

Ark drops Cerepro appeal and lifts for sale sign



[Jonathan Gardner](#)

It was a bit inevitable perhaps that Ark Therapeutics would have to consider a sale when its novel gene therapy product Cerepro was stiff-armed by European regulators for the treatment of malignant glioma. Nonetheless, it clearly did not make investors happy today when Ark announced that it was withdrawing its appeal for a European marketing authorisation and entertaining offers for the company.

Ark's stock price was already at cash-per-share levels at close of trading yesterday, and dropped another 13% to 12p by mid-afternoon trading today. Executives said in addition to offers they were also considering how to best optimise various assets and technologies held by the company.

Negative review

The decision to withdraw came following a presentation to the European Medicines Agency's Scientific Group on Oncology, which challenged the data Ark presented in support of its application for Cerepro, known generically as sitimagene ceradenovec. The presentation was part of a resubmission of Cerepro's marketing authorisation application that followed a December rejection by the EMA's Committee on Advanced Therapies.

The chief objection of the oncology group, as with the advanced therapies committee, was that the main efficacy endpoint, time to reintervention by a surgeon, was done on a case-by-case basis and was not subject to standardised decisionmaking. Although the company argued that a reintervention committee had been blinded to which treatment arm patients had been in, the oncology group was not persuaded. EMA has also raised concerns about survival data and adverse effects that include seizures and partial paralysis ([Ark sinking after EU rejection, December 18, 2009](#)).

With £28.6m (\$42.8m) in cash at June 30, 2009, and only wound care products on the market, Ark is not in a position to be considering new trials for an expensive gene therapy product. As such, the best hope for any shareholder is for a speedy purchase or liquidation.

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