Biotech Daily

Thursday February 18, 2021

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: UNIVERSAL BIO UP 7%; OPTISCAN DOWN 11%**

*** CSL RECORD H1 REVENUE UP 17% TO $7.4b, PROFIT UP 45% TO $2.3b**

*** MACH7 H1 REVENUE DOWN 22% TO $7.1m, PROFIT TO $7m LOSS**

*** VISIONEERING REVENUE DOWN 11% TO $6.7m, LOSS DOWN 27% TO $12m**

*** CELLMID H1 REVENUE DOWN 24% TO $2.8m, LOSS UP 71% TO $2.4m**

*** PREVATEX HOPES TO RAISE $2.5m FOR FOOD ALLERGIES**

*** TGA APPROVES RESONANCE HEPAFAT-AI**

*** UNI OF SOUTH AUSTRALIA TARGETS MUCIN 1 FOR PANCREATIC CANCER**

*** PALLA CODEINE-PARACETAMOL READY FOR UK SALES**

*** PARADIGM READY FOR PPS OSTEOARTHRITIS BIOMARKER TRIAL**

*** LITTLE GREEN MARIJUANA OIL FOR SYDNEY UNI QUEST INITIATIVE**

*** MEDLAB, ARROTEX DEAL FOR MARIJUANA NANOCBD FOR PHARMACIES**

*** CREDIT SUISSE BELOW 5% OF BARD1**

*** FIL INCREASES, DILUTED TO 8% OF MEDIBIO**

*** 4D APPOINTS CRAIGE PENDLETON-BROWNE CIO**

MARKET REPORT

The Australian stock market edged up 0.01 percent on Thursday February 18, 2021, with the ASX200 up 0.7 points to 6,885.9 points. Twelve of the Biotech Daily Top 40 stocks were up, 20 fell, seven traded unchanged and one was untraded. All three Big Caps rose.

Universal Biosensors was the best, up three cents or 7.1 percent to 45 cents, with 781,363 shares traded. Osprey and Resonance rose more than five percent; Prescient improved 4.2 percent; Avita, Impedimed, Patrys and Uscom were three percent or more; Antisense, CSL, Pro Medicus and Resmed rose more than two percent; Neuren was up 1.1 percent; with Cochlear and Cyclopharm up by less than one percent.

Yesterday's 15.6 percent best, Optiscan, led the falls, down two cents or 10.8 percent to 16.5 cents, with 2.4 million shares traded. Alterity, Immutep, LBT and Starpharma fell more than four percent; Dimerix and Volpara were down more than three percent; Compumedics, Genetic Signatures and Orthocell shed more than two percent; Clinuvel, Cynata, Kazia, Medical Developments, Mesoblast, Nanosonics, Nova Eye, Pharmaxis and Telix were down one percent or more; with Opthea down by 0.8 percent.

CSL

CSL says revenue for the six months to December 31, 2020 was up 16.9 percent to a record $US5,739.4 million ($A7,396.0 million) with net profit after tax up 7.5 percent to a record $US1,810.0 million ($A2,332.6 million).

CSL said that research and development expenditure fell 4.1 percent to $US427.3 million for the six months to December 31, 2020 or 7.45 percent of total revenue, compared to 9.1 percent for the six months to December 31, 2019.

The company said that diluted earnings per share was up 44.9 percent to $US3.97 and that it had cash and cash equivalents of $US2,423.4 million at December 31, 2020 compared to $US659.7 million at December 31, 2019.

CSL said the interim unfranked dividend of $US1.04, was up 7.48 percent compared to the previous corresponding period and would be paid on April 1, 2021, with a record date of March 5, 2021.

A CSL spokesperson told Biotech Daily that the increased revenue was primarily attributable to a significant rise in sales of Seqirus seasonal influenza vaccines, with revenue up 40.0 percent to $US1,425 million, along with $US80 million in funding for the discontinued severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) vaccine development with the University of Queensland, and increased sales of albumin in China.

In its statutory accounts, CSL said that total albumin sales were up 93 percent (in "constant currency") to $US546 million reflecting "the successful transition to the company's own distribution model in China where sales have returned to a more normalized level compared to the prior comparable period".

The company said that speciality product sales increase to $US899 million with sales of Haegarda for hereditary angioedema up 16 percent, Kcentra for haemophilia up six percent but affected by reduced elective surgery due to the Covid-19 pandemic.

CSL chief executive officer Paul Perreault said that he expected net profit after tax for 2020-'21 to be in the range of $US2,170 million to $US2,265, representing growth over 2019-'2020 of up to eight percent.

"Demand for CSL's core plasma and influenza vaccine products remains robust," Mr Perreault said.

"Seqirus is performing well as strong demand for influenza vaccines, together with our differentiated products portfolio will see it deliver another strong profitable year," Mr Perreault said. "Consistent with the seasonal nature of the business we anticipate, however, a loss in the second half of the year."

Mr Perreault said that Covid-19 had affected plasma collections and the company had initiatives to increase collections would ensure the equitable distribution of medicines and would "emerge strongly when the Covid-19 crisis recedes".

"The additional work we have been doing on Covid-19 vaccines in Australia has resulted in significant opportunity costs to our standard business and manufacturing operations and the re-prioritization of some [research and development] projects," Mr Perreault said.

"Subsequently, there will be an increase in operations and [research and development] spend in the second half [of the financial year] as we restart projects and build them back to scale," Mr Perreault said.

"Our people continue to work exceptionally hard to undertake the Covid-19 vaccine work without compromising the production of our core life-saving therapies - influenza vaccines and plasma and recombinant protein therapies," Mr Perreault said.

"We're proud that we've been able to meet our existing global commitments while leveraging our unique position and capabilities in Australia, resulting in what will be a significant contribution to the Covid-19 vaccine effort," Mr Perreault said.

CSL was up $7.83 or 2.78 percent to $289.00 with 1.2 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says revenue for the six months to December 31, 2020 fell 21.8 percent to $7,097,743 with net profit after tax of $674,799 turned to a loss of $7,173,986.
Mach7 said revenue included $1,226,631 in imaging software licence fees down from $4,989,630 in the previous corresponding period, with annual maintenance fees up 31 percent from $2,585,065 to $3,389,711, with professional service fees down 44 percent to $771,888 and pay-per-use subscriptions up from $128,619 to $1,709,513.
The company said it had reported $10.9 million of sales orders, most of which occurred in the second quarter and had not been recognized in revenue, “largely due to timing” with sales revenue expected to be made up in the second half of the financial year.
The company said that acquisition of Client Outlook contributed $3,471,000 of losses, including $2,221,000 of amortization charges as a result of recognizing intangible assets acquired (BD: Jul 14, 2020).
Mach7 said that Client Outlook generated a loss from ordinary activities after tax of $477,000 for the prior corresponding period.
Mach7 said it diluted earnings per share of 0.4 cents turned to a diluted loss per share of 3.1 cents, net tangible asset backing fell 46.15 percent from 13.0 cents to 7.0 cents, with cash and cash equivalents of $14,426,840 at December 31, 2020 compared to $23,283,406 at December 31, 2019.
Mach7 fell seven cents or 4.6 percent to $1.45 with 1.6 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says revenue for the year to December 31, 2020 was down 10.8 percent to $US5,105,000 ($A6,584,380) with net loss after tax down 26.8 percent to $US9,239,000 ($A11,918,370).
Visioneering said revenue was from sales of its Naturalvue multifocal one-day contact lenses.
The company said net tangible asset backing was constant at 0.2 US cents, diluted loss per share was down 75 percent to 1.0 US cents and it had cash and cash equivalents of $US2,408,000 at December 31, 2020 compared to $US1,919,000 at December 31, 2019.
Visioneering was up 0.1 cents or 5.3 percent to two cents with 3.7 million shares traded.

CELLMID

Cellmid says revenue for the six months to December 31, 2020 fell 23.7 percent to $2,790,046 with net loss after tax up 71.3 percent to $2,390,117.
Cellmid said revenue was from sales of its hair growth including Jo-Ju, Lexilis and Èvolis and attributed part of the fall to the Covid-19 pandemic.
The company said it “continued to monitor market opportunities for its portfolio of [severe acute respiratory syndrome coronavirus-2] testing devices”.
“Due to the successful handling of the pandemic domestically, a market uptake for the tests was lower than anticipated and the group made no significant sales during the reporting period,” Cellmid said.
The company said net tangible assets per share fell 8.6 percent to 4.16 cents, diluted loss per share was up 20.1 percent to 1.91 cents and it had cash and equivalents of $4,550,270 at December 31, 2020 compared to $3,883,627at December 31, 2019.
Cellmid fell half a cent or 5.1 percent to 9.3 cents.

PREVATEX PTY LTD

Prevatex says it hopes to raise $2.5 million in a “series A” offer at $2.29 a share to develop and manufacture a probiotic to prevent food allergies.

Last year, Prevatex said that a multi-institutional study found the maternal microbiome was impacted by family size and the presence of Prevotella copri is associated with a reduced food allergy risk in infants (BD: Mar 25, 2020).

The company said that the Barwon Infant Health Study, which began in 2010, is led by Geelong’s Barwon Health and Deakin University, with contributions from 10 universities and institutes.

The research paper said that “the presence of the bacterium Prevotella copri in mothers’ microbiome during pregnancy is associated with a decreased risk of their children developing food allergies during the first year of life”.

Prevatex executive chair Dr Greg Collier is also the chair of Avecho Biotechnology and the former chair of Invion and chief executive officer of Chemgenex.

Dr Collier said that the publication “adds support to our intellectual property portfolio and commercial strategy for Prevotella copri”.

Today, Dr Collier said that Prevatex intended to manufacture the probiotic to large-scale and initiate clinical trials.

Dr Collier said the funds would be used to expand the patent portfolio, finalize selection of the Prevotella copri proprietary strain and undertake a regulatory dossier.

Dr Collier said that the series A funding round would close at the end of this month.

Prevatex is a private company, in which Biotech Daily editor David Langsam owns shares.

RESONANCE HEALTH

Resonance says the Australian Therapeutic Goods Administration has approved its Hepafat-AI, fully automated artificial intelligence software to assess liver fat.

Resonance said that TGA approval meant the device conformed to Australian regulatory requirements and was approved for inclusion in the Australian Register of Therapeutic Goods, allows it to be sold in Australia.

The company said the Hepafat-AI received US Food and Drug Administration clearance last year (BD: Dec 9, 2020).

Resonance said that Hepafat-AI “automatically analyses magnetic resonance imaging datasets to assess liver fat in patients”.

The company said that the technology was able to provide doctors with “a comprehensive, multi-metric solution for use in the assessment of individuals with confirmed or suspected fatty liver disease” and assesses the images.

Resonance said that the Hepafat-AI device provided a patient report, which included steatosis grading, proton density fat fraction, volumetric liver fat fraction, and a liver fat distribution map.

The company said it intended to market Hepafat-AI to radiologists and physicians involved in the routine clinical diagnosis and management of patients with confirmed or suspected fatty liver disease.

Resonanc said that it had begun investigating reimbursement for Hepafat-AI in the US and that its Conformité Européenne (CE) mark application was pending.

Resonance was up one cent or 5.1 percent to 20.5 cents with 8.1 million shares traded.

UNIVERSITY OF SOUTH AUSTRALIA

The University of South Australia says its staff are studying the mucin 1 receptor to detect and target pancreatic cancer cells and minimize treatment side effects.

In a media release the University said that Doctor of Philosophy candidate Ashleigh Hull and the medical radiation department's Prof Eva Bezak were researching the mucin 1 receptor (MUC1-CE) commonly found in pancreatic cancer cells, but largely absent from healthy pancreas tissue.

The University said that the receptor might serve as a "biological beacon" for targeted treatment.

"Our research looks at developing a new treatment for pancreatic cancer which provides more direct damage to cancerous cells," Ms Hull said.

"To do this, we target cellular receptors that are common in the cancer cells but uncommon in the healthy cells, and in our study, we found that MUC1-CE is over-expressed on pancreatic cancer tissues, but it is minimally expressed on normal pancreatic tissue," Ms Hull said.

"We also found the expression of MUC1-CE was texturally different between pancreatic cancer tissues and healthy tissues," Ms Hull said. "In pancreatic cancer tissues, MUC1-CE expression was significantly higher and more uniform which could lead to a more definite and earlier diagnosis and treatment targeting."

The University said that MUC1-CE made it a potentially effective receptor for a process known as targeted alpha therapy, which delivered a lethal dose of radiation straight to the cancerous cells through the use of a radio-immuno-conjugate.

"A radio-immuno-conjugate is made by attaching a radioactive isotope to an immune substance, such as an antibody, that can bind to cancer cells, meaning it can target those cells only with minimal harm to healthy cells," Prof Bezak said.

"Our research findings indicate MUC1-CE is a feasible target for targeted alpha therapy of pancreatic cancer, with an expression profile which favors targeting of cancerous cells," Prof Bezak said. "We are now working on the second phase of the project, developing radio-immuno-conjugates which specifically target the MUC1-CE receptor on pancreatic cancer tissues and hope to test these conjugates in pre-clinical models soon."

The University said that pancreatic cancer had "one of the lowest survival rates of all cancers, with … only 10.7 percent of patients live five years post-diagnosis".

The University said that currently treatments, such as surgery, radiotherapy and chemotherapy, were ineffective in most patients as the disease was often identified in its later stages and pancreatic cancer cells were both evasive and resilient.

PALLA PHARMA

Palla Pharma says it has UK marketing authorization and will "start immediate retail sales of 30mg codeine phosphate-500mg paracetamol tablet and caplet combinations".

Palla said that at EUR802 million, ($A1,245.1 million) the UK codeine-paracetamol sector was the largest in Europe.

Earlier this month, the company said the UK Medicines and Healthcare products Regulatory Agency (MHRA) granted marketing authorization for its Norway production facility (BD: Feb 1, 2021).

Today, Palla said the UK was experiencing product shortages with the sale price of a 100-tablet packet of codeine-paracetamol increasing significantly from GBP2.50 in 2018 for a pack of 100 tablets to more than GBP4.00 in late 2020.

The company said it would earn 70 to 75 percent of the retail or hospital price.

Palla was up 17 cents or 30.4 percent to 73 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has ethics approval for a 60-patient, phase II trial of pentosan polysulfate sodium for synovial fluid biomarkers for knee osteoarthritis pain.
Paradigm said that the trial, in Melbourne, would investigate changes in synovial fluid biomarkers associated with pain, inflammation and disease progression of osteoarthritis, comparing patients administered Zilosul or pentosan polysulfate sodium (PPS) against those receiving a placebo.
The company said the primary endpoints would assess a change from baseline to day-56 in synovial fluid biomarkers, with secondary endpoints to include correlation between synovial fluid biomarker changes and clinical outcomes, changes from baseline at six months in one or more synovial fluid biomarker, changes from baseline at designated timepoints of pain, function, stiffness and quality of life.
Paradigm said that exploratory endpoints would assess radiographic changes in the bone and joint of participants from baseline to day-168.
The company said recruitment and screening would begin imminently, with the first dosing expected by July 2021 and a primary endpoint data readout expected by October 2021.
Paradigm said that biomarker data collected from the study would strengthen the application package to be submitted to the Australian Therapeutic Goods Administration for provisional approval and it was on track to submit its investigational new drug application to the US Food and Drug Administration by April 2021.
Paradigm was unchanged at $2.60 with one million shares traded.

LITTLE GREEN PHARMA

Little Green Pharma says it will supply marijuana oil for an up to 2,100 patient University of Sydney “quality of life evaluation study”, called the Quest Initiative.
Little Green said the Initiative aimed “to be one of the world’s largest longitudinal studies investigating the quality of life and health economics on patients with chronic disease prescribed medicinal cannabis”.
The company said it would provide funding for the two-year study which aimed to recruit the patients by June 30, 2021.
Little Green was up 2.5 cents or 3.7 percent to 70.5 cents with 1.3 million shares traded.

MEDLAB CLINICAL

Medlab says it has an agreement with Arrotex Australia Group Australia Pty Ltd to develop and distribute its marijuana-based NanoCBD to Australian pharmacies.
Medlab said the “exclusive non-binding heads of agreement” was the first partnership between a pharmaceutical company and a medical marijuana company.
The company said the agreement responded “to new opportunities presented by over-the-counter sales of eligible [Australian Therapeutic Goods Administration] approved medicines”.
Medlab chief executive officer Dr Sean Hall said the agreement was “a major milestone for both the Australian market and the budding partnership between Medlab and Arrotex”.
The company said the agreement intended “to develop a fast-track for the clinical package required for final lodgment of an application via the TGA for a near future schedule 3, or pharmacist only, medicines schedule approved pharmaceutical”.
Medlab said Arrotex was Australia’s largest generic pharmaceutical and private label over-the-counter medicines company with extensive experience in the TGA process.
Medlab was up 2.5 cents or 7.7 percent to 35 cents with 1.2 million shares traded.

BARD1 LIFESCIENCES

Credit Suisse Holdings says it has bought and sold shares in Bard1, falling below the 5.0 percent substantial shareholder level.
Yesterday, Sydney's Credit Suisse said it became substantial in Bard1 with 4,295,414 shares or 5.38 percent of the company (BD: Feb 17, 2021).
Today, Credit Suisse said that on February 15, 2021 it bought 1,364,827 shares for $3,546,227 or an average $2.598 a share and sold 1,787,693 shares for $2,603,543 or an average $1.456 a share.
Biotech Daily calculates that Cred Suisse retains 3,872,548 Bard1 shares or 4.85 percent of the company.
Bard1 fell 21 cents or 6.6 percent to $2.97 with 4.2 million shares traded.

MEDIBIO

The Hong Kong-based FIL Limited says it has increased but been diluted in Medibio from 91,785,128 shares (9.22%) to 121,928,459 shares (7.77%).
FIL said it bought 7,197,050 shares at 0.6 cents each on June 12, 2020 and a further 22,946,281 in an entitlement offer on July 13, 2020 (BD: Jun 10, 2020).
Last week, Medibio said it had raised $3 million in a placement at 0.9 cents a share and hoped to raise a further $500,000 in a share plan (BD: Feb 10, 2021).
In 2019, FIL said it bought 51,300,000 Medibio shares at one cent each in a share plan (BD: Aug 19, 2019).
Medibio was unchanged at one cent with 10.45 million shares traded.

4D MEDICAL

4D Medical says it has appointed Craige Pendleton-Browne as its chief information officer.
4D said that Mr Pendleton-Browne had more than 25 years' experience in the information technology industry, including in operations, technology and product development.
The company said that Mr Pendleton-Browne previously worked in the UK and Australia for Icare Health (now Telstra Health), the OFC Group, and News Corp.
4D said that most recently, Mr Pendleton-Browne worked in London for the online doctor service Zava and was chief technology officer at money transfer provider World First.
4D fell six cents or 3.1 percent to $1.89.