



# Biotech Daily

Wednesday March 11, 2015

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: NEUREN UP 7%, GI DYNAMICS DOWN 19%**
- \* **UK FUND'S \$13m FOR MEDICINES DEVELOPMENT RIVER BLINDNESS**
- \* **BENITEC DOSES 4<sup>th</sup> TT-034 HEPATITIS C PATIENT**
- \* **AMPLIPHI RAISES \$17m FOR BACTERIOPHAGE ANTIBACTERIAL**
- \* **GENERA TESTS ON REGISTER, CE MARK NEWS 'NEXT WEEK'**
- \* **3D SELLS MACH7 PRODUCTS TO TELSTRA HEALTH, GAINS DATA SERVICE**
- \* **ALLAN GRAY REDUCES TO 9.6% OF NANOSONICS**
- \* **ALLAN GRAY INCREASES, DILUTED TO 17.7% OF IMPEDIMED**

## MARKET REPORT

The Australian stock market fell 0.53 percent on Wednesday March 11, 2015 with the S&P ASX 200 down 31.0 points to 5,793.2 points.

Just four of the Biotech Daily Top 40 stocks were up, 24 fell, eight traded unchanged and four were untraded.

Neuren was the best, up 0.7 cents or 7.1 percent to 10.5 cents with 2.7 million shares traded. Atcor and Sirtex were up more than four percent; Pharmaxis rose 2.5 percent; with Cochlear up 0.2 percent.

GI Dynamics led the falls, down three cents or 19.35 percent to 12.5 cents with 2.2 million shares traded, followed by Phosphagenics down 15.25 percent to five cents with 2.9 million shares traded.

Patrys lost 9.1 percent; Acrux and Starpharma fell seven percent or more; Bionomics was down 5.6 percent; Antisense, Genetic Technologies and Oncosil fell four percent or more; Benitec, Compumedics and Universal Biosensors were down more than three percent; Admedus, Anteo, Cellmid, Clinuvel, Medical Developments and Viralytics shed more than two percent; Alchemia, CSL, Ellex, Impedimed, Nanosonics and Optiscan were down more than one percent; with Mesoblast and Resmed down by less than one percent.

## MEDICINES DEVELOPMENT FOR GLOBAL HEALTH

Medicines Development says the UK-based Global Health Investment Fund will provide \$US10 million (\$A13.1 million) to register moxidectin for river blindness or onchocerciasis. The Melbourne-based Medicines Development said that river blindness was a debilitating, neglected, tropical disease caused by the worm *Onchocerca volvulus*, which was transmitted through the bites of infected black flies of the genus *Simulium* and affected more than 37 million people, most of whom lived in poor communities in sub-Saharan Africa.

Medicines Development's Patty Fegan told Biotech Daily that the drug was originally developed as a veterinary product by Pfizer and Wyeth and was now off-patent and her company had licenced the moxidectin data from the World Health Organisation, would undertake the registration process and, if successfully registered, would supply the drug. The company said that from the late 1990s, the WHO-based special programme for research and training in tropical diseases worked extensively with industry, patient and community groups to evaluate the use of moxidectin for the treatment of onchocerciasis. Medicines Development said that the compound was an anthelmintic medicine with activity against a broad range of parasitic worms and insects.

The company said that the final stages of human studies in river blindness have now been completed and moxidectin has been shown to be well tolerated and effective against the disease.

Medicines Development said that the Global Health Investment Fund investment would be used to support the manufacture of moxidectin and the compilation of the regulatory dossier required for the registration process for use in humans.

The company said the agreement required that if approved, it would ensure accessibility of moxidectin for river blindness.

Medicines Development chief executive officer Mark Sullivan said that moxidectin had "the potential to be an important medicine for treating river blindness, and we are delighted to work with GHIF to achieve the goal of registering this drug for human use".

"GHIF's strategy to invest in projects that impact health particularly in low and middle-income countries could not be better matched with the reasons we established Medicines Development," Mr Sullivan said.

The company said that onchocerciasis or river blindness was widespread in sub-Saharan Africa, with pockets of infection in the Arabian Peninsula and in some parts of South America as well, with more than 100 million Africans are at risk of infection.

Medicines Development said that each adult female *Onchocerca volvulus* worm could live for up to 15 years in the human body, producing millions of microscopic offspring, or microfilaria, that migrate through the skin, eyes, and lymph nodes.

The company said that the microfilariae were the main cause of the symptoms, which included severe skin inflammation and intense itching, enlarged lymph nodes and, in some patients, visual impairment that can ultimately lead to blindness.

Medicines Development said that control and elimination of the disease relied on mass annual or biannual drug administration with ivermectin, through donations to the Mectizan Donation Program by Merck Inc, known as Merck Sharp and Dohme outside the US and Canada.

The company said the Global Health Investment Fund was a private fund structured by JP Morgan Chase & Co, the Bill & Melinda Gates Foundation and Lion's Head Global Partners, with anchor support from the Governments of Canada and Germany, the Swedish International Development Cooperation Agency and the Children's Investment Fund Foundation.

Medicines Development is a private not-for-profit company.

## [BENITEC BIOPHARMA](#)

Benitec says the fourth patient in its first-in-man phase I/IIa trial of TT-034 for hepatitis C, has been dosed at the Duke Clinical Research Unit.

Benitec said that the fifth patient was "well advanced in their preparation for dosing".

The company said that dosing with the DNA-directed RNA-interference (ddRNAi) TT-034 followed the data safety monitoring board's review of the safety data from the first patient in this cohort.

Benitec said that all three patients in the second cohort would receive a dose of TT-034 of  $1.25 \times 10^{11}$  vector genome particle per kilogram (vg/kg), a concentration that was a half log higher than the doses administered in the first cohort.

The company said that the dose level was below the concentration expected to inhibit hepatitis C viral replication and data from the second dosing cohort was expected to serve primarily as a further safety assessment.

Benitec fell three cents or 3.75 percent to 77 cents.

## [AMPLIPHI BIOSCIENCES CORP](#)

Ampliphi says it has definitive purchase agreements to raise \$US13 million (\$A17 million) in a private placement, through the issue of 78,787,880 shares at 16.5 US cents each.

Ampliphi said it was developing and commercializing novel bacteriophage-based antibacterial therapeutics, was based in Richmond, Virginia and had primary operations in Ljubljana, Slovenia and Sydney, Australia.

Ampliphi chairman and interim chief executive officer Jeremy Curnock Cook said that with strategic collaborator Intrexon Corp, "we are well positioned to finally realize the potential of phage-based therapies to make a key contribution to addressing the global need for alternative therapies that address the potentially devastating effects of drug resistant infections".

The company said that the funds would advance its three programs in methicillin-resistant staphylococcus aureus (MRSA), Pseudomonas aeruginosa infections in cystic fibrosis and Clostridium difficile.

Ampliphi said it intended to file an investigational new drug application to the US Food and Drug Administration for Ampliphage-002 in MRSA and begin phase I clinical trials by the end of 2015, complete inhalation toxicology studies in its Ampliphage-001 Pseudomonas aeruginosa program by the end of 2015 and conclude pre-clinical efficacy studies for Ampliphage-004 for Clostridium difficile during 2015.

The company said that bacteriophage were naturally occurring viruses highly specific for the bacterial hosts they infect, they could rapidly kill their host, amplifying themselves in the process.

Ampliphi said that bacteriophage were unaffected by antibiotic resistance and were able to disrupt bacterial biofilms, a major line of defence for bacteria, contributing to antibiotic resistance.

The company said that bacteriophage were able to penetrate biofilms and replicate locally to high levels, to produce strong local therapeutic effects.

Ampliphi said that Roth Capital Partners and Griffin Securities were the placement agents. According to the Nasdaq, last night on the US over-the-counter market, Ampliphi fell 0.5 US cents or 2.56 percent to 19 US cents with 274,646 shares traded.

### GENERA BIOSYSTEMS

Genera says its Paptype and RTI-plex tests as well as its QPlots software for in-vitro diagnostics have been included on the Australian Register of Therapeutic Goods. Genera said that the Paptype diagnostic for human papillomavirus and RTI-plex respiratory test were molecular diagnostics assays and with the QPlots software were classified as class 3 medical devices.

The company said that the RTI-plex simultaneously detected 12 viral and three bacterial pathogens.

Genera said it was completing the process for Conformité Européenne (CE) mark approval for the Paptype and RTI-plex tests and expected "to make an announcement regarding the outcome of this process sometime next week".

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

### 3D MEDICAL

3D Medical says it will sell Mach7 Technologies image management products to Telstra Corp division Telstra Health for development of an image and data management service. 3D said it had exclusive reseller rights in Australia and New Zealand to the South Burlington, Vermont-based Mach7 Technologies, which develops image management products for hospitals, radiology clinics and other health service providers.

The company said that Mach7 had an enterprise imaging platform designed to enable ownership, sharing and access of imaging data to improve patient care, revenues, compliance and clinician satisfaction across the enterprise.

3D said the software licence and support agreement would enable supply of Telstra's image and data management service to 3DM customers and both organizations to offer the service to a new customer base, with commercial release planned by October 2015. 3D was up two cents or 13.3 percent to 17 cents with 40.0 million shares traded.

### NANOSONICS

Allan Gray Australia has reduced its substantial holding in Nanosonics from 28,673,104 shares (10.85%) to 26,904,652 shares (9.63%).

Allan Gray said the 1,768,452 shares were sold between February 19 and March 6, 2015 for \$3,143,628 or an average price of \$1.78 a share.

Nanosonics fell two cents or 1.15 percent to \$1.72 with 3.2 million shares traded.

### IMPEDIMED

Allan Gray Australia has increased its holding in Impedimed from 31,064,002 shares to 51,831,862 shares but was diluted from 19.85 percent to 17.68 percent.

Allan Gray said that it bought and sold shares between May 3, 2012 and March 6, 2015 with average purchase prices ranging from 27.5 cents a share to 42.9 cents a share.

In December last year, Impedimed raised \$32.5 million in a rights issue at 60 cents a share (BD: Nov 3, Dec 10, 2014).

Impedimed fell one cent or 1.25 percent to 79 cents.