



# Biotech Daily

Monday July 9, 2012

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: SUNSHINE HEART UP 14%, PHYLOGICA DOWN 10%**
- \* **ALCHEMIA PREPARES FOR 3-WAY SPLIT; ASX, NASDAQ LISTINGS**
- \* **VIRALYTICS 1st PHASE II EXTENSION PATIENT DOSED**
- \* **BPH, MOLECULAR DISCOVERY, PETER MAC P53 TUMOR COLLABORATION**
- \* **MYLAN SUES MAYNE OVER DORYX**
- \* **MERIAL CHALLENGES GENETIC TECH NON-CODING DNA PATENT**
- \* **ANTISENSE PLEADS SCHULTZ, LICENCE DEAL TO ASX 20% QUERY**
- \* **CITIGROUP TAKES 11% OF PATRYS**
- \* **IMMURON TO ISSUE 1-FOR-4 BONUS OPTIONS**

## MARKET REPORT

The Australian stock market fell 0.95 percent on Monday July 9, 2012 with the S&P ASX 200 down 39.5 points to 4,118.3 points. Eight of the Biotech Daily Top 40 stocks were up, 18 fell, four traded unchanged and 10 were untraded. All three Big Caps were up.

Sunshine Heart was the best following Friday night's 65.8 percent Nasdaq rise, up 0.3 cents or 13.6 percent to 2.5 cents, with 80,000 shares traded, followed by Ellex up 11.5 percent to 14.5 cents with 8,100 shares traded.

Alchemia climbed 9.0 percent; Living Cell and Viralytics were up five percent or more; Tissue Therapies rose 2.1 percent; Circadian and Clinuvel were up more than one percent; with Cochlear, CSL and Resmed up by less than one percent.

Phylogica led the falls, down 0.4 cents or 9.8 percent to 3.7 cents with 1.1 million shares traded.

Cellmid and QRX lost more than six percent; Benitec, Genera and Nanosonics were down more than five percent; Antisense, Genetic Technologies and Prima fell more than four percent; Acrux and Optiscan were down more than three percent; Avita and Starpharma shed more than two percent; Anteo and Pharmaxis were down more than one percent; with Mesoblast, Reva and Sirtex down by less than one percent.

## ALCHEMIA

Alchemia hopes to demerge its oncology and VAST assets into Audeo Oncology and Audeo Discovery and list Audeo Oncology on both the ASX and Nasdaq, this year.

In a teleconference, Alchemia chief executive officer Dr Pete Smith said the US and Australian initial public offer would raise less than \$60 million to complete the existing phase III Hyact trial as well as cover the cost of two sets of regulatory regimes.

Dr Smith said the company hoped to submit its new drug application to the US Food and Drug Administration for Hyact by April 2014.

Dr Smith said that Audeo Oncology was a Delaware incorporated company and owned Alchemia Oncology holding the oncology assets, as well as Audeo Discovery which in turn held the sugar-based versatile assembly of stable templates (VAST) drug discovery assets.

Dr Smith and chief financial officer Charles Walker said there were restrictions on what the company could say about the US listing and a 200-page US Securities and Exchange Commission form called an S-1 form, had been filed and was available at:

<http://www.sec.gov/Archives/edgar/data/1552899/000119312512296279/d365958ds1.htm>

Dr Smith said that once the oncology and the VAST assets had been transferred and the listing of Audeo completed, the original Australian Alchemia Limited would have the revenue-returning Fondaparinux synthetic heparin as its major asset.

Dr Smith said that the transaction was subject to shareholder and regulatory approvals and further information about the proposed Audeo share price and the amount to be raised was expected to be available for a scheme vote in September 2012, with the placements and listings expected shortly after.

Dr Smith said that Alchemia shareholders would receive Audeo shares in proportion to their holdings but probably not on a one-for-one basis.

Last year, Alchemia said it would demerge the oncology assets acquired with Meditech in 2006, and also raised \$15 million in a placement and a further \$5 million in an oversubscribed share plan at 24 cents a share (Nov 7, Dec 16, 2011).

Alchemia acquired Meditech in 2006 saying the merger would “create a substantial drug development company with an extensive pipeline of products, a strong financial position and an experienced management team” (BD: Mar 9, Aug 15, 2006).

In November 2011, Alchemia said it would demerge its subsidiary Alchemia Oncology to create a stand-alone company containing all of the [hyaluronic acid (HA)] Hyact oncology assets including HA-irinotecan and would continue to be listed on the ASX with its synthetic heparin fondaparinux the primary asset of the company.

Today Alchemia said the demerger would be through a members’ scheme of arrangement which needed to be approved by shareholders and the Courts.

The company said that if the scheme was approved and the demerger proceeded, Alchemia would transfer all of its shares in Audeo Oncology, to Alchemia shareholders on a pro rata basis, based on the number of Alchemia shares owned.

Alchemia said shareholders would continue to hold their existing shares.

The company said that Dr Smith, Mr Walker and Prof Tracey Brown would be Audeo Oncology’s chief executive officer, chief financial officer and chief scientific officer, respectively. And that Dr Smith and Mr Walker would continue in their present roles at Alchemia “for a short period of time after the demerger in order to effect a smooth transition”.

The company said the demerger was subject to market conditions and shareholder, court and regulatory approvals and more detailed information would be provided in due course. Alchemia climbed 4.5 cents or nine percent to 54.5 cents with 1.75 million shares traded.

### VIRALYTICS

Viralytics says the first evaluable patient injected with Cavatak in its US phase II melanoma trial has chosen to continue treatment in the extension trial.

Viralytics said that patients could join the extension study when they had a complete or partial tumor reduction or disease stabilization at six months from initiation of Cavatak treatment.

The company said that the phase II extension study was being made available to continue Cavatak treatment for patients who had a clinical benefit and to enable the company to continue studying the effectiveness of Cavatak treatment over a further six month period. Viralytics said that under the extension study patients were offered the opportunity of receiving nine additional Cavatak injections over 24 weeks.

The company said that a positive trial outcome for the phase II study would be achieved when immune-related progression-free survival at six months is observed in 10 to 12 of the 54 evaluable patients.

Viralytics was up 1.5 cents or five percent to 31.5 cents.

### BPH ENERGY, MOLECULAR DISCOVERY SYSTEMS, PETER MACCALLUM CANCER CENTRE

BPH says Molecular Discovery Systems will collaborate with the Peter MacCallum Cancer Centre to develop cancer drugs normalizing the tumor suppressor p53.

The chairman of BPH and its 20 percent subsidiary Molecular Discovery David Breeze said that by "working with scientists ... at the forefront of p53 research for two decades, we are confident that this collaboration has ample potential to deliver highly-favorable outcomes".

BPH said that under the agreement, compounds with the desired anti-cancer activity would be identified and developed by combining the Molecular Discovery drug screening platform with procedures pioneered by researchers at Peter MacCallum.

BPH was untraded at 1.7 cents.

### MAYNE PHARMA GROUP

Mayne Pharma says that Mylan Pharmaceuticals has filed an antitrust suit against Warner Chilcott LLC, certain related entities and Mayne Pharma.

Mayne said the legal action was filed in the US District Court for the Eastern District of Pennsylvania, alleging that Mayne Pharma and Warner Chilcott engaged in conduct that constrained generic competition for Doryx, and sought unspecified damages and legal costs.

Mayne said that it and Warner Chilcott were reviewing the complaint and intended "to vigorously defend the litigation".

Mayne said it did not foresee incurring any material financial liabilities in relation to the action based on pre-existing contractual rights with Warner Chilcott.

The company said it had previously disclosed that, with Warner Chilcott, it had filed an appeal with the US Court of Appeals for the Federal Circuit in relation to the Doryx non-infringement determinations handed down on April 30, 2012 (BD: Feb 10, May 1, 2012).

Mayne Pharma fell three cents or 6.7 percent to 42 cents.

## GENETIC TECHNOLOGIES

Genetic Technologies says the US Patent and Trademark Office has granted a request from Merial LLC for re-examination of parts of its key non-coding DNA patent.

Genetic Technologies said that the of Duluth, Georgia-based Merial was contesting claims one to 18 and 26 to 32 of the 5,612,179 non-coding DNA patent entitled 'Intron sequence analysis method for detection of adjacent and remote locus alleles as haplotypes'.

The company said that requesting re-examination was a common strategy employed by defendants in patent infringement proceedings and was not unexpected from Merial which was a defendant in an action brought for infringement of the patent (BD: May 26, 2011).

Genetic Technologies said the '179 patent was "very robust having been through a previous re-examination with the USPTO".

The company said the earlier re-examination resulted in the re-issuing of the patent in full with all claims upheld (BD: May 10, 2010).

Genetic Technologies said that the '179 patent prevailed in numerous litigation filings in the US, resulting in positive outcomes in all instances and it believed that the claims of the '179 patent would be upheld in the re-examination.

The company said the Colorado infringement action could be delayed should the court(s) decide to stay matters until the reexamination process was resolved.

Genetic Technologies said the '179 patent which was the subject of the current re-examination was the oldest of the families of patents, having expired in March 2010, but remained enforceable for infringement occurring during its term.

The company said it earned "a material part of its non-coding licensing revenue in non-US jurisdictions"

Genetic Technologies said it had expanded the expanded the scope and jurisdictional reach off-balance sheet-funded assertion arrangement with the Denver, Colorado-based Sheridan Ross intellectual property law firm.

The company said that Sheridan Ross was originally limited to actions brought in the US to cover the 5,612,179; 5,851,762; 5,192,659; and 5,789,568 US patents, Sheridan Ross would covers all of its non-coding patents in all jurisdictions, including the newer non-coding patents acquired with the purchase of Brevagen from Perlegen Sciences in 2010.

Genetic Technologies chief executive officer Dr Paul MacLeman said that in Europe, his company had "secured lucrative licences in the past, but there remain numerous large infringers who have not as yet taken licences".

"It is hoped that these more formal assertion efforts will be what is required to secure licenses from these entities that until now have resisted less formal efforts to regularize their activities," Dr MacLeman said.

Genetic Technologies fell half a cent or 4.2 percent to 11.5 cents.

## ANTISENSE

Antisense has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose from 2.0 cents on July 5 to 2.4 cents on July 6, 2012, a 20 percent increase, but did not note an increase in trading volume.

Antisense said that the share price movement could be related to a June 29, 2012 announcement that it was in negotiations with a pharmaceutical company regarding ATL1103 and was applying for approval for a phase II trial for ATL1103 (BD: Jun 29, 2012)

Antisense fell 0.1 cents or 4.2 percent to 2.3 cents with 22.2 million shares traded.

### PATRYS

Citigroup Global Markets has increased its substantial share-holding in Patrys from 29,729,971 shares (8.176%) to 41,618,349 shares (11.446%).

The Citigroup substantial shareholder notice described the London and Sydney-based company as a prime broker for the holders of the shares, but gave no details about the price paid for the 11,888,378 shares.

Last month, Patrys raised \$2 million in a placement at two cents a share (BD: Jun 22, 2012).

Patrys was untraded at two cents.

### IMMURON

Immuron says it will issue shareholders one free ASX-listed option for every four shares held on July 23, 2012, exercisable at four cents a share by April 30, 2015.

Immuron said that capital raisings diluted existing shareholders, but options provided investors "the right but not the obligation to contribute capital".

The company said the funds were for the ongoing and future development projects and to provide working capital.

Immuron was up 0.2 cents or 10 percent to 2.2 cents.