



# Biotech Daily

Thursday April 9, 2015

*Daily news on ASX-listed biotechnology companies*

- \* **ASX DOWN, BIOTECH EVEN: PATRYS UP 10%, OPTISCAN DOWN 7%**
- \* **NOVOGEN ANISINA (ATM-3507) KILLS MUTATED MELANOMA IN-VITRO**
- \* **PHYTOTECH REGULATOR ASKS TARGET IF READY FOR INSPECTION**
- \* **UNILIFE APPOINTS DR RICHARD BECKMAN CHEF MEDICAL OFFICER**
- \* **BIO-MELBOURNE BREAKFASTS ON USPTO'S TERESA STANEK REA**

## MARKET REPORT

The Australian stock market fell 0.48 percent on Thursday April 9, 2015 with the S&P ASX 200 down 28.5 points to 5,932.2 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 13 fell, 10 traded unchanged and four were untraded.

Patrys was the best, up 0.1 cents or 10.0 percent to 1.1 cents with 1.3 million shares traded.

Avita and Universal Biosensors climbed more than nine percent; Admedus rose eight percent; Benitec was up 7.4 percent; Compumedics was up 6.45 percent; Sirtex rose 5.7 percent; Analytica was up 4.8 percent; Clinuvel, Ellex and Prima were up three percent or more; Actinogen rose 2.4 percent; with Bionomics and Resmed up more than one percent.

Optiscan led the falls, down 0.5 cents or 7.1 percent to 6.5 cents with 157,248 shares traded.

Atcor and Starpharma fell more than five percent; Tissue Therapies lost 4.55 percent; Impedimed, Mesoblast and Pharmaxis were down more than three percent; Antisense and Viralytics shed more than two percent; Living Cell was down 1.7 percent; with Acrux, Cochlear, CSL, Nanosonics and Psivida down by less than one percent.

## NOVOGEN

Novogen says that University of Queensland in-vitro studies have found that Anisina, formerly ATM-3507, killed melanoma cells irrespective of their mutational status.

In March, Novogen said Anisina could destroy cancer cell cytoskeleton in a mouse model and last year the company said that anti-tropomyosin drugs, like Anisina, in combination with anti-mitotic drugs boosted the cancer killing ability 20-fold against neuroblastoma cancer cells in-vitro (BD: Nov 21, 2014; Mar 18, 2015).

Today, Novogen said that the University of Queensland Diamantina Institute's Dr Nikolas Haass and Dr Brian Gabrielli screened Anisina against a panel of melanoma cells obtained from patients and which represented the spectrum of mutations, including BRAF, NRAS and c-KIT, commonly found in the community.

The company said that Anisina was uniformly cytotoxic to the panel of cells, regardless of their mutational status and the compound "showed a high level of specificity to cancer cells, with toxicity against normal melanocytes requiring a four-fold drug level".

Dr Haass said the findings from the preliminary screen with Anisina were "exciting".

"Finding a compound that is equally effective against a wide panel of melanoma cell types irrespective of the genetic background has been a long-held goal," Dr Haass said.

Novogen anti-tropomyosin program director Dr Justine Stehn said that melanoma was "a notoriously difficult cancer to treat [and] the standard first-line cytotoxic drugs, such as the taxanes and vinca alkaloids, have little anti-cancer effect".

"But we see a 20-fold increase in the cancer killing effect of these drugs when combined with Anisina," Dr Stehn said.

"We have demonstrated this combination effect with vincristine in prostate cancer cells, neuroblastoma cells, and now melanoma cells," Dr Stehn said. "The idea that we now have a means of making melanoma cells respond to potent anti-cancer drugs such as vincristine is an exciting development for patients with melanoma."

Novogen chief executive officer Dr Graham Kelly said the results "support our belief that Anisina has the potential to become one of the most widely used anti-cancer drugs across the full spectrum of cancer".

"In conjunction with our clinical advisors, we have a clinical strategy laid out which we intend to prosecute all the way through to achieving regulatory approval," Dr Kelly said.

Novogen said that the significance of the University of Queensland in-vitro studies was that melanoma was associated with a variety of mutations, with those to the BRAF gene being the most prominent.

The company said that a mutation to the BRAF gene occurred in about half of all melanoma patients and two drugs that target that mutation, vemurafenib and dabrafenib, were on the market but no targeted therapy existed for the 50 percent of melanoma patients whose tumors do not have the BRAF mutation.

Novogen said that where a response was obtained with a BRAF-inhibitor, resistance typically developed within a year of treatment, so a drug that killed melanoma cells irrespective of their BRAF or any other mutational status had become an urgent clinical imperative and Anisina had "a significant potential opportunity to meet this need".

The company said that Anisina was an anti-tropomyosin compound that targeted the cytoskeleton of the cancer cells and was expected to be in clinical trials in early 2016, as a companion drug for the anti-mitotic family of drugs, the taxanes and vinca alkaloids, for the treatment of solid cancers, with late-stage melanoma and prostate cancer in adults and neuroblastoma in children being three key target indications.

Novogen said the University of Queensland results give strength to the aim of conducting a study in patients with late-stage melanoma, combining Anisina and vincristine.

Novogen climbed 9.5 cents or 43.2 percent to 31.5 cents with 37.6 million shares traded.

## PHYTOTECH MEDICAL

Phytotech has emerged from a trading halt saying Canadian regulators have requested "confirmation of readiness" for marijuana production from merger target MMJ Bioscience. In March, Phytotech said it would acquire the Vancouver, British Columbia-based MMJ for up to \$20,685,000 through the issue of up to 68,000,000 Phytotech shares valued at 30.5 cents a share of which 8,500,000 shares were dependent on MMJ being granted a licence to produce under the Marihuana for Medical Purposes Regulations (MMPR) in Canada within 12 months of settlement (BD: Mar 24, 2015).

Today, Phytotech said that the Health Canada confirmation of readiness letter preceded the scheduling of a pre-licencing inspection.

The company said the letter specified that all MMPR requirements be in place and ready for inspection and when MMJ confirmed it was ready Health Canada could set a date.

Phytotech said the letter "also indicates that Health Canada is satisfied that MMJ's ... growing facility in Duncan, near Vancouver BC, is ready for pre-licence inspection".

MMJ chief executive officer Andreas Gedeon said his company was close to satisfying its first key commercialization hurdle under its Canadian growing strategy".

"Assuming the grant of a MMPR licence at Duncan occurs within a period of time consistent with the advice of our consultants, we are targeting revenues from the sale of [medical cannabis] before the end of this calendar year," Mr Gedeon said.

Mr Gedeon said that at full capacity, MMC subsidiary United Greeneries would be able to produce and sell up to 700,000 grams of medical cannabis a year at \$C7 to \$C10 (\$A7.25 to \$A10.35) per gram.

Phytotech said that as a consequence of the Health Canada letter it had invested \$C\$275,000 (\$A284,674) in MMJ under a secured convertible debenture and, subject to conditions, would provide a secured loan to MMJ up to \$1,000,000 to expedite cannabidiol pill sales in Europe and the grant of the MMPR licence to MMJ's growing facility.

The company said the loan would enable MMJ subsidiary Satipharm to begin pill sales in Europe from July 2015, hoping to sell a minimum of 30,000 pills a month, increasing to 135,000 per month, at a retail sales price of EUR3.00 (\$A4.20) each.

Phytotech said that Satipharm's partner, AI FAME GmbH had begun production of the cannabidiol extract with the first delivery expected to Satipharm's contract pill manufacturer by May 1, 2015 and proceeds from the loan would expedite the setup of a distribution network and marketing program.

Phytotech fell one cent or 3.2 percent to 32 cents.

## UNILIFE CORP

Unilife says it has appointed Dr Richard Beckman as its chef medical officer, senior vice-president and general manager of the ocular delivery systems business unit.

Unilife said that Dr Beckman was an ophthalmologist with 13 years of clinical practice experience and more than 20 years as a corporate executive and consultant with a number of pharmaceutical, biotechnology and medical device companies.

The company said that previously Dr Beckman was the chief medical officer at Ophthotech Pharmaceuticals and had held senior roles at Neurotech Pharmaceuticals, Alcon Laboratories, Lux Pharmaceuticals, Becton Dickinson and Allergan.

Unilife said that Dr Beckman received his medical degree from the University of Michigan, and practiced as a glaucoma specialist for 10 years in private practice and three years in academic practice at North Shore University Hospital-Cornell University Medical College, following a glaucoma fellowship at Harvard University.

Unilife was up five cents or 6.3 percent to 84.5 cents.

## THE BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says former US Patent and Trademark Office deputy director Teresa Stanek Rea will discuss changes to US patent law at its April 21 Bio-Breakfast.

The Network said that Ms Rea would describe new statutes and cases and how they affect the way in which products were brought to market.

The Bio-Melbourne Network said that the Myriad US Supreme Court decision brought a new perspective to patentable subject matter and the new patent challenge procedures in the Biologics Price Competition and Innovation Act of 2009 (BPCIA) do not allow patent challenges in district courts unless the Act is followed.

The Network said that the new post-grant proceedings in the US Patent and Trademark Office did provide an opportunity to challenge patents without following the BPCIA and Ms Rea would discuss “the interplay between these provisions”.

The Network said that Ms Rea was a partner in Crowell & Moring’s intellectual property group and a director with C&M International the company’s international trade and investment consulting firm.

The Bio-Melbourne Network said that Ms Rea’s practice concentrated on intellectual property policies and strategies, patent enforcement and post-grant administrative proceedings, trade secrets policy and enforcement and digital copyright issues.

The Network said that at the USPTO Ms Rea was actively involved in writing the regulations implementing the new inter partes review, covered business method review, and post-grant review proceedings created by the America Invents Act and negotiated numerous issues with foreign officials.

The Bio-Melbourne Network said that Ms Rea was “the senior official responsible for the administration’s formulation and implementation of US intellectual property policies, including patent, trademark, copyright, and trade secret issues”.

The April 21, 2015 Bio-Breakfast will be hosted by Minter Ellison Lawyers, Level 23, Rialto Towers, 525 Collins Street, Melbourne, with registration and breakfast from 7.15am and the presentation from 8am to 9am.