



10 December 2020

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 2020.

Operational highlights

- Dr Huw Jones appointed as Chief Executive Officer
- Completion of first out-licensing deal with Juvenescence for use of Sulforadex® technology in non-pharmaceutical markets. Up to \$10.5m receivable in milestones with royalties on sales
- Phase IIb/III trial using SFX-01 for acute respiratory distress syndrome ("ARDS") including COVID-19 patients sponsored by Dundee University, with grant funding from LifeArc; the "STAR" trial (SFX-01 treatment for acute respiratory infections)
- Patient recruitment commenced in STAR trial post the period end with data potentially available in Q4 2021.
- Strong pre-clinical data generated in a new solid tumour indication; requirements for and design of a Phase Ib/IIa trial being assessed
- Pre-clinical work commenced in a blood cancer indication based on new evidence that SFX-01 inhibits the SHP2 pathway
- Pre-clinical work proceeding to support SFX-01 use in metastatic breast cancer patients who have become resistant to CDK4/6 drugs
- Good progress in process development to scale up manufacturing and formulation of SFX-01

Financial highlights

- Financial performance in-line with expectations:
 - Loss post tax of £1.8m (2019: loss of £1.6m)
 - Cash outflow from operations of £1.9m (2019: outflow of £1.7m)
 - Cash balance at 30 September 2020 of £2.3m (30 September 2019: £5.1m)

Dr Huw Jones, Chief Executive Officer of Evgen Pharma, said: *"I am delighted to have joined Evgen Pharma during a period of such positive news for the Company. Substantial progress was made in the half year in business development and in particular in our STAR trial where patients with community acquired pneumonia from any infection including COVID-19 can be recruited. I look forward to updating the market and our shareholders on our next cancer indication in due course, where preliminary pre-clinical data look compelling. We continue to demonstrate the huge potential of our pipeline and are excited for the future progression of this."*

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About Evgen Pharma plc

Evgen Pharma is a clinical stage company developing sulforaphane based medicines with a focus on cancer and respiratory 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.

The Company has its headquarters at The Colony, Wilmslow, Cheshire, and its registered office is at the Liverpool Science Park, Liverpool. 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 150 patients in clinical trials and is well-tolerated with predominately mild side-effects.

Evgen shares are traded on the AIM market of the London Stock 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 for the six months ended 30 September 2020 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 package over this technology. Our pipeline exploits sulforaphane's activity in two oncology and inflammatory diseases, based on inhibition of the pSTAT3 and SHP2 pathways, of importance in controlling cancers, and up-regulation of Nrf2, a therapeutic target associated with a broad range of diseases characterised by excessive oxidative stress and inflammation.

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 150 patients in clinical trials and is well-tolerated with predominantly mild side-effects.

Dr Huw Jones joined Evgen recently as CEO. He has over 30 years' experience of leadership roles in public and private R&D-based companies within the biotechnology and pharmaceutical sector, with a particular focus on pre-clinical and clinical drug development, dilutive and non-dilutive financing and business development.

STRATEGY

Following the appointment of Dr Jones, Evgen's strategy has been refined as follows:

- To ensure our selected development programmes meet stringent scientific and commercial criteria
- Our core R&D efforts to be focused on our oncology and ARDS pipeline
- SFX-01 to continue to be provided to academic groups for preclinical evaluation in selected disease models
- Consideration will be given to supporting clinical evaluation of SFX-01 in non-core indications where there is compelling preclinical data and an attractive commercial opportunity
- To leverage the Sulforadex® platform by supporting Juvenescence in bringing products to market outside the pharmaceutical sector
- The business model is to establish proof of concept and then conclude partnerships.

PIPELINE

Metastatic breast cancer ("mBC")

Since 2012, Evgen has worked with University of Manchester scientists at the Cancer Research UK Manchester Institute ("Manchester") 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, compared with existing marketed therapies, in deactivating phosphorylated STAT3, a key agent in driving cancer metastases and resistance to current standards of care. This data was recently published in the prestigious journal, *Oncogene*.

In the open-label Phase II trial of SFX-01 in 46 mBC patients we demonstrated:

- Conclusive evidence of anti-cancer activity via objective responses (tumour shrinkage)
- 24% of patients showed a durable clinical benefit for at least six months, despite the late stage of disease and patients' established resistance to hormone therapy. Of these, five patients were still receiving SFX-01 at 12 months and one patient still remains on treatment after 18 months

- A mild and favourable side effect profile for an anti-cancer drug.

Since we commenced the trial 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 Manchester to assess the impact of SFX-01 in CDK4/6 resistance models. Positive data from this study would therefore support a trial in second line mBC treatment of patients who have failed on CDK4/6 inhibitors, which would be designed as a Phase II placebo-controlled study. Such a trial could commence in Q1 2022.

ARDS in COVID-19 and other patients

In June, we won a highly competitive grant process to secure funding from LifeArc to evaluate SFX-01 in patients with suspected COVID-19, in conjunction with the University of Dundee (“Dundee”). The trial, sponsored by Dundee, will investigate whether SFX-01 can reduce the severity, or prevent the onset of, acute respiratory distress syndrome (“ARDS”) associated with COVID-19 and pneumonia resulting from other infectious agents, thus reducing the need for invasive patient ventilation and potentially improving recovery times.

SFX-01 upregulates the Nrf2 pathway which is part of the natural human defence against inflammatory and oxidative stress, such as the inflammation that occurs during a severe viral infection. Preclinical studies have shown that up-regulating the Nrf2 pathway reduces the severity of ARDS, the progressive lung damage observed in COVID-19 and other pneumonia patients which can result in the need for invasive ventilation in an intensive care unit.

The Phase IIb/III study will recruit up to 300 patients with confirmed or suspected COVID-19. Patients will be drawn from both hospital and community settings and may present with COVID-19 or other respiratory diseases such as viral pneumonia. Half the group will receive SFX-01 in addition to standard hospital care while the other half will receive a placebo and standard hospital care.

Evgen will supply clinical centres with SFX-01 and a placebo as its contribution to the trial. No additional financing is required as the costs of providing SFX-01 for the trial are not material.

Up to the 7th of December nine patients had been recruited and depending on availability of COVID-19 patients and other patients with ARDS, data could be available in the final quarter of 2021. In addition, a Data Safety and Monitoring Board will review unblinded data after 100 patients have been treated with SFX-01 or placebo.

Solid tumour oncology target

In a collaboration which will be disclosed when patent filings and a scientific paper have been prepared, strong preclinical data has been generated when SFX-01 was evaluated in a model of a cancer with very poor life expectancy, and for which current treatments are limited.

In particular, *in vitro* studies with patient-derived cell lines showed dose-dependent reduction in proliferation and migration. Further, *in vivo* orthotopic xenograft models, treatment with SFX-01 increased disease-free survival and lengthened tumour progression times, an effect that is synergistic with radiotherapy.

Further preclinical work will be initiated shortly to complete the data set required for a clinical trial application and/or partnering discussions. The preclinical work should be completed by the middle of 2021 and a phase Ib/II could commence in Q1 of 2022.

Blood cancer target

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 some

cancers and we have recently agreed to support work in well-renowned university to investigate whether SFX-01 has potential in a specific blood cancer disease.

JUVENESCENCE PARTNERSHIP

In September we announced the licensing of our Sulforadex® sulforaphane stabilisation technology in a number of non-pharmaceutical applications to Juvenescence Ltd (“Juvenescence”). In particular, Juvenescence intends to market and sell a high-end nutritional health product containing a defined dose of sulforaphane extracted from natural sources. Under the terms of the license agreement the (“Agreement”), we will receive milestone and option payments of up to \$10.5m together with royalties on future product sales.

This agreement monetises one element of Evgen’s sulforaphane technology platform within a timescale considerably shorter than that typical of pharmaceutical development. Our focus will remain on progressing the therapeutic programmes, and the Agreement contains provisions which ensure a clear differentiation between potential nutritional health products and pharmaceutical products, including limitations on daily dose.

The natural source of sulforaphane to be used by Juvenescence contrasts with the synthetic sulforaphane which is used in SFX-01, the Company’s lead therapeutic product. It is envisaged that product launch by Juvenescence will occur in around two years’ time.

NON-CLINICAL PROGRAMMES

Our long-term toxicology and manufacturing process development work has continued. Initial data suggest that we will be able to demonstrate an acceptable toxicology profile for conducting clinical trials in chronic diseases where longer term dosing is required. These data are consistent with our observations of patients who received SFX-01 for extended periods in the mBC trial.

Scale-up of our formulation and manufacturing processes has progressed. In particular, a commercial scale process for producing a key intermediate in drug substance manufacture has been developed by a well-regarded contract manufacturing organisation. Also, the stabilised sulforaphane conjugate has demonstrated good flow properties in prototype solid dose formulations, enabling larger scale production.

FINANCIAL REVIEW

The financial performance for the six-month period to 30 September 2020 was in line with expectations. Our first licensing revenues (\$250k) were received following signature of the Juvenescence license. Operating losses increased on the previous period by £0.3m from £1.6m to £1.9m; this was due to the increase in activity and costs of the toxicology programmes and manufacturing process development. Consequently the total comprehensive loss for the period was £1.8m (30 September 2019: £1.6m).

The net cash outflow for the period was £1.8m (30 September 2019: inflow of £3.0m as a result of an equity fundraise).

The cash position at 30 September 2020 stood at £2.3m (30 September 2019: £5.1m), reflecting the operating loss before share-based payment charges. Since the year end HMRC has remitted R&D tax credits of £0.47m.

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 at least late 2021. They have therefore prepared the financial statements on a going concern basis.

OUTLOOK

We have achieved a great deal since our last year end including commencing the Phase IIb/III ARDS trial and our first partnership. Furthermore, we now have two interesting preclinical programmes in oncology of great potential, one of which targets a new pathway for SFX-01. We are excited about our prospects going into 2021.

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

10th December 2020

Consolidated Statement of Comprehensive Income
for the six months ended 30 September 2020 – unaudited

		Six months ended 30 September 2020 £'000 Unaudited	Six months ended 30 September 2019 £'000 Unaudited	Year ended 31 March 2020 £'000 Audited
Revenue	3	194	—	—
Operating expenses				
Operating expenses		(1,965)	(1,526)	(2,998)
Share based compensation	5	(82)	(84)	(168)
Total operating expenses		(2,047)	(1,610)	(3,166)
Operating loss		(1,853)	(1,610)	(3,166)
Other income		10	—	—
Loss on ordinary activities before taxation		(1,843)	(1,610)	(3,166)
Taxation		—	5	451
Loss and total comprehensive expense attributable to equity holders of the parent for the period		(1,843)	(1,605)	(2,715)
Loss per share attributable to equity holders of the parent (pence)				
Basic loss per share	4	(1.38)	(1.43)	(2.10)
Diluted loss per share	4	(1.38)	(1.43)	(2.10)

Consolidated Statement of Financial Position
as at 30 September 2020 - unaudited

	Notes	As at 30 September 2020 £'000 Unaudited	As at 30 September 2019 £'000 Unaudited	As at 31 March 2020 £'000 Audited
ASSETS				
Non-current assets				
Property, plant and equipment		1	3	2
Intangible assets		74	89	82
Total non-current assets		75	92	84
Current assets				
Trade and other receivables		161	113	196
Current tax receivable		446	328	446
Cash and cash equivalents		2,306	5,050	4,131
Total current assets		2,913	5,491	4,773
Total assets		2,988	5,583	4,857
LIABILITIES AND EQUITY				
Current liabilities				
Trade and other payables		434	353	653
Total current liabilities		434	353	653
Equity				
Ordinary shares	6	343	331	331
Share premium		17,932	17,831	17,831
Merger reserve		2,067	2,067	2,067
Share based compensation		1,970	1,806	1,890
Retained deficit		(19,758)	(16,805)	(17,915)
Total equity attributable to equity holders of the parent		2,554	5,230	4,204
Total liabilities and equity		2,988	5,583	4,857

**Consolidated Statement of Changes in Equity
for the six months ended 30 September 2020 – unaudited**

	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 2019	247	13,240	2,067	1,722	(15,200)	2,076
Total comprehensive expense for the period	—	—	—	—	(1,605)	(1,605)
Transactions with owners						
Share issue	84	4,919	—	—	—	5,003
Share issue – costs	—	(328)	—	—	—	(328)
Share based compensation – share options	—	—	—	84	—	84
Total transactions with owners	84	4,591	—	84	—	4,759
Balance at 30 September 2019	331	17,831	2,067	1,806	(16,805)	5,230

	Ordinary shares £'000	Share premium £'000	Merger reserve £'000	Share based compensation £'000	Retained deficit £'000	Total £'000
Balance at 1 April 2019	247	13,240	2,067	1,722	(15,200)	2,076
Total comprehensive expense for the period	—	—	—	—	(2,715)	(2,715)
Transactions with owners						
Share issue	83	4,589	—	—	—	4,672
Share issue – options exercised	1	2	—	—	—	3
Share based compensation – share options	—	—	—	168	—	168
Total transactions with owners	84	4,591	—	168	—	4,843
Balance at 31 March 2020	331	17,831	2,067	1,890	(17,915)	4,204

The registered number of Evgen Pharma plc is 09246681.

Consolidated Statement of Cash Flows
for the six months ended 30 September 2020 - unaudited

	Six months ended 30 September 2020 £'000 Unaudited	Six months ended 30 September 2019 £'000 Unaudited	Year ended 31 March 2020 £'000 Audited
Cash flows from operating activities			
Loss before taxation for the period	(1,843)	(1,610)	(3,166)
Depreciation and amortisation	9	12	21
Share based compensation	82	84	168
	(1,752)	(1,514)	(2,977)
Changes in working capital			
(Increase)/decrease in trade and other receivables	35	22	(61)
(Decrease)/increase in trade and other payables	(219)	(335)	(35)
Cash used in operations	(184)	(313)	(96)
Taxation received	—	169	497
Net cash used in operating activities	(1,936)	(1,658)	(2,576)
Cash flows (used in)/generated from investing activities			
Acquisition of tangible fixed assets	—	—	(1)
Net cash (used in)/generated from investing activities	—	—	(1)
Cash flows from financing activities			
Net proceeds from issue of shares	111	4,675	4,675
Net cash generated from financing activities	111	4,675	4,675
Movements in cash and cash equivalents in the period	(1,825)	3,017	2,098
Cash and cash equivalents at start of period	4,131	2,033	2,033
Cash and cash equivalents at end of period	2,306	5,050	4,131

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 2020. 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 2019 and 30 September 2020 is unaudited.

Full audited financial statements of the Group in respect of the period ended 31 March 2020, 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 2020 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 2020.

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 2020, the Group had cash and cash equivalents, including short-term investments and cash on deposit, of £2.3 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 held by the Group together with known receivables will be sufficient to support the current level of activities at least the end of the fourth quarter of calendar year 2021. 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 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 license 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. REVENUE

This is the up-front fee on signature of the Juvenescence licensing deal, being \$250,000.

4. 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 2020 £'000 Unaudited	Six months ended 30 September 2019 £'000 Unaudited	Year ended 31 March 2020 £'000 Audited
Loss for the year attributable to equity holders	(1,843)	(1,605)	(2,715)
	As at 30 September 2020 Number Unaudited	As at 30 September 2019 Number Unaudited	As at 31 March 2020 Number Audited
Weighted average number of ordinary shares	133,726,538	112,307,585	129,315,418
Effects of dilution:			
Share options	—	—	—
Weighted average number of ordinary shares adjusted for the effects of dilution	133,726,538	112,307,585	129,315,418
	Pence	Pence	Pence
Loss per share – basic and diluted	(1.38)	(1.43)	(2.10)

5. 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 2020	
	Number	WAEP
Outstanding at 1 April 2020	9,531,368	£0.02
Granted during the period	—	—
Exercised during the period	(4,751,178)	£0.02
Lapsed/cancelled during the period	(1,521,869)	—
Outstanding at 30 September 2020	3,258,321	£0.02

During the six month period ended 30 September 2020, a share-based payment charge of £81,504 (six months to 30 September 2019: £84,052) 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.

6. ISSUED CAPITAL AND RESERVES

Ordinary shares

	Company Share Capital	
	Number	£'000
As at 31 March 2020	132,646,263	331
Issued on exercise of options	4,751,178	12
Issued under placing agreement	—	—
At 30 September 2020	137,397,441	343

On 6 July 2020 2,957,600 new ordinary shares 0.25p each were issued in connection with the exercise of share options.

On 7 July 2020 778,378 new ordinary shares 0.25p each were issued in connection with the exercise of share options.

On 24 July 2020 1,015,200 new ordinary shares 0.25p each were issued in connection with the exercise of share options.