

## OncoGenex recovering on antisense data for prostate cancer



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Bucking the current downward spiral trend for most biotech stocks, OncoGenex Pharmaceuticals has staged a dramatic recovery this week with positive phase II data for its antisense therapy in prostate cancer and lead pipeline candidate, OGX-011; shares have risen 160% since the trial results were released on Wednesday, to \$5.83 in early trade today and on track to match the \$6.00 price the shares traded at just after OncoGenex's reverse merger into Sonus Pharmaceuticals in August.

The Sonus merger enabled OncoGenex to obtain a public listing, but as part of the deal the company undertook a 1-for-18 reverse stock split, meaning that with just 5.5 million shares in issue, even this dramatic share price rise values the company at a relatively modest \$32m. Nevertheless, the trial data highlights the potential for the much-hyped antisense therapy field in a particularly difficult to treat cancer.

### Survival benefit

What certainly appears to have stoked the fire under OncoGenex's shares is the dramatic overall survival benefit shown with OGX-011, also known generically as custirsen. First-line treatment of metastatic castrate resistant prostate cancer with OGX-011 in combination with docetaxel and prednisone generated an overall survival rate of 27.5 months, compared to 16.9 months for docetaxel and prednisone alone.

Put in perspective, the company notes that docetaxel, Sanofi-Aventis' Taxotere and mainly first-line treatment for prostate cancer, was approved by the FDA based on a survival advantage of just 2.4 months over mitoxantrone.

OGX-011 inhibits the production of clusterin, a protein that is associated with treatment resistance in a number of solid tumours and therefore is designed to enhance treatment sensitivity to compounds such as docetaxel and delay tumour progression.

### Hot research

The antisense therapy field in general has attracted massive interest in recent years from small biotech through to big pharma, often held up as a great white hope for life-threatening cancers, but not without its fair share of sceptics.

One of the industry's biggest single-product deals this year remains Genzyme's licensing of Isis Pharmaceuticals' mipomersen antisense therapy in January for a potential value close to \$1.1bn ([Partners sensing potential in Antisense, April 4, 2008](#)).

A review of deal data from EvaluatePharma reveals the recent flurry of deals for antisense therapies is gathering momentum this year, with 20 deals struck so far beating the 19 deal record set in 2006.

<b>Year</b>	<b>Antisense therapies: Count of Product Deals per Year</b>
2008 (YTD)	20
2007	15
2006	19
2005	13
2004	8
2003	8
2002	6
2001	8
2000	4
<b>Total number of deals</b>	<b>101</b>

With 179 antisense research candidates currently in active development, the field is clearly a hive of activity, however, in the absence of compelling and overwhelmingly positive phase III data, the technology is still awaiting tangible, proof-of-concept validation.

Until such data is presented, with most hopes resting on mipomersen's shoulders with phase III data in familial hypercholesterolaemia expected in the second half of 2009, critics of the technology will remain unanswered.

### **Antisense in prostate cancer**

Another possible reason investors have been excited by OncoGenex is that OGX-011 is currently the leading antisense therapy in development specifically for prostate cancer.

The data presented this week is from the fifth phase II trial to be completed for OGX-011, whereas the only other phase II candidate, Eli Lilly's Survivin ASO, only started phase II testing in March this year and results are not expected until 2010.

## Antisense therapies in development for prostate cancer

R&D Phase	Product	Company (s)	Pharmacological Class	Indication Summary	WW sales in 2014 (\$m)
<b>Phase II</b>	Survivin ASO (LY2181308)	Eli Lilly / Isis Pharmaceuticals	Survivin antisense	Hepatoma, liver cancer [Phase II]; Prostate cancer [Phase II]; Leukaemia, acute myeloid (AML) [Phase II]; Ovarian cancer [Phase I]; Non-small cell lung cancer (NSCLC) [Phase I]	81
	OGX-011	OncoGenex Pharmaceuticals / Isis Pharmaceuticals	Clusterin antisense	Prostate cancer [Phase II]; Non-small cell lung cancer (NSCLC) [Phase II]; Breast cancer [Phase II]	-
<b>Phase I</b>	OGX-427	OncoGenex Pharmaceuticals	Hsp27 antisense	Prostate cancer [Phase I]; Non-small cell lung cancer (NSCLC) [Phase I]; Breast cancer [Phase I]; Ovarian cancer [Phase I]; Bladder cancer [Phase I]; Solid tumour indications [Phase I]; General blood malignancies [Pre-clinical]	-
	Oncomyc-NG	AVI BioPharma	C-myc antisense	Breast cancer [Phase I]; Prostate cancer [Phase I]	-
<b>Pre-clinical</b>	Atu111	Silence Therapeutics	Cancer RNAi therapeutic	Prostate cancer [Pre-clinical]	-
	LErafAON	NeoPharm	Chemo & radiotherapy enhancer	Pancreatic cancer [Pre-clinical]; Prostate cancer [Pre-clinical]; Solid tumour indications [Pre-clinical]	-
	AP 11014	Antisense Pharma	TGF-beta1 inhibitor	Lung cancer [Pre-clinical]; Prostate cancer [Pre-clinical]; General cancer indications [Pre-clinical]	-

### Vital and valuable data

With respect to the potential value of OGX-011, analysts at RBC Capital Markets have pencilled in a launch date of 2015 in the US and Europe, generating sales of \$192m in this year of launch and almost reaching blockbuster status with \$946m in 2022.

Forecasting a potential 20% royalty stream, of which 6% will have to be passed on to Isis Pharmaceuticals as the licensor of the antisense technology applied to OGX-011, the revenues to OncoGenex could be significant, with \$27m in 2015 rising to \$132m by 2022.

Although the company is making good progress in agreeing a phase III trial design with the FDA, OncoGenex currently only holds around \$17m in cash, which would fund ongoing operations through the end of 2009 but is clearly not enough to start the phase III trial.

Although the sudden share price rise may tempt OncoGenex into an opportunistic share issue, this could be tricky in the current financial climate. Therefore, striking a development and commercialisation deal with a bigger player, hopefully with a reasonable upfront payment, appears to be the company's best bet.

As such, the trial data announced this week and to be formally presented at next year's ASCO conference, is likely to have significantly strengthened OncoGenex's hand in any current or future partnership discussions.

