



Biotech Daily

Friday May 15, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: GI DYNAMICS UP 32%, PATRYS DOWN 15%**
- * **CORTENDA 'UP TO \$131m' DEAL FOR ANTISENSE ATL1103**
- * **RESMED TO SELL RHINOMED MUTE ANTI-SNORING NASAL PLUGS IN UK**
- * **NOVOGEN: 'ORAL ANISINA (ATM-3507) KILLS CANCER IN MICE, NO TOX'**
- * **BURNET OPENS NANJING BIOPOINT DIAGNOSTICS LABORATORY**
- * **REVA ADDS AUSTRALIA TO FANTOM II CORONARY STENT TRIAL**
- * **CELLMID \$1m LOAN**
- * **BIODIEM EXPECTS \$40k FOR 1st FLU VACCINE ROYALTIES**
- * **REPRODUCTIVE HEALTH WORKS WITH FRANCE'S INNOPSYS**

MARKET REPORT

The Australian stock market was up 0.68 percent on Friday May 15, 2015 with the S&P ASX 200 up 38.9 points to 5,735.5 points. Fifteen of the Biotech Daily Top 40 stocks were up, 16 fell, six traded unchanged and three were untraded.

GI Dynamics was the best on no news, up 3.5 cents or 31.8 percent to 14.5 cents with 1.0 million shares traded.

Tissue Therapies climbed 6.1 percent; Analytica and Viralytics were up more than five percent; Oncosil and Optiscan rose more than four percent; Anteo, Benitec, Clinuvel, Resmed, Sirtex, Starpharma and Universal Biosensors were up more than three percent; Atcor and Impedimed rose more than two percent; with Acrux and CSL up more than one percent.

Patryst led the falls, down 0.2 cents or 15.4 percent to 1.1 cents with 17,500 shares traded, followed by Antisense down 13.3 percent to 13 cents with 2.6 million shares traded and Pharmaxis down 10.8 percent to 16.5 cents with 766,917 shares traded.

Compumedics lost 6.7 percent; Circadian was down 5.9 percent; Actinogen, Cellmid, Living Cell and Neuren fell more than three percent; Avita, Bionomics and IDT shed two percent or more; Admedus, Mesoblast and Osprey were down more than one percent; with Cochlear and Nanosonics down by less than one percent.

ANTISENSE THERAPEUTICS

Antisense says that Cortendo AB will pay an upfront fee of \$6.2 million and up to \$131 million for the rights to ATL1103 for endocrinology applications, including acromegaly. Antisense said that the Trevose, Pennsylvania-based Cortendo would pay \$3.7 million in cash and make a \$2.5 million investment in the company.

Antisense managing director Mark Diamond told Biotech Daily that the 15,025,075 share investment by Cortendo, to be held in escrow for two years, were bought at 16.75 cents a share, an 11.7 percent premium to the closing price of 15 cents when the company went into a trading halt for the announcement.

Mr Diamond said that Cortendo would pay for all further development of ATL1103 for endocrine applications, while Antisense would retain the rights for all other indications as well as the commercialization rights of ATL1103 for endocrine applications in Australia and New Zealand.

Antisense has previously investigated ATL1103 for diabetic retinopathy, nephropathy and some forms of cancer (BD: Oct 12, 2009; Apr 11, 2011).

Antisense said that additional payments from Cortendo, pending specific development and commercialization milestones could total \$131 million over the lifetime of the agreement, along with the the potential for royalty payments based upon sales performance.

Cortendo chief executive officer Matthew Pauls said his company was "dedicated to addressing the needs of the rare disease community and we are focused on developing novel therapeutic options and resources for rare diseases".

"The opportunity to advance ATL1103, a novel second-generation antisense therapeutic with potential utility in acromegaly, nicely complements COR-003, our existing phase III asset for Cushing's syndrome and builds upon our rare endocrine disease franchise," Mr Pauls said. "We are also continuing to actively explore other partnerships in endocrinology as well as other therapeutic areas for rare diseases."

"We are extremely pleased to deliver on our strategic partnering plans in endocrinology applications of ATL1103 and to be partnering with Cortendo given the company's focus in endocrine disorders and other rare diseases," Mr Diamond said.

"This is a significant deal not only for Antisense Therapeutics and its shareholders, but also for the Australian biotech industry as a whole," Mr Diamond said.

"We aim to unlock further value from our pipeline, including ATL1102 for [multiple sclerosis] and other potential indications for ATL1103," Diamond added.

Antisense said that the Cambridge, Massachusetts-based Locust Walk and the Charlotte, North Carolina-based Destum Partners acted as Cortendo's and Antisense Therapeutics' transaction advisors, respectively, through the process.

Antisense fell two cents or 13.3 percent to 13 cents with 2.6 million shares traded.

RHINOMED, RESMED

Rhinomed says that Resmed will sell its Mute nasal plugs for snoring reduction in the UK. Rhinomed said the terms of the distribution agreement were not disclosed, but Resmed would market the product online with the opening order already received.

Rhinomed chief executive officer Michael Johnson said that attracting "a high calibre sales partner like Resmed is testimony to the commercial opportunity and the efficacy of our innovative Mute technology".

The company said that the Mute technology was an over-the-counter product designed to treat snoring, by dilating nostrils to improve breathing capacity.

Rhinomed was up 2.6 cents or 96.3 percent to 5.3 cents with 242.5 million shares traded.

Resmed recovered 26 cents or 3.9 percent to \$6.99 with 29.9 million shares traded.

NOVOGEN

Novogen says that drug candidate Anisina (formerly ATM-3507) is an effective oral monotherapy against human melanoma in mice with no observed toxicities.

Novogen said that Anisina was “a potent cytotoxic in-vitro against human melanoma cells” and the activity was unaffected by the mutational status of the melanoma cells, particularly the common BRAF gene status, which makes the serine/threonine-protein kinase B-Raf. The company said the purpose of the pre-clinical study was to provide evidence that the potent anti-cancer effect could be transferred to the whole animal.

Novogen said it had reported the effectiveness of Anisina as a monotherapy in mice with human neuroblastoma tumors, justifying clinical trials in children and juveniles with solid cancers such as neuroblastoma (BD: Nov 21, 2014; Apr 9, 2015).

The company said that together, “the two results confirm the potential clinical benefit of this drug across both adult and paediatric cancers”.

Novogen said the study grew highly chemo-resistant human melanoma cells in athymic mice, which were treated either orally or intravenously with Anisina, with both routes equally effective.

Novogen anti-tropomyosin program director Dr Justine Stehn said the company was “pleasantly surprised by the degree of anti-tumor activity of this drug candidate on its own”.

“We had always seen the anti-tropomyosin technology as being an adjunct therapy for the more commonly used anti-mitotic drugs,” Dr Stehn said.

“The rationale behind its development was to destroy that half of a cancer cell’s cytoskeleton that the anti-mitotic drugs didn’t target,” Dr Stehn said. “We reasoned that destabilising the entire cytoskeleton would achieve a much higher level of anti-cancer effect than that coming from targeting either half alone and, indeed, that is what we see”. “Anisina used in combination with anti-mitotic drug, vincristine, increases the anti-cancer potency of vincristine 20-fold,” Dr Stehn said.

Dr Stehn said that despite the evidence showing that Anisina had the potential to be a stand-alone chemotherapy, Novogen intended Anisina to be a companion drug for an anti-mitotic drug.

“The initial patients however will need to be treated with Anisina on its own and this study now gives us the green light to proceed into a phase I study in the first half of 2016 ... and, the company is conducting studies in a variety of both adult and paediatric solid and non-solid cancer types in order to determine the optimal drug combination,” Dr Stehn said.

Novogen chief executive officer Dr Graham Kelly said that Anisina was a “highly versatile and promising new drug candidate with potentially broad application across the cancer spectrum”.

Dr Kelly said that the company knew the Anisina target, how it worked, that it was making the most commonly used drugs work 20-times better, as well as extending the effectiveness of the combination into tumor types unresponsive to anti-mitotic drugs, and in melanoma its effectiveness was unaffected by mutational status.

Novogen said that Anisina was a small molecule that targeted the tropomyosin isoform, Tpm3.1, which provided a rigid external scaffold to the central actin core of the microfilament component of a cell’s cytoskeleton and without the rigidity, the microfilaments were inactive.

The company said that exposure of cancer cells to Anisina led to disassembly of their microfilaments, prevention of mitosis and cell death, while Anisina showed little or no effect on normal cells at therapeutic doses.

Novogen was unchanged at 30.5 cents with 2.5 million shares traded.

THE BURNET INSTITUTE

The Burnet Institute says its spin-off company, the Nanjing Biopoint Diagnostics Technology Co has opened its research and development laboratory facility.

The Institute said the Jiangsu Province laboratory was backed by investment partners Beijing Guominxinhe Group and an agreement was signed to establish manufacturing facilities in the Jiangsu Life Science and Technology Innovation Park.

Burnet deputy director and Nanjing Biopoint chief executive officer Prof David Anderson said the laboratory and manufacturing capability would translate Burnet's diagnostic research and technologies into commercially viable products.

"Nanjing Biopoint is a strong signal of our long-term commitment to collaborative research and development in China and will facilitate timely delivery of new health technologies to our target populations worldwide through cost-effective commercial development, in conjunction with our partners at Guominxinhe Group," Prof Anderson said.

"But in the longer term, Burnet's share of profits from this venture also provides us with a tangible funding stream to support the wider work of the Institute with vulnerable communities in the Western provinces of China and other resource-poor settings," Prof Anderson said.

"The laboratory, initially staffed by two local Chinese scientists and our general manager Dr Feng Yi, will work closely with our laboratory in Melbourne to utilise and adapt core technology developed by Burnet to produce rapid, point-of-care diagnostic test technology for use in China and other countries," Prof Anderson said.

The Burnet Institute said that a point-of-care test to identify undiagnosed liver disease was the first target of research and development and commercialization and the test would help fill an unmet medical need for patients, especially those in low-income countries where laboratory testing is difficult to access and expensive.

REVA MEDICAL

Reva says that its 110-patient Fantom II cardiac stent trial has implanted its first patient in Australia at Sydney's St Vincent's Hospital, in addition to sites in Brazil and Europe.

Reva executive chairman Bob Stockman said the company was "very excited to begin patient enrollment in Australia".

"We expect Australia to play an important role in the Fantom clinical trial program," Mr Stockman said.

Reva was untraded at 51 cents.

CELLMID

Cellmid says it has a \$1,000,000 loan agreement with Platinum Road to accelerate the launch of its Évolis hair growth products and proceed with anti-midkine toxicology studies. Cellmid said the secured loan was for eight months with its Federal Government R&D Tax Credit expected in November 2015.

The company said that the Sydney-based Platinum Road had the right to up to 29,411,765 new shares at 3.4 cents a share to reduce the principal, interest would accrued monthly at 15 percent a year with a maximum liability of \$100,000 during the course of the loan and Platinum had the right to up to 4,347,826 Cellmid shares in lieu of the accrued interest at 2.3 cents a share during the course of the loan.

Cellmid said that due to its expansion of the pharmacy distribution in Australia and growth in Japan, it expects a "significant increase in sales".

Cellmid fell 0.1 cents or 3.85 percent to 2.5 cents with 1.5 million shares traded.

[BIODIEM](#)

Biodiem says it expects its first royalties from sales of the Serum Institute of India's Nasovac-S seasonal influenza vaccine based on its live attenuated influenza vaccine. Biodiem delisted in 2013 and continues as a public unlisted company (BD: Nov 8, 2013). Today, the company said that royalties from sales in India were about \$40,000 for the three months to March 31, 2015 and it was expecting a similar payment next quarter. The company said that Nasovac-S was likely to be approved for export in a few months, following the World Health Organisation pre-qualification approval. Biodiem said it had created the wholly-owned subsidiary Opal Biosciences to accelerate the development of its BDM-I anti-microbial technology (BD: Apr 30, 2014).

[REPRODUCTIVE HEALTH SCIENCE](#)

Reproductive Health says it has collaborated with French microarray scanner manufacturer Innopsys so its Innoscan 710 can work with the Embryocollect system. Reproductive Health said that the Innoscan 710 was an open system used by in-vitro fertilization laboratories and could be used for its Embryocollect pre-implantation genetic screening. Reproductive Health was untraded at 15 cents.