



Biotech Daily

Tuesday October 3, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: ACRUX UP 17%; LBT DOWN 11%**
- * **ITL SELLS MELBOURNE MEDICAL SUPPLIES TO MERIT FOR \$14m**
- * **REDHILL CUTS RHB-104 FOR CROHN'S TRIAL, SAVES \$18m, ONE YEAR**
- * **ELLEX CLAIMS 5 QUARTERS OF RISING ITRACK REVENUE**
- * **TPI COMPLETES \$26m VISTIN PHARMA OPIATE ACQUISITION**
- * **PROBIOTEC COMPLETES \$12m SOUTH PACK ACQUISITION**
- * **PRESCIENT PTX-100 FOR LYMPHOMA TRIALS, PATENT APPLICATION**
- * **CELLMID RECEIVES \$947k FEDERAL R&D TAX INCENTIVE**
- * **MGC 5-YEAR EURO MEDICAL MARIJUANA DEAL WITH LENIS**
- * **LIVING CELL PLEADS SCHULTZ TO ASX 14% QUERY**
- * **CEO RICHARD HANNEBERY TAKES 7% OF GENERA**
- * **NOVITA APPOINTS GLENN SMITH CEO, STARTS ON \$274k**
- * **PHARMAUST: ANGELA FRIMBERGER, CHRISTIAN SCHIRVEL ADVISORS**

MARKET REPORT

The Australian stock market fell 0.49 percent on Tuesday October 3, 2017 with the ASX200 down 27.9 points to 5,701.4 points. Eighteen of the Biotech Daily Top 40 stocks were up, 11 fell, five traded unchanged and six were untraded.

Acrux was the best, up 2.5 cents or 16.7 percent to 17.5 cents with 3.1 million shares traded. Ellex and Opthea climbed more than eight percent; Avita and ITL improved more than seven percent; Clinuvel was up 5.1 percent; Compumedics, Impedimed and Universal Biosensors were up more than four percent; Benitec, Pharmaxis and Pro Medicus were up more than three percent; Bionomics, Living Cell and Mesoblast rose more than two percent; with Actinogen, Admedus and Sirtex up more than one percent.

LBT led the falls, down 3.5 cents or 10.9 percent to 28.5 cents with 350,270 shares traded. Genetic Signatures lost 6.4 percent; Osprey and Starpharma fell more than five percent; Cellmid, Oncosil and Viralytics fell four percent or more; with Airxlanders and Orthocell down more than three percent.

ITL HEALTH

ITL Health says it has sold its Melbourne medical supplies packing business to the Salt Lake City, Utah-based Merit Medical Systems for \$14.4 million.

ITL executive chairman Bill Mobbs told Biotech Daily that the company would continue with its strategy of pursuing higher margin blood market opportunities.

Mr Mobbs said that he expected revenue to fall this financial year, but profits were expected to increase in later years.

Mr Mobbs said that ITL would continue with a focus on its Malaysian-manufactured invasive blood equipment, including blood-pressure monitoring, blood banking and culturing as well as the Myhealthtest personal blood test system.

Mr Mobbs said that ITL bought the Chelsea Heights facility in Melbourne's South Eastern suburbs, in 2003 when the company first listed on the ASX.

In a media release ITL said that the sale was completed yesterday October 2, 2017 through the transfer of the shares in ITL Healthcare Pty Ltd to a subsidiary of Merit and included the Melbourne manufacturing facilities, clean rooms and sterilizer, and ITL Healthcare's range of custom procedure packs, drapes and gowns.

The company said it would "retain a strong presence in Australia, including an extensive sales and distribution network across the country ... [and] retain ownership of business units that manufacture and sell ... invasive blood pressure monitoring kits sold in 46 hospitals in Australia, class 3 intra-venous starter packs and numerous sponsored products" that contributed \$8.9 million in revenue in the last financial year.

ITL said it would have net cash of about \$10 million a reduction of \$12.3 million in sales or 35 percent of group sales of \$34.8 million in the year to June 30, 2017.

The company said that the stronger balance sheet meant it would be able to accelerate growth across its remaining business units.

ITL was up three cents or 7.6 percent to 52.5 cents with 1.4 million shares traded.

REDHILL BIOPHARMA

Redhill says reducing patient numbers in its phase III RHB-104 for Crohn's disease trial will cut costs by \$US14 million (\$17.9 million) and save about one year.

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

Today the company said that the reduction from the planned 410 patients to about 325 patients, with 322 enrolled to date, would bring forward top-line results to mid-2018, while maintaining statistical power of more than 80 percent with a treatment effect of 15 percent.

Redhill said a review of the blended efficacy rate of the blinded data, as well as expert advice, suggested the total number of treatment successes was consistent with predefined expected outcomes and the study had sufficient patients to show efficacy.

The company said it remained blinded to the ongoing data from the randomized, double-blind, placebo-controlled first phase III study evaluating the safety and efficacy of RHB-104 in subjects with moderately to severely active Crohn's disease, with the primary endpoint of disease remission.

Redhill said the study was being conducted in up to 150 clinical sites in the US, Canada, Europe, Israel, Australia and New Zealand.

Redhill medical director Dr Ira Kalfus said the reduction of patient numbers was "the preferred approach in our effort to bring this potentially ground-breaking new therapy to the market as soon as possible".

On the Nasdaq, Redhill was unchanged at \$US10.81 (\$A13.83) with 490,821 shares traded.

ELLEX MEDICAL LASERS

Ellex says its Itrack has had five consecutive quarters of increasing revenue with the three months to September 30, 2017 up 70.8 percent to \$US1,980,000 (\$A2,537,010).

Ellex said that in the three months to September 30, 2016, revenue was \$US1,159,000 with unit sales of its Itrack glaucoma treatment for the comparative period up 68.9 percent from 1,750 units to 2,956 units.

Ellex chief executive officer Tom Spurling said the 71 percent increase showed “the increased traction of Ellex Itrack with US surgeons”.

In August, Ellex said that total revenue for the year to June 30, 2017 fell 1.75 percent to \$71,635,000 (BD: Aug 25, 2017).

Ellex was up 9.5 cents or 8.8 percent to \$1.18.

TPI (TASMANIAN POPPY INDUSTRIES) ENTERPRISES

TPI says it has closed the \$25.6 million acquisition of the opiate and tableting assets of the Oslo, Norway-based Vistin Pharma ASA.

TPI said that two conditions of the transaction were satisfied prior to signing with the demerger of the Vistin asset and the transfer of the operating licences issued by Norwegian Medicines Agency to TPI Norway AS.

The company said the provisional price of \$25.6 million included an estimate of inventory, subject to adjustment.

TPI said the acquired asset was located in Kragerø, 200km south-west of Oslo and it had the capacity to produce active pharmaceutical ingredient and finished dosage form products, with an existing capacity of 35 tonnes of codeine phosphate, five tonnes of pholcodine and 1.6 billion tablets a year.

The company said the acquisition provided “substantial downstream business growth opportunities with access to attractive European and global markets”.

Last week, TPI said it would add the development of medical marijuana to its opiate business (BD: Sep 29, 2017).

TPI was up two cents or 0.7 percent to \$2.76.

PROBIOTEC

Probiotec says it has completed the acquisition of Sydney’s South Pack Laboratories (Aust) Pty Ltd for \$8 million in cash and 7.9 million shares (BD: Sep 21, 2017).

Probiotec said that it expected the total consideration to be between \$11.3 million and \$13.3 million dependent on earn-out hurdles, and was a valuation multiple of between four and five times earnings before interest taxation depreciation and amortization (Ebitda), based on the prior 12 months performance.

In September, Probiotec said South Pack was a pharmaceutical and food additive contract packer and it would continue to operate at its current facility, which was being upgraded to increase capacity and capabilities and would be led by the existing management team.

Today, the company said the South Pack business would broaden its service offering through the addition of its Girraween, New South Wales facilities and “the specialist and highly efficient pharmaceutical packaging operations”.

Probiotec managing-director Wesley Stringer said he was “very optimistic regarding the opportunities the [South Pack] business and management bring to Probiotec”.

“I see this as an important stepping stone in Probiotec’s expressed strategy to grow its high quality, contract manufacturing offerings,” Mr Stringer said.

Probiotec was unchanged at 56 cents.

PRESCIENT THERAPEUTICS

Prescient says it plans to re-enter the clinic with PTX-100 for rare lymphomas, related cancers that affect the lymphatic system, which forms part of the immune system.

Prescient said that PTX-100 might have an advantage in treating lymphomas driven by a mutation of the molecular switch RhoA by disrupting the Ras, or rat sarcoma, cancer signalling pathway.

In June, Prescient said that a pre-clinical study of the geranylgeranyl transferase inhibitor GGTI- 2418, or PTX-100, played a key role in mitigating a new cancer pathway and research showed details about the tumor suppressor gene PTEN which was defective in 30 to 60 percent of certain breast, brain and uterine cancers (BD: Jun 19, 2017).

Today, Prescient said that Ras mutations were observed in one-third of all cancers, and addressing the pathway represented a large unmet need in many cancers.

The company said that development of drugs targetting Ras was difficult but PTX-100 worked downstream of Ras by preventing activation of molecular switches Rho, Ral and Rac, which were involved in cell growth and survival.

Prescient said that mutated RhoA, was inactivated by PTX-100, and was implicated in lymphomas including angio-immunoblastic T-cell lymphoma, peripheral T-cell lymphoma not other specified, adult T-cell leukaemia and lymphoma, Burkitt lymphoma and diffuse large B-cell lymphoma, with RhoA mutations in 25 percent of diffuse-type gastric cancer. Prescient said it had filed a new patent application for PTX-100 in RhoA mutant cancers, which had poor prognoses and were under-served by current treatments, thus representing a very attractive development path to commercialization and it would conduct pre-clinical studies while preparation for a clinical trial.

Prescient said that PTX-100 completed a phase I trial as a monotherapy in refractory, advanced solid tumors at Indiana and Penn Universities in 13 patients demonstrating safety, with four patients showing durable stable disease.

Prescient chief executive officer Steven Yatomi-Clarke said that PTX-100 had "potential utility in a wide variety of cancers".

"The management team and board undertook a strategic review of different development options for PTX-100 to determine the best next step for its development from scientific, clinical, regulatory and commercial perspectives," Mr Yatomi-Clarke said.

"We concluded that haematological diseases with mutated Ras and RhoA represent tremendous opportunities for Prescient," Mr Yatomi-Clarke said.

"In particular, rare diseases like [angio-immunoblastic T-cell lymphoma] have the potential for expedited development and regulatory pathways, which can be a significant advantage for companies with access to this development route," Mr Yatomi-Clarke said.

"Our research has found that there are very few RhoA inhibitors in development, almost all of which are pre-clinical or earlier in their development," Mr Yatomi-Clarke said.

"PTX-100 seems to be the most clinically advanced drug in the world in this area and gives Prescient a significant head start and unique position in RhoA mutant lymphomas," Mr Yatomi-Clarke said.

Prescient was up 0.4 cents or 6.9 percent to 6.2 cents.

CELLMID

Cellmid says it has received \$946,963 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Cellmid said the rebate related to expenditure on its midkine and FGF5 inhibitor programs for the year to June 30, 2017.

Cellmid fell 0.1 cents or four percent to 2.4 cents.

MGC PHARMACEUTICALS

MGC says it has a five year supply and distribution agreement for its medical marijuana products with the Ljubljana, Slovenia-based Lenis Farmaceutika DOO.

MGC said it would supply four of its medicinal cannabis flower materials and pharmaceutical products to Lenis to sell in Central and Eastern Europe at an agreed wholesale price, with the two companies jointly marketing the products in Germany, Croatia, Greece and Italy.

The company said the products were for the treatment or relief of symptoms of nausea, vomiting, pain, Tourette's syndrome, multiple sclerosis, uncontrollable severe epilepsy, inflammatory bowel disease, Crohn's disease, ulcerative colitis and post-traumatic stress disorder.

MGC said the agreement provided for the future supply of its Cannepil for refractory epilepsy and its anti-inflammatory topical cream Dermaplus, once they had been registered in the European Union for sale.

The company said that Lenis would be responsible for the marketing, sales, logistics, exporting, handling and pharmacovigilance, or drug safety, for the products.

MGC said the agreement had a revenue-sharing arrangement, varying on the product, minimum sales and product volume and would run for five years with an automatic extension of two years, upon agreement by both parties, with Lenis having first right of refusal to expand the agreement to include sales into any new European territories.

MGC was unchanged at 3.9 cents with 10.6 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 13.9 percent from 18.0 cents to 20.5 cents yesterday October 2, 2017 and noted a significant increase in the trading volume.

Living Cell has been climbing from about nine cents at the beginning of this year, fluctuating between 10 and 13 cents from March to August, climbing 45 percent in September and a further 13.9 percent yesterday.

The company previously said it expected results from its phase II, NTCCell encapsulated pig brain choroid cells for Parkinson's disease in November 2017.

Living Cell was up half a cent or 2.4 percent to 21 cents with 1.6 million shares traded.

GENERA BIOSYSTEMS

Genera chief executive officer Richard Hannebery says he and associated entities have become substantial in Genera with 7,024,401 shares or 6.99 percent.

The substantial shareholder notice said that co holders included Mr Hannebery's spouse Robyn Gould, EG Capital and Silica Investments.

Mr Hannebery said he acquired 1,000,000 shares as a result of the vesting of performance rights, but did not include the dates of acquisition, or cost of other shares as required by the Corporations Act 2001.

Genera was up 3.5 cents or 21.9 percent to 19.5 cents.

NOVITA HEALTHCARE (FORMERLY AVEXA)

Novita says it has appointed Glenn Smith as chief executive officer, effective from today October 3, 2017 and starting on \$273,750 a year.

Novita said that Mr Smith had more than 20 years' experience in the healthcare, recruitment and technology sectors, "with a track record of success in leading and developing customer-centric businesses through periods of rapid growth".

The company said that most recently Mr Smith was the chief executive officer of Spotjobs from start-up to a national online employment and training service.

Novita said that Mr Smith previously was an executive with Tri-Med, Occupational and Medical Innovations and Holista-Colltech.

Novita said Mr Smith's focus would be to support the commercialisation of the company's Tali Train system for attention deficit issues, and development of the Newly acquisition.

The company said the Mr Smith held a Bachelor of Arts from the University of Melbourne and a Masters of Business Administration from the University of Western Australia and was a practicing vigneron.

Novita said that apart from the base salary of \$273,750 a year, Mr Smith could receive a short term cash incentive of 50 percent of the base rate, subject to performance.

The company said that two long term incentives, each of 7,188,883 unlisted options exercisable at three cents per option, with the first tranche vesting on achieving a 20-day share price of six cents a share within 24 months from appointment and an operating profit for the six months to June 30, 2019; and the second tranche vesting on a 20-day share price of nine cents a share from three years following the commencement date and an operating profit for the six months to June 30, 2019.

Novita was unchanged at 3.3 cents.

PHARMAUST

Pharmaust says it has appointed Dr Angela Frimberger and Dr Christian Schirvel to its veterinary clinical advisory board.

Pharmaust has been developing monepantel, formerly known as PPL-1, for both human and canine cancer.

The company said that Dr Angela Frimberger and Dr Christian Schirvel were opinion leaders in animal health and would advise and assist its veterinary cancer program.

Pharmaust said that Dr Frimberger held a Doctor of Veterinary Medicine from the University of Pennsylvania Veterinary School, trained as a resident at Tufts University and undertook a research fellowship at University of Massachusetts Cancer Center.

The company said that Dr Schirvel was previously Elanco's head of business development and licencing and before that held the same position at Novartis Animal Health until it was acquired by Elanco.

Pharmaust said that prior to Novartis and Elanco, Dr Schirvel was Vétoquinol's head of business development and licencing, and before that was a Merial executive.

Pharmaust was unchanged at five cents.