Biotech Daily

Friday October 29, 2021

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: LBT UP 15%; POLYNOVO DOWN 3.5%**

*** DR BOREHAM'S CRUCIBLE: USCOM**

*** RESMED RECORD Q1 REVENUE UP 20% TO $1.2b, PROFIT UP 14% TO $290m**

*** LBT: FDA 501K APPROVAL FOR APAS INDEPENDENCE**

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*** STEFAN ROSS REPLACES PATRYS CO SEC MELANIE LEYDIN**

*** CLAIRE NEWSTEAD-SINCLAIR REPLACES INVION CO SEC MELANIE LEYDIN**

MARKET REPORT

The Australian stock market fell 1.44 percent on Friday October 29, 2021, with the ASX200 down 106.7 points to 7,323.7 points. Sixteen of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and three were untraded.

LBT was best, up 1.5 cents or 15.0 percent to 11.5 cents, with 2.2 million shares traded. Actinogen climbed 7.4 percent; Paradigm, Prescient and Proteomics improved more than five percent; Medical Developments and Resmed were up more than four percent; Cyclopharm and Nova Eye were up more than three percent; Impedimed, Imugene and Neuren rose more than two percent; Telix and Universal Biosensors were up more than one percent; with Clinuvel, CSL, Immutep and Opthea up by less than one percent.

Polynovo led the falls, down 6.5 cents or 3.45 percent to $1.82, with 2.6 million shares traded. Cochlear and Next Science lost more than three percent; Avita, Kazia, Optiscan and Pro Medicus shed more than two percent; Dimerix, Starpharma and Volpara were down more than one percent; with Genetic Signatures, Nanosonics and Osprey down by less than one percent.

DR BOREHAM'S CRUCIBLE: USCOM

By TIM BOREHAM

ASX code: UCM

Share price: 13.5 cents; **Shares on issue:** 156,590,391; **Market cap:** $21.1 million

Executive chair: Prof Rob Phillips

Board: Prof Phillips, Christian Bernecker, Brett Crowley, Xianhui Meng

Financials (year to June 30, 2021): sales revenue $3.86 million (up 11%), operating cash inflows $55,000 (previously $30,000 of outflows), net loss after tax $924,243 (previously a $1.33 million deficit), cash of $1.71 million (down 11%).

Identifiable major holders: Citi Nominees (Xianhui Meng) 21.2%, Prof Phillips 20.6%, Jetan (GR Plummer super fund) 6.5%, Gary Davey 4%

It's not even November but it's starting to feel a bit like Christmas - and the tail end of the pandemic, as nations re-open their doors and borders.

But we will be dealing with the health consequences of Covid for years to come?

Uscom chief Rob Phillips estimates up to two billion people – one quarter of the world's people - will have had the virus by the time the plague has done its dash. Many will have ongoing symptoms - the so-called Long Covid - marked by ongoing lung inflammation.

According to the Worldometer web site, about 244 million people have had the disease, with 4.96 million of them dying.

So surely two billion is an over-the-top number?

"Absolutely not," Prof Phillips says.

The reason lies with the great unknown of how many people have had Covid without knowing it. The published data is based on patients presenting with symptoms, but about 90 percent of Covid 'patients' remain asymptomatic and untested (especially in poor populous places like India).

"Despite most patients being asymptomatic, they are equally seriously afflicted with post-Covid syndrome and may get very serious symptoms, such as shortness of breath and pulmonary fibrosis," Prof Phillips says.

Pulmonary fibrosis causes poor lung function and may eventually require lung transplantation.

"We have yet to establish the long-term incidence and progress of this complication in recovered patients and its impact on public health."

Right place, right time

With its non-invasive devices to monitor cardiovascular and pulmonary function, Uscom is in pole position to cover the ongoing monitoring required.

“A critical part of understanding the cardiovascular and pulmonary systems is accurate and non-invasive measurement, and we have sector-leading technologies in the Uscom 1A and Spirosonic devices,” Prof Phillips says.

Uscom (as in Ultra-Sonic Cardiac Output Monitors) was co-founded in 1999 by Coffs Harbour native Prof Phillips, an ultrasound specialist and University of Queensland professor of medicine.

The other founder was fellow Coffs Harbour resident Gary Davey, the founding CEO of Rupert Murdoch’s Sky and Star pay TV networks in Britain.

Gazing out over the endless banana plantations, Prof Phillips saw a better way of measuring blood flows in and around the heart, other than a highly invasive pulmonary artery catheter.

“Blood monitoring techniques almost always get it wrong by measuring the wrong things using the wrong devices,” he says. “It’s about the blood flow at the heart; blood pressure reflects only a small part of understanding the circulation.”

“Furthermore, blood pressure in the arm is less accurate and predictive than pressure at the heart, which we also measure [with the company’s BP+ product].”

Uscom’s devices address conditions responsible for about 75 percent of all disease mortality, including heart failure, sepsis, fluid management, hypertension, asthma and chronic obstructive pulmonary disease.

Uscom is Sydney based and has operations in Sydney, Beijing and Budapest, with offices in Auckland, Singapore, London and Los Angeles. The company listed in December 2003 with the support of Bell Potter’s Colin Bell and more recently Chinese billionaire Xianhui Meng joined the company.

1500 reasons why

This year Uscom churned out its 1500th Uscom1A, its oldest device which to date has generated $35 million in sales.

Uscom1A is a haemodynamic monitor to measure cardiovascular function non-invasively. It is now widely used in intensive care and emergency departments, as well as for anaesthesia, paediatric care, sepsis and monitoring pre-eclampsia in pregnancy.

The device is installed in four of the top 10 US paediatric hospitals, with another three trialing it.

Early in the pandemic, China's National Health and Medical Commission recommended Uscom's devices for monitoring severe Covid cases, and has since installed another 50 devices at infectious disease centres.

This early adoption should not be surprising, given the tech got accelerated approval in Hong Kong during the 2003-'04 outbreak of SARS, Covid-19's coronavirus cousin.

BP+, a central blood pressure and pressure wave monitor, was owned by New Zealand's Pulsecore, and bought by Uscom in 2013.

Spirosonic and Spirosonic Air

Acquired via the purchase of the Budapest based Thor Laboratories in 2015, Spirosonic is an ultrasonic spirometer for asthma and chronic obstructive pulmonary disease.

Spirometers have been around for a long time, but involve blowing into a fan which results in sputum flying in all directions - the ultimate super spreaders. Ew!

They are meant to be cleaned and calibrated every day - but often aren't. Spirosonics' more hygienic disinfection method involves patients blowing through an easily-cleaned smooth-walled tube.

Meanwhile the company is advancing its Spirosonic Air, a home-use version with a wireless connection allowing a doctor to analyze the results in the hospital.

"It can remotely transmit every breath you take," Prof Phillips says.

The device is relevant for ongoing monitoring of asthma, chronic obstructive pulmonary disease (COPD) and long covid-induced inflammation. It is also useful for calibration of anaesthetic devices and continuous positive air pressure (sleep apnoea) equipment.

Research house Markets and Markets expects the spirometry market to grow by 150 percent over the next six years, from $US2.6 billion to $US6.5 billion.

The tick of approval

Uscom 1A, BP+ and Spirosonic are approved in Europe (Conformité Européenne, or CE, mark) and by the Australian Therapeutics Goods Administration. The Uscom 1A is approved by China's National Medical Products Administration (NMPA) and cleared in the US (as a 510k device) by the Food and Drug Administration (FDA).

In May this year the NMPA approved the BP+ monitors and the company is girding for commercial release in China, one of the world's largest hypertension and vascular health markets. The company is at the tail end of Chinese and FDA approval for Spirosonic.

Early in July, Russia's regulator approved Uscom 1A, to be distributed by a mob called Wondermed, after a three-year review. Depending on one's definition of Europe, Russia is Europe's biggest market with 150 million people.

Will your ventilator kill or cure you?

Uscom also plays to the Covid (and post Covid) market with Ventitest, its ultrasonic ventilation calibration device to optimize the performance (flow levels) of ventilators.

Prof Phillips notes that critical Covid patients can die from - or with – ventilation-induced lung injury (VILI), a condition caused by poorly operated or poorly calibrated ventilators.

“If you give a patient too much volume, pressure and flow during ventilation it may damage the inflamed lung linings, reducing blood oxygenation and damaging sensitive organs,” he says.

Conversely, inadequate oxygenation also has poor consequences, so like Little Bear’s misappropriated porridge the flow has to be just right. Ventilators should be calibrated at least daily but - guess what ? - they’re often not.

Because Ventitest is not a medical device per se, it doesn't need to go through the same regulatory hoops. The company is making sure the device is tickety-boo ahead of launch from mid-2022.

Finances and performance

With the lack of access to hospitals following the Delta outbreak impacting sales, Uscom’s fourth and first quarters were especially tough. Still, the company was operationally cash flow positive for the full year to June 30 2021, to the tune of $55,000 (a turnaround on previous outflows of $30,000).

Last year the Uscom 1A spoke for 77 percent of turnover, with the Spirosonics accounting for a further 19 percent. Naturally, the sales bias to Uscom 1A should moderate as the new products are rolled out.

In the US, the company has adopted a new distribution model which it planned to implement two years ago, before the pandemic delayed things.

“The US is showing really exciting signs of life for us,” says Prof Phillips, who adds that seven of the nation’s top 10 paediatric hospitals will be using Uscom 1A before too long.

As of the June 30 balance date, Uscom had a slender - but adequate - cash balance of $1.7 million. Uscom shares were worth 19 cents a year ago, falling to a 12-month low of 10 cents in mid-May 2021. They peaked at $3.75 in May 2004 and bottomed at seven cents in December 2011.

What’s wrong, me old China?

An unusual aspect of Uscom is that 64 percent of its sales were derived from China, with a further 26 percent from Europe. Normally the most important medical device market, US is lumped in with ‘other’ and accounted for eight percent. Australia is barely worth mentioning, accounting for a mere two percent of sales.

Prof Phillips says Uscom's China bias often raises eyebrows, but the company would have been in a "terrible position" otherwise, given the frozen US and European markets for the last two years.

"When you get challenges that are as unpredictable as Covid, you appreciate the value of a diversified global entity," he says.

Uscom's China involvement is reflected in Mr Meng's involvement as both Uscom's biggest shareholder and non-executive director.

Holed up in Beijing because of lockdown restrictions, Prof Phillips has an eyewitness view of the on-the-ground fallout from the strained trade relationships between China and Australia.

"From a personal viewpoint I'm terribly disappointed at the way the relationship has been handled [by Canberra]," he says. "It's pointless to offend someone who buys 35 percent of your exports when the export market is such a competitive one. It makes life unnecessarily difficult for us all trying to support Australia's export economy."

Luckily, Uscom isn't feeling the strain of Australian wine, iron ore and coal exporters as the right doors continue to remain open for medical products the Chinese can't make themselves.

Dr Boreham's diagnosis:

Investors often ask Prof Phillips why Uscom is valued at just over $20 million, given the company has grown revenues for the last nine consecutive years at an annual average rate of 24 per cent.

"I have no idea," he confides. "It miffs me when hand sanitizer companies are worth $1 billion and we have been saving kids' lives all that time."

In your columnist's opinion - not that anyone is asking for it - the lowly valuation probably stems from Uscom's still modest revenues even after two decades. Still, the company has been consistent in its approach to market and has not been strayed by the temptations of medicinal cannabis, bat dung-based cosmeceuticals or coal mining in Alabama.

Management also deserves credit for persisting with the Chinese market, especially at a time of political tensions which means the company won't get any free hits.

Prof Phillips says the company will shine next year as more regulatory approvals flow through. In the meantime, he's happy to see Uscom's devices used in literally life and death situations.

"Very few devices out of Australia have changed clinical medicine, but we have in critical care for paediatrics and maternal health."

Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has never had Covid … or may well have.

RESMED

Resmed says it has record revenue for the three months to September 30, 2021, up 20.2 percent to $US904,015,000 ($A1,199,039,420) with net profit after tax up 14.15% to $US203,613,000 ($A270,061,910).

Resmed said that the increased revenue was “driven by increased demand for our sleep and respiratory care devices and increased demand following a recent product recall by one of our competitors, partially offset by decreased Covid-19 related demand for ventilators”.

The company said that non-GAAP diluted earnings per share was $US1.51 and it would pay a dividend of 42 US cents a share for the three months to September 30, to shareholders at the record date of November 11, payable on December 16, 2021.

Previously, Resmed has said it provided both US generally accepted accounting principles (GAAP) and non-GAAP data, with non-GAAP data providing investors better insights.

Today, Resmed chief executive officer Mick Farrell said the “first-quarter results demonstrate strong performance across our business with double-digit growth in both topline and bottom-line metrics, driven by ongoing high demand for our sleep and respiratory care products, and steady growth across our software-as-a-service business”.

“It is through the extraordinary efforts of our … team that we were able to deliver products … to our customers amid unprecedented supply chain challenges that continue to restrict access to critical electronic components,” Mr Farrell said.

“As we navigate supply limitations and are forced to allocate products, we continue to ensure priority for highest-acuity and highest-need patients first, as well as working with physicians, providers, and community systems to maintain a sustainable flow of medical devices and digital health solutions to patients who need care,” Mr Farrell said.

Resmed was up $1.50 or 4.2 percent to $37.17 with 1.5 million shares traded.

LBT INNOVATIONS

LBT says it has US Food and Drug Administration 501(k) approval for its APAS Independence methicillin-resistant staphylococcus aureus (MRSA) analysis module.

In 2019, LBT said it had FDA approval for its automated plate assessment system (APAS) Independence and associated urine analysis module and would use the approval as a predicate device for the MRSA, or “golden staph” module (BD: May 20, 2019).

Last year, LBT said it filed for US Food and Drug Administration 510(k) approval of its APAS Independence methicillin-resistant Staphylococcus aureus (MRSA) analysis module but said approval would be delayed for 180 days as the FDA had requested clarification and additional information (BD: Mar 30, Jun 4, 2020).

Today, LBT said FDA clearance would enable US customers to process more tests through the Apas instrument “delivering increased cost savings for the laboratory”.

LBT managing-director Brent Barnes said that FDA approval was a “significant achievement for the company and will support the roll out of the APAS Independence with Thermo Fisher in the US”.

“To date, we have focussed on larger customers and technology leaders, with a second analysis module we will be able to meet the day-to-day needs of many more laboratory customers in the United States,” Mr Barnes said.

“The availability of the MRSA analysis module to customers in the United States delivers a high degree of efficiency by automatically reading and reporting the negative MRSA plates which typically account for over 95 percent of total MRSA workflow,” Mr Barnes said.

LBT was up 1.5 cents or 15.0 percent to 11.5 cents with 2.2 million shares traded.

IMMUTEP

Immutep says the European Medicines Agency has “supported the … view” to develop IMP321, or eftilagimod alpha, for metastatic breast cancer, including a phase III trial.
Immutep said the agreement with the regulator was based on clinical data presented at the San Antonio Breast Cancer Symposium in December 2020.
Previously, Immutep said it had enrolled all 226 patients with human epidermal receptor 2 (HER2) negative and hormone receptor (HR) positive breast cancer for its phase IIb active immunotherapy paclitaxel with IMP321 (Aipac) trial for metastatic breast cancer.
combining IMP321 with paclitaxel (BD: May 3, 2018; Jun 25, 2019).
Last year, the company said that at the September 24 data cut-off breast cancer patients receiving IMP321 with paclitaxel had a non-significant survival benefit trend and better quality of life (BD: Dec 10, 2020).
Today, Immutep chief executive officer Marc Voigt said that “receiving positive and constructive EMA advice on our clinical development program for [eftilagimod alpha], including the planned phase III trial in metastatic breast cancer is an exciting achievement”.
Immutep said additional interactions with the EMA and other regulators, including with the US Food and Drug Administration were ongoing to generate a final study design.
Immutep was up half a cent or 0.9 percent to 57 cents with 2.2 million shares traded.

CANN GLOBAL

Cann Global says it has raised $1.8 million at 0.3 cents a share in a placement to sophisticated professional investors, introduced through Melbourne’s 180 Markets.
Cann Global said the proceeds would be used for working capital and to support expansion plans.
Cann Global managing-director Sholom Feldman said the company was “approached by 180 Markets saying they had large professional investors who … had expressed strong interest to take a meaningful shareholding”.
“Following this strong, and unsolicited, investor interest we are pleased to be welcoming these professional investors to the register,” Mr Feldman said.
Cann Global fell 0.05 cents or 11.1 percent to 0.4 cents with 26.5 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says its annual general meeting voted a remuneration report first strike with 4,654,643 votes (28.96) against, with director Philip Powell resigning.
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and, if passed, the directors must stand for re-election.
Medical Developments said the election of directors Max Johnston, Gordon Naylor, Mary Sontrop and Richard Betts were passed overwhelmingly, with 3.42 percent opposition to the allocation of 15,385 securities at $6.50 each to director Christine Emmanuel.
Medical Developments 2021 annual report said it had 71,264, 672 shares on offer meaning opposition to the remuneration report amounted to 6.5 percent of the company, sufficient to requisition extraordinary general meetings.
Medical Developments director Philip Powell filed an Appendix 3Z Final Director’s interest notice.
Medical Developments was up 22 cents or 4.7 percent to $4.93.

ADALTA

Adalta says its annual general meeting will vote to issue 6,655,000 options to four directors.
Adalta said it proposed to issue 3,055,000 options to chair Dr Paul MacLeman and 1,200,000 options each to managing-director Dr Timothy Oldham and directors Dr Robert Peach and Dr David Fuller.
The company said the options would be exercisable at the 20-day volume weighted average price at the date of the meeting, expiring on November 29, 2025.
Adalta said shareholders would vote on the remuneration report, the re-election of directors Elizabeth McCall and Dr Peach, the 10 percent placement capacity and the adoption of a new company constitution.
The virtual meeting will be held on November 29, 2021, at 2pm (AEDT).
Adalta fell 0.4 cents or 4.4 percent to 8.6 cents.

MESOBLAST

Mesoblast says its annual general meeting will vote to issue 1,550,000 options to chief executive Prof Silviu Itescu and 200,000 options to director Philip Facchina.
Mesoblast said that Prof Itescu's milestone-based options would be exercisable at $1.77 each, within seven years from issue and vesting in three performance-based tranches.
The company said shareholders would vote to issue 200,000 options to newly appointed director Philip Facchina, exercisable at $2.28 each, expiring seven years from grant date and would vest three equal tranches over three years.
Mesoblast said the meeting would vote on the remuneration report, the election of directors Mr Facchina, Michael Spooner, Joseph Swedish and Shawn Tomasello, the renewal of proportional takeover approval provisions in the company's constitution and the ratification of the issue of shares and warrants to institutional investors.
The virtual meeting will be held on November 29, 2021 at 10.30am (AEDT).
Mesoblast was unchanged at $1.59 with two million shares traded.

STARPHARMA

Starpharma says its annual general meeting will vote to issue chief executive officer Dr Jackie Fairley 493,360 performance rights.
Starpharma said the performance rights would vest subject to performance indicators.
The company said the shareholders would vote on the remuneration report and the re-election of Lynda Cheng as director.
The virtual meeting will be held on November 30, 2021, at 11am (AEDT).
Starpharma fell two cents or 1.9 percent to $1.05.

BIOXYNE

Bioxyne has requested a voluntary suspension to follow the Wednesday's trading halt "pending an announcement in relation to a potential acquisition" (BD: Oct 27, 2021).
Bioxyne said it expected the suspension to last until the release of an announcement.
Bioxyne last traded at three cents

STEMCELL UNITED

Stemcell United has requested an extension to its voluntary suspension in following a trading halt “pending an announcement…in relation to a joint venture”.
In September, Stemcell requested a trading halt pending an announcement on a joint venture and later requested a voluntary suspension (BD: Sep 27, 29, 2021).
Today, the company requested an extension to the suspension which it expected to last until November 30, 2021, or the release of an earlier announcement.
Stemcell last traded at 1.4 cents.

CRONOS AUSTRALIA

Cronos says 80,125,000 shares will be released from ASX escrow on November 7, but 80,000,000 shares will stay in voluntary escrow as part of its agreement with CDA Health.
Last month, Cronos said it would acquire medical marijuana company CDA Health Pty Ltd, for up to 439,784,282 shares subject to conditions (BD: Sep 14, 2021).
Today, Cronos said that its current three largest shareholders collectively owned 80,000,000 shares, would enter into voluntary escrow agreements for a further 12 months after the date on which the merger is completed, and if the merger was not completed by December 31, 2021, the voluntary escrow agreements would terminate.
The company said the remaining 125,000 shares that were currently in escrow would not be subject to the voluntary escrow arrangements.
According to the Cronos 2021 annual report it has 128,750,000 shares including the 80,125,000 shares to be released from ASX escrow.
Cronos was unchanged at 17 cents.

PACIFIC EDGE

Pacific Edge says it has appointed Dr Peter Meintjes chief executive officer, replacing David Darling, effective from January 10, 2022.
The Dunedin, New Zealand-based Pacific Edge said Mr Darling announced his retirement in April after 19 years with the company would continue as a consultant.
The company said Dr Meintjes was previously the chief commercial officer at the Mansfield, Massachusetts-based Eurofins-Transplant Genomics and Budapest’s Omixon chief executive officer of.
Dr Meintjes’s Linkedin profile said he held a Bachelor of Science, a Master of Science and a Doctor of Philosophy from the University of Auckland.
Pacific Edge was up two cents or 1.45 percent to $1.40.

4D MEDICAL

In two Appendix 3Z final director notices, 4D Medical says director Lusia Guthrie resigned at yesterday’s annual meeting and director Heath Lee resigned in 2020.
A 4D executive told Biotech Daily that the company said in its notice of meeting that Ms Guthrie had been a director since December 13, 2017, would not be seeking re-election and would retire at the annual general meeting.
The company said that Ms Guthrie would continue as the chair of its wholly-owned subsidiary the Australian Lung Health Initiative Pty Ltd.
The 4D executive said that Mr Lee’s resignation was announced in last year’s notice of meeting but “his 3Z was accidentally omitted following his retirement”.
4D was up 1.5 cents or 1.1 percent to $1.355.

PATRYS

Patrys says Leydin Freyer's Stefan Ross will replace Melanie Leydin as company secretary effective from today.

Patrys said Mr Ross had more than 10 years' experience in accounting and secretarial services for ASX listed companies.

The company said Ms Leydin would continue to support the company through Leydin Freyer.

Patrys was untraded at 4.2 cents.

INVION

Invion says it has appointed Claire Newstead-Sinclair as company secretary replacing Melanie Leydin effective from November 1, 2021.

Invion said Ms Newstead-Sinclair was an accountant at Leydin Freyer and Ms Leydin would continue as its chief financial officer.

Invion fell half a cent or 16.1 percent to 2.6 cents with 166.1 million shares traded.