Biotech Daily

Tuesday September 25, 2012

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: UNIVERSAL BIO UP 11%, BIONICHE DOWN 23%**

*** ALCHEMIA: 82 TREATED PATIENTS - 'NO UNEXPECTED TOXICITIES'**

*** ALLAN GRAY TAKES 10% OF QRX - BUYS LOW, SELLS HIGH**

*** FIREBRICK HOPES TO CURE THE COMMON COLD IN 5 YEARS**

*** FLORIDA APPROVES GENETIC TECHNOLOGIES BREVAGEN TEST**

*** BIODIEM REQUESTS CAPITAL RAISING TRADING HALT**

*** OCTA PHILLIP LETTER TO BIOXYNE SHAREHOLDERS**

*** CONSEGNA BREATHEASSIST TRIALS, PATENT**

*** PSIVIDA REVENUE DOWN 29% TO $3m, LOSS UP 179% TO $24m**

*** NOVOGEN, KAI MEDICAL BACKDOOR LISTING FAILS**

*** BIOTA MERGER MEETING SET FOR OCTOBER 23**

MARKET REPORT

The Australian stock market fell 0.29 percent on Tuesday September 25, 2012 with the S&P ASX 200 down 12.6 points to 4,372.9 points.

Fourteen of the Biotech Daily Top 40 stocks were up, nine fell, 10 traded unchanged and seven were untraded.

Universal Biosensors was the best, up nine cents or 11.25 percent to 89 cents, with 131,523 shares traded. Genetic Technologies climbed 9.5 percent; Cellmid was up 6.7 percent; Optiscan was up 5.3 percent; Prana and Viralytics were up more than four percent; Alchemia and Phylogica were up more than three percent; Bionomics, Reva, Resmed and Sirtex rose more than two percent; with Heartware, Pharmaxis and QRX up by less than one percent.

Bioniche led the falls, down 12 cents or 23.1 percent to 40 cents with 50,000 shares traded, followed by Genera down 11.8 percent to 15 cents with 25,000 shares traded. Ellex fell 7.5 percent; Patrys lost 6.7 percent; Prima fell 5.1 percent; Acrux, Mesoblast and Neuren were down more than three percent; with Cochlear, CSL and Starpharma down by less than one percent.

ALCHEMIA

Alchemia says there have been no unexpected toxicities among the 215 patients treated in its 390-patient phase III trial of HA-irinotecan for metastatic colorectal cancer.

Alchemia said that 82 patients in the randomized trial had received 10 cycles or more of chemotherapy treatment and none of the treated patients had unexpected toxicities or suspected unexpected serious adverse reactions.

The company said the pivotal trial for second and third line metastatic colorectal cancer would compare the safety and efficacy of hyaluronic acid irinotecan of (HA-irinotecan) with irinotecan alone in a double blind trial when administered as part of the folinic acid, 5-fluorouracil and irinotecan (FOLFIRI) regimen.

Alchemia said that the primary objective was to demonstrate that HA-irinotecan provided superior efficacy as indicated by an increase in progression-free survival (PFS).

The company said that the primary endpoint would be reached when 350 patients had experienced disease progression or death, which was expected by the end of 2013.

Alchemia chief executive officer Dr Pete Smith told Biotech Daily that all 215 patients recruited so far had at least one cycle of treatment, with most having had multiple cycles.

Dr Smith said that patients would be treated with up to 16 fortnightly cycles of chemotherapy at which point the decision for further treatment was with the clinician.

Dr Smith said the average progression free survival for the control group was expected to be 16 to 20 weeks.

“We are hoping for a significant time increase before the disease progresses, without additional toxicities and that would be a real benefit to the patient,” Dr Smith said. “At this stage there is no evidence of increased toxicities in the blinded data.”

Dr Smith said the study was a “true randomized” trial and of the treated patients about half were in the active HA-irinotecan group and half were control.

In the media release Alchemia said that the first patient received their treatment on January 3, 2012.

Alchemia said that despite a higher than expected screen failure rate of 30 percent, enrolment was “on-track and within expectations”.

Alchemia said the trial was being conducted at 62 sites in Australia, Eastern and Western Europe and to meet the recruitment deadline, 14 additional sites were in the process of being opened, including four new sites in Australia.

The company said that the next meeting for the data and safety monitoring board was expected to be convened at the end of October 2012.

Alchemia was up 1.5 cents or 3.1 percent to 49.5 cents.

QRX PHARMA

Allan Gray Australia has increased its substantial holding in QRX from 12,960,965 shares (8.99%) to14,791,886 shares (10.23%).

In its substantial shareholder notice Allan Gray said it bought and sold shares between September 19, 2011 and September 20, 2012 with the largest purchase 478,888 shares for $333,5012 or 69.6 cents a share and the largest sale 283,485 shares for $510,063 or $1.80 a share.

In its most recent substantial shareholder notice for QRX, Allan Gray (then known as Orbis Investment Management), increased its substantial holding in QRX from 9,785,634 shares (7.77%) to 12,960,965 shares (8.99%) buying and selling shares between April 6 and September 16, 2011 with the largest purchase 844,601 shares for $1,094,681 or $1.296 a share (BD: Sep 20, 2011).

QRX was up half a cent or 0.7 percent to 68 cents.

FIREBRICK PHARMA

Firebrick executive chairman Peter Molloy says the private company hopes to cure the common cold with an off-patent microbicide, within five years.

A former Biota chief executive officer, Mr Molloy told Biotech Daily that the company expected its nasally inhaled drug candidate to “inactivate all cold viruses and degrade the viral load without damaging the nasal mucosa”.

Mr Molloy said the drug candidate was based on “a patentable improvement on a broad-spectrum anti-viral agent” that had never been used for this indication.

Mr Molloy said the microbicide came with extensive safety and efficacy data and modeling suggested the intra-nasal spray would shorten the duration of significant symptoms by five days from the usual seven days to two days, “by directly reducing the viral load in the nasal passages”.

“Cold is a topical infection that should be treated with a topical agent,” Mr Molloy said.

“Virtually all [cold virus] drug development to date has targeted rhinovirus which accounts for about one third of adult colds,” Mr Molloy said.

Mr Molloy said the broad-spectrum microbicide would be effective against all cold viruses.

Mr Molloy said the company would require a total of about $10 million to take the compound from validation to complete two US phase II trials, within five years.

He said that initially he wanted to raise $2.5 million for validation and pre-clinical work to have the compound ready for a phase I trial in 2014, followed by raising a further $2.5 million to take it from the phase I trial to a US Food and Drug Administration investigational new drug application for two phase II trials, in 2015, which would cost a further $5 million.

Mr Molloy said the company was targeting angel and sophisticated investors as well as institutions for the funds.

He said there were no plans for the company to become a listed entity.

Mr Molloy said Firebrick would formally launch on October 11, 2012 with former Viralytics and CBio chief operating officer Stephen Goodall as its chief operating officer and the FDA’s former head of anti-viral drug products Dr Ellen Cooper as scientific adviser.

Mr Molloy said he hoped to begin validation before the end of 2012, including compound chemistry, microbiology and formulation ready for pre-clinical testing in mid-2013.

More information is at: www.firebrickpharma.com.

GENETIC TECHNOLOGIES

Genetic Technologies says its Brevagen breast cancer test has been cleared for sale in Florida.

Genetic Technologies says the Florida approval followed the grant of a permit for its Australian-based laboratory by the Clinical Laboratory Unit of the Florida Agency for Healthcare Administration.

Last year, the US Centers for Medicare and Medicaid certified the Australian laboratory under the Clinical Laboratories Improvements Amendments allowing Brevagen to be sold in 42 states (BD: Apr 28, 2011).

Genetic Technologies said it submitted applications for out-of-state licences allowing Brevagen to be sold in Pennsylvania, Rhode Island, Nevada, Tennessee, Maryland, California and Florida, and that New York State was reviewing its application and when approved, the test would be cleared for sale in all 50 US States.

The company said that US subsidiary Phenogen Sciences had trained and placed a regional business manager in Florida and it expected to immediately start securing sales.

Genetic Technologies was up one cent or 9.5 percent to 11.5 cents.

BIODIEM

Biodiem has requested a trading halt “pending capital raising initiatives”.
Trading will resume on September 27, 2012 or on an earlier announcement.
Biodiem last traded at 6.2 cents.

BIOXYNE

The Octa Phillip group has written to Bioxyne shareholders critical of the company’s chairman and chief executive officer and arguing its case for a change of directors.
According to ASX data, Octa Phillip owned 20.92 percent of Bioxyne at March 28, 2012.
Octa Phillip said that following the share price collapse on the announcement that the phase IIb trial of HI-164OV for chronic obstructive pulmonary disease failed to meet its endpoints (BD: June 28, 2012) shareholders needed “to be assured that the management is preserving its operating capital and acting as cost-efficiently as possible, giving it as much time as possible to: succeed in commercializing HI-164OV, recognizing that the under-65 subset offers a much smaller market opportunity and as such the expected value of the technology needs to be commensurate with that; commercialize HI-164OV to ensure value is returned to shareholders and not spent on fees to a third party; secure additional assets, approved by a board of directors with proven experience in the life sciences, to create a foundation for future growth; and develop a path forward that will result in shareholder value and returns”.
Octa Phillip said it did not believe the desired outcomes could be achieved with the leadership of chair Ian Mutton and managing director David Radford.
Octa Phillip said that Bioxyne was paying $15,000 a month to Torreya Partners providing an estimated cash burn of about $65,000 a month, before any research and development, clinical development, overheads or other operating costs and the company had less than $800,000 in cash at June 30, 2012.
Octa Phillip said that HI164OV failed to reach any primary or secondary endpoints in the phase IIb trial and failed to meet endpoints in two previous phase IIa trials.
“We have come to the conclusion that original expectations for HI164OV are no longer realistic,” Octa Phillips said.
“We strongly believe that Bioxyne shareholders deserve to benefit directly from any commercialization outcome which may be achieved,” Octa Phillip said.
“Bioxyne has conducted retrospective analysis of the trial and presented a plausible, but as yet unproven, sub analysis that the technology may be effective in ‘under 65 year old [chronic obstructive pulmonary disease] sufferers that can produce phlegm’, Octa Phillip said.
“Any trials undertaken to prove this hypothesis are likely to be significantly more expensive than prior trials … because the patient recruitment requirements will be narrower and more defined, requiring significantly more study sites to be involved in order to recruit sufficient numbers of patients, in the seasonal window, for an appropriate trial,” Octa Phillip said.
The letter to shareholders said the best way to extract value from HI-164OV was to commercialize, partner, licence or sell the asset at this stage in its development to a biopharmaceutical company willing to invest in the hypothesis.
“The current Torreya Partners agreement of $15,000 per month and $1 million success fee is inappropriate given the failure of the technology in its recent trial,” Octa Phillip said.
The letter is at: http://bioxyne.biosciencemanagers.com/2012/09/letter-to-shareholders/.
Bioxyne was unchanged at 2.5 cents.

CONSEGNA GROUP

Consegna says laboratory testing has shown that its Breatheassist Elite Sports product can reduce airflow resistance by 80 percent, important for improving sports performance.
Consegna said the Breatheassist Elite Sports dilated nasal passages to increase airflow and was designed to meet the needs of athletes.
The company said that respiratory therapist Steve Tunnell evaluated an updated version of the device that was refined to improve comfort, following a period of in-field testing by professional athletes.
Consegna said the new sports version used a minimal amount of lightweight polymer to not only increase airflow but also to reduce the resistance on exhaling, a crucial requirement under extreme exertion.
The company said the study evaluated the Elite Sports model for resistance to airflow under simulated strenuous exercise and each device was subjected a targeted airflow of 30 litres per minute representing rest and 100 litres per minute representing exercise.
Consegna said an 80 percent reduction in airflow resistance was measured compared with the Breatheassist snoring variant, where some resistance was required.
Consegna's chief technology officer Dr Nicholas Ede said that during exercise the amount of air circulating through the body increases by a factor of four to five compared with airflow at rest, so being able to reduce resistance to airflow was a critical factor in sports performance.
"This study shows that Breatheassist Elite Sports can reduce inspiratory and expiratory airflow resistances by 80 percent, which is an outstanding result," Dr Ede said.
Consegna says Melbourne's Australian Catholic University has given ethics approval for a clinical trial of the Breatheassist Elite Sports model by its sport science research group to be conducted by Dr Vanessa Rice and Dr Doug Whyte.
The company said the study entitled 'The impact of a nasal dilator on the oxygen cost of breathing during exercise' would enroll about 20 recreationally active males to measure parameters associated with energy consumption during heavy exercise with and without the Breatheassist Elite Sports device.
Consegna said it had filed a new international patent entitled 'A device for improving air flow through a nasal cavity during physical pursuits' protecting the design in the Elite Sport product.
The company said the patent, filed under the Patent Cooperation Treaty, also protected novel drug delivery and performance enhancing embodiments.
Consegna was unchanged at 1.5 cents with 1.1 million shares traded.

PSIVIDA

Psivda says its net loss after tax for the 12 months to June 30, 2012 was up 178.8 percent to $US24,835,000 on revenue down 29.0 percent to $US3,526,000 ($A3,383,750).
Psivida said research and development was up 2.5 percent to $US7,039,000, general administration fell 15.25 percent to $US6,868,000, but there was a $US14,830,000 impairment of intangible assets.
The company said diluted loss per share was $US1.19 compared with 44 US cents in the previous corresponding period.
Psivida said it had cash and equivalents of $US14,571,000 at June 30, 2012 compared to $US24,128,000 at June 30, 2011.
Psivida was unchanged at $1.71.

NOVOGEN

Novogen says its planned merger with US company Kai Medical to commercialize sleep apnoea devices and wireless respiration monitoring technology has been terminated.

In July, Novogen said the agreement was subject to conditions including due diligence and shareholder approval but the deal provided Novogen shareholders "with an opportunity to participate in the growth and success of Kai Medical's revolutionary sleep apnoea therapy device" (BD: Jul 27, 2012).

Novogen said at that time that that prior to the Kai merger and subject to shareholder approval, it would undertake a capital reduction and in specie distribution to the Novogen shareholders of its shares of MEI Pharma, formerly Marshall Edwards.

Novogen chairman William Rueckert said at that time that the distribution would allow each shareholder to own their proportionate share of the MEI Pharma shares now held by Novogen as well as their Novogen shares after the merger with Kai Medical.

Today, Mr Rueckert said the termination of the deal was "a disappointing outcome".

"We were enthusiastic about the prospects for future value creation through Kai's business plan and product development," Mr Rueckert said.

"However, the details of the transaction made it impossible to ensure the continued listing of Novogen's securities on the ASX and Nasdaq markets," Mr Rueckert said.

"In making the decision, the Novogen board agreed that it is an imperative that it maintains the listings and liquidity in the company's shares," Mr Rueckert said.

"The company will continue to explore transactions that it believes will enhance shareholder value including a possible capital reduction and in specie distribution of MEI Pharma shares to the Novogen shareholders," Mr Rueckert said.

Novogen was untraded at 7.9 cents.

BIOTA

Biota says shareholders will vote on the proposed merger with Nabi Biopharmaceuticals, on October 23, 2012.

Biota said a revised timetable was approved by the Supreme Court of Victoria.

The adjourned meeting will be held at the Melbourne Convention Centre, 1 Convention Centre Place, South Wharf, Melbourne, at 2pm (AEST).

Biota was unchanged at 69 cents.