



# Biotech Daily

Tuesday October 28, 2014

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: MEDICAL DEVELOP UP 13%, CLINUVEL DOWN 11%**
- \* **MONASH BECOMES PFIZER'S 1<sup>st</sup> NON-US INNOVATION CENTRE**
- \* **PSIVIDA RECEIVES \$28m ILUVIEN MILESTONE**
- \* **UP TO 24% OF SIRTEX OPPOSE 60% DIRECTORS POOL INCREASE**
- \* **GI DYNAMICS APPLIES TO TRADE ON NASDAQ**
- \* **BAILLIEU HOLST RE-INITIATES BIOPROSPECT RESEARCH COVERAGE**
- \* **OBJ AGM FOR 45m DIRECTORS' PERFORMANCE RIGHTS**
- \* **PROBIOTEC 2<sup>nd</sup> STRIKE BOARD SPILL AGM**
- \* **IDT REQUESTS ACQUISITION, CAPITAL RAISING HALT**

## MARKET REPORT

The Australian stock market slipped 0.12 percent on Tuesday October 28, 2014 with the ASX 200 down 6.4 points to 5,452.6 points. Seven of the Biotech Daily Top 40 stocks were up, 21 fell, 11 traded unchanged and one was untraded.

Medical Developments was the best, up 14 cents or 12.6 percent to \$1.25 with 45,793 shares traded.

Genetic Technologies and Viralytics climbed more than seven percent; Mesoblast was up 5.2 percent; Sirtex rose two percent; Atcor, CSL and Neuren were up more than one percent; with Cochlear up 0.3 percent.

Yesterday's 75.2 percent best, Clinuvel, led the falls, retreating 49 cents or 10.7 percent to \$4.10 with 174,906 shares traded, followed by GI Dynamics down 10.3 percent to 26 cents with 958,331 shares traded.

Optiscan lost 9.1 percent; Uscom fell 8.3 percent; Prana and Universal Biosensors were down more than six percent; Benitec, Circadian and Ellex fell more than five percent; Oncosil, Pharmaxis and Tissue Therapies fell more than four percent; Acrux, Analytica and Anteo were down more than three percent; Avita, Bionomics, Impedimed, Prima and Starpharma were down more than one percent; with Nanosonics down one percent.

## PFIZER, MONASH UNIVERSITY

Pfizer is collaborating with Monash University as its first Australian 'Centre for Therapeutic Innovation' with first drug candidates to be considered on Thursday, October 30, 2014.

Pfizer's Centres for Therapeutic Innovation senior vice-president and chief scientific officer Dr Anthony Coyle was in Melbourne ahead of the first steering committee meeting to be held at Monash University.

Dr Coyle told Biotech Daily that Pfizer established to Centres in 2010 to better integrate the pharmaceutical company with academic discovery.

Dr Coyle said that Pfizer recognized that "we can make drugs and they do innovation" and there needed to be a better way to work together "in a true partnership" and to overcome cultural differences between the two types of institutions.

He said that Pfizer had established four Centres for Therapeutic Innovation in Boston, New York, San Francisco and San Diego collaborating closely with 24 leading universities including the University of California San Francisco, New York University, Cornell and Sloan Kettering.

Dr Coyle said that Pfizer employed about 100 staff across the Centres and had built 35 research teams, employing a total of about 500 staff, both internally and externally, who were involved in research and development from discovery to phase I clinical studies.

Dr Coyle said that collaborating academic institutions received full access to Pfizer's facilities for chemical and antibody libraries, manufacturing and toxicity studies.

He said that the teams submitted ideas to the Centre oversight board which would evaluate whether it was a worthwhile project.

Dr Coyle said that Pfizer formerly used academia as contract research organizations and key opinion leaders but didn't partner closely, while academia faced a "valley of death" in early stage development, with no US National Institutes of Health funding for pre-investigational new drug application manufacturing.

He said that the Centres for Therapeutic Innovation were intended to take jointly owned molecules from the laboratory bench to the end of phase I safety and efficacy signal studies, at which point Pfizer would either exercise its option to acquire the intellectual property or hand it back to the institution with all the data generated.

"The reason the CTI exists is to translate from discovery to the end of phase I and not just make the molecules, but take them into the clinic together," Dr Coyle said.

Dr Coyle said that the San Francisco Centre was located on the campus of University of California San Francisco close to hospitals and laboratories.

"On a daily basis we see investigators and patients," Dr Coyle said.

He said that the method of funding was more like a venture capital firm, requiring the achievement of milestones to proceed to further development, rather than a blank cheque for basic research.

Dr Coyle said that the agreement signed with Monash University was the first Pfizer Centre for Therapeutic Innovation outside the US and it would provide researchers at Monash full access to Pfizer's drug discovery, toxicology, manufacturing and investigational new drug application-enabling facilities.

He said the first steering committee meeting on Thursday would bring together representatives of Monash and Pfizer and look at "a dozen or more proposals" across oncology, immuno-oncology and inflammation.

Dr Coyle said that although the Monash Pfizer Centre would rely on virtual connections, Monash researchers would have access to Pfizer's Californian facilities for additional technology and drug development capabilities.

### PSIVIDA

Psivida says it has received Alimera Sciences \$US25 million (\$A28.3 million) milestone payment for US approval of Iluvien for diabetic macular oedema (BD: Sep 29, 2014). Psivida chief executive officer Dr Paul Ashton said the payment "together with our cash on hand should fund our planned product development and other operations into ... 2017". "In addition, we will receive 20 percent of any net profits from sales of Iluvien for [diabetic macular oedema] on a country-by-country basis as well as royalties on sales of Retisert," Dr Ashton said.

"Our lead product candidate, Medidur for the treatment of chronic posterior uveitis, uses the same micro-insert delivering the same drug as Iluvien," Dr Ashton said.

"Medidur is currently being studied in a pivotal phase III clinical trial," Dr Ashton said.

"If the FDA concurs, we plan to file a new drug application for Medidur based on data from this single trial, together with supplementary data from a study of our proprietary inserter," Dr Ashton said.

"Our pre-clinical research is focused on use of our Tethadur and Durasert platform technologies to deliver biologics to the eye and systemically, and to treat wet and dry age-related macular degeneration, glaucoma and other retinal diseases and osteoarthritis," Dr Ashton said.

Psivida was unchanged at \$4.72.

### SIRTEX MEDICAL

The Sirtex annual general meeting voted significant dissent against the 60 percent increase in the pool of directors remuneration from \$625,000 to \$1,000,000. The proposal was opposed by 6,589,824 votes (23.8%), with 21,060,071 votes (76.2%) in favor.

The company's most recent Appendix 3B new issue announcement said that Sirtex had 56,524,273 shares on issue, meaning that the votes against the increase in directors remuneration amounted to 11.65 percent of the company, sufficient to requisition extraordinary general meetings.

Sirtex said that there were 5,261,617 proxy votes (18.8%) against the remuneration report, with 22,676,087 proxy votes (81.2%) in favor.

Director Richard Hill was re-elected with 1.3 million votes against and 27.0 million votes in favor and the issue to chief executive officer Gilman Wong of 73,000 'performance rights' was passed overwhelmingly.

Sirtex climbed 50 cents or 2.0 percent to \$25.19 with 649,736 shares traded.

### GI DYNAMICS

GI Dynamics says it has filed an application to list its US common stock for trading on the Nasdaq under the symbol 'GID'.

GI Dynamics said the listing was subject to review by the Nasdaq and dependent on the company meeting all of the necessary listing requirements.

The company said it applied to list on the Nasdaq "to enhance trading liquidity and market visibility, particularly for those investors who are not able to trade in the company's Australian listed CHESS Depositary Interests (CDIs).

GI Dynamics said that if the application was successful, its CDIs would continue to be listed on the ASX, as they have been since the initial public offering in September 2011 and its US shares of common stock would trade on the Nasdaq.

GI Dynamics fell three cents or 10.3 percent to 26 cents.

## BIOPROSPECT

Bioprospect says that Baillieu Holst has re-initiated research coverage on the company and Invatec test to diagnose mental health conditions through heart rate variability. Baillieu Holst initiated coverage on Bioprospect in August 5, 2014 with analyst Stuart Roberts saying that the Invatec test was “based on measured differences in heart rate variability analyzed using proprietary algorithms”.

Mr Roberts said that Bioprospect “argues that its test is simple, non-invasive, safe and quick, with potential to become the world’s first quantitative, evidenced-based test for mental illness ... [and was] currently optimizing the technology to the point where it detects [about 90 percent] of all mental health cases where there has previously been a physician diagnosis”.

Mr Roberts said at that time and restated in the research report date October 27, 2014 that “peer-reviewed papers have established the connection between heart rate variability and depression” and quoted a University of Sydney led by psychologist Andrew Kemp in 2010 that showed in a meta-analysis of depressed patients without cardiovascular disease that depression went with lower heart rate variability and depression severity was negatively correlated with heart rate variability.

Mr Roberts’ research reports said that “Kemp et al were able to establish in 2012 that the reduced [heart rate variability] in depression was not driven by antidepressants, firmly establishing [heart rate variability] as a depression biomarker”.

But the ability to move from a 73-patient study showing a correlation between major depressive disorder and heart rate variability, to a diagnostic using heart rate variability to diagnose depression has been questioned by several correspondents, including the author Andrew Kemp.

The article by Mr Kemp entitled, ‘Depression, Comorbid Anxiety Disorders, and Heart Rate Variability in Physically Healthy, Unmedicated Patients: Implications for Cardiovascular Risk’, was published by the Public Library of Science One in February 2012 and is at: <http://www.plosone.org/article/info:doi/10.1371/journal.pone.0030777>.

A separate paper studying 4,750 patients found that “Depressed participants not taking antidepressants (n = 317) did not differ from controls on any measures of [heart rate variability]” and concluded that reductions in heart rate variability in depressed older adults were driven by the effects of antidepressant medications”.

The larger study, entitled ‘Antidepressants strongly influence the relationship between depression and heart rate variability: findings from The Irish Longitudinal Study on Ageing’ was published in Psychological Medicine in July 2014 and an abstract is available at: <http://www.ncbi.nlm.nih.gov/pubmed/25075912>.

On August 7, Mr Roberts emailed that Baillieu Holst was “Ceasing coverage” in Bioprospect and withdrew the previous price target of 0.7 cents a share saying “After reviewing our portfolio of stock coverage, Baillieu Holst Research has decided that [Bioprospect] no longer fits the industry segments which we target for coverage.” Bioprospect was trading at 0.4 cents a share at that time.

Subsequently, long term Bioprospect shareholder and former director Elias Leo Khoury reduced his holding to below substantial and former Chemgenex executive Dr James Campbell was appointed a director (Sep 8, 10, 16, 2014).

Today’s research report said that Bioprospect was trading at 0.3 cents a share and set a price target of 0.9 cents a share.

Bioprospect was unchanged at 0.3 cents with 10.45 million shares traded.

### OBJ

The OBJ annual general meeting will vote to issue directors Glyn Denison, Dr Christopher Quirk and Jeffrey Edwards 15,000,000 'performance rights' each.

OBJ said that the rights would vest on three technology licencing milestones and expire within three years of issue.

The company said that resolutions included the re-approval of the performance share plan, the employee share option plan, approval of the 10 percent placement capacity as well as the re-election of director Dr Quirk.

The meeting will be held in the John Worsford Room, Patersons Stadium, Gate 12, Level 3, Roberts Road, Subiaco, Western Australia on November 28, 2014 at 10am (AWST).

OBJ was unchanged at 9.9 cents with 5.7 million shares traded.

### PROBIOTEC

Probiotec's annual general meeting will vote on the remuneration report, a potential second strike board spill and the re-election of directors.

Last year, Probiotec's remuneration report was opposed by 3,780,094 votes (34.2%) with 7,263,123 votes (65.8%), providing the first trigger for a potential board spill at this year's annual general meeting.

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and at the later meeting and if passed by more than 50 percent of votes the directors must stand for reelection at a subsequent meeting within 90 days.

If the spill vote fails, the trigger is reset to no opposition.

Probiotec shareholders will also vote on executive option plan and the re-election of director Robin Tedder.

The meeting will be held at Probiotec, 83 Cherry Lane, Laverton North, Victoria on November 27, 2014 at 10am (AEDT).

Probiotec was up two cents or 7.1 percent to 30 cents.

### IDT AUSTRALIA

IDT has requested a trading halt pending the release of an announcement "regarding a potential acquisition and an associated capital raising".

Trading will resume on October 30, 2014 or on an earlier announcement.

IDT last traded at 22.5 cents.