Biotech Daily

Wednesday August 2, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ONCOSIL UP 15%, RESMED DOWN 6%**

*** EQT BUYS CERTARA FOR $1b; ASIA-PACIFIC, MELBOURNE EXPANSION**

*** RESMED REVENUE UP 12% TO $2.6b, PROFIT DOWN 3% TO $430m**

*** MEDIBIO MACH-3 CARDIAC RHYTHM DEPRESSION TEST '82% ACCURATE'**

*** SAFETY BOARD BACKS REDHILL PHASE III RHB-104 CROHN'S TRIAL**

*** MEDICAL DEVELOPMENTS, WALMART SAM'S CLUB SPACER DEAL**

*** RESAPP TAKES 'TRIAL UPDATE' HALT TO SUSPENSION**

*** OSPREY REQUESTS CAPITAL RAISING TRADING HALT**

*** QUEST TAKES 6.4% OF VIRALYTICS**

*** CORMORANT REDUCES TO 6.2% IN VIRALYTICS, TAKES $1.7m PROFIT**

*** ATCOR DUNCAN ROSS TO SALES, FOUNDER MICHAEL O'ROURKE GOES**

*** BIOSCIENCE MANAGERS APPOINTS ELIZABETH KLEIN FOR UK**

MARKET REPORT

The Australian stock market fell 0.49 percent on Wednesday August 2, 2017 with the ASX200 down 28.2 points to 5,744.2 points. Eight of the Biotech Daily Top 40 stocks were up, 13 fell, 13 traded unchanged and six were untraded.

Oncosil was the best, up 1.3 cents or 14.9 percent to 10 cents with 332,846 shares traded. Opthea climbed 7.7 percent; Cellmid improved four percent; Mesoblast rose two percent; Actinogen, Cyclopharm and LBT were up more than one percent; with Clinuvel, Cochlear, CSL and Medical Developments up by less than one percent.

Resmed led the falls, down 55 cents or 5.7 percent to $9.11 with 14.1 million shares traded. Living Cell and Prima fell four percent or more; Factor Therapeutics lost 3.2 percent; Admedus, Avita and Bionomics shed two percent or more; Compumedics, Genetic Signatures and Prana were down more than one percent; with Ellex, Nanosonics, Pro Medicus and Sirtex down by less than one percent.

CERTARA, D3 MEDICINE

Certara, which acquired Melbourne's D3 last year, says it has been majority-acquired by the Stockholm, Sweden-based EQT VII fund for $US850 million ($A1,067.5 million).

Last year, the privately-owned Melbourne-based D3 said it had been acquired by the Princeton, New Jersey-based Certara for an undisclosed price (BD: Sep 8, 2016).

D3 previously said it was a bio-pharmaceutical strategic advisory company for drug development programs, with former Roche and CSL executive Dr Craig Rayner as chief executive officer and former Biota and GBS Venture Partners executive Dr Leigh Farrell as chief operating officer (BD: Jul 2, Oct 9, 2014; Nov 23, 24, 2015).

Last year, D3 said its 13 staff would become part of Certara's strategic consulting division, which was "the largest consultancy of its kind … [with] more than 100 scientists … using a broad range of modelling and simulation methods and technologies to support global sponsors in bringing new therapies to patients".

Certara chief executive officer Dr Edmundo Muniz said that the acquisition of D3 strengthened his company's "ability to provide our clients with optimized and strategic drug development plans".

"Certara has helped sponsors bring more than 80 new drugs to market, including more than 40 percent of the novel drugs approved by the US Food and Drug Administration last year," Dr Muniz said.

Today, Dr Farrell told Biotech Daily that Dr Rayner was head of Certara's D3 Medicine division and he was Certara's head of strategy and business development.

Dr Farrell said that the acquisition by EQT meant that Certara would have funds available for appropriate acquisitions and Certara intended to expand the Melbourne office as part of its broader Asia Pacific expansion.

In a media release, EQT VII said that Certara was being acquired from New York's Arsenal Capital Partners, which would "retain a minority ownership stake", with the current management team, led by Dr Muniz, continuing to lead the organization "building on a multi-year track record of both organic growth and strategic acquisitions".

EQT's website said that it had EUR37 billion ($A54.9 billion) invested across 24 funds with the EQT VII an active fund established in 2015 and having EUR6.75 billion ($A10 billion) under management.

EQT partners and EQT VII investment advisor Eric Liu said his company was "deeply impressed by what the Certara management team has accomplished".

"Certara is the global leader in an exciting and rapidly developing market, uniquely positioned to transform the field of drug development," Mr Liu said.

"This new strategic partnership with EQT will enable us to strengthen our core offerings as well as to capitalize on transformative next-phase growth opportunities," Dr Muniz said.

RESMED

Resmed says that record revenue for the 12 months to June 30, 2017 was up 12.4 percent to $US2,066,737,000 ($A2,595,157,570) with net profit after tax down 2.9 percent to $US342,284,000 ($A429,801,850).

Last year, Resmed reported record revenue with net profit after tax down 0.1 percent to $US352,408,000 ($A468,654,953) (BD: Jul 29, 2016).

Today, Resmed said that cash at June 30, 2017 was up 12.4 percent to $US821,935,000, with basic earnings per share down 3.6 percent to $US2.42 and it would pay a dividend of 3.5 US cents a share dividend for the three months to June 30 for shareholders on the record date of August 17, to be paid on September 21, 2017.

Resmed fell 55 cents or 5.7 percent to $9.11 with 14.1 million shares traded.

MEDIBIO

Medibio says a 44-subject study shows its cardiac rhythm test for major depressive disorder is 82 percent accurate, with 78 percent sensitivity and 84 percent specificity.

Medibio previously said the existing standard-of-care diagnosis in US primary care was 33 to 50 percent accuracy with a 70 percent agreement rate among psychiatrists.

The company said that the Mach-3 study was the first prospective assessment of the depression algorithm, led by the Baltimore, Maryland-based Johns Hopkins principal investigators Prof Naresh Punjabi and Dr Francis Mondimore.

Last year, Medibio said that early results from a 26-subject pilot phase of its US study of its cardiac rhythm depression test showed 81 percent accuracy, 82 percent sensitivity and 80 percent specificity (BD: Dec 21, 2016).

In December, Medibio said the prospective study enrolled 11 subjects with major depressive disorder and 15 healthy controls and the results delineated those with major depressive disorder from non-depressed individuals, including those on medication for their illness, and to measure circadian heart rate, subjects were monitored by electro-cardiogram for “one day’s sleep cycle”.

Today, Medibio chief executive officer Jack Cosentino told Biotech Daily that the Mach-3 study had enrolled 21 patients with major depressive disorder and 23 subjects with no history of depression as controls.

In a media release, the company said that repeatability of the Medibio-DX results was “excellent, with 76 percent intra-subject observed agreement between independent depression diagnostic classifications derived from first and second circadian heart rate recordings in the same subject … [which compared] very favorably to inter-psychiatrist agreement surrounding the diagnosis of depression”.

Medibio said that the confirmatory validation study for the Medibio-DX as a diagnostic aid for depression would start this month.

Mr Cosentino said the pilot study result was “a pivotal achievement for our team as we aggressively continue to meet and exceed our key milestones”.

“We’re very pleased with the performance of the depression diagnostic in this much tougher phase of testing,” Mr Cosentino said.

“As we enter the confirmatory validation study this month, we believe that we are very well positioned for [US Food and Drug Administration] clearance next year,” Mr Cosentino said.

Medibio said it followed FDA recommendations that the control group be representative of patients presenting in the primary care setting and be age and gender matched with the major depressive disorder cohort.

The company said that such a control group was “a more difficult diagnostic problem due the baseline prevalence of potentially confounding, non-psychiatric comorbidities”.

Medibio said the FDA recommended a repeatability analysis to quantify agreement between the Medibio-DX diagnostic classification outputs obtained in the same subject within one to two weeks of each other and the modifications further aligned the validation pathway with FDA expectations for ultimate clearance of the device.

The company said that to capture circadian heart rate and actigraphy-based inputs for the test, subjects were monitored for two sleep-wake periods with a third-party recording device and each subject underwent home sleep-testing to identify and screen out subjects with un-diagnosed sleep apnoea, which could disrupt heart rate and sleep patterns.

Medibio said the study provided evidence that the test was “agnostic to the third-party input device”, with results similar between the previously reported pilot study and the Mach-3 study, despite the use of different monitors.

Medibio fell 1.5 cents or 3.85 percent to 37.5 cents.

REDHILL BIOPHARMA

Redhill says an independent data and safety monitoring board recommends continuing its 410-patient, phase III study of RHB-104 for Crohn's disease.

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, the company said the independent board reviewed safety and efficacy data, to which the company remained blinded, from the first 222 subjects who completed week-26 assessments in the study and gave a unanimous recommendation to continue.

Redhill said it had randomized more than 300 patients in the double-blind, placebo-controlled trial, which was expected to complete enrolment by July 2018.

Redhill medical director Dr Ira Kalfus said that RHB-104 was "a potentially ground-breaking new therapy for Crohn's disease".

The company said that RHB-104 was an oral antibiotic combination therapy, targeting a suspected underlying bacterial infectious cause of Crohn's disease, Mycobacterium avium subspecies paratuberculosis (MAP).

Redhill said the primary endpoint was disease remission, defined as a reduction in Crohn's disease activity index to less than 150 at week 26.

Redhill said that an open-label extension study was on-going to assess RHB-104 in patients who were out of remission after 26 weeks of blinded therapy.

On the Nasdaq, Redhill fell 53 US cents or 5.39 percent to $US9.30 ($A11.71) with 135,277 shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it has a "core ranging" US distribution deal for its asthma spacers with the Walmart Group's Sam's Club.

Medical Developments said that the Bentonville, Arkansas-based Sam's Club had placed its first orders for its 626 US pharmacies.

The company said it would supply its compact anti-static space chamber range through Amerisourcebergen to all of Sam's Club shops as the preferred respiratory device.

Medical Developments said it was the first time Sam's Club has allocated preferred status to a range of respiratory devices.

Medical Developments chief executive officer John Sharman said it had been "working to secure core ranging deals from a number of large US pharmacy retail chains for some time".

"We are gaining acceptance for the quality of our product and our product pricing in the US," Mr Sharman said. "There are 67,000 pharmacies across the US and our focus remains on getting deals done with the other large retail pharmacy chains."

Mr Sharman said the company was able to sell or was selling its respiratory devices in about 11,000 US pharmacies "and we expect more deals to be completed over the next twelve months".

Medical Developments was up one cent or 0.2 percent to $5.06.

RESAPP

Resapp has requested a voluntary suspension to follow the trading halt requested on July 31, 2017 pending "an update on its Smartcough-C study" (BD: Jul 31, 2017).

Resapp said it expected to make an announcement by August 9, 2017.

Resapp last traded at 31 cents.

OSPREY

Osprey has requested a trading halt “pending an announcement by Osprey in relation to a proposed capital raising”.
Last year Osprey raised $29 million in a placement and share plan at 28 cents a share.
In its most recent Appendix 4C quarterly report Osprey said its cash burn for the three months to June 30, 2017 was $3,081,000 with $15,054,000 in cash and cash equivalents.
Trading will resume on August 4, 2017 or on an earlier announcement.
Osprey last traded at 43.5 cents.

VIRALYTICS

Quest Asset Partners says it has increased its substantial holding in Viralytics from 12,462,695 shares (5.18%) to 15,453,739 shares (6.42%).
The Sydney-based Quest substantial shareholder notice said the company bought and sold shares between May 20 and July 31, 2017, acquiring 3,142,086 shares for $2,691,028 or 85.6 cents a share and disposing of 6,743 shares for $6,835 or $1.014 cents a share.
Viralytics was unchanged at 83.5 cents.

VIRALYTICS

Cormorant Healthcare says it has reduced its substantial shareholding in Viralytics from 18,091,987 shares (7.49%) to 15,019,987 shares (6.24%).
In 2014, the Boston, Massachusetts-based Cormorant Global Healthcare Master Fund acquired the first parcel of 16,420,361 shares in Viralytics in a $27 million placement at 28 cents a share (BD: Mar 13, 2014).
Today, Cormorant said that on July 31, 2017 it sold 3,000,000 shares for $2,550,000 or 85 cents a share, which Biotech Daily calculates is a pre-tax profit of $1,710,000.
Last month, Cormorant sold 3,864,605 shares at 96 cents a share taking a $2,628,232 pre-tax profit(BD: Jul 27, 2017).

ATCOR MEDICAL

Atcor says chief executive officer Duncan Ross will be replaced by an Australia-based chief executive officer as part of its strategic review.
Atcor said the review was ongoing and the company would be restructured to reduce costs and secure new sales (BD: May 18, 2017).
The company said that it was discussing applications for its Sphygmocor central blood pressure technology in the consumer wearable market and Mr Ross would “concentrate wholly on this activity” when the transition was completed.
Atcor said its operating model needed to be leaner and not rely upon pharmaceutical company revenues, which could fluctuate greatly, to achieve sustainable profitability.
The company said it had been actively developing the expanded use of Sphygmocor, with applications of its technology in the wearables device market, with four Sphygmocor physiological measures available and new income streams were a priority.
Atcor said that co-founder and inventor of the Sphygmocor technology Prof Michael O’Rourke would not seek re-election as a director at the 2017 annual general meeting.
The company said that Prof O’Rourke would continue to support the company on clinical and scientific matters after his retirement from the board.
Atcor was unchanged at 4.8 cents.

BIOSCIENCE MANAGERS

Bioscience Managers says it has appointed Elizabeth Klein as a UK investment consultant to support its and Downing LLP's life sciences Investments.

Bioscience Managers said that Ms Klein's appointment would facilitate its UK investment deal flow and support the collaboration with London investment firm Downing LLP.

The company said that Ms Klein's primary focus would be on sourcing and reviewing investment opportunities.

Bioscience Managers said Ms Klein was previously with Dresdner Kleinwort, RW Baird, Bridgewell, Teathers, N+1 Singer, Starmine Healthcare and established the consultancy Klein-Edmonds Associates in 2015.

Ms Klein's Linkedin page said that she held a Bachelor of Science from the University of Liverpool, a Master of Business Administration for Imperial College London and Master of Arts from Birkbeck University of London.