Biotech Daily

Tuesday October 20, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: AMPLIA UP 22%; PROTEOMICS DOWN 6%**

*** CSL 2020 R&D BRIEFING: SPEND UP, COVID-19 PROGRAMS**

*** ONCOSIL: RESECTED PANCREATIC CANCER SURVIVAL 31 MONTHS**

*** RESPIRI 'OVER-SUBSCRIBED' PLACEMENT RAISES $12.5m**

*** IMPEDIMED RECEIVES $2.6m R&D TAX INCENTIVE**

*** BIONOMICS RETAIL RIGHTS RAISE $1.2m; TOTAL $2.2m**

*** COCHLEAR COVID-19 RECOVERY; STEPHEN MAYNE AGM BID LOST**

*** AMPLIA PLEADS '1st CANCER PATIENT DOSING' TO ASX 22% PRICE QUERY**

*** PYC HOPES TO RAISE $55m IN PLACEMENT, 1-for10 RIGHTS OFFER**

*** ECOFIBRE PROFIT WARNING**

*** RHINOMED 12.7m CEO MICHAEL JOHNSON IN-THE-MONEY OPTIONS AGM**

*** MICRO-X $263k PETER ROWLAND PERFORMANCE RIGHTS AGM**

*** DORSAVI REQUESTS CAPITAL RAISING TRADING HALT**

*** ARIX REDUCES TO 9.9% OF PHARMAXIS**

*** ECOFIBRE APPOINTS KRISTI WOOLRYCH DIRECTOR**

*** AUSCANN LOSES CFO QUENTIN MEGSON**

*** STEMCELL TO BUY 50.1% OF SHENZEN LENTENE FOR SEA GRAPES**

MARKET REPORT

The Australian stock market fell 0.72 percent on Tuesday October 20, 2020, with the ASX200 down 44.8 points to 6,184.6 points. Thirteen of the Biotech Daily Top 40 stocks were up, 20 fell and seven traded unchanged.

Amplia was the best for the third trading day in a row, up six cents or 22.2 percent to 33 cents, with 3.5 million shares traded. Imugene climbed 10.5 percent; Mesoblast improved 5.3 percent; Antisense and Oncosil were up more than three percent; Alterity, Cochlear and Genetic Signatures rose more than two percent; with Cynata, Impedimed, Nova Eye, Orthocell, Pro Medicus and Starpharma up more than one percent.

Proteomics led the falls, down 3.5 cents or six percent to 55 cents, with 50,855 shares traded. Actinogen and Universal Biosensors fell more than four percent; Dimerix and Prescient lost more than three percent; Avita, Cyclopharm, Immutep, Nanosonics, Neuren, Opthea and Uscom shed two percent or more; Clinuvel, Compumedics, CSL, Kazia, Medical Developments, Next Science, Polynovo, Resmed and Volpara were down one percent or more; with Telix down by 0.6 percent.

CSL

CSL says investment in research and development has continued to increase and it has several programs in development in response to the Covid-19 pandemic.

In its 2020 research and development briefing, CSL said that it had “vaccine, hyperimmune and monoclonal antibodies all in clinical stages as potential preventative or treatment options in the fight against Covid-19” and had made advancements across all of its scientific platforms, including cell and gene therapy, recombinant technology, plasma fractionation and cell and egg-based vaccines.

The company said that in the year to June 30, 2020, it invested $US922 million ($A1,310 million) into its research and development portfolio, or 10 to 11 percent of total revenue.

CSL said it had multiple programs for Covid-19, including the UQ/CSL V451 vaccine candidate with the University of Queensland, currently in a phase I trial, it was working with Astrazeneca to manufacture 30 million doses of its candidate AZ1222 for supply to Australia, as well as was developing an investigational anti-severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) plasma hyperimmune product, conducting a phase II study of Garadacimab for severe respiratory distress and had partnered with Sab Biotherapeutics to manufacture SAB-185 as an immunotherapy for Covid-19.

CSL head of research and chief scientific officer Dr Andrew Nash said “the same collaborative mindset with which CSL has responded to the Covid-19 pandemic is also reflected in how we are advancing our pipeline”.

“Across therapeutic areas, strategic platforms and geographies we continue to grow our footprint and capabilities so that we can deliver a significant benefit to patients around the world,” Dr Nash said.

CSL said it continued to advance its phase III CSL112 study for acute coronary syndrome and had enrolled 10,000 patients, with the first futility analysis conducted.

The company said it had initiated a phase III study of Hizentra for dermato-myositis and had US Food and Drug Administration paediatric approval for, and was preparing to commence a phase III study of, Haegarda for hereditary angio-oedema (HAE) in Japan.

CSL said it had approval for Privigen in Japan, had US orphan drug designation for Hizentra for chronic inflammatory demyelinating polyradiculoneuropathy and for Garadacimab for HAE, which had met its primary endpoints in phase II trials and was shown to statistically significantly reduce HAE attacks.

The company said it had FDA fast track designation and US and European orphan status and had begun phase I studies of CSL200 and CSL889 for sickle cell disease, as well as a phase I study of CSL311 for mild asthmatic patients and had acquired Vitaeris Inc, including Clazakizumab or CSL300, which now had FDA orphan status and it had begun a phase III study for chronic active antibody-mediated rejection in kidney transplant patients.

CSL said it had US approval for Audenz, an adjuvanted cell-based influenza A pandemic vaccine, Fluadtetra vaccine approval for influenza in Europe and for Fluadquadrivalent vaccine in the US.

The company said it had bought the rights to Uniquire’s the adeno-associated virus gene therapy program, currently in phase III trials, and was working with Seattle Children’s Research Institute on a stem cell gene therapy for primary immunodeficiency diseases.

CSL head of research and development Dr Bill Mezanotte said that the company’s “acumen in vaccines, monoclonal antibodies, recombinant technologies, manufacturing capabilities and external partnerships, along with a therapeutic area focus and insight that includes immunology and respiratory, has supported the growth and progress of our pipeline and has also enabled us to respond quickly to the need for potential solutions in the world’s fight against Covid-19”.

CSL fell $3.09 or one percent to $301.04 with 585,932 shares traded.

ONCOSIL MEDICAL

Oncosil says that 10 resected patients in its Panco radiation study for pancreatic cancer have demonstrated a median follow up of 31.1 months.

In 2018, Oncosil said an interim analysis of the 42 patients in its study of Panco radiation with chemotherapy for pancreatic cancer showed that 37 patients (88.1%) had local disease control ($p < 0.0001$) (BD: Oct 25, 2018).

Today, Oncosil said a follow-up on the 10 patients found that four deaths had been reported to date and six patients remained alive, with a survival range of between 26.4 months and 35.3 months post enrolment.

Oncosil chief executive officer Daniel Kenny told Biotech Daily that the survival needed to be compared to the median survival for this cohort of patients of 8.5 months.

The company said that the four resected patients who died, had survived from 18.8 months to 22.1 months, and were previously classed as “unresectable”.

Oncosil said a further four patients were eligible for surgery post-treatment but were unable to undergo surgery due to co-morbidities or other considerations, which implied a 33 percent resection rate.

Oncosil said it continued to monitor patients, but the findings suggested that survival was at least in line with neo-adjuvant chemotherapy patents prior to surgical resection.

Mr Kenny said that the current median survival rate for the Panco trial was 16.1 months with the last of the 42 patients resected on July 20, 2018.

Mr Kenny said that he expected the media survival rate to continue to increase as the follow-up continued.

Last year, the company said a European committee had found “insufficient clinical benefit” to approve its pancreatic cancer radiotherapy (BD: Oct 25, 2019).

In today’s media release, Mr Kenny said that “although the median survival has not yet been reached for the Panco study participants that underwent surgery with curative intent, the median follow-up of 31.1 months suggests that the survival of this cohort could be expected to be in line with other [locally advanced pancreatic cancer] patients undergoing surgery and it highlights the significance of our device’s ability to prolong survival outcomes through its ability to convert previously deemed inoperable patients to an operable status.”

Oncosil was up half a cent or 3.7 percent to 14 cents with 2.3 million shares traded.

RESPIRI

Respiri says it has raised $12.5 million through an oversubscribed placement to institutional, professional and sophisticated investors at 20 cents a share.

The company said the price was a 6.5 percent discount to the 30-day volume weighted average to October 13, 2020 and the funds would be used for Wheezo market development activities including US and European market launches, sales and marketing, product development and research and working capital.

Respiri said Blue Ocean Equities was the lead manager and bookrunner to the placement.

Respiri fell 3.5 cents or 14.9 percent to 20 cents with 6.9 million shares traded.

IMPEDIMED

Impedimed says it has received $2,587,816 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Impedimed said the rebated related to expenditure for the year to June 30, 2020.

Impedimed was up 0.1 cents or 1.2 percent to 8.3 cents with 3.9 million shares traded.

BIONOMICS

Bionomics says it has raised $1.2 million through the retail component of its one-for-12.54 non-renounceable entitlement offer at four cents, for a total $2,173,320.
Last month, Bionomics said it hoped to raise $2,173,320 in the two-part entitlement offer and raised $893,235 in the institutional component (BD: Sep 24, 28, 2020).
Today, the company said it received applications for $1.54 million through the retail oversubscription facility, which was scaled back on a pro rata basis.
Bionomics was unchanged at 13 cents.

COCHLEAR

Cochlear says that in the three months to September 30, 2020 cochlear implants in the developed world increased in low single-digit growth reflecting a return to surgery.
Cochlear said the growth included new and rescheduled surgeries and showed market share gains, with the US, Germany and South Korea “showing good growth on last year, while many European markets, including the UK, Italy and Spain, have been regaining momentum more recently as clinics re-open and surgical throughput grows”.
The company said that clinical assessments were “close to pre-Covid-19 levels in many markets [with] solid lead generation from Cochlear’s direct-to-consumer activities” and although there was positive surgery momentum there was the risk that second waves of Covid-19 “likely to remain a reality for some time and may result in new restrictions”.
Cochlear said that in “emerging markets” unit volumes fell about 40 percent compared to the three months to September 30, 2019.
“Surgeries in China are growing but most other countries remain well behind last year,” the company said. “There continues to be uncertainty over the time it will take for some emerging markets to recover.”
The company said that the launch of the Cochlear Nucleus Kanso 2 sound processor, the growing recipient base and the adoption of remote care tools were expected to underpin demand for upgrades.
Cochlear said that acoustic revenue, primarily from the US and UK, had improved since May, while surgery volumes were recovering in the US “with strong demand for the Osia 2 system”.
Cochlear chief executive officer Dig Howitt said the company was “pleased with the pace of recovery across our developed markets”.
“We have a suite of new products that are just starting to be launched and are generating excitement and great feedback,” Mr Howitt said.
“Our investment priorities this year will be focused on strengthening our competitive position and continuing to invest in many of our growth programs,” Mr Howitt said.
Cochlear said it was expected to benefit from changes to the Federal Research and Development Tax Incentive with the lifting of the $100 million cap and the increase in the concession rate which “would have increased the 2019-’20 deductible amount from $8.5 million to $16.2 million after tax”.
Separately, Cochlear said all resolutions to its annual general meeting passed easily except the election of Stephen Mayne, which the board opposed (BD: Sep 18, 2020).
Mr Mayne won 2,699,243 votes (5.85%) with 43,406,371 votes (94.15%) opposed.
According to the company’s most recent Appendix 2A announcement, it had 65,734,141 shares on issue, meaning the votes for Mr Mayne amounted to 4.1 percent of the company, insufficient to call extraordinary general meetings.
Cochlear climbed $5.02 or 2.3 percent to $222.82 with 236,494 shares traded.

AMPLIA THERAPEUTICS

Amplia 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 22.4 percent from 29 cents to 35.5 cents today October 20, 2020 and noted a "significant increase" in the trading volume.
Earlier this month, Amplia said it had dosed the first patients in its trial of AMP945 for difficult to treat cancers and fibrotic diseases (BD: Oct 8, 2020).
On October 8, Amplia was unchanged at 17 cents.
Amplia was up six cents or 22.2 percent to 33 cents, with 3.5 million shares traded.

PYC THERAPEUTICS (FORMERLY PHYLOGICA)

PYC says it hopes to raise $55 million through a $50 million one-for-10, pro rata, non-renounceable entitlement offer and a $5 million placement at 17 cents a share.
PYC said the share price was at an eight percent discount to the last closing price and neither the placement nor entitlement offer would be underwritten.
The company said the record date for the entitlement offer would be October 22, 2020, the offer would include an institutional component, closing tomorrow October 21 and a retail component opening on October 26 and closing on November 11.
PYC said major shareholder Australian Land, which was controlled by PYC chair Alan Tribe, had committed to 100 percent of its entitlement for $15 million.
The company said the funds would be used to develop its lead drug program VP-001 to market, for pre-clinical development of PYC-001 and VP-002, development of cell penetrating peptides and proof-of-concept studies for tissue beyond the eye, expansion of its US corporate office and for general working capital.
PYC was in a trading halt and last traded at 18.5 cents.

ECOFIBRE

Ecofibre says it expects to incur a loss for the six months to December 31, 2020 and is targeting a breakeven for the year to June 30, 2021.
Ecofibre said the loss was not unexpected due to Covid-19 disruptions, the acquisition of Hemp Black North Carolina, the product development and placement in CVS Pharmacy and the costs associated with moving to its new US headquarters.
Ecofibre fell 66 cents or 26.7 percent to $1.81, with 1.99 million shares traded.

RHINOMED

Rhinomed says its annual general meeting will vote to issue chief executive officer Michael Johnson 12,690,457 options, exercisable at 11.6 cents within 48 months.
Rhinomed said it would grant Mr Johnson a $1,472,093 interest-free limited recourse loan for the options, which vest on issue.
The company said it would also vote to adopt the remuneration report, re-elect director Dr Eric Knight, to approve a 10 percent placement capacity, the long-term incentive plan and ratify the appointment of Grant Thornton Audit as its auditor.
The virtual meeting will be held at on November 20, 2020 at 10am (AEDT) via https://us02web.zoom.us/webinar/register/WN_C9COKehsQceMoITiuCJSBw.
Rhinomed was unchanged at 17.5 cents.

MICRO-X

Micro-X says shareholders will vote to issue performance and service rights valued at up to $262,723 to managing director Peter Rowland, pending performance.
Micro-X said the annual general meeting would vote to issue performance and service rights worth up to 95 percent of Mr Rowland's salary each year, currently $276,554.50.
The company said the rights would be issued in three tranches in December 2020, July 2021 and July 2022 and no later than three years from the meeting.
Micro-X said the long-term incentive performance rights would vest on achievement of agreed share price appreciation over three years, the long-term incentive service rights would vest three years from the issue date and the short-term incentive performance rights would vest upon annual performance milestones.
The company said the meeting would vote to adopt its remuneration report, re-elect directors Patrick O'Brien and David Knox, ratify the prior issue of placement shares and approve its employee incentive plan and a 10 percent placement capacity.
The virtual meeting will be held on November 18, 2020 at 10am (ACDT) at https://us02web.zoom.us/webinar/register/WN_Juna6n0RR76S8ll9bG1b7g.
Micro-X was up half a cent or 2.2 percent to 23.5 cents.

DORSAVI

Dorsavi has requested a trading halt "pending an announcement by Dorsavi in relation to a proposed capital raising from institutional and retail investors".
Trading will resume on October 22, 2020 or on an earlier announcement.
Dorsavi last traded at 3.6 cents.

PHARMAXIS

Arix Bioscience Holdings says it has reduced its substantial shareholding in Pharmaxis from 43,693,000 shares (11.1%) to 39,421,131 shares (9.9%).
The London-based Arix said that between October 14 and 16, 2020 it sold 4,271,869 shares for $394,152 or 9.2 cents a share.
Pharmaxis was unchanged at 9.1 cents with 2.1 million shares traded.

ECOFIBRE

Ecofibre says it has appointed Kristi Woolrych as an independent non-executive director effective from today.
Ecofibre said Ms Woolrych had more than 20 years' experience, was currently the chief marketing officer for KFC (Kentucky Fried Chicken) in Australia and New Zealand and previously worked at Suncorp, including as general manager of brand and marketing.
Ecofibre said Ms Woolrych held a Bachelor of Business from the Queensland University of Technology

AUSCANN GROUP

Auscann says chief financial officer Quentin Megson has resigned "for personal reasons and to pursue other interests".
Auscann said Mr Megson would assist in the transfer during his three-month notice period and if required, would continue on a part-time contractual basis.
Auscann fell half a cent or 3.45 percent to 14 cents.

STEMCELL UNITED

Stemcell says it has an agreement to acquire 50.1 percent of China's Shenzen Lantene Dingzhi Biotechnology Co.

Stemcell said Lantene was an aquaculture company that specialized in commercial scale cultivation and sale of sea grapes in China.

Last week, the company said it had a joint venture, SCU Green Aqua Farm, with Blue Aqua International to cultivate and farm Caulerpa Lentillifera or sea grapes in Singapore (BD: Oct 14, 2020).

Today, the company said it had agreed to issue 30 million shares for $540,000 or 1.8 cents a share and a 20 percent share of its subsidiary Stemcell Essential to Lantene as consideration.

Stemcell said that following the acquisition, both companies would appoint a director to the new Lantene board, which was expected to be completed by November 15, 2020.

In its prospectus of June 29, 2015, Stemcell (then On Q Group) said it would extract Resina from Daemonorops draco blume or Dragon's Blood for traditional Chinese medicines, saying that "whether or not [traditional Chinese medicine] is believed, studies have shown that Chinese herbal medicine can be successful in treating a range of disorders", (BD: May 18, 2017).

In May, the company appointed Alan Dronkers as a "marijuana advisor" having lost "the king of cannabis" Nevil Schoemakers in 2017 (BD: Sep 29, 2017; May 7, 2020).

Stemcell was up 0.1 cents or 5.6 percent to 1.9 cents with 6.25 million shares traded.