Biotech Daily

Monday February 22, 2021

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: OPTISCAN UP 21%; DIMERIX DOWN 5%**

*** EDITORIAL: YOUR R&D TAX INCENTIVE IS *NOT* REVENUE**

*** GENETIC SIGS H1 REVENUE UP 411% TO $19m, LOSS TO $4m PROFIT**

*** IMPEDIMED H1 REVENUE UP 26% TO $3.6m, LOSS DOWN 19% TO $10.4m**

*** NEXT SCIENCE REVENUE DOWN 15% TO $4.4m, LOSS DOWN 17% TO $15m**

*** CANN GROUP H1 REVENUE UP 36% TO $1m, LOSS UP 12% TO $9.4m**

*** MICRO-X 'OVERSUBSCRIBED' SHARE PLAN RAISES $3.5m; TOTAL $34m**

*** AZURE HOPES FOR $3m NSX LISTING**

*** NOXOPHARM: CANACCORD UNDERWRITES $3.7m OPTIONS**

*** CYNATA RECEIVES $1.4m FEDERAL R&D TAX INCENTIVE**

*** PHARMAXIS ENROLS 1st PXS-5505 MYELOFIBROSIS PATIENT**

*** JAPAN APPROVES TELIX TLX591-CDX PROSTATE CANCER TRIAL**

*** BIONOMICS REFORMULATED BNC210 PHARMACOKINETICS**

*** BTC TO DISTRIBUTE GPX NEOLA LUNG VOLUME, OXYGEN MONITOR**

*** INVION TO RELEASE 1.4b VOLUNTARY ESCROW SHARES**

*** CEO GEORGE SYRMALIS INCREASES, DILUTED TO 20% OF IQ3**

*** EMYRIA APPOINTS DR KAREN SMITH ADVISORY BOARD CHAIR**

*** AUSCANN: CHARLES ALTSHULER CFO, MARIA ALEXAKIS MED DIRECTOR**

*** BOD TO LOSE CFO CHARLES ALTSHULER**

*** MEDIGARD FACES ASX DE-LISTING ON FEES**

MARKET REPORT

The Australian stock market fell 0.19 percent on Monday February 22, 2021, with the ASX200 down 12.9 points to 6,780.9 points. Sixteen of the Biotech Daily Top 40 stocks were up, 16 fell and eight traded unchanged. All three Big Caps fell.

Optiscan was the best, up four cents or 21.05 percent to 23 cents, with 2.7 million shares traded. Proteomics rose 17.2 percent; Kazia climbed 13.3 percent; Genetic Signatures was up 5.7 percent; Actinogen, Next Science and Opthea improved four percent or more; Uscom was up 3.2 percent; Compumedics, Orthocell and Resonance rose more than two percent; Cyclopharm, Neuren and Pharmaxis were up more than one percent; with Cynata and Paradigm up by less than one percent.

Dimerix led the falls, down 1.5 cents or 5.4 percent to 26.5 cents, with 1.2 million shares traded, followed by Osprey down five percent to 1.9 cents, with 1.5 million shares traded. Avita, Imugene, Oncosil, Prescient and Starpharma fell more than four percent; Amplia and Polynovo were down more than three percent; Antisense, CSL and Resmed shed more than two percent; Medical Developments was down 1.3 percent; with Clinuvel, Cochlear, Nanosonics, Pro Medicus, Telix and Volpara down by less than one percent.

BIOTECH DAILY EDITORIAL

How many times do we have to say it?

Your Federal Government taxpayer-funded R&D Tax Incentive is *not* revenue.

Revenue comes from goods, products or services sold to customers. It might include interest earned on investments, but it certainly does not include the Federal Research and Development Tax Incentive, no matter what your accountant or auditor says.

A number of companies claim the Federal Research and Development Tax Incentive as "revenue" when in fact they have little or no real revenue at all. We sometimes wonder if they are doing it deliberately, or just don’t understand taxation. Either way, it is misleading to investors to claim millions of dollars in revenue, when there is little, if any.

The Tax Incentive is similar to a tax rebate and is not taxable, so it should not be called revenue; just as one's tax payment in one year is not an allowed tax-deductible expense in the following year.

Unless one goes to the fine detail (and some companies do not provide it) an investor could think the company has money when it doesn't.

Revenue does not include the Tax Incentive or grants. It does include sale of product, licence fees, milestone payments, royalties and bank interest.

All these sub-units of revenue should be made clear and investors should not need to go searching for the truth, buried deep in the notes, or have to call the company to find out what they have not announced, clearly.

David Langsam, Editor

GENETIC SIGNATURES

Genetic Signatures says revenue for the six months to December 31, 2020 was up 411.0 percent to $18,928,000 with last year's loss turned to a profit after tax of $4,497,000.
Genetic Signatures said revenue included $18,693,000 from sales of its Easyscreen diagnostics for sudden acute respiratory syndrome (SARS), gut microbial infections, sexually transmitted infections and respiratory disease, including $16,651,000 from the Asia Pacific region and $2,960,000 from Europe, the Middle East and Africa, and $623,000 from the US.
The company said diluted profit per share was up 3.09 cents compared to last year's 2.10 cents diluted loss per share, net tangible assets per security was up 16.7 percent to 35.5 cents, and it had cash and cash equivalents of $36,273,000 at December 31, 2020 compared to $40,441,000 at December 31, 2019.
Genetic Signatures was up 9.5 cents or 5.7 percent to $1.75.

IMPEDIMED

Impedimed says revenue for the six months to December 31, 2020 was up 26.15 percent to $3,579,000 with net loss after tax down 19.34 percent to $10,438,000.
Impedimed said Sozo bio-impedance spectroscopy revenue was up 53.7 percent to $3,267,000, with L-Dex lymphoedema test revenue down 59.2 percent to $280,000.
The company said diluted loss per share fell 66.7 percent to 1.0 cent, net tangible assets was constant at 2.0 cents a share and it had cash and cash equivalents of $19,021,000 at December 31, 2020 compared to $12,971,000 at December 31, 2019.
Impedimed was unchanged at 13.5 cents with 2.8 million shares traded.

NEXT SCIENCE

Next Science says revenue for the year to December 31, 2020 was down 15.3 percent to $US3,440,975 ($A4,360,922) with net loss after tax down 17 percent to $US11,912,004 ($A15,102,766).
Next Science said its revenue mainly came from sales of the Bactisure treatment for surgical cavities and implants, with US sales down 15.6 percent to $US3,353,331 and revenue from Australia was up 0.11 percent to $US87,644.
The company said diluted earnings per share was down 26.5 percent to 6.36 US cents and net tangible assets per share fell 10.3 percent to 8.54 US cents.
Next Science said it had cash and cash equivalents of $US15,339,402 at December 31, 2020 compared to $US16,910,605 at December 31, 2019.
Next Science was up six cents or 4.9 percent to $1.29.

CANN GROUP

Cann says revenue including interest for the six months to December 31, 2020 was up 35.5 percent to $1,108,000 with net loss after tax up 12.2 percent to $9,398,000.
Cann said the revenue came for the sale of marijuana products including oil for distribution in Australia and the UK, with shipments to Germany delayed awaiting final permits.
The company said diluted earnings per share was down 17 percent to 4.98 cents and net tangible assets per share fell 22.4 percent to 38 cents.
Cann said it had cash and cash equivalents of $27,651,000 at December 31, 2020 compared to $8,007,000 at December 31, 2019.
Cann fell half a cent or 0.7 percent to 69 cents with 4.15 million shares traded.

MICRO-X

Micro-X says it has raised $3.5 million in an “over-subscribed” share plan at 34 cents a share, taking the total raised to $34 million.
This month, Micro-X said it had raised $30.5 million in a placement at 34 cents a share and hoped to raise a further $2.5 million through a share purchase plan at the same price (BD: Feb 1, 2021).
Today, the company said it had applications for more than $8.6 million for its share plan and had to scale back on a pro-rata basis.
Micro-X was up 1.5 cents or 3.9 percent to 40 cents with 1.8 million shares traded.

AZURE HEALTH TECHNOLOGY (MERGED WITH INVICTUS BIOTECHNOLOGY)

Azure says it hopes to raise up to $3 million in an initial public offer at 20 cents a share to list on the National Stock Exchange for its tocotrienol food additives and supplements.
The National Stock Exchange (NSX) was previously known as the Newcastle Stock Exchange
Azure said that the offer would open on February 25 and close on March 25, with trading expected to begin on April 9, 2021.
The company said that with a $3 million capital raising it would have an indicative market capitalization or $28 million.
Last year, Invictus attempted a $10 million backdoor listing into the then-listed Azure, but said it failed to meet the ASX minimum 300 investors rule and Azure later delisted from the ASX (BD: Feb 5, Apr 28, 2020).
Today, the company said the funds would be used for pharmaceutical licencing and clinical program management, food additives manufacturing and marketing, and working capital.
Azure said it was developing and commercializing dietary supplements and prescription medicines based on natural products from tocotrienols which had “therapeutic potential, including: delayed onset muscle soreness, muscle recovery, exercise endurance, non-alcoholic fatty liver disease, non-alcoholic steatohepatitis, pancreatic cancer, hyper-lipidaemia, hypertension and diabetes”.
The prospectus is available at: https://bit.ly/2Maq0L9.
Azure is a public unlisted company.

NOXOPHARM

Noxopharm says it has an underwriting agreement with Canaccord Genuity Australia for 12,325,000 options exercisable at 30 cents each by February 28, 2021.
Noxopharm said the options were the remainder of 22,586,000 unquoted options issued to pre-initial public offer shareholders, of which 10,261,000 options had been exercised.
The company said Canaccord had underwritten the options to $3,697,000.
Noxopharm fell three cents or 3.8 percent to 76 cents with 1.2 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has received $1,391,067 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Cynata said the rebate related to research and development expenditure for the year to June 30, 2020.
Cynata was up half a cent or 0.75 percent to 67 cents.

PHARMAXIS

Pharmaxis says it has enrolled the first of 18 patients in the dose escalation phase of a phase Ic/IIa trial of a PXS-5505 for the bone marrow cancer myelofibrosis.

Pharmaxis said that the trial was cleared by the US Food and Drug Administration under an investigational new drug application to evaluate its safety and effectiveness as a monotherapy in myelofibrosis patients who are intolerant, unresponsive or ineligible for treatment with approved JAK-inhibitor drugs.

In 2019, Pharmaxis said that a 40-subject, phase Ia dose-ranging trial of its oral anti-fibrotic lysyl oxidase (LOX) inhibitor was safe, well-tolerated and showed a dose-related activity (BD: Oct 24, 2019).

Pharmaxis said at that time that the study dosed the healthy volunteers in five groups, with a single oral dose or a placebo and there were no safety signals identified.

The company said the data showed good pharmacokinetics and a dose-related inhibition of the LOX family of enzymes, including LOX, LOXL1, LOXL2, LOXL3 and LOXL4, with upper doses causing significant inhibition for 24 hours after a single application

Today, Pharmaxis said it had initiated sites at Australian and South Korean hospitals and the dose escalation phase aimed to select the optimum dose of PXS-5505.

The company said that it expected the dose escalation phase to conclude and report by the end of 2021 and be followed by a six-month dose expansion phase with 24 patients to evaluate safety and efficacy.

Pharmaxis said that sites in other countries including the US would be added for the dose expansion phase.

The company said that PXS-5505 was an oral drug that inhibits the lysyl oxidase family of enzymes and in pre-clinical models of myelofibrosis PXS-5505 reversed the bone marrow fibrosis that drove morbidity and mortality in myelofibrosis and reduced many of the abnormalities associated with this disease.

Pharmaxis chief executive officer Gary Phillips said PXS-5505 showed “good tolerability and highly effective inhibition of the enzyme in phase I studies”.

“Its potential to modify the course of the disease by directly targeting bone marrow fibrosis will make PXS-5505 an ideal monotherapy or adjunct to approved therapies in this indication,” Mr Phillips said.

“There remains a high level of unmet need in myelofibrosis and many other drugs in development have challenging side effect profiles,” Mr Phillips said.

Pharmaxis said its primary focus for PXS-5505 was myelofibrosis, the drug had potential in several other cancers including liver and pancreatic cancer where it aimed to breakdown the fibrotic tissue in the tumor and enhance the effect of chemotherapy treatment.

Pharmaxis was up 0.1 cents or 1.2 percent to 8.6 cents.

TELIX PHARMACEUTICALS

Telix says the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) has cleared the phase I trial of TLX591-CDx for its prostate cancer imaging.

Last year, Telix said it had begun a collaboration with Kanazawa University and it would conduct the trial using positron emission tomography using 68-gallium-prostate-specific membrane antigen 11 (Ga-PSMA-11) (BD: Dec 14, 2020).

Today, the company said the trial would obtain preliminary data from the patient population, to confirm the targeting and pharmacology of TLX591-CDx was equivalent to non-Japanese patients.

Telix fell three cents or 0.7 percent to $4.10 with 710,403 shares traded.

BIONOMICS

Bionomics says seven-day dosing of a new oral formulation of BNC210 in 10 healthy volunteers showed steady-state 12-hourly exposure.

Bionomics said that at 900mg twice daily, the tablet formulation of BNC210 had steady-state 12-hourly exposure levels ranging from 33 milligram-hour/litre (mg.h/L) to 57mg.h/L which exceeded the 12-hourly blood exposure of about 25mg.h/L predicted as necessary to meet the primary endpoints for effectiveness for treating post-traumatic stress disorder (PTSD) patients in future clinical trials.

The company said that the tablet formulation of BNC210 replaced the liquid suspension formulation used in a previous trial which did not provide sufficient blood exposure for efficacy.

Bionomics said that the tablet would be easier for PTSD trial participants to administer and, unlike the liquid suspension formulation, was not dependent on food intake for maximal absorption and was expected to result in substantially less variable exposure in the patients in the next phase IIb PTSD study.

In 2018, Bionomics fell 69 percent when its 193-patient, phase II trial of anti-anxiety drug BNC210 in adults with post-traumatic stress disorder (PTSD), failed to meet its primary endpoint (BD: Oct 2, 2018).

Today, the company said the recent pharmaco-kinetic results showed no gender-based difference in exposure and BNC210 was well-tolerated at the higher exposure levels achieved after seven days of dosing in the healthy volunteers.

Bionomics executive chair Dr Errol De Souza said the study showed “that we reach steady-state levels on the second day following the start of twice daily dosing and that we not only meet but exceed the blood exposure predicted from the pharmaco-metric analysis as necessary for future trials”.

“With the dose now selected, we can initiate manufacturing of the tablets, clinical site selection and regulatory filings in preparation for a phase IIb trial with BNC210 in PTSD patients projected for mid-2021,” Dr De Souza said.

Bionomics was up 2.5 cents or 7.1 percent to 37.5 cents with 25.2 million shares traded.

BTC HEALTH

BTC Health says it has distribution rights for GPX Medical AB’s Neola which measures lung volume and oxygen concentration, in Australia, New Zealand and Singapore.

BTC said the Lund, Sweden-based GPX Neola medical device was for pre-term born infants.

The company said GPX Medical expected European approval in 2023, following which it would apply for approval in Australia and New Zealand.

BTC fell 0.1 cents or 1.25 percent to 7.9 cents with 25.4 million shares traded.

INVION

Invion says that 1,432,841,408 shares held in voluntary escrow will be released on March 1, 2021.

According to the company’s most recent Appendix 2A application for quotation of securities, the company had 5,537,792,295 shares on issue.

Invion was up 0.05 cents or 4.8 percent to 1.1 cents with 3.9 million shares traded.

IQ3 CORP

George Syrmalis, have increased and been diluted in IQ3 from 20,505,112 shares (20.1%) to 20,811,112 shares (19.94%).
Mr Syrmalis said the shares were received under the employee share scheme and were held directly and by Derivative Investments, Life Science Investments, and Zero Hedge Investments.
IQ3 was up 1.5 cents or 10 percent to 16.5 cents.

EMYRIA

Emyria says it has appointed Dr Karen Smith as a chair of its strategic advisory board.
Emyria said Dr Smith was currently chief medical officer of Emergent Biosolutions, a director at Antares Pharmaceuticals and was previously executive vice president, chief medical officer and head of research and development at Jazz Pharmaceuticals.
The company said Dr Smith was the founding chief executive officer of the Minderoo Foundation's 'Eliminate Cancer Initiative' and currently an advisor to the program.
Emyria said Dr Smith held a Doctor of Medicine from the University of Warwick in UK, a Doctor of Philosophy from the University of California Los Angeles and University of Western Australia, a Master of Business Administration from the Northern New South Wales University of New England and a Master of Law from the England's University of Salford.
Emyria was up 1.5 cents or 7.1 percent to 22.5 cents with 1.3 million shares traded.

AUSCANN GROUP

Auscann says it has appointed Charles Altshuler as chief financial officer and head of supply, with Maria Alexakis appointed medical affairs director.
Last year, Auscann said that chief financial officer Quentin Megson had resigned "for personal reasons and to pursue other interests" (BD: Oct 20, 2020).
Today, Auscann said that Mr Altshuler had 16-years' experience in financial management and control, business integration, process improvements and commercialization.
The company said that Mr Altshuler's experience at Bod Australia meant he "already understands the medical cannabis prescription and over-the-counter markets".
Auscann said that Mr Altshuler held finance and supply jobs at Blackmores and Anglo American PLC.
According to his Linkedin page, Mr Altshuler holds a Bachelor of Commerce from South Africa's University of Kwazulu-Natal and a Master of Business administration from Adelaide's Torrens University.
Auscann said that Ms Alexakis had more than 20 years' experience in business development, strategic planning and execution of plans within the consumer, pharmaceutical, medical devices and medicinal cannabis industries.
The company said that Ms Alexakis previously worked for Johnson & Johnson, Sanofi Aventis, Pfizer and Astrazeneca, Australasian Medical and Scientific, Ebos and Hahn Healthcare's medical marijuana sales division.
Auscann said that Ms Alexakis held a Bachelor of Science from Sydney's Macquarie University.
Auscann was up one cent or 5.9 percent to 18 cents with 1.5 million shares traded.

BOD AUSTRALIA

Bod says that chief financial officer Charles Altshuler has resigned, effective from March 31, 2021.
Bod fell one cent or 2.2 percent to 45 cents.

MEDIGARD

The ASX says that any company which has not paid its annual listing fees by 5pm (AEDT) on Friday February 26, 2021 will be removed from the Official List that day.
The ASX provided a list of 23 companies including Medigard and Simavita.
Last week, Simavita was suspended for the ASX for its voluntary delisting from the ASX (BD: Feb 19, 2021).
In 2018, Medigard and its executive chair Ian Dixon said it had licenced the Kunovus-owned injectable KT009 for intervertebral disc degeneration, degenerative disk disease and chronic lower back pain (BD: Oct 30, 2018).
Last year, the company said that a lack of cash threatened its KT009 licence and later appointed administrators (BD: May 1, Nov 12, 2020).
Today, the ASX said that Under Listing Rule 17.15, any entity that has not paid its annual listing fees as required by Listing Rule 16.5 by 5pm (AEDT) on Friday, February 26, 2021 "will be removed from the Official List with effect from the close of trading on Friday, February 26, 2021".
Medigard last traded at two cents.