593
Total current assets		10,685	2,913	12,347
Total assets		10,751	2,988	12,418
LIABILITIES AND EQUITY				
Current liabilities				
Trade and other payables		383	434	607
Total current liabilities		383	434	607
Equity				
Ordinary shares	5	687	343	687
Share premium		27,870	17,932	27,870
Merger reserve		2,067	2,067	2,067
Share based compensation		440	1,970	359
Retained deficit		(20,696)	(19,758)	(19,172)
Total equity attributable to equity holders of the parent		10,368	2,554	11,811
Total liabilities and equity		10,751	2,988	12,418

Consolidated Statement of Changes in Equity for the six months ended 30 September 2021 – unaudited

	Ordinary shares £'000	Share premium £'000	Merger reserve £'000	Share based compensation £'000	Retained deficit £'000	Total £'000
Balance at 1 April 2021	687	27,870	2,067	359	(19,172)	11,811
Total comprehensive expense for the period	-	-	-	-	(1,524)	(1,524)
Transactions with owners						
Share based compensation - share options	-	-	-	81	-	81
Total transactions with owners	-	-	-	81	-	81
Balance at 30 September 2021	687	27,870	2,067	440	(20,696)	10,368

	Ordinary shares £'000	Share premium £'000	Merger reserve £'000	Share based compensation £'000	Retained deficit £'000	Total £'000
Balance at 1 April 2020	331	17,831	2,067	1,890	(17,915)	4,204
Total comprehensive expense for the period	-	-	-	-	(1,843)	(1,843)
Transactions with owners						
Share issue - options exercised	12	101	-	-	-	113
Share based compensation - share options	-	-	-	80	-	80
Total transactions with owners	12	101	-	80	-	193
Balance at 30 September 2020	343	17,932	2,067	1,970	(19,758)	2,554

	Ordinary shares £'000	Share premium £'000	Merger reserve £'000	Share based compensation £'000	Retained deficit £'000	Total £'000
Balance at 1 April 2020	331	17,831	2,067	1,890	(17,915)	4,204
Total comprehensive expense for the period	-	-	-	-	(2,674)	(2,674)
Transactions with owners						
Share issue - cash	344	9,938	-	-	-	10,282
Share issue - options exercised	12	101	-	(2)	-	111
Share issue - lapsed options	-	-	-	(1,417)	1,417	-
Share based compensation - share options	-	-	-	(112)	-	(112)
Total transactions with owners	356	10,039	-	(1,531)	1,417	10,281
Balance at 31 March 2021	687	27,870	2,067	359	(19,172)	11,811

The registered number of Evgen Pharma plc is 09246681.

Consolidated Statement of Cash Flows for the six months ended 30 September 2021 – unaudited

	Six months ended 30 September 2021 £'000 Unaudited	Six months ended 30 September 2020 £'000 Unaudited	Year ended 31 March 2021 £'000 Audited
Cash flows from operating activities			
Loss before taxation for the period	(1,524)	(1,843)	(3,213)
Depreciation and amortisation	9	9	18
Share based compensation	81	82	(112)
	(1,434)	(1,752)	(3,307)
Changes in working capital			
(Increase)/decrease in trade and other receivables	119	35	(39)
(Decrease)/increase in trade and other payables	(224)	(219)	(46)
Cash used in operations	(105)	(184)	(85)
Taxation received	-	-	466
Net cash used in operating activities	(1,539)	(1,936)	(2,926)
Cash flows (used in)/generated from investing activities			
Monies placed on fixed-term deposit	-	-	(6,000)
Acquisition of tangible fixed assets	(4)	-	(5)
Net cash (used in)/generated from investing activities	(4)	-	(6,005)
Cash flows from financing activities			
Net proceeds from issue of shares	-	111	10,393
Net cash generated from financing activities	-	111	10,393
Movements in cash and cash equivalents in the period	(1,543)	(1,825)	1,462
Cash and cash equivalents at start of period	5,593	4,131	4,131
Cash and cash equivalents at end of period	4,050	2,306	5,593



1. GENERAL INFORMATION

EVGEN PHARMA PLC ("Evgen", "the Group" or "the Company") is a public limited company incorporated in England & Wales whose shares are traded 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 2021. 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 2020 and 30 September 2021 is unaudited.

Full audited financial statements of the Group in respect of the period ended 31 March 2021, 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 2021 are in accordance with the recognition and measurement criteria of international accounting standards in conformity with the requirements of the Companies Act 2006 as adopted by the UK and are consistent with those which will be adopted in the annual financial statements for the year ending 31 March 2022.

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

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 2021, the Group had cash and cash equivalents, including short-term investments and cash on deposit, of £10.05 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.

The Directors estimate that the cash and cash equivalents including short-term investments and cash on deposit, held by the Group together with known receivables will be sufficient to support the current level of activities into the third quarter of calendar year 2023. They have therefore prepared the financial statements on a going concern basis.



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.

The following are significant management judgements and estimates in applying the accounting policies of the Group that have the most significant effect on the condensed consolidated interim financial information. 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 options 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 2021 £'000 Unaudited	Six months ended 30 September 2020 £'000 Unaudited	Year ended 31 March 2021 £'000 Audited
Loss for the period attributable to equity holders	(1,524)	(1,843)	(2,674)
	As at 30 September 2021 Number Unaudited	As at 30 September 2020 Number Unaudited	As at 31 March 2021 Number Audited
Weighted average number of ordinary shares	274,888,117	133,726,538	147,019,536
Effects of dilution:			
Share options	-	-	-
Weighted average number of ordinary shares adjusted for the effects of dilution	274,888,117	133,726,538	147,019,536
	Pence	Pence	Pence
Loss per share - basic and diluted	(0.55)	(1.38)	(1.82)

4. SHARE-BASED PAYMENTS

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

	Number	As at 30 September 2021 WAEP
Outstanding at 1 April 2021	6,402,754	£0.01
Granted during the period	4,743,291	£0.00
Exercised during the period	-	-
Lapsed/cancelled during the period	-	-
Outstanding at 30 September 2021	11,146,045	£0.01

WAEP is an abbreviation for weighted average exercise price.

During the six-month period ended 30 September 2021, a share-based payment charge of £80,607 (six months to 30 September 2020: £81,504) 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 Share Capital Number	£'000
As at 31 March 2021	274,888,117	687
Issued on exercise of options	-	-
Issued under placing agreement	-	-
At 30 September 2021	274,888,117	687

No new shares were issued during six-month period ended 30 September 2021.