Evaluate Vantage

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ARYx under pressure to deliver deals as promised

Amy Brown

The surprise failure of ARYx Therapeutics' tecarfarin in a phase II/III trial means pressure on the company to deliver at least one of its much vaunted licensing deals just got even greater.

Considering the lack of validating, late-stage clinical data from any of ARYx's pipeline candidates, investors were right to express nervousness yesterday, sending the stock plunging 44% to $2.35, a four-month low. Management have not been afraid to guide shareholders to expect two deals this year, just the sort of confident and specific prediction that has come back to bite many a small drug developer. Unless a deal is delivered soon investors' faith is unlikely to start recovering.

ARYx's pipeline has been generated with its proprietary RetroMetabolic Drug Design technology, which creates structurally related molecules to drugs already on the market. The aim is to retain the efficacy of the original version, but because the drug is metabolised through safer pathways, unwanted side effects can be reduced or eliminated.

Tecarfarin is an anti-coagulant slated as a safer version of warfarin, while ARYx's second partnering candidate, called budiodarone, is based on amiodarone.

First up

Although tecarfarin is the most advanced, a deal for atrial fibrillation candidate budiodarone has been promised first. Alongside first-quarter results in May the company said partnership talks were at an advanced stage, and on track to deliver a deal by mid-year.

Phase IIb data announced earlier this year was encouraging, in terms of efficacy and safety, and most commentators are optimistic a partner can be found. Expectations are running high that this will be delivered soon. A deal for tecarfarin, meanwhile, was flagged for the end of 2009.

The data announced yesterday makes that look more uncertain. The study failed to establish tecarfarin's superiority over warfarin in a trial of around 600 patients, after the latter performed much better than expected. One of the biggest problems with warfarin therapy is that the dosage needs constant monitoring and adjusting to maintain constant efficacy; in practise this often does not happen. However, patients in the trial were watched very closely, more than would happen in a real world setting, boosting the effectiveness of the drug, the company believes.

Encouragingly, the tecarfarin result was as good as expected. But the study has not established that the drug is definitively better than warfarin. This will require further work to prove, whether partners are prepared to undertake this, remains to be seen. ARYx has said that several interested partners were waiting for these data, it will be interesting to hear the company's next update on this process.

Keep your promises

With enough cash to last until the middle of next year, the company can afford this setback for now. However, as *EP Vantage*highlighted last year, ARYx was always cutting it fine on the financing front (*ARYx still walking a tightrope August 18, 2008)*.

Having floated in November 2007 at $10 a share, and then losing its first big pharma partner, Procter and Gamble, a few months later, a fundraising now with the stock so low would not be taken well, particularly coming after such emphatically made partnering promises.

A deal over budiodarone is needed to start restoring some confidence in ARYx's products, and its management.