Biotech Daily

Thursday April 16, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ALTERITY UP 29%; MEDICAL DEVELOPMENTS DOWN 10%**

*** ATOMO IPO OPENS UP 95% WITH COVID-19 ANTIBODY TEST ORDERS**

*** STARPHARMA: 'SPL7013 INHIBITS SARS-COV-2 INFECTION OF CELLS'**

*** RECCE REQUESTS 'ANTI-VIRAL RESULTS' TRADING HALT**

*** OSTEOPORE REQUESTS 'REGULATORY APPROVAL' TRADING HALT**

*** GOODBYE BENITEC**

*** PROTEOMICS CE MARK FOR PROMARKERD IMMUNOASSAY**

*** MAYNE US NDA FOR E4-DRSP ORAL CONTRACEPTIVE**

*** CLINUVEL LAUNCHES SCENESSE IN US**

*** BOTANIX DROPS DERMATOLOGY FOR ANTIMICROBIAL TARGETS**

*** ACRUX CORRECTS 'NON-MATERIAL' TGA DEFICIENCIES**

*** BATAVIA DEVELOPS IMMUTEP IMP761 CELL LINE**

*** ADHERIUM, HGE WORK ON REMOTE COPD MANAGEMENT**

*** ANTEOTECH RECEIVES $967k R&D TAX INCENTIVE**

*** REGAL FUNDS TAKES 11% OF IDT**

MARKET REPORT

The Australian stock market fell 0.92 percent on Thursday April 16, 2020, with the ASX200 down 50.4 points to 5,416.3 points. Twelve of the Biotech Daily Top 40 stocks were up, 20 fell and eight traded unchanged.

Alterity was the best, up 0.5 cents or 29.4 percent to 2.2 cents, with 1.8 million shares traded. Starpharma climbed 18.3 percent; Impedimed improved 17.65 percent; Neuren and Proteomics were up more than seven percent; Pharmaxis was up 6.4 percent; Actinogen was up five percent; Antisense and Clinuvel improved more than four percent; Immutep was up three percent; Polynovo and Resmed rose more than one percent; with CSL and Nanosonics up by less than one percent.

Medical Developments led the falls, down 81 cents or 9.8 percent to $7.43, with 524,360 shares traded. Oncosil lost eight percent; Orthocell and Resonance fell more than seven percent; Mesoblast, Next Science and Opthea shed six percent or more; Ellex, Prescient, Telix and Volpara were down more than five percent; Imugene and Paradigm fell four percent or more; Cynata and Genetic Signatures were down more than three percent; Avita and Compumedics shed more than two percent; Pro Medicus and Uscom were down more than one percent; with Cochlear and Cyclopharm down less than one percent.

ATOMO DIAGNOSTICS

Atomo opened on the ASX under the code AT1, at 39 cents, up 95 percent above its initial public offer price of 20 cents a share.

At 20 cents a share the company said it would have a market capitalization of $112 million dollars.

Atomo's share price climbed as high as 63 cents and closed the day at 39 cents, implying an estimated market capitalization of $218.4 million.

This morning, Atomo said it signed a binding agreement with French company NG Biotech on March 31 to buy up to a total of 2.5 million rapid blood self-tests for Covid-19 during calendar year 2020 for sale in France and the UK.

The company said it had confirmed orders for 947,200 kits from NG Biotech.

In March, Atomo said it was working with device and diagnostics manufacturing customers to develop new rapid blood self-tests for Covid-19 (BD: Mar 19, 2020).

The company said at that time that the Covid-19 blood tests would use its Atomo device to collect and deliver a controlled volume of blood to test for the infection by detecting the presence of antibodies generated in response to the virus.

Atomo said the tests were intended for use by individuals to self-test and could be used by health professionals to screen patients.

Earlier in March, Atomo said it hoped to raise up to $30 million at 20 cents a share to list on the ASX and commercialize its HIV and other tests (BD: Mar 5, 2020).

Today, the company said that its initial public offer was "oversubscribed" raising $30 million at 20 cents a share, implying a market capitalization of $112 million at that price and an enterprise value of $80.31 million.

Atomo said that shareholders included property developer Lang Walker, former Macquarie Bank chief executive officer Allan Moss, the Bill and Melinda Gates Foundation-backed Global Health Investment Fund and the Government of Canada's Grand Challenges Canada fund, as well as Australian institutions.

The company said that it had "strong interest" in the use of its integrated rapid test device for the testing of Covid-19 antibodies and had signed an agreement with the Guipry, France-based NG Biotech would have the right to purchase up to a total of 2,465,000 devices during calendar year 2020 for sale in France and the UK.

In 2016, Atomo said that with NG Biotech it had developed the first fully-integrated emergency department rapid blood test for pregnancy (BD: Nov 10, 2016).

Atomo said at that time that the NG-Test Blood Precision hCG test detected and measured for human chorionic gonadotropin (hCG) levels, which was a routine procedure when a female patient was admitted to an emergency department with abdominal pain or bleeding.

Today, the company said that funds raised under the initial public offer would be used to expand manufacturing and distribution capacity to support demand for tests using its devices, including for Covid-19, HIV and other purposes and continue to support its existing HIV distributors and other "original equipment manufacturing" customers.

Atomo co-founder and managing-director John Kelly said it was "a hugely significant day in Atomo's history".

"We started the listing process to underpin the expansion of our global HIV business and enable us to commercialize other opportunities in the rapid blood test market, but through the offer period determined we were also uniquely positioned to make a major impact within the Covid-19 environment," Mr Kelly said.

"We are now well-capitalized and able to quickly move to meet the significant global demand for reliable rapid testing for Covid-19 in the community," Mr Kelly said.

Atomo closed up 19 cents or 95 percent at 39 cents with 58.2 million shares traded.

STARPHARMA HOLDINGS

Starpharma says topical SPL7013 inhibits the infection of cells with the severe acute respirator syndrome-coronavirus-2 (Sars-Cov-2) in-vitro.

Starpharma said that SPL7013 or astodrimer sodium was the active ingredient in its Vivagel used for condom coatings and as a preventative for bacterial vaginosis.

The company said that the laboratory testing of SPL7013 by Melbourne's 360-Biolabs was "validated by replicate testing against a positive control compound, [Gilead's intra-venous anti-viral] remdesivir … a leading candidate for the treatment of Covid-19" the disease caused by Sars-Cov-2.

Starpharma said the finding was "significant given that SPL7013 was reported to be the best performing test compound against Sars-Cov-2 in the laboratory's assay to date".

The company said it was "evaluating product concepts and formulation options for SPL7013, which may have potential applications in the prevention and management of Covid-19".

Biotech Daily asked Starpharma chief executive officer Dr Jackie Fairley whether SPL7013 had ever been trialled as an intravenous systemic drug, but at the time of publication had not received an answer.

The company has multiple agreements with Astrazeneca for its dendrimer-enhanced product combination with existing anti-cancer drugs.

Starpharma said that given that SPL7013 was already approved as the active component of Vivagel BV for bacterial vaginosis and the Vivagel condom, with regulatory approval in Europe, Canada, Japan, Australia and South East Asia, it expected "it should be possible to fast-track certain aspects of the development path for products targeted at Covid-19".

The company said it would start additional short-term pre-clinical studies, and in parallel, confirm the pathway with regulatory authorities.

Starpharma said a patent application had been filed following the coronavirus results and it retained the rights to Covid-19-related products resulting from the findings and they would be the subject of new commercial licences and not impact existing Vivagel licences.

The company said that SPL7013 previously showed "potent anti-viral activity against … HIV, herpes simplex, hepatitis B, [human papillomavirus], Zika virus and adenovirus" and it inactivated viruses by blocking the interaction between viral surface proteins and the human cell receptor proteins.

Dr Fairley said that following the emergence of the coronavirus pandemic in February, "Starpharma instigated testing of SPL7013".

"We are very pleased to find that the compound is highly active against the coronavirus that causes Covid-19 and we are now exploring a number of product opportunities, including a potential preventative application to reduce the risk of infection," Dr Fairley said.

"Such a product could provide additional personal protection including for those in the frontline of this crisis, such as doctors, nurses and other essential workers, and is in keeping with Starpharma's strategy to expand commercial applications of our dendrimers," Dr Fairley said.

Starpharma climbed 17 cents or 18.3 percent to $1.10 with 6.4 million shares traded.

RECCE PHARMACEUTICALS

Recce has requested a trading halt "pending the release of an announcement relating to anti-viral test results".

Trading will resume on April 20, 2020 or on an earlier announcement.

Recce last traded at 32.5 cents.

OSTEOPORE

Osteopore has requested a trading halt “pending the release of an announcement regarding regulatory approval”.
Trading will resume on April 20, 2020 or on an earlier announcement.
Osteopore fell three cents or six percent to 47 cents before the trading halt.

BENITEC BIOPHARMA

Benitec says that its scheme of arrangement to leave Australia for the US has been implemented and it will be removed from the ASX at the close of trading today.
Last month, Benitec said its scheme meeting for the US-based Benitec Biopharma to become its parent company had been approved by both shareholders and the Supreme Court of Queensland (BD: Mar 26, 30 2020).
Benitec last traded at 2.6 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has Conformité Européenne (CE) mark approval for its Promarkerd immunoassay as an in-vitro diagnostic for kidney disease onset in type 2 diabetes patients.
Proteomics said its Promarkerd immunoassay was a high-throughput version of its Promarkerd mass spectrometry test system, which already had CE mark approval.
The company said it would lodge a US Food and Drug Administration application in mid-2020.
Proteomics managing director Dr Richard Lipscombe said “the CE Mark is another important milestone for Promarkerd as we move forward with new deals in the region”.
“With CE mark the immunoassay offers a higher-throughput option for testing laboratories who want access to our ground-breaking test for predicting diabetic kidney disease, one that could enable earlier therapeutic intervention to minimize the effect of this crippling disease,” Dr Lipscombe said.
Proteomics was up two cents or 7.1 percent to 29 cents.

MAYNE PHARMA GROUP

Mayne says it has submitted a new drug application to the US Food and Drug Administration for its E4-DRSP oral contraceptive.
Mayne said E4-DRSP was a novel, next generation, combination oral contraceptive containing 15mg of oestetrol (E4) and 3mg of drospirenone (DRSP).
The company said that US sales of combined hormonal contraceptives was more than $US4 billion a year and 10 million American women used oestrogen and progestin combination oral pills, patches or vaginal rings every day.
Mayne said that if approved, it expected to make E4-DRSP available to US patients by July, 2021.
Mayne chief executive officer Scott Richards said the NDA filing was “a major milestone for Mayne Pharma and our development partner Mithra Pharmaceuticals”.
“We are now one step closer to making this new oral contraceptive, that we believe to be safe, effective and well-tolerated, available to American women,” Mr Richards said.
“We confirm our earlier stated goal of bringing this product to market in the first half of calendar 2021,” Mr Richards said.
Mayne was up four cents or 11.6 percent to 38.5 cents with 19.8 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has launched Scenesse in the US for erythropoietic protoporphyria (EPP) with reimbursement support from more than 30 US insurance companies.
Clinuvel said insurance companies would provide reimbursements for treatment under prior authorization, acceptance as a specialty drug or as included in their formulary.
The company said Scenesse would be administered every two months by trained healthcare professionals in a maximum of 30 accredited specialty centres, for a minimum of eight years.
Clinuvel was up 87 cents or 4.2 percent to $21.40 with 273,017 shares traded.

BOTANIX PHARMACEUTICALS

Botanix says it will suspend or halt its synthetic cannabinoid programs for dermatology and focus resources on antimicrobial targets.
In March, Botanix said that its 200-patient, phase II trial of BTX1204 for atopic dermatitis, or eczema, did not meet its primary or secondary endpoints (BD: Mar 25, 2020).
Last year, the company said its 368-patient, phase II trial of BTX1503 for acne missed its primary endpoint for reduction of inflammatory lesions, or pimples (BD: Oct 23, 2019).
Today, Botanix said it reviewed its programs and would prioritize resources "focusing its development resources primarily on its antimicrobial platform and the progression of its first [anti-microbial] clinical program for BTX1801, while continuing to progress key assets from the dermatology platform in a clinically constrained manner".
The company said it would have an end of a phase II meetingfwith the US Food and Drug Administration on BTX1503 for acne, for guidance for a path to support a new drug application submission.
Botanix said it had suspended development of BTX1204 for atopic dermatitis, clinical development of BTX1702 for rosacea would be on hold until recruitment could begin again, BTX1308 for psoriasis would be suspended and Permetrex opportunities and partnerships would continue to be sought.
The company said it had reduced staff, consultants and directors' fees to save costs of about 70 percent and would issue options to directors to compensate for the increased workload, subject to shareholder approval.
Botanix said it would issue 17,994,914 options to chair Vince Ippolito, 11,186,028 options to Dr Michael Thurn and 4,863,490 options each to Dr Bill Bosch and Dr Stewart Washer, at a 34 percent premium to the seven-day volume weighted average price to April 15, vesting after 12 months and exercisable within 24 months.
Botanix fell half a cent or 12.8 percent to 3.4 cents with 14.6 million shares traded.

ACRUX

Acrux says it has been required to correct "a small number" of deficiencies by the Australian Therapeutic Goods Administration but they are not material.
Acrux said that no critical or major deficiencies were noted by the TGA and it was given a timeline to repair the deficiencies.
Acrux product development and technical affairs director Felicia Colagrande said "the successful inspection of the Acrux facility provides Acrux with the ability to manufacture phase II and phase III clinical trial drug product".
Acrux fell one cent or 6.9 percent to 13.5 cents.

IMMUTEP

Immutep says manufacturing partner Batavia Biosciences has “made significant progress” in the cell line development of IMP761 for autoimmune disease.
Immutep said the Leiden, Netherlands-based Batavia had developed a pharmaceutical grade, stable Chinese hamster ovary cell line, which produced significantly high product yields of IMP761, which was an immunosuppressive agonist antibody to LAG-3.
The company said it would prepare the good manufacturing practice process before clinical testing of the compound for autoimmune disease.
Immutep was up half a cent or three percent to 17 cents with 2.7 million shares traded.

ADHERIUM

Adherium says it will collaborate with HGE Health to integrate its Hailie sensor and software technology into HGE’s telemedicine platform HGE Care.
Adherium said the Fort Washington, Pennsylvania-based HGE Care was a full-service remote patient management product for chronic obstructive pulmonary disease (COPD) patients and allowed pulmonary and primary care physicians to remotely care for patients anywhere in the US.
The company said that software application-based patient data was also used to enable carer and provider reimbursement using current procedural terminology (CPT) codes.
Adherium said the collaboration would focus initially on COPD patients, targeting those at risk from Covid-19 through HGE Care’s contracted payers and providers in New Jersey, Pennsylvania, Oklahoma and Arizona, who managed more than 100,000 COPD patients.
The company said it expected to later expand to remote asthma management and to extend its Hailie sensor to include key physiological measurements including peak flow.
Adherium said it did not expect material revenue in 2020 but significant commercial impact thereafter.
Adherium was up 0.6 cents or 25 percent to three cents with 9.1 million shares traded.

ANTEOTECH (FORMERLY ANTEO DIAGNOSTICS)

Anteotech says it has received $966,562 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Anteotech said the rebate related to research and development expenditure for the year to June 30, 2019.
Anteotech fell 0.1 cents or 4.35 percent to 2.2 cents with 1.2 million shares traded.

IDT AUSTRALIA

Regal Funds Management says it has increased its substantial shareholding in IDT from 24,749,237 shares (9.96%) to 26,360,286 shares (11.01%).
The Sydney-based Regal Funds said that on April 9, 2020 it acquired 1,611,049 shares for $258,573.36 or 16.05 cents a share.
IDT was unchanged at 16 cents with 1.2 million shares traded.