Biotech Daily

Friday April 28, 2017

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market crept up 0.04 percent on Friday April 28, 2017 with the ASX200 up 2.6 points to 5,924.1 points. Nine of the Biotech Daily Top 40 stocks were up, 13 fell, 13 traded unchanged and five were untraded.

Prana was the best, up half a cent or 8.5 percent to 6.4 cents with 135,000 shares traded. Polynovo climbed 6.7 percent; Actinogen was up 4.65 percent; Acrux and Living Cell were up more than three percent; Avita, Opthea and Sirtex rose more than two percent; CSL was up 1.3 percent; with Cochlear and Medical Developments up less than one percent.

Genetic Signatures led the falls, down 6.5 cents or 15.1 percent to 36.5 cents with 14,595 shares traded. Benitec, Mesoblast and Orthocell lost more than five percent; Compumedics and Resmed fell four percent or more; Oncosil and Universal Biosensors were down more than three percent; ITL and Neuren shed more than two percent; Bionomics and Clinuvel were down more than one percent; with Pro Medicus and Viralytics down by less than one percent.

DR BOREHAM'S CRUCIBLE: PHARMAXIS

ASX Code: PXS

Market cap: $88 million; **Share price:** 27.5 cents; **Shares on issue:** 319.1 million

Chief executive officer: Gary Phillips

Board: Malcolm McComas (chairman), Gary Phillips, William Delaat, Dr Simon Buckingham

Financials (March quarter 2017): customer receipts $2.267m (year to date $3.957m), total revenue $4.146m ($11.056m), net loss $3.199m ($14.23m), net operating cash flow -$2.13m (-$11.02m), cash on hand $26.5m, estimated current quarter cash burn $9.8m

Major shareholders: BVF Partners LP 15.9%, Australian Ethical 10.2%

We love a tear-jerking redemption story and there is no more a heartening yarn than the revival of the once-tortured drug developer.

Four years ago Pharmaxis looked sicker than the patients it seeks to treat: a large trial of its Bronchitol treatment for respiratory ailments had flopped and the US Food and Drug Administration rejected approval for the use of the drug on cystic fibrosis (CF) patients.

Bronchitol works by reducing the mucus build up in the lungs that progressively restrict breathing.

In 2011 the European regulatory bigwigs said they would reject the company's marketing application, but then Pharmaxis won on appeal.

Fast forward to now and Pharmaxis continues its quest for FDA approval, this time as an adult-only cystic fibrosis treatment.

The difference is that Pharmaxis is more partnered-up than Elizabeth Taylor in her hubby-eating heyday, with its global buddies assuming most of the risk.

In crude terms, Pharmaxis can kick back and enjoy the proceeds from royalties and milestone payments – or at least focus on its busy slate of early-stage projects.

"We are quite unusual as a biotech,"' says chief executive officer Gary Phillips. "We are not out capital-raising and we have a pipeline of more than one drug."

Previously the company's chief operating officer, Mr Phillips took the top job in March 2013. Apart from retrenching 100 of the company's 160 workers in an urgent cost cutting drive, management shifted focus from 'go to whoa' drug trials to only carrying out the early stages and then seeking partnerships for the expensive stuff.

"With the business model of taking a product to the US market not available, we were going to run ourselves into the ground," Mr Phillips says.

In 2015 Italian pharma house Chiesi acquired the US rights to Bronchitol, in return for milestone payments and royalties in the high teens. Chiesi is also the exclusive European distributor, working on a different margin arrangement.

Crucially Chiesi, which already has a cystic fibrosis portfolio in the US, has funded $US22 million of the $US25 million cost of the current 423-patient global clinical trial (CF303) to satisfy the FDA gatekeepers.

Top line results are due by July 2017.

On FDA approval, Pharmaxis would pocket a $US10 million milestone payment, with on-going annual US Bronchitol sales estimated at $US50-100 million.

Fatty liver busters:

Another major deal is with German drug company Boehringer Ingelheim to develop a treatment for the liver ailment, non-alcoholic steatohepatitis (NASH), more commonly known as fatty liver disease.

This relates to the compound and so-called SSAO inhibitor, PXS-4728A. For the technically-minded, that means it inhibits the semicarbazide-sensitive amine oxidase enzyme which is involved in inflammation processes, which can lead to scarring and fibrosis.

The start of a phase II trial will trigger a $25 million payment to Pharmaxis and this is also expected before July. Given the milestone depends only on the phase II patient trial kicking off – and not on results – it's as good as money in the bank.

Not that management would say that, of course.

Should the program move to phase III, Pharmaxis receives another $55 million, with potentially another $200 million due along the way for drug and pricing approval milestones.

Mystery indication:

Then there's a mystery second indication targeted by Boehringer, which will generate a second milestone payment to Pharmaxis. In total these would be the same as the first indication, but "weighted more to the latter stage of development and approval".

Working out the mystery indication is like playing Guess Who with a daughter who cheats by giving the wrong clues. But here's a broad hint: as an anti-inflammatory, PXS-4728A has applications in chronic obstructive pulmonary disease, ocular disorders, Parkinson's disease and Alzheimer's disease.

All of these are under-treated conditions, while NASH (which affects obese people in particular) is forecast to be a $US35 billion a year market by 2025.

“We hope when we announce the $25 million payment we can give more information,” Mr Phillips says.

The third arm:

Then there’s a third arm to the partnership story.

With UK collaborator Synairgen, Pharmaxis plans to start a phase I clinical study on the lysyl oxidase type 2 enzyme (LOXL2) in the second half of 2017.

LOXL2 has anti-fibrotic qualities and its targets include NASH, cardiac fibrosis and the fatal lung disease idiopathic pulmonary fibrosis.

Synairgen is a drug discovery company linked to the University of Southampton.

Preclinical toxicology studies are being completed on two potential drugs, which are based on the same amine oxidase platform as PXS-4728A.

Dr Boreham’s diagnosis:

With Bronchitol clinical results and news on the PXS-4728A milestone and second indication due by the end of June, it’s a pivotal period for investors.

Meanwhile, March quarter sales included orders from Chiesi for the UK and German Bronchitol markets and the first sales of Bronchitol to its Russian distributor.

In the period, Pharmaxis received $1.8 million for European Bronchitol sales and $469,000 from sales of its asthma diagnosis tool Aridol.

The Pharmaxis $88 million market capitalization looks compelling given the $26 million cash backing and the dead-cert $25 million milestone.

Investors have discounted most or all of the vaunted NASH milestone payments and the royalties from a successful launch of Bronchitol in the US.

Pharmaxis expects a cash burn of $15-20 million a year as it dabbles in proof of concept and phase-one studies. At this rate, the company should be self-funding for some years.

On a risk-reward analysis, we’ve certainly seen worse roughies at Randwick and not necessarily the horses.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is also partnered up for life but expects no imminent milestone payments.

RESMED

Resmed says that revenue for the three months to March 31, 2017.was up 13.3 percent to $US514,204,000 ($A688,220,000) compared to the previous corresponding period.
Resmed said that excluding the contribution from the Brightree business acquired in April 2016, revenue for the quarter was up 5.6 percent to $US479.2 million.
The company said it had declared a cash dividend of 33 US cents a share for the three month period, for the record date of May 11 and payable on June 15, 2017.
Resmed chief executive officer Mick Farrell said the company had "solid double-digit constant currency revenue growth … led by our Brightree software solutions as well as mask and device sales".
"This quarter we saw strong demand for our new Airfit 20 range of masks [and] we also made significant progress on software innovation with the launch of enhanced integration capabilities with Brightree and our AirSolutions cloud-based software platform," Mr Farrell said.
"In our current quarter, we are launching our latest market-leading innovation, the Resmed Airmini, the world's smallest [continuous positive airway pressure mask]," Mr Farrell said
Resmed fell 38 cents or four percent to $9.16 with 3.2 million shares traded.

RESAPP HEALTH

Resapp says it has licenced software to screen for childhood pneumonia from Uniquest, the University of Queensland's main commercialization company.
Resapp said that the software was a set of machine-learning algorithms that used a combination of clinical features to screen for childhood pneumonia and would complement its existing cough-based diagnostic technology.
The company said that unlike the existing Resappdx, the new software did not use cough sound analysis, but relied on observations including heart rate, temperature, the presence of chest in-drawing or oxygen saturation.
Resapp said that the technology was developed at the University of Queensland by the team led by Dr Udantha Abeyratne with funding from the Bill and Melinda Gates Foundation and was the subject of a recently-filed provisional patent application.
The company said that pneumonia was the leading cause of mortality for children below five years of age.
Resapp said that the majority of incidents occur in poor countries where doctors and healthcare workers relied on the World Health Organisation Integrated Management of Childhood Illness criteria, which has been shown to yield very low specificity.
The company said that a recently published peer-reviewed study showed that the new algorithms achieved a sensitivity of 90 percent and specificity of up to 72 percent for diagnosis of childhood pneumonia on a 134-subject dataset, compared to up to 38 percent achieved by the World Health Organisation Integrated Management of Childhood Illness criteria.
Resapp chief executive officer Tony Keating said the new algorithms were "a significant improvement over the current standard of practice in the developing world and a unique opportunity to deploy an effective pneumonia screening tool in situations where a smartphone is not available or a cough recording is not possible".
Resapp said it would pay Uniquest a royalty on products that used the new algorithms and agreed to abide by the Gates Foundation global access objectives and make the technology accessible with respect to cost, quantity and applicability to the people most in need within the developing countries of the world.
Resapp fell half a cent or 1.5 percent to 32.5 cents.

OPTHEA

Opthea says it has completed its $45 million capital raising (BD: April 3, 2017).
Opthea said the proceeds would enable the acceleration and diversification of its clinical development of OPT-302 for wet age-related macular degeneration and diabetic macular oedema.
The company said it raised $35 million in a placement, $7 million in an institutional one-for-14 entitlement offer and $3 million in a retail rights offer, all at 93 cents.
Opthea was up 2.5 cents or 2.8 percent to 93 cents.

ESENSE-LAB

Esense says it has begun delivery of its initial commercial order of cannabis terpene to electronic vaporizer company Allor Vaporizers.
Esense said it had an agreement with the Hallandale Beach, Florida-based Allor to supply its reconstructed cannabis terpene profiles, with a total order value of about US470,000 ($A628,794).
The company said it hoped to enter into similar arrangements with the potential clients who are recipients of about 1,000 commercial samples, comprising of a selection of its 10 commercially ready medical cannabis terpene profiles.
Esense chief executive officer Haim Cohen said the shipment was “an important commercial milestone … [which] demonstrates Esense’s ability to supply high quality product, at commercial production volume and at an attractive price to other potential customers that are currently evaluating our terpene profiles”.
Esense fell 6.5 cents or 15.5 percent to 35.5 cents with 1.9 million shares traded.

BIOTECH DAILY APPENDIX 4C REPORTS

Biotech Daily reports all the significant announcements to the ASX.
Biotechnology companies bleeding money is not news, unless the company involved has less than two quarters of cash.
When companies clearly explain that they expect an R&D Tax Incentive, have equity draw-down facilities or loans or are about to have a capital raising, Biotech Daily will not report their Appendix 4C statement.
Where there is no explanation or it is not clear, and the company has less than six months of cash reserves, it will be reported, as will maiden revenues or profits.
Companies reporting after the close of business will be reported in the following edition.

David Langsam
Editor

GI DYNAMICS

GI Dynamics says its net operating cash burn for the three months to March 31, 2017 was $US2,964,000 with cash at the end of the quarter of $US5,365,000.
GI Dynamics did not provide any further information, other than it expected a cash burn for the coming three months of $US3,000,000.
The company said that a US Securities and Exchange Commission Form 10-Q to be filed on or before May 15, 2017 would include “management’s discussion and analysis of financial condition and results of operations”.
GI Dynamics was up 0.8 cents or 13.8 percent to 6.6 cents with 1.1 million shares traded.

MEDLAB CLINICAL

Medlab says its net operating cash burn for the three months to March 31, 2017 was $1,568,000 with cash at the end of the quarter of $2,752,000.
Medlab did not provide any further information.
Medlab was up 2.5 cents or 2.9 percent to 88.5 cents.

INVITROCUE

Invitrocue says its net operating cash burn for the three months to March 31, 2017 was $354,000 with cash at the end of the quarter of $567,000.
Invitrocue did not provide further details.
Invitrocue fell 1.5 cents or 17.65 percent to seven cents.

NEUREN PHARMACEUTICALS

Neuren says its net operating cash burn for the three months to March 31, 2017 was $3,453,000 with cash at the end of the quarter of $1,622,000.
Neuren said that it received a $981,507 Federal Government R&D Tax Incentive on April 17, which would be included in cash inflows for the three months to June 30, 2017 (BD: Apr 4, 2017).
The company said that it expected a net cash outflow of $600,000 for the three months to June 30, 2017 with payments reduced significantly to $1.6 million, offset by the Tax Incentive and payments are expected to reduce further in the three months to September 30, 2017, due to the conclusion of the phase II Rett syndrome trial.
Neuren said it was “giving careful attention to a range of possible funding and partnering options, in order to support the future plans for Rett syndrome and other indications”.
Neuren fell 0.2 cents or 2.8 percent to 6.9 cents with 2.2 million shares traded.

PHOSPHAGENICS

Phosphagenics shareholders will vote to grant chief executive officer Dr Ross Murdoch 15,000,000 options, with 6,750,000 options for four directors.
The Phosphagenics notice of annual general meeting said that Dr Murdoch’s 15,000,000 options would replace 15,000,000 conditional rights and would be exercisable at 2.3 cents each, a 10 percent premium to the 5-day volume-weighted average price to the “invitation day”, by September 9, 2021 and vesting in three tranches, pending share price rises of 50 percent, 100 percent and 150 percent on September 11, 2017, September 7, 2018 and September 9, 2019, respectively.
The company said it proposed to issue chairman Dr Greg Collier 2,250,000 options, with directors Peter Lankau, Dr Geert Cauwenbergh and David Segal each to receive 1,500,000 options, exercisable at 2.3 cents each, by September 9, 2021 and vesting in three tranches, not pending share price rises on September 11, 2017, September 10, 2018 and September 9,2019.
Phosphagenics said that shareholders would vote on the re-election of Dr Cauwenbergh, approve the employee equity incentive plan and ratify the prior issue of 33,948,150 employee options.
The meeting will be held at the Oliphant Auditorium, National Centre for Synchrotron Science, 800 Blackburn Road, Clayton, on May 31, 2017 at 9:30am (AEDT).
Phosphagenics fell 0.2 cents or 11.8 percent to 1.5 cents with 1.8 million shares traded.

NUHEARA

Stephen Coupe says he and his superannuation fund have reduced their holding in Nuheara to below five percent of the company.

The ceasing substantial shareholder notice said that Mr Coupe, care of accountants Oxley Parners of Bong Bong Street, Bowral, New South Wales, acquired shares between November 23, 2016 and February 17, 2017 and sold shares between January 25 and April 20, 2017 with the single largest purchase 1,500,000 shares for $175,950 or 11.7 cents a share and the single largest sale 4,000,000 shares for $400,317 or 10 cents a share.

Mr Coupe became substantial in Nuheara in November 2016 (BD: Nov 15, 2017).

Nuheara fell 0.4 cents or 5.6 percent to 6.8 cents with 6.6 million shares traded.