



Biotech Daily

Tuesday October 25, 2016

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: OSPREY UP 8%; BENITEC DOWN 12%**
- * **J&J'S DR JEANNE BOLGER: 'NO LIMIT TO OUR INVESTMENT'**
- * **PROF IAN GUST: 'CSL - OUTSTANDING LEADERSHIP, LASER FOCUS'**
- * **RACE APPOINTS IRISYS FOR BISANTRENE MANUFACTURE**
- * **CRESO IPO RAISES \$5m FOR MARIJUANA FOOD ADDITIVES**
- * **NUHEARA REQUESTS CAPITAL RAISING TRADING HALT**
- * **SIRTEX 14.25% DISSENT AGAINST CEO PERFORMANCE RIGHTS**
- * **ASX APPROVES UNILIFE RETURN TO TRADING**
- * **ANALYTICA 60m DIRECTOR OPTIONS AGM**
- * **BIOXYNE 9.75m DIRECTOR OPTIONS AGM**
- * **PATRY'S 15m CEO OPTIONS AGM**
- * **SIRTEX PROMOTES NIGEL LANGE TO COO**
- * **ANDREW WILKS, PROTAGONIST, RESAPP WIN AUSBIOTECH, J&J GONGS**

MARKET REPORT

The Australian stock market was up 0.63 percent on Tuesday October 25, 2016 with the ASX200 up 34.3 points to 5,442.8 points. Fourteen of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and one was untraded.

Osprey was the best, up three cents or 7.8 percent to 41.5 cents with 383,428 shares traded. Uscom climbed 6.1 percent; Atcor and Opthea were up more than three percent; IDT rose 2.4 percent; Clinuvel, Pharmaxis, Polynovo, Reva, Sirtex, Starpharma and Universal Biosensors were up more than one percent; with Airxpanders, CSL, Cyclopharm and Resmed up by less than one percent.

Yesterday's 40 percent best, Benitec, led the falls, down 1.5 cents or 11.5 percent to 11.5 cents with 1.4 million shares traded. Dimerix lost 10 percent; Factor Therapeutics shed 7.25 percent; Bionomics and Cellmid fell five percent or more; Oncosil and Prana were both down 4.2 percent; Prima shed 2.7 percent; Acrux, Admedus, Cochlear, Ellex, Nanosonics, Orthocell, Pro Medicus and Viralytics were down one percent or more; with Medical Developments and Mesoblast down by less than one percent.

JOHNSON & JOHNSON INNOVATION

Johnson & Johnson Innovation venture investments vice-president Dr Jeanne Bolger says the world's biggest healthcare company has no limit on its investments.

In a talk entitled 'Bringing Smart Money to Your Business', Dr Bolger told the Ausbiotech Conference today that Johnson & Johnson Development Corp was the oldest corporate venture capital company in health care, had "no ticket size [and] we can lead or follow".

"What can venture capital do for economic development in your country?" Dr Bolger asked.

"How can we drive innovation and create value together?" Dr Bolger asked.

Dr Bolger said that Johnson & Johnson had more than 100 companies and more than \$US1 billion in its investment portfolio between 2013 and 2015.

"We are a strategic investor and geography agnostic" prepared to invest in pharmaceutical and biotechnology companies, medical technologies and consumer health as well as disruptive technologies in health care including electronic health, Dr Bolger said.

Dr Bolger said that Johnson & Johnson was prepared to invest in "a number of different forms" including initial public offers, mergers and acquisitions, seed investment, pure equity and through structured deals.

She said that Protagonist Therapeutics was spun-out from the University of Queensland's Institute of Molecular Biology in 2001, and supported by the Johnson & Johnson Development Corp had a \$US90 million (\$A118 million) initial public offer on the Nasdaq (PTGX) in August 2016.

Dr Bolger said that globally there were currently more than 7,000 medicines in development with a fail rate of about 10 in 12, and with 60 percent of a pharmaceutical company's pipeline sourced outside the company.

"Biopharma adds the most value of any industry per employee but that's just the economic argument," Dr Bolger said.

"Patient needs are more important," she said.

Dr Bolger said that founders and inventors brought great science, ideas, intellectual property, passion, deep domain expertise and networking to the development table, with investors providing adequate and timely capital, expertise in start-ups and growing early stage life sciences businesses, as well as networks for board and management appointments and follow-on funding.

She said that corporate venture partners like the Johnson & Johnson Development Corp had deep domain expertise, "we are patient investors", provided collaborations and exit strategies through acquisition.

Dr Bolger said that Johnson & Johnson Development Corp made its first investment in life sciences in 1973 and was "a strategic investor to support innovation through relationships with venture capital".

Dr Bolger said that Johnson & Johnson Innovation had offices in Silicon Valley California, New Brunswick in New Jersey, Boston Massachusetts, London, Shanghai in China and Tel Aviv in Israel, with the director of new ventures for Australia and New Zealand, Kathy Connell, heading the Sydney and Brisbane offices.

"We have moved from a US-centric model to a more diverse model to be embedded in innovation centres," Dr Bolger said.

Dr Bolger said that her company preferred to engage early "not just because later stage is more expensive but the cake is nearly baked and there is less you can do to change it".

"We have serious scientists like Kathy Connell to engage early and invest through funds, research collaborations and milestone-based agreements," Dr Bolger said.

AUSBIOTECH: PROF NANCY MILLIS ORATION: PROF IAN GUST ON CSL

University of Melbourne professorial fellow Prof Ian Gust says that CSL “has survived by constant adaptation”.

Delivered the Prof Nancy Millis oration, entitled ‘The rise fall and rebirth of an Australian public health icon’ Prof Gust told the Ausbiotech conference that from 1917 until 1973 the then Commonwealth Serum Laboratories filled a void producing drugs from overseas but following World War II was diminishing in importance.

He said that CSL had early successes, mass producing horse-based anti-serum for tetanus and diphtheria, as well as a treatment for the 1918-’19 Spanish influenza pandemic, along with the scale up of penicillin in 1944 and managing Australia’s blood supply, extracting plasma proteins, albumin and haemoglobins for the public, and the later development of snake and spider venoms.

Prof Gust said that from 1974 to 1992 CSL faced what he politely called “headwinds” and said that “from the 1960s [the Federal Government] failed to support CSL at a level that could compete”.

Prof Gust said that in 1990 chief executive officer Dr Brian McNamee was able to convince the then Hawke Government Health Minister Dr Brian Howe that CSL should be privatized rather than sold overseas.

He said the funds allowed the construction of the new facility at Broadmeadows which was “a turning point for CSL”.

Prof Gust said that Dr McNamee expanded the company internationally and returned profits to research and development, rising from \$10 million in 1990 when he joined the company to \$30 million in 2000 when he left, and \$800 million today.

Prof Gust said that the company’s expertise was in blood plasma fractionation and Dr McNamee was able to convince Switzerland’s Red Cross, or ZLB, to merge with CSL in 2000, followed with the acquisition of the US-based Nabi’s plasma business.

“The market saw the logic and the Aventis plasma business allowed CSL to operate internationally and at scale,” Prof Gust said.

He said that with the Aventis Behring acquisition in Marburg Germany the company had production in Australia, Europe and the US.

Prof Gust said that Paul Perreault was appointed to lead the company in 2013.

He said that the company had laboratories at Melbourne’s Bio21 Institute, working with the University of Melbourne, while most clinical development work was undertaken in the US.

Prof Gust said the 2006 acquisition of Zenyth Therapeutics [a listed entity from the Victoria State Government-established Amrad] for \$108 million gave CSL access to its monoclonal antibodies business and pipeline of early stage compounds.

Prof Gust said that the Novartis influenza business provided CSL a worldwide influenza vaccine business.

He said that there were seven main principles in CSL growing from 20 staff in 1916 to more than 16,000 staff today.

Prof Gust said that the critical success factors were:

A deep understanding of unfashionable fields such as plasma fractionation;

Acquiring an unloved business unit from a large company;

Understanding the value that could be unlocked;

Flying under the radar, due to its Australian home allowing low cost acquisitions;

Respect for the skills and abilities of the acquired business unit; and

Willingness to act swiftly and with an appetite for risk.

Dr Gust said the final attribute was “outstanding leadership with a laser-like focus”.

CSL was up 45 cents or 0.4 percent to \$102.98 with 747,188 shares traded.

RACE ONCOLOGY

Race says it has appointed the San Diego, California-based Irisys LLC to develop and manufacture Bisantrene for acute myeloid leukaemia.

Race said that Irisys would complete the development of the final Bisantrene formulation and manufacture the finished product for named patient program sales and use in further US clinical studies.

Race managing-director Peter Molloy said that the appointment of Irisys was “an important milestone to Race, because it completes the chain of assets we need for successful production and marketing of Bisantrene”.

Mr Molloy said that “all the pieces are now in place” with Sai Life Sciences in India manufacturing the active pharmaceutical ingredient, Irisys producing the finished product and Carthagenetics managing the distribution and sales in Europe.

“The company is working with Camargo Pharmaceutical Services in the US, who are facilitating the regulatory process needed to open the way for sales and on-going clinical studies,” Mr Molloy said.

Race was up one cent or four percent to 26 cents.

CRESO PHARMA

Creso says it raised \$5,000,000 at 20 cents a share to list on the ASX to develop marijuana-based food additive products for human and animal health.

Creso opened on the ASX on Thursday October 20 at 25 cents climbing to 27.5 cents before closing at 26 cents, rising to 29.5 cents on October 21 and closing at 36 cents yesterday October 24, 2016.

The Perth, Western Australia-based Creso Pharma is the fifth company to list on the ASX to develop medical marijuana following MMJ Phytotech, Medlab Clinical, MGC and Botanix (BD: Jan 22, Mar 4, May 12, Jul 13, 15, 2015; Jun 27, 2016).

Two other companies, Auscann and Zelda, have also said they intend to raise funds to develop medical marijuana (BD: May 9, Aug 24, 2016).

Creso said it was “focused on growing hemp and developing and producing [cannabinoid] extracts for use in its own products as well as other third-party owned products” (BD: Oct 13, 2016).

Creso said its executive chairman was Boaz Wachtel, Phytotech’s chief executive officer prior to the merger with MMJ (BD: Jan 22, Aug 20, 2015), with directors included managing-director Dr Miriam Halperin Wernli, Adam Blumenthal, Dr James Ellingford and Dr Simon Buckingham.

The prospectus said that the lead manager was Everblu Capital.

Creso fell 4.5 cents or 12.5 percent to 31.5 cents with six million shares traded.

NUHEARA

Nuheara has requested a trading halt pending the release of an “announcement regarding a capital raising”.

Trading will resume on October 27, 2016 or on an earlier announcement.

Nuheara last traded at 8.1 cents.

SIRTEX MEDICAL

The Sirtex annual meeting passed all resolutions but saw 14.25 percent opposition to the issue of 62,881 performance rights to chief executive officer Gilman Wong.

The resolution to issue Mr Wong performance shares worth about \$1.95 million was supported by 27,113,214 votes (85.75%) and opposed by 4,506,457 votes (14.25%), while the proposal to raise the aggregate remuneration of directors by 40 percent to \$1,400,000 was passed with 31.2 million votes in favor and 593,809 against, with the re-election of Dr John Eady and the remuneration report passed overwhelmingly.

Last year, the Sirtex annual general meeting passed all resolutions but saw 11.9 percent opposition to the issue of 45,930 performance rights to Mr Wong (BD: Oct 27, 2015).

In 2014, up to 23.8 percent of the meeting opposed the increase in the pool of directors remuneration from \$625,000 to \$1,000,000 (BD: Oct 28, 2014).

The company's most recent Appendix 3B said that Sirtex had 57,686,562 shares on issue meaning that the opposition to Mr Wong's performance rights amounted to 7.8 percent of the company's shares on issue, sufficient to requisition extraordinary general meetings. Sirtex was up 54 cents or 1.85 percent to \$29.74 with 180,401 shares traded.

UNILIFE CORP

The ASX says that Unilife's suspension will be lifted tomorrow, October 26, 2016, following receipt of its audited statements for the year to June 30, 2016.

Unilife said it had filed its annual report on US Securities and Exchange Commission form 10-K for the fiscal year 2016, as well as its quarterly report for the three months to March 31, 2016 and other financial documents.

Unilife said it had completed the internal investigation of former chief executive officer Alan Shortall and former chairman Jim Bosnjak, accelerated the purchase by Amgen Inc of \$US10 million of a senior secured convertible note and provided an update on the restructuring of its business to prioritize key wearable injector customer programs.

The company said the investigation into violations of its policies and procedures and possible violations of law and regulation by Mr Shortall and Mr Bosnjak had not identified any material financial loss and had not identified any additional financial loss other than was identified in the July 28, 2016 statement (BD: May 9, Aug 1, 2016).

Unilife last traded at 5.5 cents.

ANALYTICA

Analytica will vote to grant chairman Dr Michael Monsour 20,000,000 options and four directors 10,000,000 options each.

Analytica said the directors were Dr Thomas Lönngren, Warren Brooks, Ross Manglesdorf and Carl Stubbings and the options would be exercisable at 1.3 cents each, 185 percent of the closing price of 0.7 cents on October 5, 2016 and within five years.

The company said that half of each of the directors options would vest over three years and become exercisable on the Pericoach intra-vaginal pelvic floor strengthening system being licenced in the US or a change in control of the company with the balance exercisable on a European licence or change in control of the company.

Analytica said shareholders would vote to adopt the remuneration report, re-elect director Mr Manglesdorf, ratify four previous placements and the enhanced placement capacity.

The meeting will be held at the Flinders Room, Level 1, Christie Conference Centre, 320 Adelaide Street, Brisbane, on November 24, 2015 at 10am (AEST).

Analytica fell 0.2 cents or 22.2 percent to 0.7 cents with 5.7 million shares traded.

BIOXYNE

Bioxyne will vote to grant four directors 9,750,000 options and re-elect directors Dr Peter French and George Cameron-Dow.

Bioxyne said it proposed to grant 1,000,000 class A options, 2,000,000 class B options and 3,000,000 class C options to Dr French, 1,500,000 class A options to Anthony Ho, 1,250,000 class A options to director Patrick Ford and 1,000,000 class A options to Mr Cameron-Dow.

The company said that class A options would be exercisable at 2.34 cents each by November 24, 2019; 40 percent of the class B options vest on achieving 75 percent of the budgeted net profit after tax (NPAT) for 2016-'17 and all vest on reaching that target, exercisable at 2.6 cents a share by November 24, 2020, with 50 percent of the class C options vesting on achieving 75 percent of the budgeted NPAT for 2017-'18 and all vest on reaching that target, exercisable at 3.03 cents a share by November 24, 2021.

Bioxyne did not disclose its budgeted NPAT for either year, but in August the company's net profit after tax for the 12 months to June 30, 2016 was \$223,846 (BD: Aug 31, 2016).

Bioxyne said shareholders would vote on the remuneration report, a 10 percent placement capacity and the re-election of directors Dr Peter French and Mr Cameron-Dow.

The meeting will be held at RMS Australia, Level 13, 60 Castlereagh Street, Sydney, on November 24, 2016 at 12pm (AEDT).

Bioxyne was up 0.1 cents or five percent to 2.1 cents.

PATRY'S

Patry's shareholders will vote to grant chief executive officer Dr James Campbell 15,000,000 options vesting in three tranches.

The Patry's annual general meeting notice said that 5,000,000 options would vest immediately, 5,000,000 options would vest at 12 months or when the 20-day volume-weighted average price (VWAP) reached 2.0 cents or greater, and 5,000,000 options would vest at 24 months or when the 20-day VWAP reached 4.0 cents or greater.

The company said that the exercise price would be a 30 percent premium to the 5-day VWAP at the time of the agreement when the board approved the issue subject to shareholder approval, and would expire on November 24, 2021.

Patry's said the meeting would vote to approve the remuneration report, re-elect director John Read, approve the executive option plan, ratify a prior issue, renew proportional bid provisions in the constitution and approve the 10 percent placement facility.

The meeting will be held at Arnold Bloch Leibler, Level 21, 333 Collins Street, Melbourne on November 24, 2016 at 10am (AEDT).

Patry's was untraded at 0.7 cents.

SIRTEX MEDICAL

Sirtex chief executive officer Gilman Wong says the company has promoted Nigel Lange to chief operating officer.

Mr Wong said that in 2000 Mr Lange launched yttrium-90 therapy and had been with Sirtex for 14 years, starting as head of US sales before moving to Germany to establish and manage the Europe, Middle East and Africa business and had been overseeing the Asia-Pacific business.

Mr Wong said that the company was currently recruiting new heads for the Asia Pacific region and for the Europe, Middle East and Africa region and Mr Lange would continue to oversee these regions in the interim".

AUSBIOTECH, JOHNSON & JOHNSON INNOVATION

Ausbiotech and Johnson & Johnson Innovation say that Prof Andrew Wilks, Protagonist and Resapp have won the industry excellence awards.

An Ausbiotech media release said that Synthesis executive chairman Prof Wilks won the industry leadership award, Protagonist Therapeutics won the company of the year and Resapp Health won the emerging company of the year.

The media release said that the awards recognized “innovative companies and individuals in Australia’s world-class biotechnology, medical technology and healthcare sectors”.

Ausbiotech said that Prof Wilks was recognized for his role in the development of the Australian biotechnology sector over the last 20 years, working with Synthesis Medchem, Qubist Molecular Design, Synthesis Research, Synkinase, Reagency and Cytopia Research, which developed a JAK1/2 inhibitor momelotinib, formerly known as CYT397, that was purchased for US\$510m (BD: Oct 6, 2009; Dec 13, 2012).

The industry organization said that Protagonist was “a clinical-stage biopharmaceutical company focused on discovering and developing [oral] peptide-based new chemical entities to address significant unmet medical need” including inflammatory bowel disease.

Ausbiotech said that Resapp was recognized for its development of digital healthcare products to diagnose and manage respiratory disease.