2018 is a key year in the development of Evgen Pharma (EVG:AIM), the Cheshire-based business which has made rapid progress since joining AIM. It now has two Phase II clinical trials underway, one in advanced breast cancer and one in a type of stroke known as subarachnoid haemorrhage (SAH).

During June 2018, the company will announce its first-ever Phase II clinical data. The data will be the interim read-out from the breast cancer trial. The company is on track to announce the final read-outs from both trials around the end of 2018.

Steve Franklin, Evgen’s CEO, says: 'This is a tremendously exciting year for us as we are on track to announce a substantial amount of clinical trial data, which is what we have been working towards since joining AIM in October 2015.'

LAYING THE FOUNDATIONS
Evgen was founded in 2007 to have a lower risk profile than many in its peer group. Its drug pipeline is based on sulforaphane, a naturally occurring molecule originating in brassicas such as broccoli. A huge amount of academic research has been published on sulforaphane, highlighting its potential in medical conditions ranging from solid tumour cancers through multiple sclerosis, Parkinson’s disease and autism.

Whilst compelling, this academic work has yet to be translated into a marketed medicine because of the difficulties of creating a sulforaphane-based drug. Evgen has overcome these challenges; its patent-protected Sulforadex platform enables the manufacture of proprietary, synthetic and stable sulforaphane-based drugs. Since IPO, the company has been building out its patent estate in relation to sulforaphane with a view to establishing a dominant worldwide position in sulforaphane-based drugs and related compounds.

SFX-01, the company’s lead product, is the first of these synthetic drugs and is currently being investigated in Phase II trials in both advanced breast cancer and SAH. SFX-01 represents the first of an aspiring new class of pharmaceuticals, underlining its commercial value and its potential to have a major impact on patient outcomes.

SFX-01 is being used as a potential treatment in two very different therapeutic areas because of its ability to influence two contrasting biochemical disease pathways, one in cancer and the other in neurological diseases. Product lines containing SFX-01 can be differentiated by both dose and/or formulation.

POTENTIAL CANCER TREATMENT
In cancer, SFX-01 has the ability to inhibit the target STAT3 thereby preventing the biochemical sequence that results in the generation of cancer stem cells and tumour metastases. In neurological diseases, SFX-01 activates the target Nrf2 thereby stimulating production of...
cytoprotective proteins to combat oxidative stress and inflammation.

Dr Franklin says: 'Mechanistic studies have shown that SFX–01 targets cancer stem cells in both early and metastatic breast cancers and has the potential to overcome hormone resistance in ER+ breast cancers. This mechanistic work continues via collaborations with Imperial College London and the University of Manchester.'

Evgen Pharma's STEM (SFX–01 in the Treatment and Evaluation of Metastatic Breast Cancer) trial is a multi-centre, Phase IIa clinical trial recruiting a total of 60 patients from multiple sites in the UK, Belgium, France and Spain and led from the Christie Hospital in Manchester. STEM patients have ER+ metastatic breast cancer and have been on hormone treatment.

Patients who join the trial have responded to hormone therapy for at least six months but then show hormone resistance via tumour growth. Once on the trial, patients continue to receive their failing hormone therapy in addition to SFX–01 and have regular scans through to week 24, leaving the trial immediately on confirmed tumour growth or symptomatic clinical progression.

The trial had an important milestone in June last year when a compassionate use programme was initiated after the first patient reached week 24 without disease progression; the programme enables such patients to receive SFX–01 on an ongoing basis.

Dr Franklin says: 'The patients in our first exploratory trial have become resistant to hormone therapies and have progressive disease, with little other treatment options. In this salvage setting, which is the highest efficacy challenge there is for any new drug, clinicians will be looking to see if SFX–01 is safe, well-tolerated and can halt progression. We are informed by our clinical advisors that if 20% or more of patients have their tumour growth halted for the entire six months, which is a non-trivial challenge in this patient group, then we have an interesting drug on our hands.'

ON THE THRESHOLD

Breast cancer affects a very large number of people whereas the company’s other Phase II trial, in SAH, is studying a relatively rare condition, accounting for around only 5% of all strokes. SAH is the form of stroke recently suffered by Sir Alex Ferguson, the former Manchester United manager.

There has been no new drug for SAH since the launch in the 1980s of nimodipine, the current standard of care. Whilst affecting a relatively small number of people, SAH is an attractive niche market awaiting a new treatment option.

Evgen Pharma's Phase II trial of SFX–01 in SAH is a double-blind, placebo-controlled study of 90 patients; 45 of them receiving nimodipine and placebo and 45 receiving nimodipine and SFX–01. This trial is also on track to read out at around the end of this calendar year.

Dr Franklin says: 'Evgen Pharma is an exciting company on the threshold of its first Phase II trial data. The wealth of existing scientific data on sulforaphane gives us confidence as we pursue our strategy of leading the development of this new class of drugs and taking ownership in all key commercial markets of the intellectual property surrounding sulforaphane-based medicine.'