Biotech Daily

Wednesday December 9, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: RESONANCE UP 81%; UNIVERSAL BIO DOWN 9.5%**

*** QUEENSLAND GRANT FOR ELLUME SARS-COV-2 TEST EXPANSION**

*** RESONANCE: FDA CLEARS HEPAFAT AI LIVER TEST**

*** USCOM H1 5-MONTH REVENUE UP 183% to $2.2m, LOSS TO $180k PROFIT**

*** ANTEO OPTIONS RAISE $3.9m FOR COVID-19 TESTS**

*** CANN GLOBAL RAISES $3.75m FOR CONVERTIBLE NOTE LIABILITIES**

*** INDIA APPROVES AROA WOUND TREATMENTS**

*** MTP CONNECT $10m FELLOWSHIPS PROGRAM OPENS NEXT WEEK**

*** KAZIA: RESULTS CONFIRM CANTRIXIL OVARIAN CANCER RESPONSES, DOSE**

*** TELIX: TLX591-CDX NDA READY FOR FDA REVIEW**

*** DORSAVI 12-MONTH MEDTRONIC EVALUATION**

*** CYNATA REQUESTS $20.5m CAPITAL RAISING TRADING HALT**

*** RESPIRI DROPS WHEEZO PRICE 67% FOR VOLUME; ORDERS FOR 7k UNITS**

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*** CRESO WINS $288k IN RECREATIONAL MARIJUANA ORDERS**

*** MGC SELLS $1.3m UNMARKETABLE PARCEL SHARES**

*** STEM CELL PLEADS SCHULTZ TO ASX 128% QUERY**

*** SIMAVITA POSTPONES AGM TO JUNE 2021**

*** PARADIGM APPOINTS AMOS MELTZER DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.61 percent on Wednesday December 9, 2020, with the ASX200 up 40.8 points to 6,728.5 points. Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and two were untraded.

Resonance was the best, up 12.5 cents or 80.65 percent to 28 cents, with 21.4 million shares traded. Proteomics climbed 12.4 percent; Uscom rose 9.4 percent; LBT improved 7.7 percent; Kazia and Mesoblast were up more than four percent; Alterity and Optiscan were up more than three percent; Avita, Clinuvel and CSL rose more than two percent; Nanosonics, Opthea, Orthocell, Polynovo, Pro Medicus and Resmed were up more than one percent; with Starpharma up 0.8 percent.

Universal Biosensors led the falls, down 4.5 cents or 9.5 percent to 43 cents, with 462,465 shares traded. Antisense lost 8.6 percent; Telix retreated 5.3 percent; Imugene, Osprey and Paradigm fell more than four percent; Genetic Signatures, Impedimed and Next Science were down more than three percent; Volpara shed 2.2 percent; Compumedics, Immutep and Prescient were down one percent or more; with Cochlear down 0.1 percent.

ELLUME HEALTH

Ellume says it has received a significant but undisclosed grant from the Queensland Government to expand manufacturing of its Sars-Cov-2 test.

In October, Ellume said the US National Institutes of Health has granted $US30 million ($A42 million) for testing and manufacturing its at-home severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) antigen test (BD: Oct 7, 2020).

In August, Ellume said it had applied for US approval of the Qiagen NV Qiareach Anti-Sars-Cov-2 Total Covid-19 blood antibody test, with partner Qiagen filing an emergency use authorization application and pre-ordering 900,000 tests (BD: Aug 27, 2020).

The company said that in November Qiagen began marketing and distributing the Qiareach test in the US.

Ellume said its at-home test was one of three Sars-Cov-2 antigen tests and included point-of-care and high-throughput tests.

Today, the company said the “generous Queensland Government grant will assist Ellume to hire many of the 300 staff needed to meet production demand by the end of the year."

Ellume said the Queensland Government grant through its Essential Goods and Supply Chain Program would enable expansion of its Brisbane manufacturing facility, “the largest of its kind in the Southern Hemisphere”.

The company said it would install multiple “state-of-the-art automated production lines to speed up and enhance production capability” and production was underway and on-track to ship more than 100,000 tests a day from next month (January) and more than 250,000 tests a day by March 2021.

Ellume said it planned to deliver 20 million tests by July 2021.

Ellume chief executive officer Dr Sean Parsons said the technology was “world class and the State Government’s investment boost will mean we can take our ground-breaking Covid-19 tests to the world”.

Dr Parsons told Biotech Daily the company produced 30,000 Sars-Cov-2 tests yesterday, “the highest daily production number yet, and it’s increasing”.

The company said that the expanded project was expected to support more than 500 jobs when fully operational, with up to an additional 200 jobs created during construction.

Ellume is a public unlisted company.

RESONANCE HEALTH

Resonance says the US Food and Drug Administration has cleared its artificial intelligence product Hepafat-AI to assess liver fat.

Resonance said that Hepafat-AI assessed the volumetric liver fat fraction, proton density fat fraction and steatosis grade in individuals with confirmed or suspected fatty liver disease.

The company said that Hepafat-AI "automatically analyzed magnetic resonance imaging (MRI) datasets to assess liver fat in patients, providing doctors with a comprehensive, multi-metric tool for use in the assessment of fatty liver".

Resonance chair Dr Martin Blake said the approval was "a great milestone in the company's history and a magnificent achievement in the field of quantitative MRI".

Resonance chief executive officer Alison Laws said that the use of artificial intelligence in medical image review and assessment had "the ability to support and transform radiology via the delivery of rapid, reproducible results whenever needed".

"Hepafat-AI, the company's second AI-based medical device to gain clearance from the FDA, will enable radiologists to report three key parameters [volumetric liver fat fraction, proton density fat fraction] and steatosis grade in patients in this significant and ever-increasing addressable market," Ms Laws said.

"The clearance from the FDA to assess and report all three metrics in Hepafat-AI patient reports is an outstanding result for the company and an outstanding result for the product itself," Ms Laws said.

Resonance was up 12.5 cents or 80.65 percent to 28 cents with 21.4 million shares traded.

USCOM

Uscom says revenue for the five months to November 30, 2020 was up 182.5 percent to $2.26 million compared to $960,000 for the six months to December 31, 2019.

Uscom said the net profit for the five months to November 30, 2020 was $180,000 from a net loss of $1.5 million for the six months to December 31, 2019.

Uscom executive chair Prof Rob Philips said it had "updated the market of significantly changed financial results consistent with its continuous disclosure obligations."

In February, the company told the ASX that orders for its Uscom 1A ultra-sonic cardiac output monitor were up 123.5 percent in the first five weeks of 2020, compared to the first two months of 2019 and that China's Hubei province had recommended haemodynamic monitoring for the diagnosis and treatment of coronavirus infected children (BD: Feb 6, 10, 11, 12, 14, 2020).

Uscom was up 1.5 cents or 9.4 percent to 17.5 cents with 1.5 million shares traded.

ANTEO TECH

Anteo says it received $3.9 million from the exercise of 195,187,019 listed options exercisable at two cents each, expiring on December 6, 2020.

Anteo said that along with its $1.19 million Federal Research and Development Tax Incentive it had a total to more than $6 million in cash to commercialize its Covid-19 antigen Rapid Test and Covid-19 antigen, influenza A and influenza B multiplex test.

Anteo fell 0.3 cents or 3.2 percent to 9.1 cents with 1.9 million shares traded.

CANN GLOBAL

Cann Global says it has raised $3,750,000 in a placement at 0.5 cents a share “to clear the company’s liabilities including the [$3 million] outstanding convertible note liabilities”.
Cann Global said it would issue one attaching option for every 2.4 new shares, exercisable at 1.2 cents each by January 31, 2022, with a further 15,000,000 options to be issued to the unnamed broker to the placement.
Cann Global was up 0.6 cents or 100 percent to 1.2 cents with 1.1 billion shares traded.

AROA BIOSURGERY

Aroa says it has regulatory approval to sell its wound treatment products, Myriad, Endoform Natural and Endoform Antimicrobial, in India.
Aroa said the sheep stomach-based products were approved by the national regulatory authority of India, the Central Drugs Standard Control Organisation.
Aroa chief executive officer Brian Ward said that regulatory approval was “an exciting milestone for the company, given the scale of patient need in India”.
“It is estimated that 20 million patients in India suffer from chronic wounds, with about 11 million suffering from diabetic ulcers,” Mr Ward said. “Introduction of the three products … will give a large number of people access to advanced wound care in a market where traditional wound care has been the primary treatment approach.”
The company said the estimated value of the advanced wound care market in India ranged from $US225 million to $US485 million ($A303.5million to $A654.3million) in 2020.
Aroa said it expected to begin distribution in India from July 2021.
Aroa was up 1.5 cents or 1.2 percent to $1.22.

MTP CONNECT

MTP Connect says applications open next week for grants up-to $250,000 for up-to 40 fellowships in the medical technology, biotechnology and pharmaceutical sector.
MTP Connect said the Researcher Exchange and Development within Industry (Redi) initiative gave the industry “the opportunity to select a researcher, academic, clinician or technology transfer professional to collaborate on distinct projects involving discovery, translation and commercialization”.
The Federally-funded industry organization said the program was available to Australian industry organizations, including multinationals and ASX-listed companies.
MTP Connect chief executive officer Dr Dan Grant said that “creating links between industry and research is critical for the growth and success of the … sector”.
“Our fellowship program will require that the researcher or clinician return to their home institution for a period at least equal to the term of the fellowship,” Dr Grant said. “This will help address the issue of brain drain of researcher talent into companies and ensure we embed high-level commercial experience in the research sector.”
MTP Connect said the fellowship application process was industry-led, so an eligible company or organization) needed to submit an application which identified a potential fellow, matched with a specific research and development project and universities, medical research institutes and hospitals were not eligible sponsors.
The organization said that applications open on December 15, 2020 and would remain open until either the funds were fully committed or until October 2022, whichever was first.
MTP Connect said it would hold an information session on December 17, 2020 from 11am to 12pm (AEDT), and to register and for more information about the program go to: https://www.mtpconnect.org.au/Category?Action=View&Category_id=293.

KAZIA THERAPEUTICS

Kazia says final top-line data confirms one complete and two partial responses in its 25-patient, phase I study of Cantrixil for metastatic ovarian cancer.
In April, Kazia said its then 24-patient, study of Cantrixil for metastatic ovarian cancer resulted in one complete response and two partial responses (BD: Apr 17, 2020).
Today, the company said the "trial achieved its primary objective determining the maximum tolerated dose of Cantrixil to be fivemg/kg".
Kazia said that "overall, 16 patients were evaluable for efficacy, one patient demonstrated a complete response and two patients experienced a partial response, … making an overall response rate of 19 percent".
"The patient who experienced a complete response remains in remission some three years after her last dose of Cantrixil," the company said.
Kazia chief executive officer Dr James Garner said the company was "very pleased to see the Cantrixil phase I study completed".
"The data unambiguously demonstrates the potential for Cantrixil to provide benefit in this very challenging patient population," Dt Garner said.
"With this positive data in hand, our focus now shifts to partnering activity and we hope to transition Cantrixil to a company which both shares our belief in its potential and is able to apply the necessary resources and expertise to realize that potential over the next chapter of its development," Dr Garner said.
Kazia was up 6.5 cents or 4.8 percent to $1.42 with 959,407 shares traded.

TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration has confirmed its new drug application for TLX591-CDx "is sufficiently complete to permit a substantive review".
Telix said TLX591-CDx was a kit for preparation of 68-gallium-prostate specific membrane antigen 11 (68Ga-PSMA-11) for the diagnosis of prostate cancer.
The company said the FDA "indicated that the … NDA submission will be subjected to a standard review … with a mid-cycle review meeting date of February 16, 2021 and a label review date of May 30, 2021".
Telix said the FDA provided intermediate milestones for the review process and indicated in their initial assessment that "no major issues were identified" and did not plan to hold an advisory committee meeting for the application.
Telix chief executive officer Dr Christian Behrenbruch said that "with proximal review timelines for our NDA submission and considering the recent limited approval of 68Ga-PSMA for both imaging of high-risk men prior to prostatectomy and biochemical recurrence, we feel our package is in a strong position to complete review in a timely fashion".
"Telix's kit-based formulation of 68Ga-PSMA is a game-changer in terms of delivering access to this important technology and we look forward to working with the FDA to conclude the technical and clinical review of our submission during 2021," Dr Behrenbruch said.
Telix said it was progressing a marketing authorization application for TLX591-CDx in the European Union, Canada and Australia.
On Monday, the Australian Therapeutic Goods Administration granted priority review status for TLX591-CDx (BD: Dec 7, 2020).
Telix said that in all jurisdictions where marketing authorization had been filed, the proposed product name for TLX591-CDx was Illuccix.
Telix retreated 20 cents or 5.3 percent to $3.55 with 1.7 million shares traded.

DORSAVI

Dorsavi says it has an initial up-to 12-month agreement with Medtronic to evaluate and test its wearable sensors to assess patients undergoing surgical evaluation.
Dorsavi said the Dublin-based Medtronic was “among the world's largest medical technology, services and solutions companies”.
Dorsavi chief executive officer Dr Andrew Ronchi said the partnership “aims to capture novel insights that we are confident will help Medtronic achieve better clinical evaluations for patients.”
Dorsavi was up 0.2 cents or 5.9 percent to 3.6 cents with 13.5 million shares traded.

CYNATA THERAPEUTICS

Cynata has requested a trading halt “pending an announcement … in relation to a proposed capital raising”.
Cynata said it hoped to raise about $15 million in a placement and a further $5.5 million in a one-for-15 rights offer, both at 70 cents a share.
Trading will resume on December 11, 2020 or on an earlier announcement.
Cynata last traded at 78.5 cents.

RESPIRI LIMITED

Respiri says it has dropped its Wheezo asthma monitor price and distributor Cipla has increased its initial purchase by 250 percent from 2,000 units to 7,000 units.
Respiri said that unit pricing of Wheezo had been lowered from $299 to $99.50 following feedback “to accommodate a higher number of patients able to afford the upfront or buy now pay later cost of device acquisition”.
The company said that the change would “result in a significantly lower product gross margins … in the short term [but] volumes are expected to increase at the lower price point”.
Respiri said that the monthly “software as a solution” fee had been increased by 24 percent to $9.95 a month “as customers are prepared to pay a higher price for the convenience of a monthly subscription, based on feedback to date”.
Respiri was up half a cent or 3.2 percent to 16 cents.

PRESCIENT THERAPEUTICS

Prescient says initial Doherty Institute testing of its anti-cancer assets for severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) is “inconclusive”.
Prescient said the evaluation was to determine the anti-viral activity of its assets in Sars-Cov-2 infected African green monkey kidney cells.
The company said the program would “involve multiple tests over time, as this is typical in pre-clinical stage research”.
Prescient said it expected to begin testing in late December with the next set of results expected by April 2021.
Prescient fell 0.1 cents or 1.5 percent to 6.5 cents with four million shares traded.

TALI DIGITAL

Tali says it has been granted a Japan patent for its Detect and Train products for attention and learning disorders and its “soon-to-released … maintenance program”.
Tali said the patent, titled ‘System And Process For Cognitive Assessment And Training’ would protect its intellectual property until March 31, 2035.
Tali said the patent covered the process for cognitive assessment and training, the assessing and training cognitive performance, a computer program product for cognitive assessment and training and a method for cognitive assessment and training.
Tali managing-director Glenn Smith said the patent “paves the way for the company to enter the Japanese market via a partnership model”.
“With over 15 million children in Japan, under the age of 15 years, the country represents a large potential market for the range of Tali cognitive assessment tools,” Mr Smith said.
Tali fell 0.8 cents or 14.8 percent to 4.6 cents with 69.3 million shares traded.

CORRECTION: NYRADA

Last night’s edition reported Nyrada saying that Eleanore Goodridge reduced her substantial holding to 9,134,832 Chess depository instruments (CDIs) (8.34%).
Nyrada and Ms Goodridge did not disclose the sales price of the shares.
Biotech Daily incorrectly added “as required under the Corporations Act 2001” which is the case for substantial shareholder notices for the overwhelming majority of ASX-listed companies.
However, Nyrada is a Delaware incorporated company and is not regulated by the Corporations Act.
The company told Biotech Daily today that as part of its listing process Nyrada entered into a deed poll with the ASX to provide information in lieu of not being regulated under the Corporations Act 2001.
Nyrada said it must disclose movements by a substantial shareholder of at least one percent along with name of the substantial holder, the date of the change and the number of securities held.
The company said, and Biotech Daily accepts, that there was no breach of disclosure under the Corporations Act 2001 and the company has complied with the ASX Listing Rules.
Biotech Daily apologizes unreservedly to Eleanor Goodridge and Nyrada and has taken the Tuesday substantial shareholder notices sub-editor down to the woodshed for a good and proper thrashing.
Nyrada was up half a cent or 2.2 percent to 23.5 cents.

CRESO PHARMA

Creso says Canadian subsidiary Mernova Medicinal has three orders worth $C275,023 (A$288,159) for its recreational marijuana products.
Creso said that the purchase orders were for its subsidiary Mernova’s products HPG13, Lemon Haze and Mimosa, with the first purchase order for $C232,826 from Truro Cannabis Company, the second order was from Yukon Liquor Corporation worth C$24,333 and the third from Nova Scotia Liquor Corp for C$17,863.
Creso was up 6.5 cents or 27.7 percent to 30 cents with 537.3 million shares traded.

MGC PHARMACEUTICALS

MGC says it has sold 50,696,634 unmarketable parcel shares for an average price of 2.5 cents a share, returning the proceeds to the small parcel investors.
MGC said that 1,139 shareholders holding 12,480,489 shares elected to continue holding shares and 360 shareholders with 4,663,914 shares elected to top up their share parcel to above a market value of $500.
MGC was up 0.8 cents or 29.6 percent to 3.5 cents with 299.3 million shares traded.

STEM CELL UNITED

Stem Cell has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 127.8 percent from 1.8 cents to 4.1 cents "in the last few days" and noted a "significant" increase in the trading volume.
Stem Cell was up 0.8 cents or 34.8 percent to 3.1 cents with 254.5 million shares traded.

SIMAVITA

Simavita says that British Columbia Securities Commission has approved the extension of its annual general meeting from December 22, 2020 to June 26, 2021.
Simavita said it had withdrawn all resolutions that were due to be considered at the meeting and would prepare new materials after consideration of all relevant matters.
Simavita was untraded at 1.6 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has appointed Amos Meltzer as an independent, non-executive director, effective from today.
Paradigm said Mr Meltzer was a scientist and intellectual property lawyer with more than 25 years' of experience in trade, commercializing technologies and life sciences and formerly was the chief executive officer at Immuron.
The company said that Mr Meltzer previously worked with law firms Freehills and K and L Gates, and worked for Israel-based Compugen and Gilat.
Paradigm said that Mr Meltzer was currently Synchron chief operating officer and the chair of Vasculab.
The company said Mr Meltzer held a Bachelor of Agricultural Science and a Bachelor of Laws from the University of Melbourne.
Paradigm fell 13 cents or 4.6 percent to $2.71 with 1.4 million shares traded.