Biotech Daily

Tuesday December 4, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: OSPREY UP 8%; AIRXPANDERS DOWN 12%**

*** REDHILL PHASE III CONFIRMS RHB-105 FOR HELICOBACTER PYLORI**

*** AVITA RAISES $40m FOR US SALES**

*** ATOMO: 'TGA APPROVES HIV SELF-TEST'**

*** FEDERAL $10m FOR MTP CONNECT**

*** NUHEARA 'OVERSUBSCRIBED' PLACEMENT RAISES $5m**

*** REVA FANTOM ENCORE 1st ITALY IMPLANT**

*** ANTISENSE RECEIVES $285k FEDERAL R&D TAX INCENTIVE**

*** PHYLOGICA PEPTIDES DELIVER CAS9 TO LABORATORY CELLS**

*** MEDLAB EUROPE SUBSIDIARY FOR EMA REGISTRATION**

*** JENCAY, BRETT ROCK INCREASE TO 7% OF UNIVERSAL BIOSENSORS**

*** BORI LIBERMAN, JAGEN TAKE 7% OF OPTHEA**

*** CARDIEX REQUESTS 'CAPITAL RAISING ACTIVITY' TRADING HALT**

*** ADMEDUS APPOINTS DR KIRAN BHIRANGI CMO**

*** CORRECTION: BDI-40 WITH MARKET CAPITALIZATION**

MARKET REPORT

The Australian stock market fell 1.01 percent on Tuesday December 4, 2018 with the ASX200 down 58.1 points to 5,713.1 points. Seven of the Biotech Daily Top 40 stocks were up, 18 fell, 11 traded unchanged and four were untraded. All three Big Caps fell.

Osprey was the best, up one cent or 8.3 percent to 13 cents, with 123,658 shares traded. Nanosonics, Orthocell and Polynovo rose more than two percent; Genetic Signatures was up 1.4 percent; with Ellex and Pro Medicus up by less than one percent.

Airxpanders led the falls, down 0.4 cents or 11.8 percent to three cents, with 1.6 million shares traded. Telix lost 8.6 percent; Actinogen was down 6.5 percent; Immutep fell 5.3 percent; Mesoblast and Proteomics were down more than four percent; Benitec, Optiscan, Patrys and Pharmaxis lost more than three percent; Dimerix and Universal Biosensors shed more than two percent; Avita, Clinuvel, Cochlear, Compumedics, Medical Developments, Resmed, Starpharma and Volpara were down one percent or more; with CSL down 0.9 percent.

REDHILL BIOPHARMA

Redhill says its randomized, 455-patient, confirmatory phase III trial shows that Talicia (RHB-105) is significantly superior to standard of care for Helicobacter pylori ($p<0.0001$).
Redhill said the 'Eradicate Hp2' phase III trial compared Talicia, an all-in-one oral capsule combining the antibiotics rifabutin and amoxicillin and proton pump inhibitor omeprazole, to the combination of amoxicillin and omeprazole at equivalent doses.
The company said the study showed that Talicia eradicated Helicobacter in 84 percent of patients compared to 58 percent for the amoxicillin and omeprazole combination, with no safety issues reported and Talicia was well tolerated.
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, Redhill said the study investigated dyspepsia patients with confirmed Helicobacter pylori infection, randomized to receive four capsules, three times daily, of either Talicia or the comparator, for 14 days, with assessment at least 43 days after the start of treatment.
The company said that a "high resistance to standard-of-care antibiotics observed in the Eradicate Hp2 study is consistent with the diminishing efficacy of standard-of-care therapies, which has declined to approximately 60 percent".
Redhill said the trial supported the potential of Talicia as a best-in-class, first-line therapy for Helicobacter pylori, with an estimated 2.5 million patients treated each year in the US.
The company said it was preparing for a potential new drug application to the US Food and Drug Administration by July 2019 and a commercial US launch by the end of 2019.
Redhill said it was pursuing the indication of Helicobacter pylori, regardless of ulcer status, "a significantly broader indication than current standard treatments".
The company said Talicia had FDA qualified infectious disease product and fast-track designation, including eligibility for six-month priority review and eight years market exclusivity.
Redhill chief executive officer Dror Ben-Asher said that the company was "delighted with these excellent top-line results and are preparing for US new drug application submission, expected in the first half of 2019, subject to FDA feedback".
"Our established US commercial operations team and [gastro-intestinal]-focused sales force are well-positioned for the potential US commercial launch of Talicia, expected in the second half of 2019, subject to FDA approval," Mr Ben-Asher said.
On the Nasdaq, Redhill fell 33 US cents or 3.92 percent to $US8.08 ($A10.98) with 369,246 shares traded.

AVITA MEDICAL

Avita says it has commitments to raise $40 million at eight cents a share to fund US marketing and sales of its Recell burns treatment and will offer a retail share plan.
Avita said the second of the two-tranche placement to institutional and sophisticated investors would require shareholder approval and the funds would be used for research and development to advance its pipeline and general working capital.
Avita chief executive officer Dr Mike Perry said the US Recell for burns approval was "a transformative event for Avita" and the proceeds would allow the company to advance its pipeline beyond burns to high-value areas including traumatic wounds and vitiligo.
The company said that a share plan for holders on the record date of December 3, 2018 would allow investors to buy up to $15,000 in shares.
Avita said the placement was managed by New York's Cowen and Company LLC as lead placement agent and Bell Potter as lead Australian manager.
Avita fell 0.1 cents or 1.2 percent to 8.1 cents with 4.2 million shares traded.

ATOMO DIAGNOSTICS

Atomo says the Australian Therapeutic Goods Administration has approved its HIV self-test for sale in Australia, the “first rapid diagnostic test for home use”.
Atomo said that the test was the only TGA-approved diagnostic self-test for HIV and would be made available throughout Australia in the coming months.
The company said that earlier this year, the Australian Federation of AIDS Organisations said “it would welcome the approval in Australia of HIV self-tests.”
Atomo said self-tests would increase testing frequency in populations with a higher prevalence of HIV and reach populations not presenting at healthcare facilities for testing, and was considered “an essential tool to facilitate earlier diagnosis of HIV worldwide”.
Atomo chief executive officer John Kelly said that TGA approval was “a major achievement”.
The company said the handheld device incorporated a sterile safety lancet, blood collection and delivery system, sensitive HIV diagnostic test strip, requiring a small drop of blood from the fingertip and displayed results within 15 minutes.
The company said the device was approved for sale in Europe and passed by the World Health Organisation's Unitaid expert review panel for diagnostics.
Atomo is a private company.

FEDERAL GOVERNMENT, MTP CONNECT

MTP Connect says the Federal Government will provide $10 million to fund the “growth centre” organization for an additional two years.
MTP Connect chief executive officer Dr Dan Grant welcomed the funding announced by the Federal Minister for Industry, Science and Technology Karen Andrews.
“In the nearly three years since our establishment, MTP Connect has been helping to accelerate the growth of the [medical technologies and pharmaceuticals] sector by forging stronger connections between research and industry and maximizing opportunities for the translation and commercialization of our discoveries,” Dr Grant said.
MTP Connect said that through the Federal Department of Industry, Innovation and Science’s Project Fund Program it had invested $15.6 million across 37 collaborative projects, engaging more than 160 consortium members and leveraging $22 million of matched cash funding from industry and a further $3.7 million in-kind support.

NUHEARA

Nuheara says it has raised $5 million an “oversubscribed” placement at 7.5 cents to increase Iqbuds Boost inventory levels following the UK NHS hearing aid contract.
Last week, Nuheara said the UK National Health Service selected Iqbuds Boost hearing buds for mild to moderate hearing loss, the first time a smart hearing bud was able to be prescribed alongside traditional hearing aids (BD: Nov 28, 2018).
Today, the company said the funds would be used to increase related sales and marketing activities and the development and manufacture of new products including Iqstream TV and Iqbuds Max.
Nuheara said the 7.5 cent placement price was a four percent discount to the most recent closing price and a 10 percent discount to the 30-day volume-weighted average price.
The company said the raising was supported by many of its existing institutional shareholders including the largest shareholder Farjoy Pty Ltd, with Sydney’s APP Securities Pty Ltd and Perth’s Patersons Securities the placement’s joint lead managers.
Nuheara was up 0.9 cents or 11.5 percent to 8.7 cents with 8.0 million shares traded.

REVA MEDICAL

Reva says its Fantom Encore bioresorbable coronary artery scaffold has been implanted in the first patient in Italy.
Reva said that the implant was performed by Prof Antonio Colombo at Milan's Columbus Clinic Centre.
Prof Colombo said the patient was 53 years old and "during the procedure, I was impressed by Fantom Encore's ease-of-use owing to its thinner strut profile and strength".
The company said the Fantom Encore was a third-generation coronary bioresorbable scaffold with a thin strut profile compared to other commercially available stents.
Reva chief executive officer Dr Reggie Groves said that with distributor the Bio Vascular Group it was "actively working to expand geographic access through new partnerships in other regions of Europe and Asia".
Reva was unchanged at 20 cents.

ANTISENSE

Antisense says it has received $284,900 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Antisense said the rebate related to research and development expenditure for the year to June 30, 2018 and "a higher amount is anticipated for the following year in line with the greater R&D spend associated with the ongoing clinical trial of ATL1102 in [Duchenne muscular dystrophy]".
Antisense was unchanged at 3.2 cents.

PHYLOGICA

Phylogica says its cell penetrating peptide can deliver CRISPR-associated protein 9 (Cas9) into ex-vivo animal cells in the laboratory.
Phylogica said that it used its first-generation cell penetrating peptide, formerly known as phylomers, to deliver the DNA editing clustered regularly interspaced short palindromic repeats (CRISPR)-associated protein 9 into the nucleus of "a difficult to transfect cell line".
The company said the delivery of the Cas9 cargo knocked down the expression levels of a receptor on the surface of the cells as a result of the Cas9 gene-editing.
Phylogica said it would determine the optimal conditions for cell penetrating peptide-mediated Cas9 delivery to assess the relative efficacy and safety of the peptides compared to other delivery approaches for Cas9.
The company said it would investigate primary cells, or cells derived directly from a living organism rather than the immortalized laboratory cells used in the current study, to "demonstrate the absolute numbers of cells that we are able to successfully achieve gene-editing in relative to alternative delivery approaches, for example electro-poration and lipid-based delivery systems".
Phylogica said the primary cells used in the current study would be the cell type for the ex-vivo commercial applications of the CRISPR/Cas9 technology and should therefore directly inform the commercialization prospects for the program.
The company said that in parallel to the testing of the first generation of cell penetrating peptides in the context of Cas9 delivery, it had identified and matured second generation peptides that were substantially more efficient at delivering cargoes into the target cell of interest in the Cas9 program, which had been ordered and would be available for evaluation in the CRISPR/Cas9 program by April 2019.
Phylogica was unchanged at 2.9 cents with 2.2 million shares traded.

MEDLAB CLINICAL

Medlab says it has incorporated wholly-owned subsidiary MDC Europe for registration dealings with the European Medicines Agency regarding its Nanabis medical marijuana.
Medlab said it had held meetings with the EMA on the pathway for registration of Nanabis and conditional approval was “likely” and that registration with a significant fee reduction required the company to be domiciled in Europe.
Medlab chief executive officer Dr Sean Hall said that his company was “strategically placed to progress commerce in Europe through potential trade deals, especially in conjunction with the recently announced granting of an export licence for Nanabis”.
Medlab was up half a cent or 1.3 percent to 38.5 cents.

UNIVERSAL BIOSENSORS

The Sydney-based Jencay Capital says it has increased its substantial holding in Universal Biosensors from 10,824,146 shares (6.14%) to 13,061,444 shares (7.39%).
The notice signed by director Brett Rock said that between June 16 and November 28, 2018 Jencay acquired 2,237,298 shares for $535,113, or 23.9 cents a share.
Universal Biosensors fell half a cent or two percent to 24 cents with 1.65 million shares traded.

OPTHEA

Jagen Pty Ltd says it has become a substantial shareholder in Opthea with 18,202,068 shares or 7.31 percent.
In a barely legible replacement substantial shareholder notice, Jagen said it acquired 4,256,294 shares for $1,569,111 or 8.6 cents a share.
The South Yarra, Melbourne-based Jagen is an investment vehicle for Bori Liberman.
The notice said the holders included Borl Limited, JL, LL and NL Family Nominees.
Opthea was unchanged at 56 cents.

CARDIEX

Cardiex has requested a trading halt “pending a material announcement regarding the company’s capital raising activity”.
Trading will resume on December 6, 2018 or on an earlier announcement.
Cardiex last traded at 3.3 cents.

ADMEDUS

Admedus says it has appointed Dr Kiran Bhirangi as its chief medical officer.
Admedus said that Dr Bhirangi would be responsible for accelerating the research projects to generate new products and drive the transcatheter and surgical aortic valve replacement projects, and other catheter-based expansions of its Adapt-treated products.
The company said that Dr Bhirangi was a vascular surgeon with knowledge of regulation and reimbursement and previously was Cardiome AG’s head of clinical development and medical affairs, Shire human genetic therapies head of medical affairs and Johnson & Johnson ortho-biotech products medical director.
Admedus said that Dr Bhirangi held a Bachelor of Medicine and Bachelor of Surgery, and a Master of Surgery from Bombay University.
Admedus was up 0.1 cents or 1.9 percent to 5.3 cents with 1.5 million shares traded.

CORRECTION: BDI-40 WITH MARKET CAPITALIZATION

Last night's edition included a previous chart of the Top 40 companies by market capitalization at November 30, 2018. The correct chart appears below.

Company $Am	**Dec-17**	**Nov-18**	**Dec-18**
Cochlear	10,400	10,249	9,770
CSL	64,828	85,156	80,355
Resmed	15,976	21,089	21,360
BDI-20			
Avita	66	125	110
Clinuvel	384	766	814
Compumedics	75	64	68
Cyclopharm	64	72	78
Ellex	133	93	101
Impedimed	364	152	97
LBT Innovations	36	20	18
Medical Developments	372	316	279
Mesoblast	635	990	659
Nanosonics	760	899	939
Neuren	276	126	138
Opthea	146	134	119
Pharmaxis	82	108	112
Polynovo	248	388	395
Immutep	59	126	111
Pro Medicus	780	945	1,045
Reva	264	104	83
Starpharma	519	542	575
Telix	128	178	148
Volpara	61	245	222
Second 20			
Actinogen	28	52	49
Airxpanders	201	37	20
Antisense	5	15	12
Benitec	40	42	35
Cynata	57	107	101
Dimerix	14	17	15
Genetic Signatures	31	59	70
Imugene	47	72	83
Kazia	18	21	25
Oncosil	73	123	114
Optiscan	40	24	25
Orthocell	28	20	17
Osprey	144	54	54
Patrys	15	34	29
Paradigm	34	107	152
Prescient	15	19	17
Prana	37	24	20
Proteomics	11	19	39
Universal Biosensors	60	42	44
Uscom	17	19	20