Biotech Daily

Monday July 21, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS UP: NEUREN UP 30%, LIVING CELL DOWN 13%**

*** BIOTA LOSES GSK LEGAL GAMBLE; BACK TO DRUG DEVELOPMENT**

*** BIO-GUIDE BRIEF NOTE: BIOTA LITIGATION**

*** ADVANCED SURGICAL ACCESS DEVICE USED IN CARDIAC SURGERY**

*** NEURODISCOVERY COMPLETES 2nd PHASE I PAIN DRUG TRIAL**

*** NEUREN WINS WINDHOVER 'TOP 10 NEUROSCIENCE PARTNER' GONG**

*** SAFETY MEDICAL SHARE PLAN RAISES $223k**

*** TISSUE THERAPIES HOPES TO RAISE $700k**

*** APOLLO EGM TO SPILL BOARD, OR NOT**

*** ANTISENSE SAYS TEVA MS DEAL TRANSFORMS BUSINESS**

MARKET REPORT

The Australian All Ordinaries Index bounced back 160.1 points on Monday July 21, 2008 up 3.3 percent to 5,075.4 points.

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

Neuren was best, up three cents or 30 percent to 13 cents on modest volumes, followed by Mesoblast up 11.61 percent to $1.25 and Phosphagenics up 10.47 percent to 9.5 cents.

Peplin climbed 7.35 percent; Psivida was up 5.28 percent; Avexa was up 4.92 percent; Cathrx, Prana, Resmed and Starpharma were up more than three percent; Cochlear, Labtech and Sirtex rose more than two percent; with Chemgenex up one percent.

Living Cell led the falls, down three cents or 13.04 percent to 20 cents, followed by Progen down 6.25 percent to $1.20.

Agenix and Universal Biosensors lost more than five percent; Benitec and Optiscan fell more than four percent; Biota, Pharmaxis and Polartechnics shed more than three percent; with Acrux, Alchemia and Arana down more than one percent.

BIOTA

Glaxosmithkline has agreed to pay Biota $20 million to settle the long-running Relenza case, but Biota's legal costs are more than $30 million.

Biota said it had concluded its litigation against Glaxosmithkline which began in 2004 and claimed between $564 million and $704 million from Glaxosmithkline for "failing to support the influenza drug, Relenza, discovered by Biota and licenced to Glaxosmithkline in 1990" (see Biotech Daily July 31, 2007).

Today's announcement followed formal mediation between by the parties ordered by the Victorian Supreme Court.

Biota said the mediation "provided the parties with the opportunity to resolve their differences and eliminate the uncertainty and costs associated with the legal process".

The agreement provided for each party to bear their own legal costs.

The payment will be made on August 18, 2008 and the existing master agreement between the parties remains unchanged.

Biota's chief financial officer Damian Lismore told Biotech Daily that total legal fees would be $35-$40 million.

"This settlement does put us in a stronger financial position," Mr Lismore said. "It's removed a significant cost outlay and adds to the cash balance."

Mr Lismore said that with Glaxosmithkline focused on Relenza the royalties to be received over the coming seven years of patent coverage could be more than the amount claimed in the court case. He said Biota received royalties of $40 million in 2006-'07 with $25-30 million expected in 2007-'08.

Biota and Glaxosmithkline agreed "to normalize their relationship to pursue the best interests of Relenza, with senior executive liaison and co-operation between the companies to be restored and strengthened".

The focus will be on developing the Relenza franchise particularly in the important market of pre-pandemic influenza risk management, an area of considerable concern to both governments and business.

Biota's chairman John Grant said that in striking the agreement the board "had taken some hard decisions".

Recent advice, sought following the May postponement of the scheduled trial date, indicated a significant lengthening of overall time-scales, including of the trial itself and a consequent large escalation in costs and risks, Biota said.

Mr Grant said the advice "required us to review rigorously all aspects of the litigation in a new light including the impact of current and further possible delays and the growing scale and complexity of the litigation".

He said Biota could now concentrate on investing its significant Relenza royalty stream into developing its strong discovery and clinical stage pipeline and on furthering its valuable corporate partnerships, including with Glaxosmithkline.

Glaxosmithkline chief executive officer Andrew Witty said his company was "pleased to have reached a settlement that is satisfactory for both companies and brings an end to this litigation".

"GSK remains committed to working collaboratively with external organizations and biotech companies, such as Biota, in our ongoing efforts to bring innovative medicines and vaccines to patients," Mr Witty said.

Following the announcement, ABN Amro Morgans gave Biota shares a fair value and price target of $1.26 a share.

Biotech Daily's Marc Sinatra has valued Biota at $1.37 a share (see comment below).

Biota fell 2.5 cents or 3.21 percent to 75.5 cents.

Biotech Daily editor David Langsam owns shares in Biota.

MARC SINATRA'S BIO-GUIDE: BIOTA

For followers of Australian biotechs, Biota has taught us a lot.

It has given us lessons regarding deal structure, intellectual property, the US Food and Drug Administration new drug approval process and the perils of taking over a foreign technology company.

It has now given us a lesson about suing a major pharmaceutical partner.

Given that Biota chose to sue Glaxosmithkline and the bullishness with which they did, Biota investors are entitled to be disappointed with the outcome.

The meager $20 million payout they will receive won't cover Biota's court costs and is well below the $74 million the market was valuing the litigation in July last year (See Biotech Daily July 18, 2007).

At the time, I also noted that it was very difficult, based on available information, to determine what the outcome of the litigation might be, Biota's bullishness aside, and that investors needed to be prepared to wear this risk.

Even up until today, assessing Biota's chances have been difficult.

The only reliable signal that things might not be going Biota's way has been the falling share price, despite the imminent court case and a possible big pay day.

Although I am tempted to say that the lesson from today's news is: don't sue a big pharmaceutical company, I think that would be simplistic.

More realistically, I think the lesson is that you must have extreme confidence in the managers who handled the original deal, the litigation and everything in between, before heading down the legal path.

Biota is and has been a true Australian biotech trailblazer in just about everything it has done. But, by definition, a trailblazer is inexperienced.

It is this inexperience that investors and analysts, this writer included, probably should have factored into Biota's chance against Glaxosmithkline a bit more.

The good news is that Biota can now focus on what they should be doing - drug development. Hopefully, this will push them toward my new target price of $1.37.

ADVANCED SURGICAL DESIGN & MANUFACTURE

Advanced Surgical says its Peripheral Access Device has been used for the first time in cardiac bypass surgery.

Advanced Surgical's chief executive officer Dr Greg Roger told Biotech Daily the surgery was performed on July 16, 2008 at a major public teaching hospital in Sydney.

He said the Peripheral Access Device (PAD) was used as an access port.

In an investor update the company told the ASX the device had the advantage of minimal leakage during the course of the bypass pumping.

Intended for increasing blood supply to gangrenous legs the Peripheral Access Device allows a large bore (8mm) tube to be sewn into the femoral artery and then using a cardiac pump increase pressure up to 300mmHg, to increase blood flow and vascular regeneration in the affected limb (see Biotech Daily; February 13, 2008).

In this first cardiac trial, 5 litres of blood were pumped every minute for 10 hours, with the device saving blood loss and keeping the operative field clear.

Advanced Surgical said the resealable device allowed it to be left in place to allow, further access which is often required in the recovery period.

Advanced Surgical said the device's use in surgery was "an experimental development" and part of the company's ongoing support and fostering of innovation.

The company said it showed “there was a potential market over and above saving gangrenous limbs” and exposes the peripheral access device’s advantages to a new group of surgeons.
Advanced Surgical said a clinical trial for Australian Therapeutic Goods Administration approval with the device, to save limbs threatened with amputation from gangrene, was “progressing well”, with two more patients successfully treated.
Advanced Surgical was up one cent or 2.56 percent to 40 cents.

NEURODISCOVERY
Neurodiscovery says it has completed its phase I multiple ascending dose clinical trial of NSL-043 for neuropathic pain.
Neurodiscovery said it was the second of two phase I trials, designed to test the safety, tolerability and pharmacokinetics of an oral formulation of NSL-043 for neuropathic pain.
The company said “successful completion of the first, single ascending dose trial was announced April 9, 2008 (see Biotech Daily of that date).
Both trials were collaborations with equal partner, the Tokyo-based Sosei Co by Simbec Research at a single site in Merthyr Tydfil, Wales.
Neurodiscovery said healthy male volunteers were given a repeated twice daily dose of NSL-043 in capsule form for 10 days.
There were four treatment groups, each with nine participants, receiving doses of 100mg to 2000mg of NSL-043 or placebo twice daily.
Neurodiscovery said NSL-043 demonstrated good safety and tolerability.
At the highest dose tested, there were reports of mild events on the sensory system which may be consistent with the therapeutic use of NSL-043.
Neurodiscovery said the study allowed it to assess the pharmacokinetics of NSL-043 in humans after repeated oral dosing for 10 days.
The concentration of NSL-043 found in patients overlapped with concentrations effective in preclinical models of neuropathic pain, showing the blood concentrations of the active ingredient were at the levels expected, reducing one of the major risks in clinical development.
A company spokesperson said the blood concentrations gave an indication of the required doses and therefore a general idea of the quantities of active ingredient required for future trials.
Neurodiscovery said the positive data from the phase I trials “facilitates the ongoing enabling work required to examine the efficacy of the compound in patients”.
Neurodiscovery chief executive officer Dr Iain Chessell said the company was “delighted to find further evidence that NSL-043 has an excellent profile”.
“All information to date gives us confidence that NSL-043 may represent a real breakthrough for the treatment of neuropathic pain,” Dr Chessell said.
Neurodiscovery said neuropathic pain was associated with peripheral or central nervous system injury and could persist for months or years after the initial insult.
It is often described as burning or shooting in nature and can be continuous or paroxysmal. It is estimated that up to five percent of the general population of the US, Europe and Japan are affected by neuropathic conditions including diabetic neuropathic pain and post-herpetic neuralgia.
The condition has a poor prognosis and is a significant cause of morbidity. The neuropathic pain market is forecast to be more than $6.3 billion by the end of 2017
Neurodiscovery was untraded at 9.5 cents.

NEUREN

Windhover Information has selected Neuren's lead drugs as "one of the Top 10 most promising neuroscience projects available for partnering".

Neuren said it was selected "by an independent committee assembled by Windhover Information, a leading provider of business information products and services to senior executives in the pharmaceutical, biotechnology, and medical device industries".

The two drugs are Glypromate for neuroprotection in cardiopulmonary bypass which is in phase III trials and NNZ-2566 for traumatic brain injury which is scheduled to begin two phase II trials by the end of 2008.

Earlier this year (see Biotech Daily; January 21, 2008) Neuren expected two NNZ-2566 phase II trials to start in the US and New Zealand in mid-2008, one examining severe traumatic brain injury and the other studying mild to moderate traumatic brain injury.

Neuren quoted Windhover Information managing director Roger Longman saying the selected companies were "screened using a strict set of judging criteria for the Top 10 award and represent what our committee considered the most attractive neuroscience opportunities the industry has to offer".

"Winners have met rigorous criteria including: unmet medical need, market potential, diversity of indications, strong science, multi-level partnering opportunities (biotech and pharma), potential for new opportunities beyond initial indications, and corporate stability," Mr Longman was quoted as saying.

Neuren chief executive officer Larry Glass said the company was "extremely proud that Glypromate and NNZ-2566 have been selected as one of the Top 10 most interesting neuroscience programs available for partnering, further recognition that these compounds have significant potential as innovative therapies for the treatment of acute brain injury from multiple causes".

As a selected company, Neuren will present on Glypromate and NNZ-2566 at Windhover's Philadelphia conference in November 2008.

Neuren climbed three cents or 30 percent to 13 cents.

SAFETY MEDICAL

Safety Medical says its share purchase plan raised $223,000 with 2,230,000 shares issued with 1,115,000 free attaching options.

Safety Medical directors reserved the right to issue any shortfall under the share plan to professional and sophisticated investors, in their discretion.

The funds will be used for working capital in the ongoing commercialization and expansion of the company's suite of products.

Safety Medical was untraded at seven cents.

TISSUE THERAPIES

Tissue Therapies hopes to raise up to $700,000 through a share purchase plan.

Shareholders can buy up to $5,000 of shares at eight cents a share.

The record date for eligible shareholders is August 4, 2008 and the offer closes on August 25, 2008.

Tissue Therapies chief executive officer Dr Steven Mercer told Biotech Daily the funds would be used to continue clinical trials, further product research and development and strengthen the company's intellectual property position.

Tissue Therapies climbed one cent or 10 percent to 11 cents.

APOLLO LIFE SCIENCES

Apollo has been requisitioned to call an extraordinary general meeting to replace existing directors.

The shareholders have called for the removal of chief executive officer John Priest and Prof Antony Basten as directors to be replaced by Dr Thomas Wenkart and John Maher.

Dr Wenkart is the chief executive of Macquarie Health Corporation. He is named in many articles relating to the company as well as a former business partner of medical entrepreneur, Geoffrey Edelsten, who was de-registered as a doctor.

According to Apollo's 2007 annual report Mr Priest held 53.45 of the company's issued capital.

The meeting will be held at 147 Queen Street, Beaconsfield New South Wales on August 19, 2008 at 10am.

Apollo is in a voluntary suspension and last traded at four cents.

ANTISENSE

Antisense says it is a new business with sufficient cash to continue all operations until the end of 2009.

Antisense chief executive officer Mark Diamond told Biotech Daily that today's business and strategy update included a projected cash position for the first time.

The update said the projected cash position would "provide funding to the end of 2009 with no further expenditure on ATL/TV1102 as this is to be undertaken by Teva Pharmaceuticals".

"We're a different business as a result of the deal with Teva," Mr Diamond told Biotech Daily.

Antisense has received and/or had confirmed milestone payments of $6 million with continued payments as Teva takes ATL/TV1102 through phase III trials for multiple sclerosis and to registration, as well as royalties once the drug is on the market.

"We are an income producing and diversified biotechnology company," Mr Diamond said. The funding risk has been removed," he said.

Mr Diamond said Antisense was either the first or one of very few companies to licence a drug to a major pharmaceutical company following a phase II trial.

The update said the company's pipeline included ATL1103 for growth and sight disorders, which is expected to begin human clinical trials in 2009 and ATL1101 for prostate cancer which is in the pre-clinical research stage.

Antisense was unchanged at 6.5 cents.