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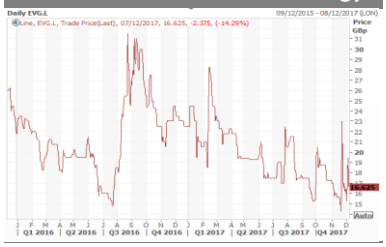
Pharmaceuticals & Biotechnology



Source: Eikon Thomson Reuters

Market data	
EPIC/TKR	EVG
Price (p)	14.0
12m High (p)	30.2
12m Low (p)	13.0
Shares (m)	93.3
Mkt Cap (£m)	13.1
EV (£m)	11.1
Free Float*	59%
Market	AIM

**As defined by AIM Rule 26*

Description

Evgen is a virtual pharmaceutical company using its proprietary technology, Sulforadex, to create new synthetic and stable variants of the natural product, sulforaphane. Lead product, SFX-01, is now in two Phase II trials

Company information

CEO	Dr Stephen Franklin
CFO	Richard Moulson
Chairman	Barry Clare
	+44 (0) 151 705 3532
	www.evgen.com

Key shareholders

Directors	2.8%
North West Fund	17.4%
Rising Stars	12.8%
AXA	7.1%
South Yorkshire	4.0%
Seneca	3.8%

Next event

28 Dec 17	General Meeting
1H 2018	Interim data STEM trial
2H 2018	SAS trial read-out

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Evgen Pharma

Funded to the end of Phase II trials

Evgen is a virtual pharmaceutical company focused on the development of a synthetic version of a natural product, sulforaphane, which is known to modulate key signalling pathways involved in cellular protection and inflammation. Evgen's proprietary technology, Sulforadex, creates new and stable variants of sulforaphane, enabling it to be used as a therapeutic for the first time. SFX-01 is progressing in Phase II clinical trials for both subarachnoid haemorrhage and ER+ breast cancer, with readouts expected in or around the end of 2018. EVG has strengthened its balance sheet with a Placing to raise new funds of £2.3m gross.

- **Strategy**: Evgen is focused on the clinical development of synthetic and stable variants derived from sulforaphane using its proprietary technology, Sulforadex. Lead candidate SFX-01 is being assessed in Phase II trials for both SAH and breast cancer, both strategic entry portals for other uses in neurology and oncology.

- **Interims:** Consistent with its strategy, most operating expenditure is being invested into R&D to support the SFX-01 clinical programme. Recruitment into two trials is progressing with an expansion of sites. A compassionate use programme has commenced following the 24-week STEM trial treatment period.

- **Placing:** Concomitant with the release of the interim results, Evgen has conditionally raised £2.3m gross through a Placing to new and existing shareholders as well as the Management. Proceeds will be used to advance both Phase II trials, for working capital purposes, and to explore new indications.

- **Risks:** As with all drug development companies, there is a risk that products will fail in clinical trials. However, sulforaphane has been through a number of encouraging clinical trials despite its stability and dosing limitations. Therefore, coupled with two potential targets, Evgen's risk profile is arguably reduced.

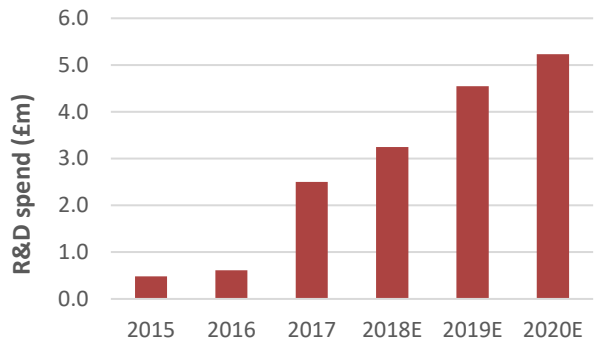
- **Investment summary:** SFX-01 would be entering multi-billion dollar global markets that are currently unsatisfied. There is also potential to use sulforaphane in other indications. Evgen intends to out-license its drugs to the pharmaceutical majors for global commercialisation. The enterprise value afforded to Evgen by the market does not reflect properly the development stage of SFX-01 and lower than usual risk profile.

Financial summary and valuation

Year end March (£000)	2015	2016	2017	2018E	2019E	2020E
Sales	0	0	0	0	0	0
SG&A	-312	-620	-949	-1,063	-1,105	-1,161
R&D	-484	-612	-2,500	-3,250	-4,550	-5,233
EBITDA	-789	-1,224	-3,432	-4,296	-5,638	-6,376
Underlying EBIT	-796	-1,232	-3,449	-4,313	-5,655	-6,393
Reported EBIT	-1,246	-2,434	-3,658	-4,532	-5,886	-6,635
Underlying PBT	-1,853	-2,015	-3,435	-4,307	-5,655	-6,393
Statutory PBT	-2,303	-3,217	-3,644	-4,526	-5,886	-6,635
Underlying EPS (p)	-6.2	-3.9	-3.9	-4.6	-5.0	-5.6
Statutory EPS (p)	-7.8	-6.3	-4.2	-4.8	-5.2	-5.9
Net (debt)/cash	-903	7,126	3,859	2,455	-2,353	-7,631
Capital increase	0	8,565	0	2,185	0	0

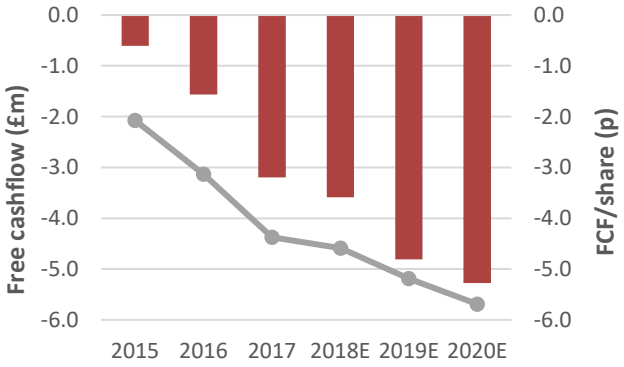
Source: Hardman & Co Life Sciences Research

R&D investment



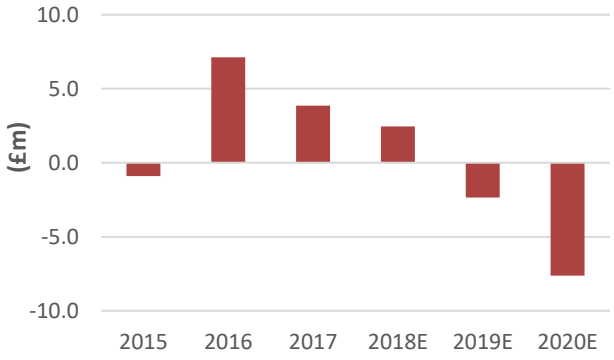
- Investment in R&D has been ramped up to fund the current Phase II trial programmes with SFX-01
- Total cost of the ongoing two trial programme is estimated at -£5.5m spread over a two-year period (fiscal 2017 & 2018)
- Evgen has sufficient funds to complete the Phase II clinical trials with SFX-01 in metastatic breast cancer and subarachnoid haemorrhage

Free cashflow



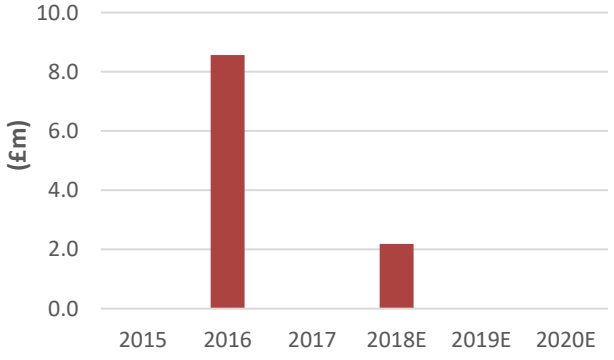
- Cashflow is driven by the corporate overhead (SG&A) and R&D investment
- Cash burn of ca.£0.3m per month
- Timing of receipt of HMRC tax credits is important – £454k received post the period end

Net cash



- Cash at 30th September of £2.2m
- Forecast net cash at the end of March 2018 is now estimated to be £2.5m
- Evgen has enough capital to complete both Phase II trials in SAH and breast cancer

Capital increases



- Evgen raised £8.6m net of expenses in pre-IPO and IPO funding during fiscal 2016
- Gross funds of £2.3m (est £2.17m net of expenses) have been conditionally raised in December 2017 and allocated to fiscal 2018

Source: Company data; Hardman & Co Life Sciences Research

2017 interim results

Key highlights

SFX-01 in advanced breast cancer

- A third country has been opened for the Phase IIa STEM trial with SFX-01 in addition to standard treatment in metastatic breast cancer, with recruitment now across UK, Belgium and Spain. Interim data are expected in 1H 2018
- A compassionate use programme has commenced for patients that responded positively to 24 weeks' treatment and where tumour growth was halted; one patient has been dosed with SFX-01 for nearly a year
- Research conducted at the University of Manchester suggests that SFX-01 and sulforaphane inhibit the STAT3 protein, which has a known role in cancer resistance and tumour growth. A scientific publication is being prepared for release next year

SFX-01 in subarachnoid haemorrhage

- Recruitment at the University Hospital Southampton is now fully running and a second site at the Queen Elizabeth Hospital Birmingham has been initiated. Up to three further sites are being considered to accelerate the rate of recruitment.
- To date, 34 patients (38%) have been recruited of a total target of 90 in the two arms that comprise the SAS Phase II trial, with read-out expected end 2018

Building up the pipeline

- Screening of SFX-01 analogues of utilising the Sulforadex technology is underway in cancer cells at the University of Liverpool, with data read-out expected in 1Q 2018
- Collaboration with the Manchester Cancer Research Centre has been initiated; a pre-clinical study is focusing on the effect of SFX-01 in triple-negative breast cancer
- Following requests by potential partners, Evgen is evaluating the use of SFX-01 in several other indications including stroke, autism and bone generation

Financial highlights

- **R&D spend:** R&D investment was lower than forecast at £1,130k (£1,200k), which may reflect timing differences and slower rates of recruitment into trials
- **Net cash:** Evgen had £2.2m cash at 31st September 2017
- **New funds:** Post period-end, Evgen has raised £2.3m gross new capital through a Placing at 12p, enough to complete both Phase II trials, subject to shareholder approval

Evgen results summary – actual vs expectations

Interims to end September (£000)	1H'17 actual	1H'18 actual	1H'18 forecast	Delta Δ
R&D spend	-1,200	-1,130	-1,320	+190
Administration	-395	-503	-530	+27
Underlying EBIT loss	**-1,595**	**-1,633**	**-1,850**	**+217**
Net cash/(debt)	5,548	2,207	2,000	+207

Figures may not add up exactly due to rounding

Source: Evgen Pharma; Hardman & Co Life Sciences Research

R&D update

Pipeline

In-house programmes

An updated pipeline extending the use of sulforaphane in several disease areas

Evgen has two Phase II programmes in oncology and neurology, with both being on schedule to have initial read-outs of data in 2018.

- **Subarachnoid Haemorrhage:** Sulforaphane activates the Nrf2 pathway leading to a reduction in oxidative stress and toxicity caused by free haemoglobin from the haemorrhage that usually occurs after the brain incident
- **Advanced Breast Cancer:** Sulforaphane is thought to exert its cytoprotective properties via the inhibition of the NF-κB, through the modulation of enzymes that are active in the initiation phase of carcinogenesis. In addition, sulforaphane has been proven to stop the replication of cells through its action on the cell cycle at the G2/M stage
- Potential new in-house Phase II clinical programme(s) in 2018 in multiple sclerosis (MS) and/or prostate cancer, which would need further capital, with promising pre-clinical data

Pipeline

Drug	Indication	2017	2018	2019
SFX-01	Subarachnoid Haemorrhage	Phase II		
SFX-01	Metastatic Breast Cancer	Phase IIa		
SFX-01	Potential Company-Sponsored Phase II in core area (MS or Prostate Cancer)		Phase II (tbc)	
SFX-01	Potential Investigator-Initiated Phase II in non-core area (e.g. autism, regenerative medicine)		Phase II (tbc)	
New SFX analogues	Various	Preclinical		

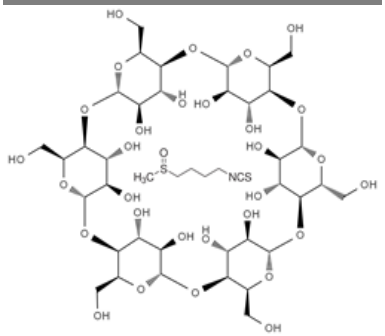
Source: Evgen Pharma

Collaborations

Although Evgen is concentrating all of its resources on the two leading clinical programmes, during the last six months, the company has been approached with great opportunities to assess sulforaphane analogues in a number of other disease areas through collaborators using grant funding:

- **Breast Cancer:** In line with its current clinical pipeline, a preclinical programme is about to start/has started at the University of Manchester, funded by the UK charity Shine Bright Foundation, focusing on triple negative breast cancer. The study will focus on and the way SFX-01 would enhance the effect of chemotherapy on patient-derived triple negative breast cancer
- **Bone Regeneration:** Collaboration with the Mayo Clinic (US) and the London Royal Veterinary College (RVC) for the use of SFX-01 in bone regeneration for osteoporosis and osteoarthritis, respectively. Mayo demonstrated an increase in bone mass by increasing osteoblast differentiation, while the RVC presented data showing the effect of SFX-01 in improvement of bone architecture and gait in an osteoarthritis model

SFX-01



Source: Evgen Pharma

- Opportunities for Phase II clinical programme(s) that would be progressed by collaborators aimed at demonstrating the potential of sulforaphane in other disease areas (e.g. autism, regenerative medicine and stroke)

SFX-01: Phase IIa in advanced breast cancer

Clinical update

The STEM (**S**FX-01 **T**reatment & **E**valuation in Patients with **M**etastatic Breast Cancer) programme is a multicentre study, with two centres already recruiting in Manchester and Brussels, led by Principal Investigator Dr Sacha Howell of the Christie Hospital in Manchester. This trial is recruiting advanced breast cancer patients who originally responded to hormone treatment but who then started to show resistance and disease progression.

No tumour progression has been observed after 24 weeks of treatment with SFX-01

The first patient was dosed in January 2017 and on the 30th September, 18 patients had received SFX-01 as part of their 24 week treatment programme. Following encouraging results, Evgen has initiated a compassionate use programme for those patients that have finished their treatment and positively responded without disease progression. Several patients are following this compassionate programme with one that has reached the 1 year anniversary, providing confidence that the trial will satisfy one of the primary end-points: safety and tolerability.

Tumour progression has been assessed by four consecutive scans and analysis of the image. No tumour progression has been observed during the treatment period. Seven sites are now open for recruitment across the UK, Spain and Belgium. Given that the trial is 'open label', Evgen is projecting that interim data from at least one of the cohorts will be available in 1H 2018, with the final trial read-out towards the end of 2018.

Investigating the mechanism of action

SFX-01 reduces the number of CSCs in breast cancer xenograft studies, hypothesised to bring resistance in hormone treatment

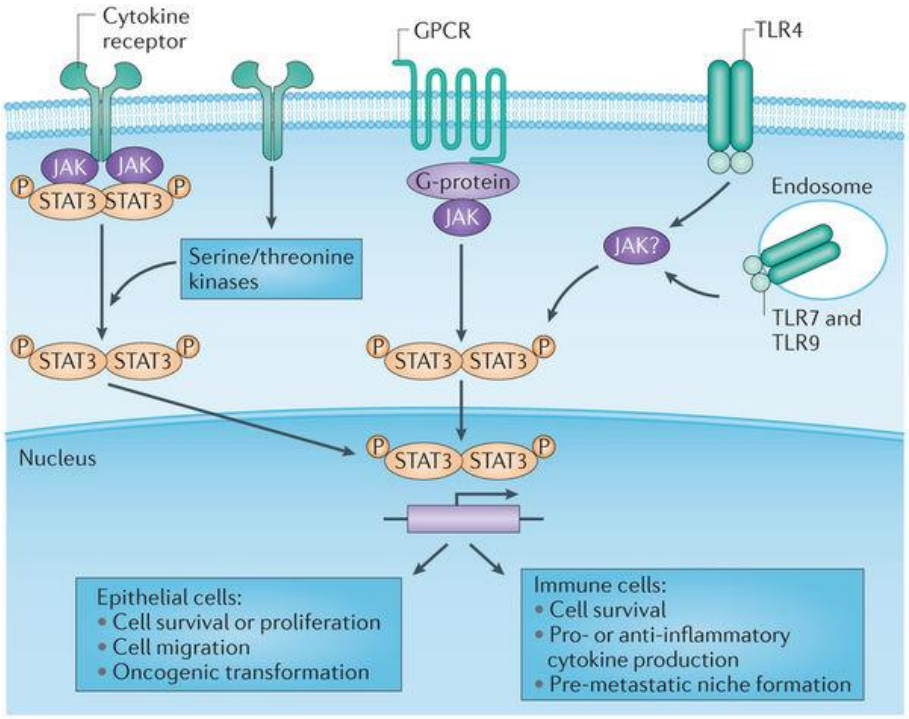
The Manchester Research Centre (MRC) is a long-standing partner of Evgen, with the collaboration highlighting the role of SFX-01 in reducing the number of cancer stem cells (CSCs) in patient-derived breast cancer tissue in xenograft models. It is thought that, while hormonal treatment is affecting cancer cells, it leaves the CSCs untouched allowing them to proliferate. This ultimately brings the cancer into relapse and permits the tumour to become hormone-independent.

New studies show that SFX-01 down-regulate the oncogenic activity of the STAT3 protein

Also, new studies from the MRC have highlighted recently the effect of SFX-01 in inhibiting the STAT3 (Signal Transducer and Activator of Transcriptase 3) signalling pathway. STAT3 is a transcription activator that plays a crucial role in many cellular processes:

- **Cancer:** Increase activity of STAT3 is associated with poor prognosis in cancer patients due to its role in cell growth and apoptosis, as well as metastasis
- **Autoimmune disease :** Activation of STAT3 in cancer cells leads to changes in the function of protein complexes that control expression of inflammatory genes seen in thyroid disease, intestinal inflammation and diabetes

STAT3 signalling pathway



Source: Hua Yu et al. Nature Reviews Cancer 2014, 14, 736-746

Out of seven STAT family members, STAT3 and STAT5 are widely recognised as being master regulators of the cellular functions that lead to the cancer phenotype. STAT3 and its partner the Janus Kinases (JAKs) are both two promising new targets for cancer therapy. While inhibitors of JAKs, acting up-stream to the STAT3 protein, have been already approved in human and dogs for various autoimmune conditions. There are many STAT inhibitors currently in early stage clinical trials, with Napabucasin, (BBI-608, Boston Biomedical) currently running in 13 studies from Phase I to Phase III in multiple cancer conditions, predicted to be first-in-class.

Marketed JAK inhibitors

Drug	Company	Target	Indications
Ruxolitinib	Novartis	JAK1/JAK2	Psoriasis, myelofibrosis, rheumatoid arthritis
Tofacitinib	Pfizer	JAK3	Psoriasis, rheumatoid arthritis
Oclatinib	Zoetis	JAK1	Pruritus in dogs

Source: Hardman & Co Life Sciences Research

Description of the STEM trial

SFX-01 is added to the current hormone therapy in breast cancer patients

The primary objective of the open label STEM trial is evaluation of safety and efficacy and, in addition, the effect of SFX-01 on tumour size, as measured by RECIST criteria. SFX-01 (300mg bid[1], corresponding to 92mg of sulforaphane) is being given in combination with three different hormone-based therapies in 60 ER+ patients in three cohorts, following their current therapy:

- **Cohort 1**: SFX-01 (300mg twice daily) + Aromatase inhibitors
- **Cohort 2**: SFX-01 (300mg twice daily) + Tamoxifen
- **Cohort 3**: SFX-01 (300mg twice daily) + Fulvestrant

[1] Twice daily

Although this trial is quite broad, open label, and enrolling patients that are 'quite poorly', the outcomes will allow a better decision to be made regarding the subsequent Phase II trial.

SFX-01 as an anti-cancer agent

Also, during the last 12 months, there has been an increasing number of scientific research papers demonstrating that sulforaphane, the active ingredient of SFX-01, is an effective chemo-protective and therapeutic agent against a vast number of tumours. Sulforaphane is thought to exert its cytoprotective properties through the modulation of enzymes that are active in the initiation phase of carcinogenesis. Importantly however, sulforaphane has been proven to stop the cell cycle at the G2/M stage by inhibiting cell proliferation in a dose-dependent manner in xenograft and cellular cancer models, ultimately triggering cell apoptosis and suppressing angiogenesis and metastasis.

SFX-01: Phase II in subarachnoid haemorrhage

Phase II clinical trial update

The Phase II trial, SAS (**S**FX-01 **A**fter **S**ubarachnoid Haemorrhage), was initiated in May 2016 in patients suffering aneurysmal subarachnoid haemorrhage. The study is being led by the principal investigator, Diederik Bulters, Consultant Neurosurgeon at the University Hospital Southampton NHS Foundation Trust. In addition, Evgen announced that a second site, Queen Elizabeth Hospital in Birmingham, has just been added. To accelerate recruitment, Evgen is also in discussion to open up to three further sites.

34 SAH patients have been enrolled into the SAS trial with no safety and tolerability concerns

To date, 34 patients have been enrolled into the two arms of the trial, which is being monitored by an independent Data Safety Monitoring Board (DSMB). Following its second recent meeting regarding analysis of the unblinded data, the committee confirmed that, as expected, there are no safety issues attributable to the administration of SFX-01.

However, the DSMB observed that there was a difference in the baseline status (disease severity) of patients in the two arms and recommended an algorithm to rebalance the cohorts. Consequently, there was a temporary pause (1-2 months) in recruitment while this stratification process was implemented. This has now been completed, allowing continuation of the trial which is now expected to read-out around the end of 2018.

Trial design

The SAS clinical trial is assessing the safety, tolerability, pharmacodynamics (PD) and pharmacokinetics (PK) of SFX-01 in patients affected by a type of aneurismal stroke called subarachnoid haemorrhage. Evaluation of the clinical benefit will be measured by ultrasonography of blood flow in the brain.

The improved trial design will enrol a total of 90 patients, and consists of two arms, and will now include the severity stratification criteria in both arms:

- 45 patients receiving nimodipine, the current standard of care, and placebo
- 45 patients receiving SFX-01 (300mg bid) in addition of nimodipine

SFX-01 is administered as capsules or as a suspension *via* a nasogastric tube for up to 28 days, within 48h of experiencing SAH.

SFX-01 for subarachnoid haemorrhage

Subarachnoid haemorrhage is a $1.7bn market opportunity with a high unmet medical need

Evgen is targeting the population affected by aneurysm SAH, estimated at more than 80,000 individuals in the US and Europe. Our estimation of the market opportunity equates to $1.7bn. SFX-01 is not attempting to cure blood leakage or to even prevent SAH, but aims to prevent the oxidative stress and the toxicity caused by free haemoglobin from the haemorrhage that usually occurs after the brain incident.

SFX-01 aims to inhibit the oxidative stress usually occurring after the vascular incident

When blood is released into this space, it increases pressure, irritates the surrounding tissues and induces vasospasm. Moreover, the vascular event deprives this area of brain of oxygen when it previously received oxygen-rich blood, resulting in a stroke. The pressure resulting from the excess of blood creates a complication called vasospasm that narrows the inside diameter of nearby arteries that could cause a secondary stroke 4 to 10 days after SAH.

Sulforaphane is a known activator of the antioxidant transcription factor Nrf2, bringing protection against oxidative stress caused by the blood leakage. Administration of sulforaphane has been shown to reduce inflammation and neurological deficits in rats after intracerebral haemorrhage and subarachnoid haemorrhage. In addition, Nrf2 deficient mice are significantly more prone to the neurological deficits of haemorrhagic brain injury.

Opportunities

Multiple sclerosis

SFX-01 shows superior effects compared to Tecfidera, the standard of care in MS animal models

Efficacy of SFX-01 in multiple sclerosis (MS) has been validated through *in vivo* studies and has been compared to Tecfidera (Biogen), which is the current standard of care. In a mouse autoimmune encephalomyelitis (EAE) model which replicates some features of MS, SFX-01 was shown to have a superior effect compared to Tecfidera, and in a dose dependent manner. SFX-01 appears to produce a maximum effect in the course of the disease by enabling superior neurological recovery during the chronic stage after relapse. By upregulating the Nrf2-mediated anti-oxidant protective mechanisms and inhibiting NF-κB-mediated inflammatory responses, SFX-01 is thought to have a dual therapeutic potential in MS.

Following a full strategic review of the MS opportunity, Evgen has adopted a prudent stance and will be considering two additional set of data with minimal further investment prior to committing to a major trial.

Collaborations

Research publications and clinical studies that claim to have used sulforaphane are plentiful. However, most investigators are using sulforaphane in the form of a frozen broccoli sprout extract that contains only an unmeasurable approximate level of the active ingredient.

Therefore, the fact that Evgen has managed to successfully synthesise a stable version of sulforaphane that can be used as a therapeutic agent is attracting many research groups and charities. These studies require minimal investment from Evgen other than the supply of SFX-01, as they are completely or largely supported by the investigator through grants or through relevant charities. This is illustrated by the two on-going collaboration with the University of Manchester and the Mayo Clinic (US) together with the London Royal Veterinary College (London) in breast cancer and bone regeneration, respectively.

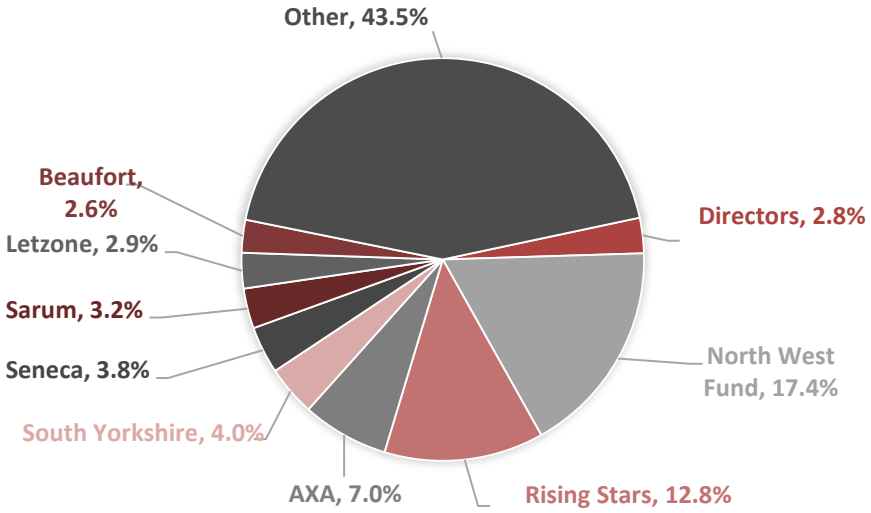
Capital increase

Evgen conditionally raised £2.3m gross via a Placing to new and existing shareholders

Evgen has conditionally raised £2.3m gross (est £2.17m net of expenses) through a Placing of 19,166,667 new Ordinary shares at 12p per share to new and existing shareholders, together with Barry Clare (Chairman), Steve Franklin (CEO) and Richard Moulson (CFO). This represents 20.55% of the enlarged share capital.

The total number of shares in issue will be **93,276,858** following approval of the resolution at the General Meeting to be held on 28 December.

Shareholders



Source: Evgen, Hardman & Co Life Sciences Research

Use of proceeds

Proceeds will be used to complete both Phase II trials and pre-clinical works

The majority of the proceeds will be used to complete both Phase II trials –SAH and STEM – which are expected to have data read-outs during the next calendar year. However, some funds will be used for the following:

- Minimal investments that Evgen has committed with current and future partners for further investigational studies with SFX-01
- General working capital purposes
- Modest investment to progress some in-house pre-clinical work
- Exploring additional therapeutic indications of SFX-01

Conclusion

Newsflow from Evgen has been sparse over the last 12 months while management has simply been getting on with the job in hand – initiating and progressing the recruitment of patients into two Phase II trials and using collaborators to enhance the knowledge and understanding of the mechanism of sulforaphane/SFX-01. With both trials due to report results during 2018, the next year should see a big uplift in newsflow from the company.

Financial summary

- **SG&A** – Evgen has a corporate overhead of ca.£1.0m p.a. SG&A is expected to rise only modestly given that Evgen is committed to retaining a virtual drug development model with only five FTEs
- **R&D** – Investment rises sharply as a consequence of the Phase II trial programmes for SFX-01 in SAH (accounting for an estimated 1/3 of the spend) and breast cancer (accounting for 2/3). Short-term, only very modest investment will be made into other studies
- **Cashflow** – Cashflow is driven entirely by R&D investment and SG&A spend from the P&L account
- **Net cash** – At the 30th September 2016, Evgen had net cash of £2.2m; post the period-end, the company received an R&D tax credit from HMRC
- **Placing** – New funds from the Placing (£2.3m gross) have been allocated in 2018. Our forecast for net cash at the end of March 2018 is now £2.5m

Summary financials

Year end March (£000)	2015	2016	2017	2018E	2019E
Profit & Loss					
Sales	0	0	0	0	0
SG&A	0	-312	-949	-1,063	-1,105
R&D	-445	-484	-2,500	-3,250	-4,550
Licensing/Royalties	0	0	0	0	0
Underlying EBIT	**0**	**-796**	**-3,449**	**-4,313**	**-5,655**
Share based costs	0	-155	-209	-219	-230
Statutory EBIT	0	-1,246	-3,658	-4,532	-5,886
Net financials	0	-1,057	14	6	0
Underlying PBT	**0**	**-1,853**	**-3,435**	**-4,307**	**-5,655**
Statutory PBT	0	30	85	576	749
Tax liability/credit	0	30	576	749	1,048
Underlying net income	0	-1,823	-2,859	-3,558	-4,607
Underlying basic EPS (p)	**0.00**	**-6.25**	**-3.92**	**-4.56**	**-4.98**
Statutory basic EPS (p)	0.00	-7.79	-4.21	-4.84	-5.23
Balance sheet					
Share capital	0	73	183	183	183
Reserves	0	-1,260	6,904	4,045	2,672
Loans & borrowings	1,649	0	0	0	0
less: Cash & deposits	163	7,126	3,859	2,455	-2,353
Invested capital	**0**	**-284**	**369**	**400**	**601**
Cashflow					
Underlying EBIT	-445	-796	-3,449	-4,313	-5,655
Working capital	0	81	194	131	88
Company op cashflow	**0**	**-708**	**-3,238**	**-4,165**	**-5,550**
Capital expenditure	0	-1	-8	-6	-7
Share issues	0	8,565	0	2,185	0
Change in net debt	**0**	**-606**	**-3,267**	**-1,404**	**-4,808**
Opening net cash	-297	163	7,126	3,859	2,455
Closing net cash	**163**	**7,126**	**3,859**	**2,455**	**-2,353**

Source: Hardman & Co Life Sciences Research

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