Biotech Daily

Thursday February 21, 2019

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: CYCLOPHARM UP 8%; AVITA DOWN 13%**

*** MESOBLAST H1 REVENUE DOWN 7% TO $19m, PROFIT TO $62m LOSS**

*** EDITORIAL: YOUR R&D TAX INCENTIVE IS NOT REVENUE**

*** SOMNOMED H1 REVENUE UP 15% TO $28.8m, LOSS UP 90% TO $12.4m**

*** PRO MEDICUS H1 REVENUE UP 60% TO $25.4m, PROFIT UP 184% TO $9m**

*** POLYNOVO H1 REVENUE UP 109% TO $5.7m, LOSS DOWN 41% TO $1.9m**

*** CELLMID H1 REVENUE UP 12% TO $3.6m, LOSS UP 221% TO $3.5m**

*** ALLEGRA H1 REVENUE DOWN 22% TO $1.8m, LOSS UP 142% TO $481k**

*** IMPEDIMED H1 REVENUE UP 19% TO $1.8m, LOSS DOWN 16% TO $12.1m**

*** BIOXYNE H1 REVENUE UP 83% TO $1.4m, LOSS DOWN 72% TO $203k**

*** PROTEOMICS US BIOMARKER PATENT FOR KIDNEY DISEASE TARGET**

*** RESMED, FISHER & PAYKEL SETTLE PATENT DISPUTE**

*** SUDA IMPROVING ANAGRELIDE SOLUBILITY**

*** ALTHEA: CANNVALATE AUSTRALIA MARIJUANA DISTRIBUTOR**

*** AUSCANN TO BUY MARIJUANA RESIN FROM MEDIPHARM**

*** ANTEO, GENEODX TO LAUNCH ANTEOBIND IN CHINA**

*** NOXOPHARM REVIEW: PRIORITIZE PROSTATE CANCER, US LISTING**

*** BOTANIX APPOINTS DR STEWART WASHER INTERIM CHAIRMAN**

*** JULIAN ROCKETT REPLACES VISIONEERING CO SEC LEANNA RALPH**

MARKET REPORT

The Australian stock market was up 0.7 percent on Thursday February 21, 2019, with the ASX200 up 42.7 points to 6,139.2 points. Twelve of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and four were untraded.

Cyclopharm was the best, up 8.5 cents or 7.7 percent to $1.185, with 2,500 shares traded. Nanosonics and Pro Medicus climbed more than five percent; Benitec and Patrys improved more than four percent; Polynovo and Proteomics were up more than three percent; Kazia, Volpara and Universal Biosensors rose two percent or more; Ellex was up 1.7 percent; with CSL, Opthea and Resmed up by less than one percent.

Avita led the falls, down two cents or 13.3 percent to 13 cents, with 7.3 million shares traded. Impedimed lost 6.25 percent; both Antisense and Imugene fell 5.9 percent; Medical Developments was down 4.3 percent; Immutep retreated 3.2 percent; Clinuvel, Dimerix and Paradigm shed more than two percent; with Actinogen, Cochlear, Compumedics, Cynata, Mesoblast and Pharmaxis down more than one percent.

MESOBLAST

Mesoblast says that revenue for the six months to December 31, 2018 fell 7.3 percent to $US13,507,000 ($A18,840,660), with last year's $US6,681,000 net profit after tax turned to a $US44,103,000 ($A61,526,770) loss.

In its Appendix 4C quarterly report filed on January 31, 2019, Mesoblast said that receipts from customers for the six months to December 31, 2018 increased 295.7 percent to $US28,510,000 ($A39,253,994) (BD: Feb 1, 2019).

Today, Mesoblast said that the $US13,507,000 revenue included $US3.2 million from sales of Temcell in Japan by JCR, $US10.0 million from Tasly's China milestone payments and interest payments.

A Mesoblast executive told Biotech Daily that the company received further milestone payments of $US10.0 million from Tasly and $US5 million from Takeda, which were included in the Appendix 4C but not the half year accounts, due to the timing of the receipt of the funds.

The company said that net cash outflows were reduced by $US17.7 million to $US17.2 million, "primarily due to the timing of receipts of milestone payments".

Mesoblast said the increased loss was due to investment in manufacturing and financing and non-cash gains in the previous corresponding period from the revaluation of tax and contingent consideration.

Mesoblast said that research and development spending increased 7.5 percent to $US33,975,000, manufacturing commercialization costs were up 479.1 percent to $US9,717,000, with management and administration expenses up 0.1 percent to $US10,742,000.

Mesoblast chief executive Prof Silviu Itesco told the teleconference that the company's mesenchymal stem cell product for graft versus host disease, marketed as Temcell in Japan, was the only fully-approved allogenic stem cell product in Japan and Europe and pending US Food and Drug Administration approval would be the only fully-approved allogenic stem cell product in the US.

Prof Itescu said that Mesoblast's Japan partner, JCR was in the process of applying for approval for the product to be used for epidermolysis bullosa.

Prof Itescu said that the Alofisel mesenchymal stem cell product was approved in Europe but Takeda had not yet begun commercial scales, pending pricing.

He said that should the FDA approve Remestemcel-L for graft versus host disease it would be the first allogeneic stem cell product approved in the US.

Prof Itescu said that the market opportunity for graft versus host disease in the US and Europe was more than $US700 million.

Prof Itescu said that if Revascor was approved for heart failure the potential was "a multi-billion-dollar market in the US alone".

He said the 566-patient phase III Revascor congestive heart failure trial was expected to be completed within 12 months and if successful would be sufficient for FDA approval.

Prof Itescu said the 404-patient phase III trial of MPC-06-ID for chronic lower back pain was due to be completed by July 2019.

The company said that its net tangible liability per ordinary security fell from 12.35 US cents at December 31, 2018 to a net tangible liability per share of 0.10 US cents.

Mesoblast said that the diluted earnings per share of 1.46 US cents for the six months to December 31, 2017 turned to a diluted loss per share of 9.08 US cents for the six months to December 31, 2018.

The company said that it had cash and cash equivalents of $US77,022,000 at December 31, 2018, compared to $US47,386,000 at December 31, 2017.

Mesoblast fell 1.5 cents or 1.3 percent to $1.17 with 1.5 million shares traded.

BIOTECH DAILY EDITORIAL

A number of companies have been claiming the Federal Research and Development Tax Incentive as "revenue" when in fact they have little or no real revenue at all.

The Tax Incentive is similar to a tax rebate and is not taxable, so it should not be called revenue; just as one's tax payment in one year is not an allowed tax-deductible expense in the following year. It can be classified as “other income” along with grants.

Unless one goes to the fine detail (and some companies do not provide it) an investor could think the company has money when it doesn't.

Revenue does not include the Tax Incentive or grants. It does include sale of product, licence fees, milestone payments, royalties and bank interest.

All these sub-units of revenue should be made clear and investors should not need to go searching for the truth, buried deep in the notes, or have to call the company to find out what they have not announced clearly.

David Langsam
Editor

SOMNOMED

Somnomed says revenue for the six months to December 31, 2018 was up 15.4 percent to $28,814,680 with net loss after tax up 90.4 percent to $12,432,104.
Somnomed said revenue was from sales of its devices for the treatment of obstructive sleep apnoea in Europe, North America and the Asia Pacific.
The company said the loss included $12,389,661 from the discontinued operation of its Renew Sleep Solutions.
The company said diluted loss per share was up 107.1 percent from 10.33 cents to 21.39 cents for the six months to December 31, 2018, with net tangible assets down from 29.37 cents to 18.08 cents and cash and cash equivalents of $8,513,399 at December 31, 2018, compared to $7,578,486 at December 31, 2017.
Somnomed was up 10.5 cents or 6.4 percent to $1.735.

PRO MEDICUS

Pro Medicus says revenue for the six months to December 31, 2018 was up 60.1 percent to $25,441,000 with net profit after tax up 184.3 percent to $9,082,000.
Pro Medicus said revenue came from its Visage 7 technology, radiology information system, picture archiving and communication system and its electronic health products.
The company said that a fully franked interim dividend of 3.5 cents a share for shareholders on the record date of March 8 would be paid on March 22, 2019, with a fully franked special dividend of 2.5 cents per share as an advance on the final dividend in September 2019 to be paid on May 17, 2019.
Pro Medicus said diluted earnings per share climbed 184.3 percent from 3.06 cents to 8.70 cents for the six months to December 31, 2018, with net tangible assets up 37.5 percent to 22 cents.
The company said it had cash and cash equivalents of $24,735,000 at December 31, 2018, compared to $22,796,000 at December 31, 2017.
Pro Medicus climbed 70 cents or five percent to $14.65 with 287,234 shares traded.

POLYNOVO

Polynovo says revenue for the six months to December 31, 2018 was up 108.5 percent to $5,665,864 with net loss after tax down 40.6 percent to $1,917,758.
Polynovo said revenue came from sales of its Novosorb biodegradable temporizing matrix (BTM) in Australia, New Zealand, the US, South Africa, Saudi Arabia, India, Israel and the UK, and its US BARDA contract clinical trial program for deep burns.
The company said diluted loss per share was down 46.3 percent from 0.54 cents to 0.29 cents for the six months to December 31, 2018, net tangible assets per share fell 4.8 percent to 0.4 cents and cash and the company held cash and cash equivalents of $20,814,360 at December 31, 2018, compared to $25,709,407 at December 31, 2017.
Polynovo was up 2.5 cents or 3.6 percent to 72.5 cents with 1.7 million shares traded.

CELLMID

Cellmid says revenue for the six months to December 31, 2018 was up 11.6 percent to $3,577,048 with net loss after tax up 221.2 percent to $3,504,477.
Cellmid said it had revenue from the sale of its hair growth products, fibroblast growth factor 5 (FGF5) inhibitors and its Evoliscope service in Australia, Japan and the US.
The company said net loss after tax was “partially due to the one-off, and now concluded, litigation with Ikon” and from additional employee compensation expenditure.
Cellmid said that diluted loss per share was up 125.5 percent from 2.12 cents in the previous year to 4.78 cents in the six months to December 31, 2018, with net tangible assets up 65.2 percent from 4.6 cents to 7.6 cents, and cash and cash equivalents of $5,412,207 at December 21, 2018 compared to $3,509,134 at December 31, 2017.
Cellmid was up 2.5 cents or 11.1 percent to 25 cents.

ALLEGRA ORTHOPAEDICS

Allegra says revenue for the six months to December 31, 2018 was down 22.4 percent to $1,829,072 with net loss after tax up 142.4 percent to $480,865.
Allegra said revenue was down due to continued investments in the orthopaedic ligament-replacement market, with a collaborative $2.4 million project to manufacture kangaroo-derived ligaments and Sr-H-Gahnite fixation anchors and screws for a spinal cage device.
The company said diluted loss per share was up 118.2 percent from 0.22 cents to 0.48 cents for the six months to December 31, 2018, with net tangible assets down from 6.78 cents to 5.81 cents and cash and cash equivalents of $1,180,731 at December 31, 2018, compared to $2,251,183 at December 31, 2017.
Allegra was untraded at 20 cents.

IMPEDIMED

Impedimed says revenue for the six months to December 31, 2018 was up 18.7 percent to $1,801,000 with net loss after tax down 15.9 percent to $12,144,000.
Impedimed said it had contracted revenue of $7.0 million and annual recurring revenue of $2.5 million for contracts of its Sozo bio-impedance spectroscopy (BIS) systems.
The company said diluted loss per share fell 25 percent from 0.4 cents in the previous year to 0.3 cents in the six months to December 31, 2018, net tangible assets down 45.5 percent from 11 cents to 0.6 cents, with cash and cash equivalents of $22,638,000 at December 31, 2018 compared to $42,406,000 at December 31, 2017.
Impedimed fell 1.5 cents or 6.25 percent to 22.5 cents.

BIOXYNE

Bioxyne says revenue for the six months to December 31, 2018 was up 83.0 percent to $1,409,569 with net loss after tax down 71.9 percent to $202,888.
Bioxyne said revenue was from sales of its probiotic Lactobacillus fermentum VRI-003, or PCC, with direct selling licences in Malaysia and Indonesia.
The company said diluted loss per share fell 75 percent to 0.03 cents, with net tangible assets constant at 0.1 cents and cash and cash equivalents of $2,650,309 at December 31, 2018, compared to $4,137,085 at December 31, 2017.
Bioxyne was unchanged at two cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics it has been granted a US patent covering the use of one of the core Promarkerd diabetic kidney disease test biomarkers as a potential drug target.
Proteomics said the patent, titled 'Method for Identifying an Agent for Treating Abnormal Kidney Function' would provide coverage until September 20, 2031.
The company said the Promarkerd test measured a panel of protein markers found in the blood, and the new patent was centred on the CD5 antigen-like (CD5L) protein.
Proteomics said that CD5L was previously considered to act as a regulator of lipid synthesis and results published by Proteomics showed that CD5L was a diagnostic marker for diabetic kidney disease, with other research supporting the company's data, and suggests CD5L, also known as apoptosis inhibitor of macrophage, or AIM, was involved in a patient's response to acute kidney injury.
The company said that CD5L "could be a novel therapeutic target to treat kidney disease, and the new patent covers methods for identifying such drugs", with further research required to confirm the role played by CD5L and confirm its viability as a drug target.
Proteomics said that to avoid patent infringement, any company using a method covered by the claims in the patent in the US, to develop a treatment using CD5L as a target would need its agreement.
The company said there was also the opportunity for the Promarkerd test to be used as a companion diagnostic alongside any therapeutic treatment concerning the CD5L target, both as a pre-treatment and post-treatment diagnostic tool.
Proteomics was up one cent or three percent to 34 cents.

RESMED FISHER & PAYKEL HEALTHCARE

Resmed and Fisher & Paykel say they have settled all outstanding patent disputes in all venues, with no payment or admission of liability by either side.
In 2017, Resmed said a German court concluded that Fisher & Paykel's Simplus, Eson and Eson 2 sleep apnoea and snoring masks infringed two of its European patents and in the UK it was proceeding to trial in defence of one of three UK patents that Fisher & Paykel challenged, while agreeing to revoke the other two UK patents (BD: Oct 9, 2017).
Today, the companies said that all ongoing proceedings against named products would be dismissed and each party would bear its own costs, with all other terms confidential.
Resmed and Fisher & Paykel said that as a result of the settlement, there would be no further infringement proceedings against Resmed products, including Airsense flow generators, Airfit P10, Swift LT and Swift FX masks and Climateline heated tubes, nor against Fisher & Paykel Healthcare products including Simplus, Eson and Eson 2.
Resmed was up six cents or 0.4 percent to $14.00 with 3.6 million shares traded.
Fisher & Paykel was up 93 cents or 7.3 percent to $13.73 with 512,334 shares traded.

SUDA PHARMACEUTICALS

Suda says its technical team has been able to improve the solubility of anagrelide by more than 10,000-fold using solvent compositions and solubility enhancers.
Suda said that anagrelide prevented the formation of blood platelets, which were involved in cancer progression and a reduction of platelets could help prevent tumor growth and metastasis, but anagrelide was “a challenging drug to formulate”.
The company said anagrelide was “virtually insoluble in all major pharmaceutically acceptable solvents with a water solubility of just 0.002mg/mL, which [was more than] 1000 times less than needed for an oro-mucosal spray which requires a concentration of about 2.5mg/mL” and it was insoluble in most non-aqueous solvents. as well.
Suda said it was working on developing a formulation with the solubility and stability characteristics required for a pharmaceutical product and it was confident it could achieve this and were testing a number of formulations in-vitro using artificial membrane models.
The company said that once a suitable oro-mucosal formulation had been developed, pre-clinical testing would be conducted to confirm the ability of an oral spray formulation to reduce the formation of the cardio-toxic metabolite, paving the way for demonstrating proof-of-concept in humans.
Suda was unchanged at half a cent with 13.2 million shares traded.

ALTHEA GROUP HOLDINGS

Althea says it has a supply and distribution agreement with the Melbourne-based Cannvalate for its medicinal marijuana products.
Althea said Cannvalate would distribute its medicinal marijuana in Australia through its network of more than 1,000 medical marijuana prescribing doctors and 600 pharmacies.
The company said that Cannvalate accounted for more than 30 percent of all Australian medical marijuana prescriptions.
Althea was up three cents or 7.7 percent to 42 cents.

AUSCANN GROUP HOLDINGS

Auscann says it has a supply agreement with the Barrie, Ontario-based Medipharm Labs to buy cannabis resin for its hard-shell cannabinoid capsules.
Auscann said the first supply would begin “in the coming months” and to mitigate supply risks, it would attempt to secure multiple cannabis resin suppliers.
Auscann fell three cents or 6.7 percent to 42 cents with 3.2 million shares traded.

ANTEO DIAGNOSTICS

Anteo says the Shanghai-based Geneodx Biotechnology it will launch sales of its Anteobind particle conjugation diagnostic technology in China next month.
Anteo said it appointed Geneodx a distributor last year (BD: Dec 13, 2018).
Anteo said it had technical and commercial meetings with diagnostics companies and a life science group to reach the in-vitro diagnostics and point-of-care markets in China.
The company said its particle conjugation kits were “enthusiastically received” to improve assay performance in pregnancy testing, cardiac assessment, infectious disease detection and cancer diagnosis and it would launch its Anteobind products at the China Association of Clinical Laboratory Practice Expo in Nanchang, Jiangxi Province, March 20 to 24, 2019.
Anteo was up 0.2 cents or 11.8 percent to 1.9 cents with 2.0 million shares traded.

NOXOPHARM

Noxopharm says an “internal strategic review” concluded it should prioritize Veyonda (NOX66) for prostate cancer, realize shareholder value and consider a US listing.
Noxopharm said its Lupin program aimed to show that Veyonda boosted the anti-cancer effect of 177-lutetium-PSMA, with the first read-out of the phase Ib/IIa study to be made public in June 2019 and the Darrt Veyonda program would “amplify the effect of palliative doses of external beam radiotherapy, applied to single lesions, such that a generalized anti-cancer effect is generated that enables patients to live longer”.
The company said that chief executive officer Dr Graham Kelly would move to group chief executive officer, with overall responsibility for Noxopharm and subsidiary, Nyrada Inc, chief medical officer Dr Greg van Wyk promoted to chief executive officer, with, Dr Gisela Mautner appointed global medical director.
Noxopharm said it would consider a secondary listing on a US securities exchange to facilitate the ability of US investors to invest in the company through American depositary receipts, which would require US Securities and Exchange Commission approvals.
The company said that there was no assurance that approval or permission would be obtained from the SEC or the relevant US securities exchange and to date no registration statement has been lodged with the SEC and no application made to a US exchange.
Noxopharm was up two cents or five percent to 42 cents.

BOTANIX PHARMACEUTICALS

Botanix says it has appointed Dr Stewart Washer as its interim non-executive chairman.
Botanix said Dr Washer had more than 20 years’ experience in mergers and acquisitions in capital markets and had served as a chairman, director and chief executive officer of biotechnology companies.
The company said Dr Washer was a current a board member of Orthocell, Zelda Therapeutics and Cynata Therapeutics.
Botanix said that previously, Dr Washer was an investment director at Bioscience Managers and a venture partner with the Swiss Inventages Fund.
The company said Dr Washer would receive 1,000,000 options exercisable at the higher of the closing price the day before issue and the 7-day volume-weighted average price to the date of issue, within one year, as well as 4,000,000 options exercisable at a 33 percent premium to day before issue, within three years.
Dr Washer holds a Bachelor of Science from the University of Western Australia and a Doctor of Philosophy from Perth’s Murdoch University.
Botanix was up one cent or 10 percent to 11 cents with 4.4 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says it has appointed Julian Rockett as company secretary, replacing Leanna Ralph, effective immediately.
Visioneering said Mr Rockett was a corporate lawyer and company secretary for a range of ASX-listed companies.
Visioneering fell half a cent or 4.35 percent to 11 cents.