Biotech Daily

Friday July 19, 2019

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.77 percent on Friday July 19, 2019, with the ASX200 up 51.2 points to 6,700.3 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 10 fell, six traded unchanged and three were untraded.

Amplia was the best, up one cent or 9.5 percent to 11.5 cents, with 13,200 shares traded. Cynata, LBT and Resonance climbed more than eight percent; Compumedics was up 7.9 percent; Avita and Medical Developments improved more than four percent; Benitec and Orthocell were up more than three percent; Genetic Signatures, Neuren, Prescient and Telix rose more than two percent; Kazia, Nanosonics, Oncosil, and Paradigm were up more than one percent; with CSL and Starpharma up by less than one percent.

Clinuvel led the falls, down $2.35 or seven percent to $31.20, with 285,054 shares traded. Ellex and Uscom lost more than six percent; Pharmaxis fell 4.2 percent; Impedimed, Optiscan and Universal Biosensors were down more than three percent; Immutep shed 2.3 percent; Cochlear, Mesoblast, Opthea, Polynovo and Volpara were down more than one percent; with Pro Medicus down 0.2 percent.

DR BOREHAM'S CRUCIBLE: PHARMAXIS

By TIM BOREHAM

ASX code: PXS

Share price: 23 cents; **Shares on issue:** 394,315,798; **Market cap:** $90.7 million

Chief executive officer: Gary Phillips

Board: Malcolm McComas (chairman), Gary Phillips, William Delaat, Dr Kathleen Metters, Edward Rayner

Financials (March quarter): receipts $1.4 million, cash burn $6.1 million, cash of $35.1 million, estimated current quarter outflows $7.9 million

Major shareholders: BVF Partners (Biotech Value Fund) 22%, Arix Bioscience 11%, D&A Income Ltd 7%, Australian Ethical 8%, Allan Gray Australia 5.6%.

Pharmaxis chief Gary Phillips is keen to differentiate the drug developer from his local peers, noting the company has several potential paths to glory rather than a singular approach.

"A lot of biotechs in Australia are a one-product play, they will either get there or bust," he says. "We have more than one asset coming up to potential valuation points."

Long standing (and long suffering) Pharmaxis holders will be pleased to hear that one of these inflection points is within tantalizing reach.

In early May, the US Food and Drug Administration's pulmonary-allergy drugs advisory committee (Padac) recommended Pharmaxis's Bronchitol should be used to treat adult cystic fibrosis patients in the US. (Bronchitol works by reducing the mucus build up in the lungs that progressively restrict breathing.)

After eight hours' deliberation, Padac's 16 esteemed members voted nine to seven in favor, on the question of whether the benefits of the mannitol (dry powder) outweighed the risks. Ok, it wasn't an overwhelming endorsement but as Scott Morrison would attest, a majority's a majority.

In a complete response letter - the FDA's dictate on what needs to be done to win approval - the authority requested changes to Bronchitol's packaging so that the administration instructions were clearer.

"The letter doesn't ask us to do any more clinical work, just make sure the packaging is up to scratch," Mr Phillips says.

Pharmaxis's distribution partner Chiesi expects to respond to the FDA letter by the end of this year, with approval expected by April 2020. The likely approval marks the end of a six-year wait for Pharmaxis, given Padac nixed approval in 2013.

Students of the company will recall that in 2011 the European regulatory bigwigs said they would reject the company's marketing application, but in 2012 Pharmaxis won on appeal.

In 2015 Chiesi kindly expended $35 million on a further 423-patient US-required study.

"We are confident because the product has been on the market in Australia and Europe for seven years and treated thousands of patients with little by way of adverse events reported," Mr Phillips says.

If Bronchitol is approved, Pharmaxis will receive a $US10 million ($14 million) milestone payment on commercial launch, as well as mid to high teen percentage royalties.

Mr Phillips estimates Bronchitol's peak US market sales at $US50 million a year.

Inflammation is the work of the Devil and can lead to scarring and fibrosis, which is at the core of numerous ailments.

The second leg of the Pharmaxis story

In 2015, Ingelheim, Germany-based drug giant Boehringer Ingelheim acquired the rights to the company's AOC3 inhibitor program, exotically titled BI 1467335.

BI 146 … whatever … is being targeted for the liver disease non-alcoholic steatohepatitis (NASH) and diabetic retinopathy. Characterized by leaky blood vessels, diabetic retinopathy is a leading cause of blindness in type two diabetic patients.

"It's a very high unmet need," Mr Phillips says.

Boehringer Ingelheim, which is responsible for the clinical program, is expected to announce the initial results of a 114-patient phase IIa NASH trial in September or October this year.

Mr Phillips notes a number of potential NASH treatments have flopped, highlighting the need for new mechanisms of action. "It was pleasing to see the prominence that this program was given at Boehringer Ingelheim's annual research update," he says.

Pharmaxis pocketed a handy $42 million in milestones from the Boehringer Ingelheim transaction in 2017-'18. Since acquiring the program in 2015, Boehringer Ingelheim has paid a total of $83 million in milestones.

Should either program move to phase III, Pharmaxis trousers a further EUR35 million for the first indication and EUR25 million for the second (a total of 95 million Aussie pesos).

Then there's another $200 million or so of potential drug and pricing approval milestones.

All up, Pharmaxis is eligible for up to $625 million more if both the NASH and eye indications are approved.

Wait - there's more

Management is just as excited - or almost - about its third program based on inhibiting the enzyme LOXL2, which is linked with fostering fibrosis. Current targets are NASH and the fatal lung disease idiopathic pulmonary fibrosis.

Known to its friends as lysyl oxidase-like 2, LOXL2 promotes the linking of collagen fibres, rather like the fibreglass mesh repair on a boat for nautical types.

Manifested as scarring, this process is desirable in the case of wound repair, but not so much in the case of lungs and livers which are meant to be soft and squishy rather than hard and fibrotic. Pharmaxis's boffins have developed two molecules that inhibit the enzyme. Both have been through the usual phase I safety stuff.

"The Pharmaxis LOXL2 program is one of the very few truly anti-fibrotic mechanisms in clinical development," Mr Phillips says.

Initially, Pharmaxis partnered with Synairgen, a drug discovery company linked to the University of Southampton, but in 2017, Pharmaxis bought back the program for GBP5million ($9 million) although Synairgen is entitled to 17 percent of any milestones.

Separately, Pharmaxis is carrying out separate programs for 'pan Lox', which covers the broader family of LOX1 to LOX4 inhibitors. The program targets pancreatic cancer and myelofibrosis (which stops the bone marrow from producing cells). In the case of pancreatic cancer, fibrosis prevents effective oncology drug delivery which is probably why it's one of the most fatal cancers.

Phase I safety trials have been carried out on healthy volunteers - and none of them died. "There's good evidence the drug could be useful for both indications," Mr Phillips says.

Don't forget the Aridol

We shouldn't forget Pharmaxis's original product Aridol, an asthma diagnosis tool relaunched by US distributor Methapharm last December.

There's a bit of history here because the FDA approved Aridol in 2011, before Pharmaxis moved its Sydney manufacturing facility, but had to end US Aridol sales temporarily as uneconomic. The new factory in Frenchs Forest is fully approved and it's game on.

Financials and performance

Pharmaxis March quarter Bronchitol sales was flat at $1.3 million with, $239,000 from Australia, $936,000 from Western Europe and $239,000 from Russia and Eastern Europe.

Nostrovia! [Or formally: Na Zdorovie - Russian Ed]

The company also generated $634,000 of Aridol sales, compared with $421,000 previously.

Overall, Pharmaxis lost $5.7 million, reducing the previous deficit of $8.1 million and it has $35.1 million in cash, having raised $24 million in a two-tranche placement last year that delivered UK healthcare investment fund Arix Inc to the register.

The company cites assets of $52 million (including cash). But on the liability side it has a $23.4 million financing agreement, repayable only as a percentage of US and European Bronchitol revenue

The company's overall results have been dragged down by the loss-making status of its manufacturing operation at its Frenchs Forest facility. The factory lost $3 million in the nine months to March 2019, with a likely $4 million full-year loss.

But this is likely to change because the underused facility has big orders for Bronchitol from European customers that just missed the 2018-19 financial year.

Dr Boreham's diagnosis:

Despite the likely US approval, Mr Phillips says the most promising blue sky comes from the drug discovery program, "which is a little bit out of sight".

Pharmaxis has had its fair share of woes since listing in 2006 at 50 cents a share, having raised $25 million. A secondary listing on the Nasdaq was abandoned in 2009 for cost reasons.

The company certainly looks healthier than when Mr Phillips took the top job in March 2013, and oversaw the retrenchment of 100 of the company's 160 workers in an urgent cost cutting drive.

Since then, the company's focus shifted from fully developing drugs in favor of partnering the big stuff and dabbling in the early stage development programs.

The clinical targets of Pharmaxis and its partners are all big dollar prospects, but NASH (which affects obese people in particular) is forecast to be a $US35 billion a year market by 2025.

We're also wary of seeing more NASH repeats - not a reference to the Korean War soapie but to the danger of yet another trial flop for the indication.

When we last covered Pharmaxis in April 2017, the stock traded at 27 cents and a market cap of $88 million. So, despite the tangible process on several fronts, the stock is treading water, having assaulted the 33 cents level in late July last year.

As chairman Malcolm McComas told last November's AGM: "The Pharmaxis share price does not reflect the value created over the years."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He doesn't mind NASH, er MASH repeats, but only when he has exhausted all 180 Seinfeld episodes – again.

CYNATA THERAPEUTICS

Cynata has told the ASX that the Osaka, Japan-based Sumitomo Dainippon Pharma has offered $2.00 a share to acquire the company valuing it at $203,770,106.
The ASX said the company's share price rose 37 cents or 30.1 percent from $1.23 to $1.60 over the five days to July 16, 2019.
Cynata said it had a non-binding proposal from Sumitomo, had not agreed to it and did not believe it was "public information or would explain the recent trading in its securities".
The company said potential factors for the increase in its share price could include its Cymerus technology featuring in presentations at the International Society of Cell and Gene Therapy meeting in May 2019 and it provided a progress update on the Fujifilm its licence option extension in its June quarterly report on July 4, 2019.
The company said its securities traded at $1.79 a share in March, before the Fujifilm licence extension and "materially above the levels witnessed at close of trade of July 16" with articles recently published by bloggers, industry commentators and share traders.
Cynata chief executive officer Dr Ross Macdonald told Biotech Daily that the Fujifilm response deadline was September 19, 2019.
Cynata was up 14 cents or 8.75 percent to $1.74 with 962,832 shares traded.

IMPEDIMED

Impedimed says it has raised $13.9 million in a fully underwritten, non-renounceable one-for-three entitlement offer at 11 cents a share.
Last month, Impedimed said the rights issue price was at a 9.2 percent discount to the 15-day volume weighted average price, with Canaccord Genuity and Wilsons Corporate Finance joint lead managers and underwriters (BD: Jun 27, 2019).
Today, the company said it received applications for $9.7 million and the remaining 38,353,639 shares would be issued under its underwriting arrangements.
Impedimed fell half a cent or 3.2 percent to 15 cents with 1.3 million shares traded.

NOXOPHARM

Noxopharm says it has up to $26 million in equity draw down facilities with New York's Lind Partners and Toronto's CST Investment Funds.
Noxopharm said the facilities included a $4,560,000 convertible security with a six-month lock up and $22,200,000 in placements over 12 months.
The company said it would be able to vary monthly share issues of between $200,000 and $2,000,000, subject to mutual agreement and it would receive $4,000,000 on closing the facility, including a $3,800,000 convertible security and the first tranche of $200,000.
The company said shares would be sold at either 90 percent of the five lowest daily volume weighted average price (VWAP) of the 20 days prior to the share issue or 58 cents a share, 130 percent of the 20-day VWAP prior to the facility.
Noxopharm said the investors would be granted 4,722,222 options, exercisable at 58 cents a share, 3,000,000 shares would be held as collateral, it would pay a $213,000 fee and be able to pay a $150,000 termination fee or pause the facility for up to three months.
Noxopharm said the funds would be used to meet ongoing working capital needs, to expand and accelerate its clinical programs.
The company said the share issue prices were linked to its trading prices thereby "minimizing dilution for existing shareholders".
Noxopharm said Laidlow & Co was the financial advisor for the transaction.
Noxopharm was up 3.5 cents or 7.7 percent to 49 cents.

RESONANCE HEALTH

Resonance says it has a $1 million contract with an unnamed US company to provide its magnetic resonance imaging products and services for a clinical trial.
Resonance said the company was a Nasdaq-listed pharmaceutical company and work on the trial would begin in July 2019.
The company said it would be paid $US1 million for the 48-month duration of the trial as consideration for its services.
Resonance was up one cent or 8.3 percent to 13 cents with 1.7 million shares traded.

MEDIBIO

Medibio says it has a second agreement with the Chertsey and Surrey, England-based food service provider Compass Group PLC for an Ilumen mental health pilot study.
Medibio said Compass' UK offshore and remote division employees would access its Ilumen mobile and internet applications to screen for early symptoms of mental health issues including depression, anxiety and stress.
The company said users would be provided with a "well-being snapshot" to monitor and make improvements over time and Compass would receive aggregate data to support and manage the mental health of its 600,000 workforce.
Medibio said the pilot study would begin in late September 2019.
Medibio was up 0.8 cents or 66.7 percent to two cents with 165.9 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says the US Food and Drug Administration requires one animal study to address clinical hold concerns for its Penthrox methoxyflurane analgesic.
Last year, Medical Developments said the FDA requested detailed information regarding an appropriate patient population and idiosyncratic liver reaction concern for its phase I trial (BD: Aug 29, 2018).
Today, the company said it would conduct a six-month animal study to replicate a human dosing regimen for Penthrox.
Medical Developments said the FDA agreed that a second animal study to predict idiosyncratic liver reaction to Pethrox would not be required and it expected to submit a full response to the clinical hold in early 2020.
Medical Developments was up 27 cents or 4.7 percent to $6.06 with 208,464 shares traded.

TELIX PHARMACEUTICALS

Telix says it expects to file a Japan clinical trial notification for a phase II bridging trial of TLX250-CDx for renal cancer imaging by July 31, 2019.
Telix said it was required to consult with the Japanese Ministry of Health, Labour and Welfare (MHLW) about managing discharged patients who had been administered its radioactive imaging agent, TLX250-CDx, which was "a well-established procedure" in most of the world but Japan had "limited experience with novel isotopes".
The company said the clinical trial notification would be filed to Japan's Pharmaceutical and Medical Devices Agency.
Telix was up 3.5 cents or 2.15 percent to $1.665 with 1.5 million shares traded.

ZELDA THERAPEUTICS

Zelda says it will collaborate with the Perth and Sydney-based Emerald Clinics to access de-identified data on the use of medical marijuana for pain and insomnia.

Zelda said it would pay Emerald an initial fee of $40,000 for the data on dosages, responses to treatment, the impact on non-cannabis medicine usage such as opioids and real-time data on patients treated with its own formulations, which it aimed to commercially launch in 2020, and subscription fees for additional data would be negotiated at a later date.

Zelda managing director Dr Richard Hopkins said that “Emerald’s approach to collection and curation of patient data makes this information a very valuable commodity world-wide”.

“Being able to access real-world data, in real-time, from patients treated with regulated cannabis medicines, including, in the near future, our own clinically validated products, will provide Zelda with a significant competitive advantage,” Dr Hopkins said.

“This information will inform the design of future clinical trials, reduce the risks and costs of development and accelerate the path to market,” Dr Hopkins said.

Zelda was up half a cent or 7.5 percent to 7.2 cents with 3.9 million shares traded.

BOD AUSTRALIA

Bod says Hong Kong’s Health & Happiness Group will pay $1.5 million, invest $5.5 million to commercialize its marijuana products and take two board seats.

Bod said that the Health & Happiness innovation arm NewH2 would buy 14,864,865 new shares at 37 cents a share, and pay a separate $1.5m upfront cash payment “to be used to transition into [the Health & Happiness research and development] and innovator of cannabidiol and hemp products”.

The company said that following the transaction, NewH2 would hold 17.64 percent.

Bod was up 14.5 cents or 39.7 percent to 51 cents with three million shares traded.

IMPEDIMED

Impedimed 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 rose 3.5 cents or 26.9 percent from 13 cents to 16.5 cents in the five days to July 18, 2019.

SIMAVITA

The ASX says that following the lodgement of its half yearly reports for the six months to December 31, 2018, Simavita has been reinstated to quotation.

Simavita was up 0.4 cents or 23.5 percent to 2.1 cents.

IMMUTEP

Australian Ethical Investment says it has become a substantial shareholder in Immutep with 181,013,867 shares or 5.06 percent.

The Sydney-based Australian Ethical said that it acquired 39,523,810 shares for $830,000 or 2.1 cents a share on July 17, 2019.

Immutep fell 0.05 cents or 2.3 percent to 2.1 cents with 6.9 million shares traded.

AVECHO BIOTECHNOLOGY (FORMERLY PHOSPHAGENICS)

Avecho says joint company secretary Michael Sapountzis has resigned, effective from today, and Melanie Leydin will continue as sole company secretary.
Avecho was up 0.05 cents or 14.3 percent to 0.4 cents with 1.4 million shares traded.

ELLEX MEDICAL LASERS

Ellex says it has appointed Maria Maieli as interim chief executive officer, replacing Ged Wallace effective from today.
In April, Ellex said it appointed Mr Wallace as chief executive officer to replace Tom Spurling (BD: Apr 8, 2019).
Today, the company said Mr Wallace informed the board of his decision to resign … [and] the company agreed that the resignation can take effect immediately".
Ellex did not provide any reason for Mr Wallace's resignation.
The company said that Ms Maieli would step down as company secretary, replaced by group financial controller Kimberley Menzies.
Ellex said Ms Maieli had more than 25 years of senior financial management experience and was currently its chief financial officer.
The company said Ms Maieli was currently a non-executive director of the Australian Diabetes Educators Association.
Ellex said Ms Maieli held a Masters of Professional Accounting from the New South Wales and Queensland-based Southern Cross University.
The company said Ms Menzies was previously its senior auditor and held a Masters of Commerce and Accounting from the University of Adelaide.
Ellex fell four cents or 6.6 percent to 57 cents.