The Speculator: Hopes in new cancer cure trials

By David Haselhurst, ninemsn Money
February 11, 2009,

Our cancer-cure hopeful Viralytics <VLA.AX> has launched a new clinical trial aimed at combating head and neck cancers. Results should emerge over the next few months.

If successful, they should turn this company’s share price around in the two markets where it is traded – the Australian Stock Exchange and the American over-the-counter market.

The company announced yesterday it had started its fourth clinical trial with the injection of the first patient in its recently announced head and neck cancer trial. Ethics approval for the trial was granted in December.

The study will involve a nine-patient dosage escalation trial using the company’s trade-marked CAVATAK oncolytic virus technology. The prime objective of the study is to determine the safety and efficacy of CAVATAK given by injection. Secondary objectives include the evaluation of the agent’s replication, immune response and evidence of anti-tumor activity.

The nine-patient trial will comprise three groups of patients. The first group will receive one injection, the second group three injections and the third group six injections.

The trial is being conducted at the Calvary Mater Hospital, Newcastle, NSW, with principal investigators Professor Stephen Ackland and Dr Girish Mallesara.

Data obtained from this new trial, together with that already accumulated from existing clinical evaluations of CAVATAK in patients with late-stage melanoma, breast and prostate cancer (all solid tumors), will expand the product profile of tolerance, bio-availability and anti-cancer mode of action in solid tumors.

Professor Ackland commented: "There are limited effective treatments for cancers of the head and neck that either re-grow or are too advanced to be managed by surgery or radiation. We are interested as to whether injection with CAVATAK will show an effect on such cancers.

"In addition, data generated in this study will allow a greater understanding of the mechanism of action of CAVATAK and the nature of the immune response of the patient."

Cancers of the head and neck, including the larynx, pharynx, thyroid, salivary glands and nose/nasal passages, account for about six percent of all malignancies in the USA. Approximately 45,000 new cases of head and neck cancer are diagnosed each year.

If caught early, according to Viralytics, the prognosis is excellent. However, about half of all cases of head and neck cancer are not identified until the disease is at an advanced stage.

Viralytics, in common with most other biological research stocks, has had to sharply re-focus its programs in the wake of the worldwide credit crunch. Fortunately for Viralytics, its loyal shareholders subscribed $716,000 under a share purchase plan at the end of December. That should enable the company to meet its budgeted targets to beyond mid-2009 before needing to raise further capital.

The latest fund-raising (17.9 million shares at 4c each) took issued capital to 299 million shares which, at the issue price of 4c, gives the company a market capitalisation of $11.96 million.

That leaves a modest value on the company’s patented intellectual property and its promising clinical trials. We’ll retain our holding in the portfolio.

(Readers of the June, 2008, edition of Money magazine may recall that Viralytics was reconstructed in 2007 out...
of the shell of Medical Innovations, with a new board and management. That included a capital raising of $6.6 million and buying of a portfolio of patents and applications from the University of Newcastle (NSW) for $2 million cash and 15.5 million shares.

How the portfolio stands

<table>
<thead>
<tr>
<th>Company</th>
<th>ASX code</th>
<th>Shares</th>
<th>Bought</th>
<th>Purchase price*</th>
<th>Value 11.2.2009</th>
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<tr>
<td>Viralytics</td>
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</table>

Total value of portfolio: $27,050
Cash at bank: $11,860
Total: $38,910

Portfolio change since 1.1.2009: **-2.725 percent**
All Ordinaries change since 1.1.2009: **-6.30 percent**

Portfolio notes

* The first four shares in this year’s portfolio were carried over from the 2008 portfolio, hence the 2008 purchase dates. However, to accurately track the 2009 portfolio, the Speculator has assigned a "beginning of year" value to each carry over share. The current value is based on the last sale price prior to market open 11.2.2009.

Disclosure: The author’s family holds shares in Laserbond.