Biotech Daily

Thursday May 13, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PHOSPHAGENICS UP 23%; PATRYS DOWN 12.5%**

*** EDITORIAL CORRECTION: WE SPOKE TOO SOON, PLENTY LEFT TO CUT**

*** MARC SINATRA'S BIOGUIDE: ANGIOBLAST GETS THE BLOOD PUMPING**

*** RESEARCH & DEVELOPMENT TAX CREDIT BILL GOES TO PARLIAMENT**

*** RUDD BUDGET 2010 AXES LINKAGES PROGRAM**

*** VIRALYTICS MEETS US FDA FOR PHASE II CAVATAK MELANOMA TRIAL**

*** ANDREW DOYLE INCREASES TO 7% OF NUSEP**

*** CIRCADIAN APPOINTS SUSAN MADDEN COMPANY SECRETARY**

*** WORLD HEART APPOINTS VENTRACOR'S DR JOHN WOODARD V-P**

*** OBJ FIELD-IN-MOTION POWERED BY KINETIC ENERGY**

MARKET REPORT

The Australian stock market was up 1.75 percent on Thursday May 13, 2010 with the S&P ASX 200 up 79.8 points to 4652.8 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 10 fell, eight traded unchanged and four were untraded. All three Big Caps were up for the second trading day in a row.

Phosphagenics was best, up three cents or 23.1 percent to 16 cents with 3.6 million shares traded, followed by Optiscan up 10 percent to 5.5 cents with 60,000 shares traded.

Viralytics climbed 9.3 percent; Prana was up 6.45 percent; Genetic Technologies, Pharmaxis and Tissue Therapies were up five percent or more; Alchemia, Cellmid, Living Cell and Universal Biosensors were up more than four percent; Bionomics was up 3.3 percent; Biota, Heartware and Resmed rose more than two percent; with CSL and Circadian up more than one percent.

Patrys led the falls, down 1.5 cents or 12.5 percent to 10.5 cents with 143,739 shares traded. Antisense and Uscom lost more than five percent; Clinuvel and Psivida fell four percent or more; Cellestis lost 3.1 percent; with Novogen, QRX and Starpharma shedding more than two percent.

BIOTECH DAILY EDITORIAL CORRECTION: FEDERAL BUDGET

Biotech Daily apologizes for speaking too soon on the Federal Government's third Budget.

We said there was nothing left to cut, but the creative thinkers in Treasury and Innovation found the Linkage Grants that Innovation Minister Senator Kim Carr has been proudly announcing over the years and there is a fear that the numbers of the National Health and Medical Research Council grants don't add up.

Research Australia's policy adviser Dr Gabby Fennessy says the NHMRC grants appear to be falling by about six percent in 2011-'12 and a further nine percent in 2012-'13, despite Federal Government claims that it is increasing the research grants.

On Linkage grants, last year biological sciences and biotechnology were Rudd-promised (that's like a Howard non-core promise) $14,001,185 over four years, of the total allocation of $71,281,782 in Linkage Project grants (BD: Jun 5, 2009). But there appears to be no provision in this Budget for ongoing funding beyond June 30, 2011.

On May 28, 2009 the Minister for Innovation Senator Kim Carr said Linkage Projects supported national and international collaboration and encouraged further investment in research of national importance.

"The 238 projects … have forged partnerships with 554 national and international government, private and non-profit organizations," Senator Carr said last year. "Partner organizations are contributing a total of $126.8 million in cash and in-kind support," Senator Carr said.

The Linkage Projects scheme is part of the Australian Research Council's National Competitive Grants Program.

While the "biological sciences and biotechnology" sector won the greatest amount of Linkage funds, most of the projects were for agriculture and bio-fuels rather than human health applications.

But just in biotechnology, the grants included collaborations with Biota, Anadis (now Immuron), Cochlear, CSL, Novo-Nordisk, CBio, Ausbiotech, Syngenta, Multiple Sclerosis Research Australia, the University of Melbourne, Monash University, Griffith University, the University of New South Wales, the University of Adelaide and the University of Canberra, along with non-biotechnology Linkage collaborations.

Well, axing that program and cutting National Health and Medical Research Council grants is "innovative" just as previous governments have used "reform" to dispossess Aboriginal people, lock up legitimate refugees and indiscriminately kick unemployed people off the dole.

Reform as in Reform School rather than the Reformation; innovation as in thinking outside the box, because there's not much box left.

David Langsam
Editor

MARC SINATRA'S BIOGUIDE: ANGIOBLAST SYSTEMS

Overview: A successful float, post-float share price performance and an ability to hit milestones has made Mesoblast a very successful Australian biotech. However, the market knows little about its closely-related sister, Angioblast Systems.

In fact, Angioblast is the older of the two companies and owns the intellectual property that both companies are developing. In addition to sharing technology, the companies share certain shareholders, directors and employees. They are about as close to each other as they can be without being a single company.

So, who is Angioblast and what sort of valuation would it attract if it were listed?

Angioblast & Mesoblast: Like Mesoblast, Angioblast is developing a range of tailored, off-the-shelf, adult, stem cell-based products for a range of indications. Angioblast is initially targeting the cardiac and bone marrow transplant markets. Mesoblast, via a licence from Angioblast, is developing the same technology, but for application to bone and joint diseases only.

Directors: Non-executive chairman, Carter Eckert; chief executive officer, Dr Silviu Itescu; non-executive directors, Robert Campbell, Donal O'Dwyer and Michael Esposito.

Angioblast has an excellent board, providing a solid mix of management, commercialization and scientific skills.

Products in Development:
1) Congestive heart failure: The product, Revascor, is in phase II trials for congestive heart failure (CHF) and CHF patients fitted with a mechanical heart assist device. Early results have been positive and full results should be released in the not-too-distant future;

2) Cord blood expansion: Currently in a phase I/II trial, the product is aimed at expanding the number of haematopoietic cells collected from umbilical cord blood. Cord blood is the preferred source of cells for bone marrow transplant, but the low yield of cells limits their usefulness;

3) Myocardial infarction: Presently being studied in a phase II trial, initiated on the back of a successful pre-clinical study in sheep. It is progressing more slowly than expected, although a protocol change should speed up recruitment;

4) Macular degeneration and diabetic retinopathy: Scheduled to enter human trials soon, a 2008 animal study showed the combination of Angioblast's adult stem cells and Lucentis, a drug for macular degeneration, significantly reduced blood vessel leakage in the eye by 25 percent compared to Lucentis alone;

5) Type II diabetes: Also due to enter human trials soon. The indication is being investigated following a mouse model trial of type II diabetes, which showed mice treated with Angioblast's stem cells had significantly more insulin-producing cells 21 days after chemical destruction of the pancreas than controls.

Significant Product Markets: Angioblast's later stage products are aimed at a combination of large and small markets.

Congestive heart failure affects 5.7 million Americans with 550,000 new cases each year. $US6.7 billion is spent each year for drugs and other therapies to treat the disease. Many cases of CHF are the result of the 1.1 million cardiac arrests each year in the US.

The US cord blood expansion market is small, with 19,000 bone marrow transplants in 2005, but the cost ranges from $US50,000 to $US200,000 each, making bone marrow transplant a solid orphan indication.

Valuation: Using a standard, risk-adjusted, discounted cash-flow method, I have arrived at a market capitalization valuation for Angioblast between $237 million and $292 million or $113 to $140 a share. While this valuation seems high for an unlisted company, it is hard to argue with it, after performing a series of reality checks.

Osiris Therapeutics, the other major adult stem cell company, has a market capitalization of $250 million, despite numerous trial failures. Mesoblast owns 33 percent of Angioblast, has product markets distinct from Angioblast's and has a market cap of $280 million.

Angioblast has added significant value after capital raisings. Following a $5.6 million placement to Abbott Laboratories at $84 a share, Angioblast gained orphan status and produced positive preliminary phase I/II results for its cord blood expansion product and returned positive preliminary results from its phase II congestive heart failure trial, among other achievements. An August 2009 convertible note issue was followed by positive results from the CBE trial, the low-dose CHF trial and type II diabetes animal data.

Opinion: Angioblast is of equivalent quality to its sister company Mesoblast although it is probably a higher risk - higher return proposition.

Two important factors distinguish Angioblast from the disappointing trial results emanating from Osiris. The first is that Angioblast is using a decidedly different, more defined, adult stem cell population. The second is that while Osiris by-passed animal testing of its products and moved straight into clinical trials, Angioblast has chosen products to develop based on positive animal trial data. Obviously, this reduces the risk of future trial failures of Angioblast's products.

Angioblast is also tailoring its products on an indication-by-indication basis, whereas Osiris is a two-products-fits-all company. Again, this also reduces the risk of trial failures, but it also allows for differential pricing of products and prevents cannibalism between Angioblast's products.

The proposed merger of Angioblast and Mesoblast values Angioblast at $240 million, an acceptable price at the lower end of my $237 to $292 million range.

Marc Sinatra's Bioguide,
marc@biotechdaily.com.au

*This BioGuide was derived from a research note on Angioblast Systems prepared by Marc Sinatra, under contract, for Lodge Partners Pty Ltd.

FEDERAL GOVERNMENT, R&D TAX CREDIT

Innovation Minister Senator Kim Carr says the research and development tax credit legislation was introduced into Federal Parliament today.

In a media release, Senator Carr said the research and development tax incentive was contained in the Tax Laws Amendment (Research and Development) Bill 2010 and the Income Tax Rates Amendment (Research and Development) Bill 2010.

Senator Carr said that from 2010-'11, the Government would replace the complex and outdated R&D Tax Concession with a simplified R&D Tax Credit that gave business better incentives to invest in research and development.

Expenditure from July 1, 2010 will be claimable after June 30, 2011.

"The R&D Tax Credit doubles the incentive for small and medium enterprises - the engine room of the economy - while increasing by a third the incentive for big business to undertake R&D," Senator Carr said.

"The R&D Tax Credit will focus on supporting genuine R&D and be worth $1.5 billion a year to industry," Senator Carr said.

Under the R&D Tax Credit, companies can invest, knowing they can claim a tax offset of at least 40 percent of their expenditure on R&D activities, rising to 45 percent for companies with a turnover of less than $20 million a year (BD: Jan 18, 2010).

Biotech Daily understands from Liberal Party sources that the Coalition is unlikely to oppose the R&D Tax Credit or request a broadening of its scope (BD: Apr 22, 2010.

FEDERAL GOVERNMENT, SCIENCE LINKAGES PROGRAM

A spokesman for Innovation Minister Senator Kim Carr has told Biotech Daily that the International Science Linkages program "is scheduled to end on June 30, 2011".

"The program is one of several ways the Government supports collaboration between Australian scientists and their international counterparts - and by no means the largest," Senator Carr said.

"There will be another Budget before the program terminates," Senator Carr's said.

"This is not the year to be asking for more money," Senator Carr said.

VIRALYTICS

Viralytics says it will meet a US Food and Drug Administration specialist panel in June for a pre-investigational new drug meeting on a phase II Cavatak trial for melanoma.

Viralytics said the meeting was scheduled for June 22, 2010 when the FDA would review a dossier summarizing the company's proposed phase II clinical trial and its supporting data from in vitro (laboratory) and in vivo (animals) studies, as well as the manufacturing and process controls that would be used to produce the clinical batch of Cavatak and the phase I clinical data accumulated to date.

Viralytics' managing director Bryan Dulhunty said that following the pre-IND meeting and providing any additional information or data requested by the FDA the company planned plans to complete and lodge an investigational new drug application (IND) to conduct its international phase II melanoma study centred in the US.

The company said once the application was lodged it was deemed authorized with 30 days of the application if the FDA raises no further comments or questions.

Viralytics said it chose the FDA as the regulatory authority to review its development program as the FDA was "arguably the most capable and influential regulatory agency in the world".

Viralytics was up 0.4 cents or 9.3 percent to 4.7 cents with 1.7 million shares traded.

NUSEP

Andrew Winston Doyle has increased his substantial shareholding in Nusep from 1,808,345 shares (5.3%) to 2,284,212 shares (6.7%).
In the substantial shareholder notice Mr Doyle of Orchard Post Office, Singapore said he bought the shares on market for $155,802 or an average price of 23.7 cents a share.
Nusep was up half a cent or 2.1 percent to 24.5 cents.

CIRCADIAN

Circadian has appointed finance manager Susan Madden as company secretary of Circadian and its subsidiary companies effective from May 14, 2010.
Circadian said Ms Madden joined the company in September 2009 after three years as head of finance at the Cancer Council Victoria and 14 years with Shell Australia.
Circadian was up one cent or 1.45 percent to 70 cents.

WORLD HEART CORP, VENTRACOR

The Salt Lake City based World Heart Corp has appointed former Ventracor chief scientist Dr John Campbell Woodard as senior vice-president of scientific affairs.
In a news release on its website World Heart said Dr Woodard would be responsible for clinical affairs and would guide the development of World Heart's next-generation technologies.
Dr Woodard most recently served as Ventracor's chief scientific officer and prior to that, served in senior management positions in a number of medical device companies.
Dr Woodard has a Bachelor in Electrical Engineering, a Master of Science in Biophysics and a Doctor of Philosophy in Biomedical Engineering at the University of South Wales.
World Heart chief executive officer J Alex Martin said World Heart was "extremely pleased to have a well recognized and respected leader in the field of mechanical circulatory support join World Heart".
Dr Woodard will be based at World Heart's headquarters in Salt Lake City, Utah.
World Heart said its Levacor ventricular assist device was the only fully magnetically levitated, bearingless, implantable centrifugal pump to move into clinical trial.

OBJ

OBJ says its Field-in-Motion format of magnetic micro-array film is its third product platform for drug delivery.
OBJ said Field-in-Motion or FIM was designed to be incorporated into products that are moved during normal consumer rubbing, brushing and wiping actions.
The company said the magnetic micro-array would "capture the energy of the motion, similar to a generator and redirects that consumer energy to enhance the performance of a wide range of consumer, household and industrial products".
OBJ said that using the free energy of normal consumer action to create more efficient products using fewer chemicals addressed a key commercial objective of its partners.
OBJ was up 0.2 cents or 7.7 percent to 2.8 cents with 36.0 million shares traded.