Biotech Daily

Wednesday October 7, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PATRYS UP 11%; ALTERITY DOWN 6%**

*** BUDGET RESPONSE: SWANSON REED, AUSBIOTECH, AUSTRALIAN ACADEMY OF SCIENCE, MEDICINES AUSTRALIA**

*** US NIH $42m FOR ELLUME SARS-COV-2 AT-HOME TEST**

*** CRESO COMMITMENTS FOR $9m**

*** US FDA REJECTS MAYNE NUVARING, CONTRACEPTIVE PILL**

*** CELLMID DISPUTES CALL TO REMOVE CHAIR DR DAVID KING**

*** IMAGION: PHASE I MAGSENSE BREAST CANCER TRIAL APPROVED**

*** DIMERIX: 'DMX-700 INHIBITS COPD RECEPTOR SIGNALS, IN-VITRO'**

*** PYC: 'VP-001 EFFECTIVE FOR RETINITIS PIGMENTOSA IN-VITRO'**

*** REGENEUS: CANADA PATENT FOR SYGENUS ACNE TREATMENT**

*** MEDIBIO, MEDRIDGE DEPRESSIVE BURDEN SLEEP TRIAL**

*** MGC LAUNCHES CANNEPIL APPLICATION, 'LIBRARY OF CANNABINOIDS'**

*** MEURS TAKES 7.3% OF ADALTA**

*** L1 TAKES 12% OF CRESO**

*** CRESO APPOINTS BRUCE LINTON ADVISOR**

MARKET REPORT

The Australian stock market was up 1.25 percent on Wednesday October 7, 2020, with the ASX200 up 74.3 points to 6,036.4 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 15 fell and four traded unchanged. All three Big Caps were up.

Patrys was the best for the second day in a row, up 0.2 cents or 11.1 percent to two cents, with 51.4 million shares traded. Dimerix and Uscom climbed more than five percent; Antisense and LBT improved four percent or more; Imugene, Neuren and Resonance were up more than three percent; Nanosonics rose two percent; Cochlear, Compumedics, CSL, Kazia, Next Science, Nova Eye, Orthocell, Pharmaxis, Polynovo, Pro Medicus and Telix were up by more than one percent; with Cyclopharm, Opthea, Resmed and Volpara up by less than one percent.

Alterity led the falls, down 0.3 cents or 5.9 percent to 4.8 cents, with 1.8 million shares traded. Immutep and Oncosil fell four percent or more; Cynata, Impedimed, Prescient and Proteomics lost more than three percent; Amplia shed 2.9 percent; Avita, Mesoblast, Paradigm, Starpharma and Universal Biosensors were down more than one percent; with Clinuvel and Medical Developments down by less than one percent.

R&DTI: SWANSON REED TAX ADVISORS

Specialist R&D tax advisors Swanson Reed tax principal Damian Smyth says changes to the Federal Research & Development Tax Incentive apply from July 1, 2021 for the year to June 30, 2022.

Mr Smyth said that for companies with a turnover of less than $20 million the research and development tax offset rate, currently 43.5 percent, would be 18.5 percent above a company's tax rate, with the company tax rate for 2021-'22 scheduled to be 25 percent, meaning the rate would be 43.5 percent.

He said that for companies with a turnover of more than $20 million a year the rate would be based on two tiers of "intensity" or the percentage spent on research and development, with companies spending 2.0 percent or less on research and development able to claim 8.5 percent above their company tax rate, the same benefit currently available to most large companies, while companies spending more than 2.0 percent on research and development would be able to claim 16.5 percent above their company tax rate "a significant increase in R&D Tax benefit for relevant companies".

Mr Smyth said the annual cap on eligible research and development expenditure would increase from $100 million to $150 million.

"The headline proposals are encouraging, and a welcome change to what was previously before the Senate," Mr Smyth said. "The government has also flagged changes to the administration, integrity and transparency of the R&D Tax Incentive, and the relevant detail underlying these elements will need to be examined in due course."

Mr Smyth said the Government was widely criticized for the proposed R&D Tax budget reforms and "should be commended for seeing reason and shifting position".

"Parties that have lobbied the Government on the flaws of the previously proposed reforms should also be commended," Mr Smyth said. "Once these proposals are introduced, we call on both sides of politics to commit to a stable R&D Tax Incentive and cease the persistent policy shifts and proposed changes."

Biotech Daily notes that the 45 percent R&D Tax Incentive was introduced by the previous Labor Government and all the changes have been made or proposed by the Abbott-Turnbull-Morrison Governments.

AUSBIOTECH

Ausbiotech says it "congratulates the Government as tonight's Federal Treasurer delivered significant news on the Research and Development Tax Incentive".

Ausbiotech said the announcement showed "the Government understands how Australia's post-Covid-19 recovery will be supported by business expenditure for research and development and has provided a welcome change of position on the RDTI that will support and incentivize growth in [research and development] and manufacturing as we recover from the pandemic".

Ausbiotech chief executive officer Lorraine Chiroiu said the change was "excellent news for our industry, and will preserve the highly-skilled [science, technology, engineering and mathematics] based jobs in Australia".

"Tonight's RDTI announcement, together with the support for medical manufacturing, is a recognition of the economic and social value research and development in life sciences delivers to Australia, particularly in response to the current pandemic," Ms Chiroiu said.

"While the calculations for companies will be dependent on the applicable corporate tax rate, the announcement tonight signifies is an importance and positive shift in the appreciation of the benefits brought by [research and development]," Ms Chiroiu said.

Ausbiotech said that the refundable component of the RDTI had been increased five percentage points from the earlier 2019 Bill before the Senate, the $4 million cap would

not proceed and the complex intensity measure was reduced from three tiers to two, with support increased, while the increase in the expenditure maximum from $100 million to $150 million remained unchanged.
The industry organization said that compared to the reforms before the Senate, the Government was “investing a further $2 billion in the RDTI over the forward estimates, that’s $240 million over the forward estimates compared to current policy settings”.
“As the most critical policy for the industry, the announcements tonight will support our leading sector by giving companies and investors the certainty they need to commercialize and deliver new, innovative treatments to Australian patients,” Ms Chiroiu said.

THE AUSTRALIAN ACADEMY OF SCIENCE

The Australian Academy of Science said the Budget was “a significant response to the crisis facing Australia’s scientists as a result of the pandemic”.
The academy said that the additional $1 billion of funding in 2021 to support research at Australia’s universities hit badly by the pandemic was “welcomed”.
“An increase in 505 jobs in a cross section of government science agencies will also assist in research recovery,” the Academy said.
The Academy said it “applauds the strategic decision to back proven [science, technology, engineering and mathematics] school education programs by injecting $27.3 million over five years as an investment in the future workforce”, including $9.6 million over five years to support programs delivered by the Australian Academy of Science.
The Academy said it also welcomed $10 million to extend the Women in STEM (science, technology, engineering and mathematics) and Entrepreneurship Program (WISE) and the extension of the term of the Women in STEM ambassador, both of which assisted in the continuation of the implementation of the Academy’s Women in STEM Decadal Plan.
The Academy said that it welcomed the “recognition of the impact of the pandemic on Australia’s national science agencies, in particular the Commonwealth Scientific and Industrial Research Organisation, the Bureau of Meteorology and the Australian Nuclear Science and Technology Organisation, with $965.6 million in additional funding over four years.

MEDICINES AUSTRALIA

Medicines Australia chief executive officer Elizabeth de Somer said the “linkages between our health and productivity have never been clearer with the Government’s announcement of the new medicines funding guarantee, worth at least $2.8 billion over four years, starting immediately and at the same time, removing the requirement for cost offsets for new medicine listings on the [Pharmaceutical Benefits Scheme)”.
“This is going to allow for medicines to be listed faster, without the need to find additional savings from other critical health areas," Ms de Somer said.
Medicines Australia said that a framework for a new strategic agreement had been developed, intended to deliver greater long-term certainty for both industry and Government following the expiry of the existing agreement in June 2022.
“Alongside the substantial investment committed to health in the Budget, predictable savings to the Government, commencing in 2023, are required to continue the effective management of the challenging Budget backdrop,” Ms de Somer said.
Ms de Somer said that the Federal Government was “fast-tracking electronic prescribing [spending $5 million] and home delivery of medicines”.
“Medicines Australia also welcomes the investment of $12 million to modernize the Therapeutic Goods Administration business systems to streamline processes for the medicines industry and reduce red tape for new medicines,” Ms de Somer said.

ELLUME

Ellume says the US National Institutes of Health has granted $US30 million ($A42 million) for testing and manufacturing its at-home Sars-Cov-2 antigen test.

In August, Ellume said it had applied for US Food and Drug Administration approval of its Access Anti-severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) Total Covid-19 blood antibody test, with partner Qiagen NV filing an emergency use authorization application and pre-ordering 900,000 tests (BD: Aug 27, 2020).

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

Ellume said the funding was the result of early feasibility studies with the National Institute of Health's rapid acceleration of diagnostics initiative.

The company said its at-home test used a Bluetooth-connected analyzer with a smartphone to analyze a self-collected nasal sample, with results within 15 minutes.

Ellume said the technology was adapted to create a digital point-of-care testing device for medical clinics, pharmacies and for in-field use, called Ellume-lab.

The company said that following authorization by the US Food and Drug Administration, it would launch Ellume-lab in the US for both a Sars-Cov-2 serology test and antigen test.

Ellume said it was also developing a high-throughput version of Ellume-lab in partnership with Qiagen for airport, stadium, church gathering and other mass screenings.

Ellume chief executive officer Dr Sean Parsons said the company was "working intensely to expand access to fast, accurate and affordable testing for use in communities across the US, and this funding enables significant acceleration of our efforts."

Ellume is a public unlisted company.

CRESO PHARMA

Creso says it expects to raise $8,992,531 through a placement at 2.91 cents a share.

Creso said $7,992,000 had been committed by institutional, professional and sophisticated investors and $1 million from chairman Adam Blumenthal, who had agreed to extend an up-to $3 million short-term loan facility, subject to shareholder approval.

The company said the issue price was a 25 percent discount to the 3.88 cents closing price on September 30, 2020.

Creso said it would issue investors one option for every four shares issued, exercisable at five cents within 24 months and subject to shareholder approval.

The company said the funds would be used to repay debt and amounts owed to L1 Capital Global Opportunities Master Fund, Lind Global Macro Fund LP and Chifley Portfolios for outstanding convertible notes, including $1,802,653 and 29,169,010 collateral shares for L1, $222,927 and 21,000,000 collateral shares for Lind and $325,000 and 2,555,555 collateral shares for Chifley.

Creso said it would also pay Suburban Holdings $250,000, Suburban would purchase a reduction in its collateral shares and it would grant Suburban the right to elect to either be repaid the outstanding $1,250,000 from a further capital raising or to convert this amount into shares and options, to cancel its convertible securities.

The company said the funds would also be used to develop its Canada and Switzerland business units, for operational expenses and to accelerate growth across its existing human and animal health cannabidiol products.

Creso said Everblu Capital, of which Mr Blumenthal was the chairman, was the lead manager and corporate advisor to the placement and would receive a six percent fee and one share and seven options for every $1 raised.

Creso fell half a cent or 13.2 percent to 3.3 cents with 32.9 million shares traded.

MAYNE PHARMA GROUP

Mayne says the US Food and Drug Administration has rejected applications for its Nuvaring contraceptive and an unnamed product believed to be a contraceptive pill.

In a media release titled 'Mayne Pharma provides update on women's health pipeline', the company said the FDA had provided two complete response letters for abbreviated new drug applications (ANDAs) for a generic version of the Nuvaring intra-vaginal contraceptive ring, and for an undefined "potential first-to-market women's health generic product", believed to be a contraceptive pill.

Mayne said it was "working closely" with partner Mithra Pharmaceuticals and the FDA to address the questions raised in the Nuvaring complete response letter.

The company said that following submission of the response to the FDA letter it would receive a new target action date from the FDA.

Mayne chief executive officer Scott Richards said the company was confident it could address the issues raised in the Nuvaring complete response letter "in a timely manner".

"Pleasingly, the FDA has indicated that Mayne Pharma and its development partner Mithra have an acceptable manufacturing process for generic Nuvaring," Mr Richards said. "Furthermore, the market opportunity continues to be highly attractive with only one independent generic approved and an addressable market of $US920 million."

In 2018, Mayne said the FDA has accepted its abbreviated new drug application for generic Nuvaring intra-vaginal hormonal contraceptive device combined etonogestrel and ethinyl estradiol delivered over a three-week period (BD: Mar 20, 2018).

Mayne Pharma said that on the unnamed "women's health generic product" the FDA found all key disciplines of the abbreviated new drug application "adequate with the exception of the packaging facility which was assessed by a desk-top audit rather than an in-person inspection due to Covid-19".

The company said that it was "working closely with the FDA and its development partner to close out this application as soon as possible".

Mayne Pharma said it also undertook a mid-cycle review meeting with the FDA for its E4-DRSP combination oral contraceptive containing 15mg of oestetrol (E4) and 3mg of drospirenone (DRSP), renamed Nextstellis, and no substantive issues or major safety concerns were raised (BD: Apr 16, Jun 24, 2020).

Mr Richards said "the Nextstellis mid-cycle review meeting with the FDA provided us with some insights into the review process so far, and we are pleased that no significant issues and no major safety concerns were raised".

"This meeting marks the half-way point of the Nextstells NDA review process, and with approximately six months until the Prescription Drug User Fee Act date, we continue to advance our US commercial strategy and infrastructure to support the potential launch of this novel contraceptive in the first half of calendar 2021," Mr Richards said.

Mayne was up half a cent or 1.6 percent to 32 cents with 9.6 million shares traded.

CELLMID

Cellmid says it has received a notice under Section 249D of the Corporations Act 2001 calling for the removal of chair Dr David King as a director.

Cellmid said it had received legal advice that the notice was not valid and at this stage, did not intend to call an extraordinary general meeting.

The company said Dr King would stand for re-election at its annual general meeting, which would be held before an extraordinary general meeting could be called.

Cellmid was unchanged at 11 cents.

IMAGION BIOSYSTEMS

Imagion says it has ethics approval for a phase I study of its Magsense technology for human epidermal growth factor receptor 2 (HER2) metastatic breast cancer.
In August, Imagion says it has submitted applications for trials at two study sites in Melbourne and one in Sydney and was considering additional sites (BD: Aug 5, 2020).
Today, the company said it had completed bulk batch production of the Magsense human epidermal growth factor receptor 2 (HER2) nanoparticle formulation for the study and would finalize contracts with individual study sites.
Imagion said it expected to complete the final step of good manufacturing practice compliant packaging on time to support the start of the study, which was expected by December 31, 2020.
Imagion was up 0.1 cents or 1.25 percent to 8.1 cents with 19.4 million shares traded.

DIMERIX

Dimerix says in-vitro studies have shown that DMX-700 inhibits key signalling by receptors associated with chronic obstructive pulmonary disease (COPD).
Dimerix said studies by the University of Western Australia and the Nottingham, England-based Excellerate Bioscience Laboratories found that DMX-700 blocked interleukin-8 receptor beta (IL-8Rβ, also known as CXCR2) and angiotensin II receptor type 1 (AT1R), which were expressed at elevated levels in chronic inflammatory diseases.
The company said DMX-700 also abolished receptor signalling involved in neutrophil recruitment, which was abnormal in COPD and caused lung tissue damage.
Dimerix said the simultaneous inhibition of IL-8Rβ and AT1R might improve treatment efficacy for COPD, and it would progress with an in-vivo assessment to confirm the data.
The company said it had lodged a Patent Cooperation Treaty application for the treatment, amelioration or prevention of COPD with DMX-700.
Dimerix was up 1.5 cents or 5.1 percent to 31 cents with 6.1 million shares traded.

PYC THERAPEUTICS (FORMERLY PHYLOGICA)

PYC says initial results from five patient-derived models of lead drug program VP-001 has indicated that it is effective for all patients with retinitis pigmentosa type 11.
PYC said it assessed VP-001, which was developed with the Perth, Western Australia-based Lions Eye Institute, on retinitis pigmentosa type 11 skin samples, turned into stem cells and then into retinal pigment epithelium cells.
PYC was up two cents or 12.5 percent to 18 cents with 4.4 million shares traded.

REGENEUS

Regeneus says the Canadian Intellectual Property Office has issued allowed a patent for its Sygenus adipose tissue-derived secretions treatment for acne.
Regeneus said the patent, titled ‘Pharmaceutical Compositions and Topical Use Thereof’ would protect its intellectual property until 2032.
The company said Sygenus was a topical serum and gel for pain and inflammation conditions composed of selective bioactive molecules from the stem cell secretome.
Regeneus said that Sygenus had been shown in pilot studies to improve the appearance of acne, non-inflammatory lesions, such as blackheads and whiteheads, as well as inflammatory papules, and was safe and tolerated (BD: Feb 6, 2018).
Regeneus was up one cent or 6.7 percent to 16 cents.

MEDIBIO

Medibio says it has a clinical trial agreement with the Greenville, South Carolina-based Medbridge Healthcare for a sleep analysis of depressive burden trial.
Medibio said the trial aimed to identify clinical depressive burden in sleep disturbance patients undergoing a sleep study in a clinical environment.
Medibio was up 0.1 cents or 10 percent to 1.1 cents with 34.05 million shares traded.

MGC PHARMACEUTICALS

MGC says it has launched its Cannepil mobile application and will provide access to its proposed international library of cannabinoids.
MGC said the application would record patient responses to medical questionnaires as part of a treatment plan and would be available for download from the Apple App Store and Google Play Store.
The company said the proposed international library of cannabinoids was part of its collaboration with the Royal Melbourne Institute of Technology.
MGC was up 0.2 cents or 9.1 percent to 2.4 cents with 2.5 million shares traded.

ADALTA

Meurs Holdings says it has increased its substantial shareholding in Adalta from 10,356,001 shares (5.08%) to 17,856,001 shares (7.28%).
The Melbourne-based Meurs said that on September 8, 2020 it acquired 7,500,000 shares for $750,000 or 10 cents a share.
Adalta was up 1.5 cents or 13.0 percent to 13 cents with 1.5 million shares traded.

CRESO PHARMA

L1 Capital Global Opportunities Master Fund says it has become substantial in Creso with 49,412,496 shares or 11.99 percent of the company (see above).
In July, the Cayman Islands-based L1 said it had ceased to be substantial in Creso and Biotech Daily calculated that it retained 4.7 percent of the company (BD: Jul 15, 2020).

CRESO PHARMA

Creso says subsidiary Creso Pharma Switzerland has appointed Canopy Growth founder and former executive chair Bruce Linton as a strategic advisor.
Creso said Mr Linton had been appointed for a 24-month term and would be issued 30,000,000 options, exercisable at 3.0 cents within five years, in consideration.
The company said Mr Linton had extensive experience as a founder, chief executive officer and adviser to several marijuana companies and was currently the executive chair of Gage Cannabis Co and a director of Mind Medicine Inc.
Creso said Mr Linton was the co-chairman and former chief executive officer of Martello Technologies Group Inc and the co-founder of Ruckify Software.