Biotech Daily

Wednesday July 14, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: CHEMGENEX UP 33%; NOVOGEN DOWN 7%**

*** CHEMGENEX COMBINES TRIALS FOR NEW FDA NEW DRUG APPLICATION**

*** ANTEO, MERCK CHIMIE AGREE SECOND SUPPLY DEAL**

*** PHYLOGICA DIRECTOR ANTHONY BARTON RETIRES**

*** AVEXA'S DR JONATHAN COATES BACK TO WORK WITH CHINA HIV DEAL**

*** BENITEC SAYS GRAHAM FAMILY PATENT GRANTED IN US, INDIA, JAPAN**

*** 2 OF 11 COMMERCIALISATION AUSTRALIA GRANTS FOR BIOTECH**

*** VICTORIAN BIO-BEERS IS BACK!**

MARKET REPORT

The Australian stock market was up 1.9 percent on Wednesday July 14, 2010 with the S&P ASX 200 up 82.1 points to 4462.4 points.

Fifteen of the Biotech Daily Top 40 stocks were up, eight fell, nine traded unchanged and eight were untraded.

Chemgenex was best, up 9.5 cents or 33.3 percent to 38 cents with 2.6 million shares traded, followed by LBT up 1.2 cents or 19.35 percent to 7.4 cents with 6,670 shares traded.

Cathrx climbed eight percent; Biota and Prana were up more than six percent; Bionomics, Universal Biosensors and Virax were up five percent or more; Prima and QRX were up more than four percent; Heartware was up 3.8 percent; Circadian and Phosphagenics rose more than two percent; with Pharmaxis and Resmed up more than one percent.

Novogen led the falls, down one cent or 7.1 percent to 13 cents with 49,500 shares traded, followed by Sunshine Heart down 6.25 percent to three cents with 427,877 shares traded.

Cellestis, Clinuvel and Living Cell lost more than two percent; with Alchemia down 1.3 percent.

CHEMGENEX

Chemgenex says Omapro (omacetaxine mepesuccinate) for chronic myeloid leukemia could be approved by the US Food and Drug Administration as early as mid-2011.

Chemgenex said it would be allowed to combine two separate trials into a new FDA new drug application which was expected to be filed by the end of 2010.

The company faced significant FDA regulatory hurdles when the Oncologic Drug Advisory Committee required a diagnostic test for the T315I mutation in the company's original new drug application (BD: Mar 23, 2010). Questions were also raised about data inclusion and drug vial size.

Today's announcement effectively ends the T315I application and rolls it into a second trial the company was undertaking for chronic myeloid leukemia (CML) patients who had failed two or more tyrosine kinase inhibitors, which the company was not expecting to file until mid next year.

In a teleconference, Chemgenex chief executive officer Dr Greg Collier said his company was "very excited with a very positive outcome with the FDA" following a type A meeting, which included discussion of a regulatory path forward and addressed outstanding issues regarding the previously received complete response letter (BD: Apr 12, 2010).

Dr Collier said that most of the 103 patients in the first trial for patients with the T315I mutation had also failed two tyrosine kinase inhibitors and there were more than 100 patients in the trial group who had failed two or more tyrosine kinase inhibitors.

"We weren't expecting to file [the second new drug application] until mid next year," Dr Collier said.

Dr Collier told Biotech Daily that the meeting with the FDA was very positive and the US regulator had suggested that rolling the data into one package would be a better way to file the application.

"This completely gets around having to define mutational status," Dr Collier told the teleconference.

He said the FDA agreed to merge the data and enrolment in both trials had been completed.

Dr Collier said the "many thousands of pages" of the new drug application was expected to be filed "by the end of this year" and the combined data had already been presented (BD: Jun 7, 2010).

He said it was wrong to assume that there would be a second Oncologic Drug Advisory Committee meeting.

"There might not be. If we are granted priority review, Omapro could be approved six months after filing," he said.

He said the company had cash to next year.

"We have no intention of doing a capital raising at this stage. We are looking at other creative ways of bringing cash into the company," Dr Collier said.

Dr Collier said European approval for Omapro for chronic myeloid leukemia patients with the T315I mutation was "on-track for the first quarter of 2011" and that with its European partner Hospira, Chemgenex intended to follow that with an application for patients who had failed two or more tyrosine kinase inhibitors.

Chemgenex chief medical officer Dr Adam Craig told the teleconference that despite further approvals of drugs for chronic myeloid leukemia there was "still an umet need for third-line treatments".

In a media release Chemgenex said it was continuing discussions with the FDA's Center for Devices and Radiological Health for approval of a T315I mutation diagnostic test and the existing NDA for T315I positive CML patients who have failed imatinib remained open.

Chemgenex was up 9.5 cents or 33.3 percent to 38 cents with 2.6 million shares traded.

ANTEO DIAGNOSTICS

Anteo says it has agreed terms with the France-based Merck Chimie SAS Diagnostics for a four year supply agreement to manufacture two bead-based products.

Anteo chief executive officer Dr Geoff Cumming told Biotech Daily that although the deal would not be material, it was the second agreement with a significant pharmaceutical company this year. In March Anteo signed a deal with the US-based Bangs Laboratories (BD: Mar 4, 2010).

Dr Cumming said the agreement with Merck Chimie would have his company receive two different sized diagnostic beads from Merck Chimie which Anteo would coat with Mix&Go and return to Merck Chimie.

Dr Cumming said the beads were one and two microns in diameter and were used to hold the antibodies in Elisa (enzyme-linked-immunosorbent assay) diagnostic tests.

“Mix&Go is basically a glue, a very good glue, that binds the Fc portion of an antibody,” Dr Cumming said.

“We coat the beads in Mix&Go and bind [the protein] streptavidin to the beads and send it back to Merck,” Dr Cumming said.

In a media release to the ASX Anteo said that the new product launch by Merck Chimie was expected within the next two months.

Anteo said that “immediate financial returns are not expected to be material, but recurring revenues are expected over the medium to long term”.

Anteo said Merck instigated an extensive review and testing, by external reference laboratories, of the Mix&Go technology and wanted to formalize a commercial relationship and the agreement was expected to be signed this week.

The company said Merck would be responsible for the sales and distribution of the new products which would be launched in the Bio-Estapor product line.

Anteo said initial sales were expected to be minimal as Merck focused on assessing the market for the new products within their existing customer base and distribution network.

Similarly to the agreement with Bangs, initial revenue streams were consistent with a sales cycle associated with new technologies, the company said.

The agreed terms do not require Merck to provide forecast product requirements until 2012 after which 12 month rolling forecasts were to be provided.

Anteo said it had “appropriate systems in place to meet Merck’s expected production requirements”.

Dr Cumming said it was “further validation by another industry leader of the benefits of our Mix&Go technology”.

Anteo said it continued to be in discussions, and was working collaboratively, with several other companies and major industry participants, had 10 material transfer agreements under consideration and was optimistic that some would result in additional deals.

The company said it was “working towards the commercialization of its Mix&Go technology in the global pathology and clinical research markets” and as it met its objectives, would devote increasing attention to alternative markets for the technology, including point-of-care applications, biological separations and non-biological markets.

Anteo fell 0.3 cents or 4.4 percent to 6.5 cents with 32.7 million shares traded.

PHYLOGICA

Phylogica says director Anthony Barton has retired as a non executive director.

Phylogica said the resignation followed the appointment of Nick Woolf as a non executive director in April (BD: Apr 22, 2010).

Phylogica was unchanged at 7.5 cents.

AVEXA

Avexa has signed a licence agreement with the Shanghai Institute of Organic Chemistry to develop one of its HIV integrase inhibitor series.

Avexa said the Shanghai Institute of Organic Chemistry would be responsible for all future development costs for the program in China and will pay Avexa 50 percent of any net commercialization revenues.

Avexa said it retained all development and marketing rights for the program outside China.

The company's interim chief executive officer Dr Jonathan Coates said that the series of molecules had shown "a high level of potency similar to the existing HIV integrase inhibitors on the market or in development".

"The synthesis of this series of molecules is relatively simple and provides opportunities in the Chinese market," Dr Coates said.

"Avexa is determined to realize the value and opportunities from its early programs for the benefit of shareholders," Dr Coates said.

Avexa said that the series of compounds in the licence was one of the first discovered by the company and showed "considerable potency and a relatively simple synthesis route".

The company said the profile of the molecules was similar to Merck's HIV integrase inhibitor Isentress and could have potential in emerging markets and may provide further competitive opportunities in traditional markets.

Avexa said it discovered additional series of HIV integrase inhibitors whose profile was improved compared to Isentress as they retain activity against viruses resistant to the marketed and late stage development integrase inhibitors.

The company said the new generation HIV integrase inhibitors had considerable potential and it was exploring ways to commercialize them, including partnering options.

Avexa said it focused on generating a once-a-day, non-boosted integrase inhibitor that targeted viruses resistant to existing integrase inhibitors that were either on the market or in late stage clinical development.

Avexa was up 0.4 cents or 12.12 percent to 3.7 cents with 14.6 million shares traded.

BENITEC

Benitec says it has been granted a US patent in the family of the 'Control of Gene Expression' patents.

Benitec said the patent was a continuation derived from the Graham '099 patent under re-examination in the US, with a hearing date has for August 4, 2010.

The company said it followed the grant of a Japanese patent covering claims to synthetic genes for silencing target genes in animal cells (BD: Mar 12, 2010).

Benitec said the Indian, Singaporean and Slovakian patent offices had confirmed the allowability of the 'Control of Gene Expression' applications.

The company said the claims of the Indian application, directed to methods of silencing gene expression in vertebrate animal cells by RNA interference using genetic constructs capable of targeting one or more gene sequences in the cell, were allowed after a successful appeal.

Benitec said the Singapore patent had claims to synthetic genes which were capable of silencing genes in animal cells and the use of those synthetic genes in silencing methods.

Benitec chief executive officer Dr Peter French said his company and the Commonwealth Scientific and Industrial Research Organisation were "delighted to have made such good progress with this family of applications and consider allowance of them to be a validation of their value in the field of RNAi therapeutics".

Benitec was unchanged at 3.2 cents.

COMMERCIALISATION AUSTRALIA

Innovation Minister Senator Kim Carr has announced $2.2 million for 11 eleven projects including two in biotechnology related programs.

A media release from Senator Carr said that Commercialisation Australia was the Australian Government's primary source of assistance for businesses transforming their ideas into commercial realities.

The largest grant of $685,099 was awarded to Crucible Carbon Pyrolysis to prepare its technology for sales, “based on a production facility that demonstrates commercial scale operations for the conversion of timber industry biomass residues to gas suitable for generating on-site heat and power at wood processing plants”.

Queensland’s Athlomics was awarded $250,000 for its Septicyte product which it said was “a molecular biomarker-based sepsis diagnostic test, … faster [less than three hours] and more accurate (85 to 95% performance) than all competitors”.

Athlomics said it aimed to evaluate its use in continuous patient monitoring which could improve market opportunity, patient surveillance and survival and reduce antibiotic costs and hospital stays.

South Australia’s Re-Time was awarded $20,200 “to commercialize light therapy glasses for the treatment of insomnia and related disorders, including jet lag and depression. The project will involve conducting a business case analysis and developing a commercialization strategy.”

The Australian Capital Territory’s Kord Defence was awarded $250,000 for “a weapon-mounted rifle input control and body-worn Kord Pad for international markets including defence, paramilitary, homeland security, police, emergency and public safety”.

The media release said that a new design for motorcycle safety helmets to reduce the risk of injury and the creation of light therapy glasses for the treatment of insomnia, jet lag and depression were among the bright new ideas to be supported by Commercialisation Australia.

“Increasing our focus on innovation, knowledge-based industries, and new business growth is the key to renewing and growing the Australian economy,” Senator Carr said.

“Commercialisation Australia helps bridge the gap between promising ideas and a commercially viable business, which will provide jobs, skills and prosperity,” Senator Carr said.

BIO-BEERS

Organized by Dr Chris Booth and Ian Dixon the Bio-Beers session is free to attend and an open invitation is extended to the biotechnology industry

Dr Booth and Mr Dixon said the event was as “after-work networking” session attracting executives, innovators, researchers and students, providing an informal setting for people involved in the biotech and life sciences sector to come together and share ideas and contacts.

This month’s Bio-Beers will be held at the Treasury Bar at the Sebel Hotel, on the corner of Collins Street and Queen Street, Melbourne on July 15, 2010 from 6-8pm.

Bio-Beers is expected to return on the third Thursday of alternate months.

Inquiries and RSVPs to: christopher.booth@thomsonreuters.com.