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GTx's future is brightening



[Amy Brown](#)

After a couple of tough years, the future is looking brighter for GTx. Having lost two partners in as many years and seen its lead drug rebuffed by the FDA, two new compounds are moving into late stage testing that could reinvigorate the company's prospects ([GTx in soul searching mode following toremifene failure](#), May 26, 2010).

This has only just been appreciated by investors – shares in the company were struggling to break through \$3 until the last four weeks, when the stock has doubled in value. With a promising prostate cancer drug due to generate phase IIb data later this year and a therapy to treat muscle wasting associated with cancer about to enter pivotal trials, GTx is lining up two shots on goal that could help score new partners.

Blocking production

Capesaris is probably piquing the most interest – the drug is an oestrogen receptor alpha agonist, a novel form of androgen deprivation therapy (ADT) for prostate cancer. The compound is more targeted than other ADTs, like Abbott Laboratories' LHRH analogue Lupron, binding to only one type of oestrogen receptor.

As well blocking the production of testosterone in the testes, the drug also induces the production of a liver protein which regulates free testosterone in the blood, something other LHRH analogues do not do. The company believes this dual mechanism of action makes Capesaris a more effective castration therapy, with the more targeted mechanism causing fewer side effects. Bone loss, hot flashes, changes in body composition and cardiovascular problems plague this class.

To test the hypothesis GTx plans to run a head-to-head trial versus Lupron, which will start next year. Lupron sold \$748m last year; the LHRH class as a whole was worth \$3.38bn, according to *EvaluatePharma*.

Capesaris also carries the advantage of being orally available; existing therapies are injected. ADT is the cornerstone of first line prostate cancer therapy and continues to be used even when second and third line treatments are initiated. Therefore GTx believes that if it can prove that Capesaris can deliver at least equivalent efficacy with fewer side effects, the drug would be a viable new competitor in the class.

Ongoing trials

With the FDA only requiring that GTx establish Capesaris can lower testosterone levels as well Lupron over a 60-day period – it is not requiring evidence of a survival impact – the drug's development path is not too onerous.

An ongoing phase IIb open label trial will generate data later this year and will inform a phase III study, which will start straight afterwards. The company believes positive data from the study will be a strong indication of pivotal success – phase III data should emerge towards the end of 2013.

Meanwhile, the company also recently announced it would be starting two phase III studies with a second candidate, Ostarine. The drug is being tested in patients with muscle wasting caused by non-small cell lung cancer.

GTx is striving to distinguish this indication from cachexia, which it describes as an end of life condition. With little progress in treating cachexia and few big companies showing an interest in the condition at this stage, it is perhaps not surprising the company is trying to position the drug in a more valuable oncology indication ([Therapeutic focus - Cachexia pipeline gaining weight](#), May 12, 2011).

The company should get data by the end of next year and plans to file for approval in 2013. It estimates the market potential as \$750m in the US alone.

Fundraising

With \$50m in cash at the end of March, the company says it has funds to last until the second half of 2012. Partners will be sought for the products, but it seems likely a fundraising will happen at some point, particularly given the recent share price jump.

Meanwhile, equity analysts are starting to ascribe a bit more value to the products and the company.

Citi recently doubled its price target on the stock to \$8, pencilling in sales of \$300m for Capesaris by 2017. Leerink Swann has \$190m of sales from both products in its model for 2016 – the bank also recently doubled its price target to \$6.

Shares in the company breached \$6 in early trade today, for the first time since October 2009. Positive data from Capesaris would justify further gains.

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