Biotech Daily

Friday November 6, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: VIRALYTICS UP 16%; GENETIC TECHNO DOWN 29%**

*** BIOTECH DAILY 10th BIRTHDAY**

*** VIRALYTICS, MERCK CAVATAK, KEYTRUDA CANCER COLLABORATION**

*** PSIVIDA EXPANDS TO OSTEOARTHRITIS PAIN**

*** UNILIFE WEARABLE INJECTOR DEAL WITH MEDIMMUNE**

*** GENETIC SIGNATURES, UCLA COLLABORATE ON MOLECULAR TESTING**

*** MEDIBIO, VITAL CONVERSATIONS 1st STRESS TEST CUSTOMER**

*** RESAPP REQUESTS 'STUDY RESULTS' TRADING HALT**

*** ACTINOGEN TO RELEASE 125m CORTICRINE ESCROW SHARES**

*** GOLDMAN SACHS BELOW 5% OF NANOSONICS**

MARKET REPORT

The Australian stock market was up 0.42 percent on Friday November 6, 2015 with the ASX200 up 22.0 points to 5,215.0 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 10 fell, 11 traded unchanged and four were untraded.

Viralytics was the best, up 9.5 cents or 16.2 percent to 68 cents with 796,448 shares traded.

Circadian climbed 8.2 percent; Compumedics was up 6.7 percent; Anteo, Cellmid, Polynovo, Starpharma and Universal Biosensors were up more than three percent; Admedus, Benitec, CSL and Impedimed rose more than one percent; with Acrux, Bionomics, Cochlear, Pro Medicus and Sirtex up by less than one percent.

Yesterday's 100 percent best, Genetic Technologies led the falls, retreating 1.1 cents or 28.95 percent to 2.7 cents with 22.3 million shares traded.

Living Cell and Orthocell fell six percent or more; Biotron lost 5.45 percent; Prana fell 4.2 percent; Clinuvel and Psivida were down more than three percent; IDT, Medical Developments and Neuren shed more than one percent; with Resmed down 0.1 percent.

BIOTECH DAILY 10TH BIRTHDAY EDITORIAL

Tonight's edition will be a momentous marker for Biotech Daily, having published about 250 editions a year, for 10 orbits of the Sun, with an average of 10 articles per edition.

Ten years ago, most of the life science companies were in pre-clinical, phase I or, at best, phase II trials. Many of them, including Acrux, Arana, Avita, Bionomics, Cellestis, Chemgenex, Compumedics, Cytopia, Heartware, Impedimed, Medical Developments, Mesoblast, Nanosonics, Peplin, Pharmaxis, Psivida, Sirtex, Starpharma, Universal Biosensors and Uscom, have gone through phase III to registration and/or acquisition.

It was serendipity that Biotech Daily began publishing in 2005, a time when a number of life science companies had just listed. Each year has had its wins and losses.

And 2015 has been a very different year to the previous one, with a raft of new listings, backdoor transformations, capital raisings, trial and regulatory successes, not to mention a welcome change in Federal Government personnel and policy.

This time last year, the Australian biotechnology community was reeling at the convictions of Phosphagenics chief executive officer Dr Esra Ogru and Genetic Technologies founder Dr Mervyn Jacobson, with former Acuvax chief executive officer Dr William Ardey also before the courts and gaoled in May this year – and all for fraud of one sort or another.

The co-inventor of the troublesome peptide fragment AOD9604 Dr Woei-Jia Jiang should be released from gaol tomorrow for his part in the Phosphagenics Three fraud, with Dr Jacobson expected to be released later this month, albeit unable to run a company for a further four years. Dr Ogru and her co-conspirator Dr Robert Giannello face another year behind bars, while Dr Ardrey has three and half years to go. Select Vaccines Martin Soust remains banned from running a company for another few years.

There's a moral in this account: don't lie and cheat and steal. If only Listing Rule 3.1 on transparency was ever enforced it might set an example. But then again, as Captain Barbossa says "The Pirates Code is more like yer guidelines than yer actual regulations".

The good news begins with the renewed interest in the sector from the Coalition Federal Government of Prime Minister Malcolm Turnbull, along with similar good intentions for innovation being expressed by the State Labor Governments of Victoria's Daniel Andrews and Queensland's Annastacia Palaszczuk. Having governments of different political persuasions in agreement is a great start. Hopefully the intentions will result in funding.

The return of the Biotech Daily Top-40 Index above the cumulative $7,000 million mark on Monday was also a positive sign, although we all know that share prices can go down as well as up.

Without going into great detail about the year so far, it is fair to say that the successes have been the best in many years, with the Spinifex and Hatchtech deals giving the sector a major lift, along with Avita and Polynovo winning significant BARDA contracts, and major deals by Antisense, Pharmaxis and Starpharma.

As we go to publication tonight Mesoblast is in the middle of the biggest capital raise the (non-Big Cap) sector has seen, about $100 million.

Good news, indeed.

In reviewing a decade of reporting on the life sciences, I am reminded of the question that the manager of the Commonwealth Scientific and Industrial Research Organisation's Central Information Service and Scientific Attache to Washington, Clyde Garrow, would ask his children at the dinner table after school: "So, what did you learn, today?"

There are a number of lessons worth mentioning:

1.) If you think it will cost $20 million to complete a licence agreement at the end of phase II, don't listen to brokers who say raise $5 million now and raise again when you meet milestones. No. Raise $40 million because it will take twice as long and cost twice as much as you expect.

2.) And if you have that money, be polite to, but totally ignore, shareholders complaining about the share price. Hire an in-house investor relations person to soothe the nervous jitters, while the executives get on with real work. Watching the share price will drive you mad, but that could be an opportunity for an anxiety drug currently in development.

3.) Burying negative information on page 13 of a 20 page 'Quarterly Investor Newsletter' or a 'Corporate Presentation' is not transparency, although the ASX accepts that it is. You will be smacked by the market for the bad news and smacked twice for hiding it. And we shall all remember.

4.) Almost as bad is burying good news in the middle of a media release after spending several paragraphs talking gobbledygook about how wonderful your company is and the global value of the indication. The drug worked for the indication at a statistically significant higher rate than the current standard treatment.

5.) Promise less and deliver more.

6.) Do not shovel funds for trials into your personal accounts, do not prop-up share prices to win an end-of-year bonus or keep a margin call at bay.

7.) Do re-subscribe to Biotech Daily.

At the end of this year, to mark the 10 years of continuous publication without missing a single important announcement, Biotech Daily will take advantage of the fall of Christmas and Australia Day on the calendar and take a five-week instead of the usual four-week Summer Holiday. The last edition will be Friday December 18, returning with a Summer Catch-Up Edition and back to normal transmission on January 27, 2016.

To acknowledge the fact that none of this would have been possible without you, our subscribers, the subscription rates for 2016 will remain unchanged.

Thank you, kindly.

David Langsam, Editor

VIRALYTICS

Viralytics says it will collaborate with Merck & Co in an 80-patient phase Ib evaluation of Cavatak with the anti-programmed death receptor-1 Keytruda in cancer.

Viralytics said the agreement with the Kenilworth, New Jersey-based Merck, known as Merck Sharp and Dohme outside the US and Canada, would evaluate the safety and efficacy of the immunotherapy combination in patients with either advanced stage non-small cell lung cancer or metastatic bladder cancer.

The company said the trial was planned to begin in 2016.

Viralytics said that both Cavatak and Keytruda were immunotherapies “designed to enhance the body’s own defences in fighting cancer”.

The company said that Cavatak was based on the Coxsackievirus A21 cold virus that had been shown to preferentially infect and attack cancer cells and Keytruda was a humanized monoclonal antibody that worked by increasing the ability of the body’s immune system to help detect and fight tumour cells, by blocking the interaction between programmed death receptor-1 (PD-1) and its ligands, PD-L1 and PD-L2, and might affect both tumor cells and healthy cells.

Viralytics chief executive officer Dr Malcolm McColl said the trial was “the first to explore the combination of an intravenously delivered oncolytic virotherapy with a checkpoint inhibitor such as Keytruda in non-small cell lung and metastatic bladder cancer”.

Merck Research Laboratories head of oncology early-stage development Dr Eric Rubin said that “there may be potential benefit in combining Cavatak with our anti-PD-1 therapy, Keytruda, which have different, yet complementary approaches to engaging the immune system to fight cancer”.

Viralytics said that the phase Ib combination trial would be the second stage of its ongoing systemic treatment of resistant metastatic disease (Storm) clinical trial.

The company said that the first stage of the study focussed on assessing the intravenous administration of Cavatak as a monotherapy in late-stage solid cancers.

Viralytics said that initial results indicated that multiple intravenous infusions of Cavatak were well-tolerated and produced potential tumor viral replication in some advanced cancer patients, with anti-tumor activity seen in some individual lesions.

The company said that the second stage of the Storm trial hds been re-designed to assess the intravenous delivery of Cavatak in combination with Keytruda in patients with advanced non-small cell lung cancer or metastatic bladder cancer.

Viralytics said that the trial would be an open-label, multi-centre study with dose escalation of Cavatak in combination with fixed doses of Keytruda, followed by an expansion cohort phase.

The company said that the final cohort would contain about 80 patients, across both indications.

Viralytics said that the aim of the study was to establish a recommended dose regimen for the Cavatak-Keytruda combination and to evaluate anti-cancer activity and patient tolerability.

The company said that patient biopsies would be assessed for changes in the tumor micro-environment that might provide a further signal of activity.

Viralytics said it would provide Cavatak and sponsor the study, while Merck would provide Keytruda and conduct biomarker analysis.

The company said that the agreement included a provision that the parties could extend the collaboration to include a potential phase III clinical trial.

Viralytics said that additional details of the collaboration were not disclosed.

Viralytics climbed 9.5 cents or 16.2 percent to 68 cents.

PSIVIDA

Psivida says it is collaborating with the New York-based Hospital for Special Surgery to develop an implant for the treatment of pain associated with severe knee osteoarthritis.
The company said that the implant comprised a screw with an embedded Durasert device surgically implanted in the knee designed to deliver a corticosteroid directly to the joint on a sustained basis to provide long-term pain relief and delay or eliminate the need for knee replacement surgery.
Psivida said that following promising preclinical data an investigational new drug application had been filed to the FDA and the collaboration was awaiting information from the FDA for any additional requirements for initiating a clinical trial.
The company said that the FDA had approved the use of six month rather than 12 month data in its phase III trials of Medidur for posterior uveitis.
Psivida said it planned to file a new drug application based on six-month efficacy data from its two phase III trials, rather than 12-month data from one trial and six-month data from the second trial (BD: Sep 29, 2015).
The company said that all patients in the first phase III trial completed six months of follow-up in September 2015 and it expected to report top-line results from the first trial in December 2015, while enrolment in the second trial was on schedule, with the new drug application for Medidur to be filed by July 2017.
Psivida said it was in discussions with the European Union's Medicines and Healthcare Products Regulatory Agency to determine approval requirements for the EU.
The company said that top-line results from an ongoing study of low and high doses of Medidur showed a statistically significant reduction in recurrence of uveitis ($p = 0.014$), which was also the primary endpoint in the phase III trials, and a statistically significant improvement in visual acuity ($p = 0.014$) at the last follow-up visit in eyes treated with Medidur compared to those not treated with Medidur (BD: Jul 14, 2015).
Psivida fell 19 cents or 3.5 percent to $5.20.

UNILIFE CORPORATION

Unilife says it has signed the first supply agreement under its November 2013 development and supply agreement with Astrazeneca's Medimmune.
Unilife said that the agreement provided commercial terms for the supply of a customized device from its Precision-Therapy platform of wearable injectors for a monoclonal antibody in late-stage clinical studies.
The company said that the agreement followed the terms defined in the 2013 agreement for the customization and supply of wearable injectors for use with Medimmune's drug candidates.
Unilife said the customization phase for the lead wearable injector program for MedImmune was nearing completion and device production had begun, with wearable injectors to be shipped to Medimmune by the end of the year.
The company said that along with development and material fees already paid by Medimmune, it would generate revenue from the sale of the devices this year.
Unilife said that the supply agreement provided minimum purchase commitments from Medimmune for the initial four years following the commercial launch of the biologic, and has unit pricing for the devices.
Unilife fell 2.5 cents or 9.1 percent to 25 cents with 3.7 million shares traded.

GENETIC SIGNATURES

Genetic Signatures says it will collaborate with the University of California, Los Angeles to analyze molecular testing methods for bacteria, viruses and parasites.
Genetic Signatures said that UCLA's Dr Scott Binder and his team would compare molecular testing to traditional testing in an effort to reduce the spread of infection in the US healthcare system.
Genetic Signatures chief executive officer Dr John Melki said that "quick and accurate identification of co-infections including pathogens that are difficult to detect, such as [Dientamoeba] fragilis are vital in improving outcomes".
"Broad pathogen detection improves targeted use of anti-microbial treatment, patient triage and reduced average length of stay," Dr Melki said.
Genetic Signatures was unchanged at 52.5 cents.

MEDIBIO

Medibio says its cardiac corporate stress product partner Vital Conversations has signed its first customer.
In September, Mediobio launched its "corporate wellness partner program" with an agreement to provide its cardiac corporate stress product to the Perth Western Australia-based Vital Conversations (BD: Sep 25, 2015).
The Vital Conversations website describes its staff as psychologists and coaches and says it specializes in psychology, coaching, organisational development, profiling and leadership.
Today, Medibio said that Vital Conversations had reached agreement with its first customer, a corporation, which cannot be disclosed due to commercial sensitivities, but had more than 5,000 employees in Australia and 200,000 worldwide.
The company said that the agreement covered a commercial pilot program involving the corporation's Western Australian staff, which would generate revenue.
Medibio said it would provide data analytics and reporting on a per test basis to Vital, the customer, and the customer employees who were tested.
The company said that it expected the pilot program would open for staff enrolment in December with a launch date for the testing and revenue in February 2016.
Medibio was up half a cent or 1.2 percent to 41.5 cents.

RESAPP

Resapp has requested a trading halt "pending the release of an announcement regarding additional clinical study results".
Trading will resume on November 10, 2015 or on an earlier announcement.
Resapp last traded at 7.8 cents.

ACTINOGEN

Actinogen says that the 12 month voluntary escrow period for 125,000,000 shares issued for the acquisition of Corticrine will expires on December 1, 2015.
In 2014, Actinogen acquired Corticrine from the University of Edinburgh for its Alzheimer's disease drug candidate, UE2343, which Actinogen later renamed Xanamem (BD: Aug 27, Dec 1, 2014).
Actinogen was untraded at 5.5 cents.

NANOSONICS

The Delaware-based Goldman Sachs Group says it has ceased its substantial shareholding in Nanosonics, yet again.

After the market closed last night and following the notice yesterday morning that it had again become substantial in Nanosonics with 14,619,538 shares or 5.16 percent, Goldman Sachs said it had reduced its holding below the five percent substantial shareholder threshold (BD: Oct 2, 5, 15, 16, 20, 21, 23, 27, 28, Nov 5, 2015).

Goldman Sachs said that subsidiary Rothesay Life returned 998,390 shares “to the counterparty under a repurchase agreement” for no applicable consideration.

Previously, under a counterparty agreement, Goldman Sachs said it had returned, lent and borrowed shares held by subsidiaries, Rothesay Life, JP Morgan Chase, RBC Dexia Australia, HSBC Custody Nominees and the Bank of New York Mellon (BD: Apr 13, 2015).

Nanosonics was unchanged at $1.65.