Biotech Daily

Monday March 28, 2011

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: ANTISENSE UP 15%; PHOSPHAGENICS DOWN 5%**

*** AVEXA, FDA AGREE ATC FOR HIV PATH**

*** BIOGUIDE BRIEF: ATC HARDER TO KILL THAN A COCKROACH**

*** QRX FDA MEETING LEADS TO MID-YEAR APPLICATION**

*** CBIO RHEUMATOID ARTHRITIS TRIAL DOSED; LUPUS PATENTS**

*** BIONOMICS REQUESTS 'TRIAL RESULTS' TRADING HALT**

*** BIOTRON RAISES $770k; PLACEMENT FOR $1.7m**

*** BIOTA APPOINTS PIPER JAFFRAY AS FINANCIAL ADVISOR**

*** HEALTHLINX SHARES, OPTIONS, DIRECTOR EGM**

*** ATCOR: STUDY SHOWS SPHYGMOCOR GOOD FOR SHOCK PATIENTS**

MARKET REPORT

The Australian stock market fell 0.19 percent on Monday March 28, 2011, with the S&P ASX 200 down nine points to 4733.6 points.

Fourteen of the Biotech Daily Top 40 stocks were up, eight fell, five traded unchanged and 13 were untraded.

Antisense was best, up 0.2 cents or 15.4 percent to 1.5 cents with 101.4 million shares traded, followed by Genera up 9.4 percent to 29 cents with 5,700 shares traded and Prana up eight percent to 27 cents with 5.8 million shares traded.

Pharmaxis and Psivida climbed more than six percent; Patrys was up five percent; Prima and QRX were up more than four percent; Tissue Therapies rose three percent; with Cellestis and Mesoblast up more than one percent.

Phosphagenics led the falls, down 0.5 cents or 4.55 percent to 10.5 cents with three million shares traded, followed by Phylogica down 4.2 percent to 6.8 cents with 855,916 shares traded.

Genetic Technologies lost 3.85 percent; Impedimed and Viralytics shed more than two percent; with Biota, Living Cell and Nanosonics down more than one percent.

AVEXA

Avexa says “a comprehensive and highly productive meeting with the US Food and Drug Administration” has found a regulatory pathway for the anti-HIV drug apricitabine (ATC).

Avexa chief executive officer Dr Jonathan Coates told Biotech Daily that the company retained about $20 million in cash, but any new trial would primarily be funded by a partner for the drug.

“I want to find a partner for the trial, the marketing and distribution and I am not contemplating a capital raising,” Dr Coates said.

In its media release, Avexa did not say how large a new phase III trial would be or what it would cost but more than 100 patients and at least $100 million appear to be minimum requirements.

Avexa said in its media release that the FDA recognized and gave credit “for the significant amount of previous ATC clinical studies conducted by Avexa, in particular the latest ATC study AVX-301”, the last phase III trial reported in February 2010 (see below).

Avexa said that as a consequence, the remaining regulatory requirements for an ATC approval were “considerably less complicated and less extensive than previously assumed and less than that required for other recently approved drugs”.

The company said it could expect a simpler, faster regulatory path; considerable risk mitigation; lower costs; an immediate phase III trial with near term approval potential; and to be far more attractive economically to potential partners.

Avexa said apricitabine would be developed initially for multi-drug resistant HIV patients.

Avexa said ATC had shown “great potential as a therapy in the fight against multi-drug resistant HIV” and as a twice-a-day dosed drug ATC complemented new generation drugs such as Merck’s HIV integrase inhibitor Isentress, which was also twice daily.

Avexa said apricitabine was a novel nucleoside, a class of drug that was “a vital component of anti-HIV therapy” and offered an extension to existing therapies in the treatment of HIV especially for patients with limited therapeutic options.

“This is a significant milestone for Avexa and its shareholders,” Dr Coates said.

“We can now plan the next regulatory steps for the program with confidence and secure the commercialization of this very valuable anti-HIV drug,” Dr Coates said.

Last year, following the publication of 24-week phase III trial results showing a non-significant positive clinical benefit for apricitabine compared to the standard of care 3TC, Avexa dropped its ATC phase III program, chief executive officer Dr Julian Chick resigned and a board spill was requested (BD: Feb 4, 5, 15; May 10, 2010).

Avexa said last year that it would “cease any further development of … ATC following the unsuccessful conclusion of partnering discussions with global pharmaceutical companies”.

Avexa said it had shown that 34 of the 36 patients who completed the phase II ATC study maintained “undetectable viral loads up to week 144” and detailed phase III results were provided to interested parties to secure a licencing transaction, but on May 6, 2010, the last party involved in the process said it did not intend to submit a term sheet.

The company conducted a review, but the details of the review were never made public.

Avexa acquired 24 percent of Allied Medical and agreed to sell 19.9 percent of that company to Biomd. Allied Medical has a major interest in Coridon Vaccines which is developing vaccines for infectious diseases and cancers (BD: Feb 24, 2011).

Last December, chairman Joe Baini and chief executive officer Dr Jonathan Coates told Biotech Daily that Avexa would be an anti-viral focused company with two main assets, a second generation HIV integrase program and the stake in Allied Medical which controls Coridon (BD: Dec 13, 2010). Mr Baini said Avexa had licenced its anti-biotic programs to Valevia for up to $66 million with no up-front fee but significant milestone payments.

Avexa was up 2.1 cents or 52.5 percent to 6.1 cents with 147.2 million shares traded.

MARC SINATRA'S BIOGUIDE BRIEF: AVEXA

The only people who seemed to believe that Avexa's HIV drug apricitabine (ATC) wasn't dead, were a few at Avexa's headquarters.

A major complaint of Avexa's current management has been that the former management did not engage with the US Food and Drug Administration as much as they should.

According to Avexa's announcement today, they were right.

Faster to market, less risk, less cost, better returns, an immediate phase III trial (funny, I thought they had already been in a phase III trial) and, of course, ATC will be more economically attractive to potential partners.

Now a few HIV market facts:
Intelence was the last HIV drug approved – three years ago;
Of the seven drugs for HIV in late stage testing three years ago, none have made it to market;
Combination pills rule the HIV landscape – and new ones appear to be on the way;
New delivery methods mean even less than once-a-day dosing is likely;
The efficacy of existing therapies makes it very difficult to show a benefit with a new drug; and
Doctors want years of performance before they put a patient on a new drug.

The upshot of all of this is that current treatments for HIV are very good and that the disease is now a chronic one, not a death sentence.

So, is there a possible role for ATC in HIV treatment? The answer to that question seems to be possibly, but not likely.

HIV is very adept at mutating and eventually we are likely to see a new strain for which current therapies seriously lack efficacy. ATC may well be able to treat these new strains, but it is likely that a whole bunch of other HIV drugs that have failed to get to market will be able to do so as well.

And then there is the elephant in the room, ATC's patent life. Should everything go exceptionally well, ATC may get on the market just as its patent expires in 2013. Yes, there will probably be extensions and data exclusivity for new chemical entities, but we are talking bare bones protection.

Avexa says they have manufacturing patents which provide cover until the "mid-20s", a strategy that has worked for Chemgenex, but verifying these claims is exceedingly difficult.

For Avexa's sake and Australian biotechnology's sake, let's hope Avexa can get ATC to market and that significant cash flows result.

I might not hold my breath, though.

Marc Sinatra
Analyst
marc@biotechdaily.com.au

QRX PHARMA

QRX says that following its pre-new drug application meeting with the US Food and Drug Administration it is on-track to file its Moduo IR for pain application in mid-2011.
QRX said that the FDA reviewed “a number of critical components” of its planned submission and the application for Moduo IR (immediate release) was for the target indication of the management of moderate to severe acute pain in patients who need an opioid analgesic.
QRX chief executive officer Dr John Holaday said that “nearly four years to the date of our [initial public offer] and ASX listing, we are preparing to apply for registration of our first product with the FDA”.
“This represents a major milestone for the company and I am proud of the progress we’ve made, not only with Moxduo IR, but also with our portfolio of other product candidates,” Dr Holaday said.
“The pre-NDA meeting considered QRX Pharma’s regulatory strategy and the FDA provided constructive feedback on specific sections of the planned NDA,” Dr Holaday said.
“We expect to submit our NDA mid-year once the comprehensive data analysis is complete,” Dr Holaday said.
QRX said that Moxduo was a patented three-to-two ratio fixed dose combination of morphine and oxycodone.
The company said it had conducted 11 clinical trials, including three pivotal phase III studies and that about 800 subjects, most with acute or chronic pain, had received Moxduo IR.
QRX said the studies consistently demonstrated the benefits of dual opioids, achieving as good or better pain relief with fewer incidences of moderate to severe side effects.
QRX was up 6.5 cents or 4.6 percent to $1.475.

CBIO

CBio says the last of 155 patients has been dosed in its phase IIa Xtoll rheumatoid arthritis clinical trial.
CBio said the data would be collated and audited in the next three months with data tables and listings relating to the trial by June 2011, when it would be analyzed before being presented to pharmaceutical companies and final report due for completion later in 2011.
CBio said it had lodged two more patent applications claiming the use of XToll for the “Prevention and treatment of cutaneous lupus erythematosus” through the Patent Cooperation Treaty system, with a corresponding application in Taiwan.
The company said the first application in the patent family was with the US Patent and Trademark Office and the priority date for the patent family was March 30, 2010.
Cbio fell five cents or 6.6 percent to 71 cents.

BIONOMICS

Bionomics has requested a trading halt pending “the announcement of results from its European phase Ib clinical trials of BNC210”.
Bionomics is developing BNC210 as an anti-anxiety drug and has published pre-clinical results indicating that it has a better safety and side-effects profile than diazepam or anti-depressants (BD: Aug 30, 2010).
Trading will resume on March 30, 2011 or on an earlier announcement.
Bionomics last traded at 43 cents.

BIOTRON

Biotron says its share plan raised $770,000 through the issue of 8,105,215 shares at 9.5 cents a share, with a placement planned to raise a further $1,710,000 at the same price.
The company said in February that it could issue up to 36,556,455 shares to raise up to $3,472,863 (BD: Feb 24, 2011).
Biotron said it was pleased with the “encouraging level of participation” by shareholders.
Biotron said a further 18,000,000 shares would be placed by Bell Potter securities to raise a further $1,710,000.
Biotron was up half a cent or 4.8 percent to 11 cents.

BIOTA HOLDINGS

Biota has appointed Piper Jaffray & Co as its lead financial advisor.
Biota said Piper Jaffary would to assist by working with the board and management to further develop plans to maximize value from its programs and identifying the appropriate path for Biota to achieve superior returns from the its research and development programs especially the potential to pursue the direct commercialization of the second generation influenza antiviral, laninamivir, in the US and other markets.
Earlier this month, Biota chief executive officer Peter Cook met with investors to explain the potential of a current grant application to either a US or European agency to pay for a major phase III trial for laninamivir (BD: March 15, 2011).
Biota said it intended “to obtain maximum shareholder value from its most advanced development compound laninamivir, a second generation neuraminidase inhibitor and influenza antiviral”.
The company said laninamivir had been launched in Japan as Inavir by Biota’s commercial partner, Daiichi Sankyo.
Biota restated that its alternatives were securing non-dilutive agency funds; raising funds from international capital markets; and/or investigating merger or acquisition structures.
The company said that Piper Jaffray would advise it in all financial and strategic aspects to achieve timely completion of that goal.
Biota said Piper Jaffray was “a leading US based middle market investment bank serving clients both in the US and internationally”.
Biota fell one cent or one percent to 99.5 cents.

HEALTHLINX

Healthlinx shareholders will vote to ratify the allotment and issue of 38,206,250 placement shares.
Healthlinx said shareholders would vote on the issue of shares to Allen & Caron Inc in lieu of cash payment for work done, along with up to 10,000,000 options to “an [unnamed] appropriate full service investment bank (or their nominee)” in lieu of cash payment for work done.
The company said a resolution would seek permission for the issue of up to 50,000,000 shares and 50,000,000 options in a placement.
Healthlinx said shareholders would vote to ratify shares and options to Springtree Special Opportunities Fund for its equity draw-down facility.
Shareholders will also vote on the election of Dr John Chiplin as a director.
The meeting will be held at Healthlinx, 576 Swan Street, Richmond, Victoria on April 28, 2011, at 12pm (AEST).
Healthlinx fell 0.1 cents or 1.8 percent to 5.6 cents.

ATCOR MEDICAL

Atcor says its non-invasive Sphygmocor central blood pressure measure equaled an invasive catheter for assessing improvements in cardiac performance of patients in shock.

Atcor said that a study entitled ‘Changes in pulse pressure following fluid loading: a comparison between aortic root (noninvasive tonometry) and femoral artery (invasive recordings)’ was published in the current edition of the journal Intensive Care Medicine and an abstract is at http://www.springerlink.com/content/xv224k221674741t/.

The company said the prospective study compared non-invasive central blood pressure measurement using Sphygmocor with simultaneous invasive recording with an indwelling catheter in patients in shock who required volume expansion therapy.

Atcor said investigators found that non-invasive monitoring of central pulse pressure was equal to invasive monitoring in terms of its ability to track changes in the stroke volume of the heart in response to therapy.

“The arterial tonometry analysis of aortic pulse pressure changes induced by volume expansion should potentially represent an alternative approach for patients in whom invasive recordings are not possible or not desirable, especially elderly patients,” Atcor quoted the study authors saying.

Atcor chief executive officer Duncan Ross said the company’s system had the potential to reduce mortality and hospital costs.

“This is an extremely important study,” Mr Ross said.

Atcor was untraded at 9.2 cents.