Biotech Daily

Monday December 6, 2010

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: OPTISCAN UP 16%; COMPUMEDICS DOWN 12.5%**

*** BIOGUIDE BRIEF– BIONICHE BLUE SKY OVER SOLID GROUND**

*** CHEMGENEX OMAPRO EFFICACY IN DRUG RESISTANT CML**

*** BIOGUIDE BRIEF: CHEMGENEX REVALUED FROM $5.50 to $2.90, MAYBE**

*** ADVANCED SURGICAL DEVICE PREVENTS AMPUTATIONS**

*** LBT UNVEILS AUTOMATED PLATE ASSESSMENT SYSTEM**

*** IB BIOSCIENCE FUND 1 RETURNS 100% OR $20m**

*** QRX PHASE III MOXDUO TRIAL ENROLLED; DELAYED 60 DAYS**

*** MESOBLAST REQUESTS 'MAJOR TRANSACTION' TRADING HALT**

*** ATCOR IN $1.1m PHARMACEUTICAL CONTRACT**

*** TGA LICENCES CYCLOPHARM'S CYCLOPET AT MACQUARIE**

*** QUEENSLAND CREATES LIFE SCIENCES ORGANIZATION**

*** ANNMAC INCREASES, DILUTED TO 20.5% AGENIX**

*** PHYLOGICA DIRECTOR HARRY KARELIS RESIGNS**

MARKET REPORT

The Australian stock market slipped 0.12 percent on Monday December 6, 2010 with the S&P ASX 200 down 5.6 points to 4688.6 points. Thirteen of the Biotech Daily Top 40 stocks were up, 11 fell, eight traded unchanged and eight were untraded.

Optiscan was best, up 0.7 cents or 16.3 percent to five cents with 10,000 shares traded, followed by Immuron up 14.7 percent to 7.8 cents and Phosphagenics up 14.3 percent to 12 cents. Advanced Surgical climbed 11.3 percent; Cellmid and Tissue Therapies climbed more than four percent; Virax was up 3.85 percent; CSL and Uscom rose more than two percent; with Acrux, Chemgenex, LBT and Pharmaxis up more than one percent.

Compumedics led the falls, down 1.5 cents or 12.5 percent to 10.5 cents with 230,884 shares traded, followed by Benitec down 10.7 percent to 2.5 cents. Genetic Technologies lost 5.1 percent; Clinuvel, Nanosonics and Resmed shed more than two percent; with Alchemia, Bionomics, Sirtex and Universal Biosensors down more than one percent.

MARC SINATRA'S BIOGUIDE BRIEF– BIONICHE

Bioniche is a Canadian-based, Toronto Stock Exchange-listed, biopharmaceutical company with three divisions: animal health, human health and food safety, each with a research and development arm.

The animal and food divisions have products on the market, but the more than 60 animal products drove the group's $C27 million ($A27.1 million) 2010 operating revenues.

Investor interest is focused on the company's bladder cancer product Urocidin which was licensed to Endo Pharmaceuticals in 2009 for $US20 million up-front, $US110 million in milestones and a sales related price for supply of Urocidin to Endo, rather than a royalty.

Offer Details

Price: $1.50; funds sought: $C30 million; market cap at offer price: $C150 million.

Directors & Management

Chairman and CEO Graeme McRae; non-executive directors Dr Stanley Alkemade, Albert Beraldo, Dr Margaret Cunningham, Dr James Johnson, Nick Photiades, Lyle Vanclief.

Bioniche's board is solid with experience in veterinary and human pharmaceuticals, marketing, intellectual property and venture capital.

Significant Products

1. Folltropin-V is a follicle stimulating hormone used in cattle for embryo transfer, a process by which numerous embryos can be collected from a desirable mating. Folltropin-V was responsible for more than one third of Bioniche's operating revenue in 2010.
2. Urocidin is an optimized complex of the DNA and cell wall from Mycobacterium phlei. Currently, live attenuated Bacillus Calmette-Guerin (BCG) is used to generate an immune response to try to eliminate certain bladder tumors. Results from two phase I/II Urocidin studies were solid. Results from an open-label, phase III study completed in April, were not released, but Bioniche earned a $4 million milestone from Endo on Urocidin achieving a contractual efficacy goal. A second phase III trial is expected to begin this month.

Comment

Bioniche is a solid company with significant revenues, but hasn't established itself as profitable, yet. Operating expenses limited profits from sales in two of the last three years; a healthy R&D budget pushing results into the red in all three. 2010 sales were down 18 percent on 2009.

The deal with Endo looks excellent from all angles. Endo has a strong urology and oncology franchise and is a perfect partner for Bioniche and Urocidin. The absence of results from the first phase III trial is ameliorated by meeting pre-set efficacy targets.

Urocidin could be quite lucrative. The incidence of bladder cancer is not high (Bioniche puts it at 135,000 a year globally), but based on prevalence figures, Bioniche believes that Urocidin for refractory non-muscle invasive bladder cancer could be used in more than 130,000 patients a year.

If Endo were to negotiate a price per patient of $10,000 per year, which seems reasonable, the potential market could be around $1.5 - $2 billion.

Bioniche will appeal to investors who like the stability of the veterinary business mixed with the risk of human drug development. Purists might prefer one or the other.

Bioniche last traded down seven Canadian cents or 4.8 percent at $C1.40.

Marc Sinatra
Analyst

CHEMGENEX PHARMACEUTICALS

Chemgenex says updated data shows that Omapro produced durable responses in up to one-third of leukemia patients, who had failed with several tyrosine kinase inhibitors.

Chemgenex said the data, presented at the American Society of Hematology meeting in Orlando, Florida, showed that Omapro or omacetaxine mepesuccinate produced durable haematologic and cytogenetic responses in a significant proportion of chronic phase chronic myeloid leukemia patients, who had failed previous attempts to control their disease with two or three US Food and Drug Administration-approved tyrosine kinase inhibitors.

Chemgenex lead investigator and the chair of the chronic myeloid leukemia section of the University of Texas MD Anderson Cancer Center Dr Jorge Cortes concluded that Omapro was a new potential therapy for patients with multi- tyrosine kinase inhibitor-resistant chronic myeloid leukemia (CML).

The company said that data from 61 evaluable CML patients in chronic phase - defined as those who had been adjudicated by an independent data monitoring committee and had a bone marrow report available for cytogenetic assessment.

One third (33%) of patients who had failed two TKIs had a major cytogenetic response (MCyR). These patients failed imatinib and were also resistant to dasatinib or nilotinib.

There was a major cytogenetic response rate of 20 percent in patients that had failed three TKIs, imatinib, dasatinib and nilotinib.

Chemgenex said data was also presented from the complete group of 85 chronic phase patients analyzed on an intent to treat basis.

Chemgenex said the data showed an overall major cytogenetic response rate of 20 percent with a median duration of response of 7.4 months (range 0.9 - 26+ months; along with a complete haematological response rate of 73 percent with a median duration of 8.2 months (range 0.7 - 42+ months); and a median overall survival of 30 months.

Chemgenex said the most commonly reported (>5%) grade 3 and 4 treatment-emergent adverse events in the larger, 85 chronic phase patient population were thromobocytopenia (64%), anemia (34%), neutropenia (47%), febrile neutropenia (14%), leukopenia (21%), lymphopenia (18%), pancytopenia (9%) and bone marrow failure (11%) and fatigue (5%). Grade 3 and 4 events were infrequent and managed by decreasing the days of dosing per cycle.

The poster, 'Subcutaneous Omacetaxine (OM) Treatment of Chronic Phase (CP) Chronic Myeloid Leukemia (CML) Patients Following Multiple Tyrosine Kinase Inhibitor (TKI) Failure' is available at: http://ash.confex.com/ash/2010/webprogram/Paper31550.html

Chemgenex chief executive officer Dr Greg Collier said the company was "very pleased with the data presented today that reveals the potential clinical benefit Omapro could have for a significant number of CML patients who, at present, have very limited treatment options".

Chemgenex said it planned to file a new drug application for Omapro for the treatment of chronic myeloid leukemia patients who have failed two or more tyrosine kinase inhibitors.

Chemgenex said the analysis was based on data from existing phase II clinical trials designed to evaluate the safety and efficacy of subcutaneously-administered omacetaxine in patients who had failed imatinib and had the T315I mutation, or were intolerant to two or more tyrosine kinase inhibitors respectively.

Eligible patients were adult CML patients in chronic, accelerated, or blast disease phase and were given 1.25 mg/m2 omacetaxine twice daily for 14 days every 28 days until a haematologic response for induction therapy. For maintenance therapy, patients were dosed 1.25 mg/m2 omacetaxine twice daily for seven days every 28 days.

Chemgenex was up half a cent or 1.1 percent to 45.5 cents.

MARC SINATRA'S BIOGUIDE BRIEF: CHEMGENEX

As the world knows, earlier this year, Chemgenex didn't gain US Food and Drug Administration approval for its drug Omapro to treat chronic myeloid leukaemia patients with the T315I mutation, which creates resistance to the current treatments for CML. This had a very negative impact on Chemgenex's share price.

With FDA encouragement, Chemgenex has focused on Omapro's second indication, chronic myeloid leukaemia patients who have failed two or more tyrosine kinase inhibitors, rather than the T315I indication.

In a surprise move in October, Cephalon Inc agreed to subscribe for up to $15 million dollars of convertible notes, at a conversion price of 50 cents share, a 13 percent premium to the share price. At the same time two major shareholders, Stragen International NV and Merck Sante SAS, entered into an option agreement for Cephalon to acquire up to 19.9 percent of the combined shares held by them at an exercise price of 70 cents. Stragen and Merck received no other fee for granting this option apart from $10.

The options are convertible anytime before the later of March 31, 2011 or one week after the data collection and analysis period has been completed for the study in patients who have failed multiple tyrosine kinase inhibitors. Similarly, no interest will be payable on the convertible notes and a charge taken over Chemgenex's assets released if the collection and analysis is completed by March 31, 2011.

So what do we make of all of this? I think the first point is that Cephalon is very interested in Chemgenex and its Omapro, but does see the data collection and analysis of the trial as a fairly big risk. I don't think the issue is whether Omapro works, plenty of independent studies demonstrate it does. Furthermore, the updated trial results announced by Chemgenex today are very good.

The issue in the eyes of Cephalon is whether Chemgenex has performed its study adequately to show Omapro works, as compared to the problems demonstrating efficacy to the FDA with the previous T315I indication application.

The logic of Stragen and Merck granting a virtually free option over their Chemgenex shares is probably due to the nature of their holdings. Stragen was paid in shares for Omparo patents and Merck Sante invested in the previous metabolic-focused Chemgenex and has held those shares, possibly awaiting a reasonable offer. Omapro isn't really a strategic fit with either company. Stragen is a generics developer and manufacturer and while Merck Sante does have an interest in cancer, that interest is in solid tumors mainly through its antibody-based therapeutic Erbitux and other products in development.

It should be noted that Stragen and Merck Sante are not investment houses. If they take a stake in another company, there will be, or at least should be, a strategic rationale behind it. Once that stake is no longer strategic, it is a disposable asset. My guess is that Stragen and Merck took the view that it was worth holding their stakes in Chemgenex based on the share price appreciation and increased liquidity that the T315I approval would have brought. This, in turn, would have allowed them to sell what they considered to be a disposable asset rather easily into a more liquid market at a good price.

Unfortunately, for them (and me) that didn't happen and they have simply decided to get out at the first available opportunity.

The remaining major shareholders, Alta Partners and GBS Ventures, are investment houses and together control about 23 percent of Chemgenex. Because they are investment houses, by definition, their investments in Chemgenex are strategic and they are likely to hold as long as they believe they will make an acceptable return.

So, what does all of this mean for my pre-FDA T315I hiccup valuation of $5.50 for Chemgenex? In short, I have cut my valuation to $2.90 for two main reasons.

The first is the delay in taking Omapro to the market that the FDA's T315I hiccup has brought. The second and bigger issue is that I have now factored in a much higher level of clinical trial risk, given the comments by the Oncologic Drugs Advisory Committee during and after review of Omapro's new drug application for the T315I mutation and the nature of the deals Cephalon has struck with Chemgenex, Stragen and Merck.

The next question is: will the share price ever see this valuation? For it to happen, one of two things needs to occur.

Firstly, another party interested in Chemgenex has to enter the fray with an ensuing bidding war. Such a war broke out for Vision Systems in 2006, pushing its price from around $1.65 to $3.75.

It is worth noting, however, that both Stragen and Merck have directors on the Chemgenex board and would know who has expressed interest in the company. The obvious suitors for Chemgenex are Hospira, which has licenced the European rights of Omapro; Novartis, who makes the TKI's Gleevec (imatinib) and Tasigna (nilotinib); and Bristol-Myers Squibb, whose TKI Sprycel (dasatinib) was recently granted approval for first-line therapy of CML. The latter two companies are huge, $US126 billion and $US44 billion, respectively. If either decided they wanted Chemgenex, they would get it and my target valuation may well be seen.

The other scenario is that Alta Partners, whose 15 percent stake in Chemgenex could block Cephalon from proceeding to compulsory acquisition, holds out. This may be a risky move, though, since Cephalon, as a 30 percent shareholder, would have a significant say over the make-up of the board and would only need to acquire 21 percent more of Chemgenex to completely control it.

In all likelihood, though, I don't think we are going to see $2.90 a share, but how much lower than $2.90 it will go, I don't know and we probably won't see any great level of share price appreciation until data collection and analysis is complete.

At the moment, it looks like Cephalon may pick up another Australian biotechnology bargain, as it did buying Arana therapeutics in 2009 for $329 million, well below many analysts' valuations.

Marc Sinatra
Analyst

* Both Marc Sinatra and Biotech Daily editor David Langsam hold Chemgenex stock.

ADVANCED SURGICAL DESIGN AND MANUFACTURE

Advanced Surgical says interim results for the first five patients enrolled in its peripheral access device clinical trial has met the primary goals of the trial for all treatment sessions.

Advanced Surgical said the first group of patients in the 40 patient trial were all discharged from hospital after treatment.

The company said the first patient, with significantly advanced and complex pathology, subsequently went on to amputation, while the following four patients, also requiring imminent major amputation at the time of admission to the trial, were discharged from hospital with their legs intact.

The end point of the study, at six months after treatment, is yet to be reached.

Advanced Surgical said the peripheral access device (PAD was an implantable medical device for the reperfusion of limbs and in the treatment of patients suffering chronic peripheral artery disease and the pending amputation of a limb.

The device allows the patient's own blood to be returned under higher than normal pressures to aid the perfusion of blood to the affected limb.

The company said the trial's purpose was to assist patients in improving their quality of life and would be used to collect clinical evidence as part of national and international regulatory requirements for a class III device.

Advanced Surgical said Prof Rod Lane was both the principal investigator and the inventor of the treatment.

In his interim report Prof Lane said that all five patients were facing major amputation and all of the normal standard vascular approaches had been exhausted.

Prof Lane said all had rest pain, ischaemic ulcers, or gangrene.

"All patients had implantation of extraction and inflow devices with immediate significant pain relief," Prof Lane said.

"All five had significant improvement in the non-invasive estimates of blood flow," Prof Lane said.

"All patients were discharged with limbs intact," Prof Lane said.

"In three patients there was no gangrene, the ulcers had healed and there was no rest pain," Prof Lane said.

"One had significant residual gangrene and one had a healed ulcer but significant residual gangrene," Prof Lane said.

"As a practicing surgeon these results give great hope that we may soon be able to save thousand of patients' legs, improve their quality of living and cut healthcare costs for this terrible condition," Prof Lane said.

"For the patients themselves, each leg saved, along with the relief from pain and ulceration, is a great result," Prof Lane said.

The company said that peripheral artery disease was a major source of morbidity and mortality, with more than 1,000 limbs amputated daily in the western world.

About 40 percent of amputees die within 12 months of amputation.

Advanced Surgical chief executive officer Dr Greg Roger said his company was "very encouraged by the early results from this trial".

"Peripheral artery disease is a terribly debilitating, painful disease," Dr Roger said.

"We hope to be able to bring this innovative technology quickly to market and to help the many thousands of patients who are currently offered amputation as the only means of ending the shocking pain that these people suffer over a period of years," Dr Roger said.

Advanced Surgical was up 3.5 cents or 11.3 percent to 34.5 cents.

LBT INNOVATIONS

In a newsletter LBT said it had unveiled its latest technology for the microbiology laboratory market among annual general meeting documents on November 15, 2010.
LBT said its automated plate assessment system or APAS was a platform technology for the automation of agar plate screening and sorting.
The company said its first product, the Previ-Isola, automated the inoculation and streaking of agar plates and the APAS streamlined the next stages of the process.
LBT said the automated plate assessment system was “a digital technology for automated plate screening, evaluation and sorting” or “an intelligent digital eye”.
LBT said hundreds and sometimes thousands of plates were assessed in laboratories every day and each one had to be examined by a microbiologist for the presence of bacterial colonies.
The company said the automated plate assessment system “automatically sorts out the 60-90 percent of plates that are negative, freeing up the microbiologist’s time to look at the positive ones”.
LBT said it was seeking commercialization partners for automated plate assessment system and was in discussions with potential international partners.
The company said it had working prototype hardware and software and was ready to take the product through to full development.
In the LBT newsletter, chairman Bob Finder said APAS was that based on the results of extensive market research, “there appears to be substantial potential for the product across the global markets”.
“After only very modest expenditure on the development of APAS, it is to the stage where APAS is ready to go to the next step towards commercialization, which is a substantial achievement,” Mr Finder said. “LBT has commenced discussions with a view to licencing the technology to global commercial players.”
LBT was up 0.1 cents or 1.1 percent to nine cents

IB BIOSCIENCE MANAGERS

IB Bioscience Managers Australian Bioscience Fund 1 has returned 100 percent or $20 million to investors in the 29 months from July 1, 2008 to November 30, 2010.
IB Bioscience said the $2 unit price included all management fees, set-up costs and $20.5 million in return on capital and distributions.
IB Bioscience said the fund’s focus was on “active investment in innovative mid-stage Australasian bioscience companies, targeting outstanding technologies near or in clinical trials that offer international commercial opportunity and superior investment return by addressing unmet medical needs at a managed risk”.
The group said that current investments included Alchemia, Bionomics, Biota, Heartware, Hunter immunology, Pharmaxis and Sunshine Heart, with exits including Acrux, Arana, Neuren and Peplin.
Investors include Telstra Super, Meat Industry Employees Superannuation Fund, Asia Union Investments, Australian National University and IB Australian Bioscience Fund.
The fund is fully invested and closed.
The IB Fund Manager said it was launching the IB Asia Pacific Healthcare Fund II with “a wider investment universe, expanded team, and is targeting up to $200 million in funds under management.
Contact chief investment officer Matt McNamara via email at: enquiries@ibmanagers.com or telephone: +613 9629 8288.

QRX PHARMA

QRX says it has completed patient enrolment of its 141-patient pivotal phase III registration trial for its immediate release Moxduo IR.

QRX said the comparative study was designed to evaluate analgesic efficacy and safety of Moxduo IR, a fixed-dose combination of morphine and oxycodone, for managing moderate to severe pain in patients who have undergone total knee replacement surgery.

QRX chief financial officer Chris Campbell told Biotech Daily the trial's timeline had slipped by about two months, with results expected in February 2011 instead of the end of this year and a new drug application to be filed with the US Food and Drug Administration by July, instead of April 2011.

The company previously said that the comparative study at 10 centres in the US was evaluating the analgesic efficacy and tolerability of a flexible dose regimen (12mg and 8mg) versus a fixed low dose (3mg and 2mg) of Moxduo IR in patients with moderate to severe pain following total knee replacement surgery (BD: Sep 1, 2010).

Today the company said that due to the number of hospital sites reporting and potential delays over the holiday season, the company expected to release top-line data in February 2011, prior to the filing of its new drug application (NDA) with the FDA.

In the QRX media release chief executive officer Dr John Holaday said that when the study reached 50 percent enrolment, "we reported an interim data analysis that indicated a greater than a 90 percent probability of successfully detecting differences in analgesic effect".

"Now that patient enrolment is complete, we are optimistic that pending analysis of the final data will confirm statistical significance," Dr Holaday said.

"In study after study, Moxduo IR has consistently demonstrated as good or better pain relief with fewer incidences of moderate to severe side effects than current standards of care," Dr Holaday said.

"We expect that this study will not only achieve the primary analgesic endpoint, but also satisfy the remaining clinical study requirements for NDA filing," Dr Holaday said.

QRX was up half a cent or 0.4 percent to $1.16.

MESOBLAST

Mesoblast has requested a trading halt pending an announcement relating to a major deal with a pharmaceutical company.

Mesoblast said it was "concluding a major corporate transaction with a global pharmaceutical company, which may have a material impact on the price or value of the company's securities".

Trading will resume on December 8, 2010 or on an earlier announcement.

Mesoblast last traded at $3.33.

ATCOR MEDICAL

Atcor says it has signed a $US1.1 million contract with an existing customer to supply Sphygmocor systems and clinical trial support services.

Atcor said the customer was "a major international pharmaceutical company".

Atcor develops and markets the Sphygmocor non-invasive measurement of central blood pressures and arterial stiffness.

Atcor chief executive officer Duncan Ross said the contract was the company's "fifth new engagement since US healthcare reform legislation was signed".

Atcor was unchanged at eight cents.

CYCLOPHARM

Cyclopharm says the Australian Therapeutic Goods Administration has approved its cyclotron production and research facility at Macquarie University Hospital.

Cyclopharm said its wholly-owned subsidiary Cyclopet had been awarded the good manufacturing process (GMP) licence for the manufacture of its positron emission tomography radiopharmaceuticals.

Cyclopharm said the Macquarie University Hospital Cyclopet facility was “Australia’s most technologically advanced production and research facility for the manufacture of PET radiopharmaceuticals”.

The company said the facility was also Australia’s first commercial cyclotron radiopharmaceutical production centre to be collocated within a hospital.

Cyclopharm said Cyclopet would begin its commercial activities by producing the radiopharmaceutical compound F18 Flurodeoxyglucose (FDG), the most commonly used injectible radioactive marker used in positron emission tomography.

Cyclopharm fell half a cent or 5.9 percent to eight cents.

LIFE SCIENCES QUEENSLAND

The Queensland Government, the Queensland Clinical Trials Network and other industry stakeholders have created a new industry body - Life Sciences Queensland.

A media release from the Queensland Clinical Trials Network said Life Sciences Queensland was formally announced on December 3, 2010 to bringing together a broad range of stakeholders in the life sciences sector.

Queensland Clinical Trials Network chief executive officer and member of the Life Sciences Queensland steering group Mario Pennisi told Biotech Daily that the new body was borne from discussions with Premier Anna Bligh to emulate the success of Canada’s Life Sciences BC (British Columbia).

Mr Pennisi said the group responded to the question: “What does the Queensland industry need to take it to that level?”

In its media release the Queensland Clinical Trials Network said Life Sciences Queensland would “assist the growth of individual firms and organizations and build the profile, capacity and capability of the sector to ensure long term economic, social and environmental benefits to Queensland”.

The Network said the major focus of said Life Sciences Queensland would be to facilitate the future growth and sustainability of Queensland’s life sciences industry and enhancing Queensland’s national and international reputation as a centre of commercial and research excellence in life sciences”.

The Network said foundation supporters included Alchemia, the Australian Institute of Marine Science, Davies Collison Cave, Ernst and Young, Griffith University, Impedimed, James Cook University, Price Waterhouse Coopers, Queensland University of Technology, Sanofi Aventis, the University of Queensland and the University of the Sunshine Coast.

The president of the Queensland Clinical Trials Network management committee Prof Tony Webber said that Life Sciences Queensland would give the local industry a global advantage.

The Network said the Queensland Government had committed to providing financial support to Life Sciences Queensland during the implementation phase and its first four years of operation, with industry organizations and universities pledging financial support and committed to being founding supporters.

AGENIX

Annmac Investment trading as the Anne McNamara Investment Fund has increased its substantial holding in Agenix and been diluted thorough its capital raisings.
Annmac said in its substantial shareholding that it increased and was diluted from 142,319,876 shares (21.70%) to 147,251,831 shares (20.49%).
Agenix was unchanged at 2.2 cents.

PHYLOGICA

Phylogica says founding director Harry Karelis has resigned as a director.
Phylogica said Mr Karelis had “regrettably advised that he has tendered his resignation due to his conflicting business interests and other constraints on his capacity to continue as a director of Phylogica”.
The company said Mr Karelis had been with Phylogica since listing in 2005 and as a representative of one of the largest shareholders would maintain contact with the board.
Phylogica was untraded at five cents.