Biotech Daily

Friday December 4, 2020

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.28 percent on Friday December 4, 2020, with the ASX200 up 18.8 points to 6,634.1 points. Fourteen of the Biotech Daily Top 40 stocks were up, 16 fell and 10 traded unchanged. All three Big Caps fell.

Uscom was the best, up 1.5 cents or 9.4 percent to 17.5 cents, with 1.6 million shares traded. Polynovo climbed 5.95 percent; Optiscan improved 4.35 percent; Alterity, Genetic Signatures and Impedimed were up more than three percent; Amplia and Pharmaxis rose more than two percent; Mesoblast, Nova Eye and Prescient were up more than one percent; with Clinuvel, Cyclopharm and Nanosonics up by less than one percent.

Telix led the falls, easing 20 cents or 4.8 percent to $3.95, with 1.7 million shares traded. Next Science and Proteomics fell more than four percent; Compumedics, Cynata, Medical Developments and Oncosil were down more than three percent; Kazia, Orthocell, Paradigm and Universal Biosensors shed two percent or more; Avita, Cochlear and Opthea were down more than one percent; with CSL, Neuren, Pro Medicus, Resmed and Volpara down by less than one percent.

DR BOREHAM'S CRUCIBLE: PALLA PHARMA (TASMANIAN POPPY INDUSTRIES)

By TIM BOREHAM

ASX code: PAL

Market cap: $103.2 million; **Share price:** 82 cents; **Shares on issue:** 125,947,977

Chief executive officer: Jarrod Ritchie

Board: Simon Moore (chair), Mr Ritchie, Todd Barlow, Stuart Black, Sue MacLeman

Financials (six months to June 2020): revenue $12.3m (down 55%), loss of $9m (previously $4 million deficit), net tangible assets per share 34 cents (previously 36 cents), cash of $1.64 million, debt of $12.8 million

Identifiable major holders: Washington H Soul Pattinson 19.9%, Thorney Opportunities 18.7%, Wentworth Williamson 8.5%, Sico Holdings ATF Oranje Trust 6.6%, Australian Ethical 6.3%.

While dozens of ASX-listed cannabis stocks vie for supremacy in the overgrown weed patch, Palla Pharma enjoys an elite status as one of only six legal medical opium growers in the world - and only one of three that are fully integrated from opiate extraction to tableting.

But that doesn't mean Palla has enjoyed drug-lord style margins on its products. On the contrary, the company has struggled to turn a profit since it listed as TPI Enterprises in August 2015.

One reason is that Palla has focused on providing either the raw material (the poppy straw) or narcotic raw material (such as morphine and codeine) to other manufacturers as an active pharmaceutical ingredient. As a result, it's missed out on some of the best margins.

But management promises all of this will change with the company entering the British market to sell codeine phosphate/paracetamol tablets.

Britain's Medicines and Health Products Regulatory Agency (MHRA) in November approved Palla's marketing application for the tablets, which consist of 30 milligrams codeine phosphate and 500 milligrams of paracetamol (best known to users as Panadeine Forte or strong Panadol).

"All our approvals and interaction with the regulators have gone well and we are on track to start selling codeine to the UK by [early 2021]," Palla founder and chief executive Jarrod Ritchie says.

He says revenue for every kilogram of codeine phosphate sold in tableted form is 2.4 times higher for that sold as an active pharmaceutical ingredient: $1,200 a kilogram versus $500 a kilogram.

Early this year the company won a contract to supply 270 million codeine phosphate tablets to a “major UK customer”.

In late breaking news, the MHRA has asked for more information about the application, but the company assures us the timelines remain intact.

From Apple Isle to Opium Island

Mr Ritchie founded the then Tasmanian Poppy Industries in 2004 to exploit the company’s patented technology and to “disrupt the traditional and outdated processes and dynamics of large players in the industry”.

He said high barriers to entry such as regulatory hurdles and the cost of production normally made it difficult for smaller companies to compete.

TPI’s first crops were in Tasmania, where fields of colorful poppies flourish by public roads.

Known as Opium Island, the Apple Isle accounts for at least half of the world’s legal poppy supply, with Palla rival Johnson & Johnson establishing the rival Tasmanian Alkaloids in the 1980s. (Tasmanian Alkaloids is now owned by private equity and headed by Dr Ross Murdoch, the former chief executive of Phosphagenics, now Avecho).

Until 2014, Tassie was the only place in Australia where the crops could be legally grown. But following a succession of poor harvests there, the Victorian government opened up its fiefdom for growing.

In 2015, Palla paid $8.15 million for an 8.5 hectare property with a 17,428 square metre (1.7ha) factory in an undisclosed Melbourne location.

In 2017, the company shelled out $25.7 million for a Norwegian tableting facility at Kregero, 200km south-west of Oslo. The factory, which will supply the British customers, is capable of producing 35 tonnes of active pharmaceutical ingredient and 1.66 billion finished tablets annually.

Palla, by the way, is a Nordic verb meaning “to have the energy to do something”.

Where did the marijuana go?

Also in 2017, TPI said the Federal Office of Drug Control had granted licences allowing it to research the cultivation of marijuana and produce marijuana or resin for research relating to medicinal cannabis and cultivate plants and produce marijuana or resin for medicinal purposes. And that was the last public mention of marijuana by the opiate company.

Palla transferred its opiate manufacturing operations to Melbourne in 2018. Under its “dual hemisphere” strategy the company has contract growers in New South Wales, Victoria and Hungary while Tasmania remains a key growing region.

In September, Palla sold its Tassie manufacturing facility for $2.98 million, but struck a long-term lease with the new owners to store poppy straw before being freighted to Melbourne.

In 2019, the company attempted to acquire a stressed UK customer, but the deal never happened. But not to worry: Palla ended up with the unnamed entity's seven UK marketing authorizations anyway.

Palla's secret formula

Because the sector is so strictly regulated, opium-derived medications essentially are of the same quality no matter who provides them. The suppliers therefore need to compete on costs and in this respect Palla has an advantage with its patented water-based extraction process.

The method replaces organic solvents, which are highly explosive and therefore require special facilities.

Because of this obviated risk of detonation, Palla's plants are one-fifth cheaper to build. Mr Ritchie says that as well as requiring less capital, the process is kinder to the environment as it does not produce toxic solvents (unlike the traditional methods).

Finances and performance

Palla expects earnings generated from its UK codeine phosphate tablets to be a "significant contributor ... at a significantly higher gross profit margin."

Mr Ritchie says other factors come into play too, including increases in product pricing and increasing monthly finished dosage formulation (FDF) revenue to $12 million after the Norwegian capacity expansion.

In Palla's first (June) half accounts, external auditor KPMG studiously noted the material uncertainties that "may cast doubt on the group's ability to continue as a going concern".

At June end, Palla had cash of $1.6 million, with its biggest shareholder Washington H Soul Pattinson extending a $16 million facility to support working capital.

The directors argue that the cash and the $3.7 million undrawn component of the facility will keep the wolves from the door (our words, of course).

After the British medical gatekeeper approved the marketing authorizations in November, Washington Soul temporarily extended this limit to $20 million. The facility reduces to $13 million next April when the Tasmanian property sale proceeds are expected to be banked.

In a "transition period", Palla's six months revenue to June 30 slid 55 percent to $12.3 million, with an underlying loss of $9.1 million compared with a $2.3 million deficit previously.

Apart from the aforementioned customer loss, revenues were affected by unfavorable growing weather and the exit of a legacy non-opiate supply agreement.

“This year’s sales and earnings will be heavily skewed to the second (current) half as we transition from a producer of low-margin, non-opiate products to higher margin opiate-based products sold via Palla-owned marketing authorizations,” Mr Ritchie says.

While calendar 2020 revenues are expected to be “modestly lower to flat” on the previous $54.8 million, the effect of the higher margin sales will be felt from the December quarter.

To meet demand, Palla plans to spend about $4 million expanding its Norway facility, to give the capacity to increase monthly revenues from $4 million to $12 million.

Palla shares have traded between 48 cents (March 30 this year) and $1.31 (July 26 last year). The stock has perked up from 68 cents in late November to around 80 cents now.

Mandatory Covid-19 bit

Palla has been able to continue its normal operations with the usual precautions.

“Pain relief products are deemed essential goods, so we’re not affected by general lockdown decrees,” Mr Ritchie says. “Our supply chains and operations remain relatively unaffected; however, logistics and general cash flow preservation by customers have created some volatility.”

He adds that the company’s diversified production across all of the supply chain allows for more consistent and reliant supply than its competitors. Having said that, Palla was affected by disruptions relating to shipping costs and slower receivables. In Italy, orders were delayed because the company could not get hold of material such as paracetamol.

The coronavirus pandemic means Palla is carrying more inventory than usual, but working capital will be freed up as stock levels return to normal over the next six months or so.

America’s state of addiction

Of course, there’s a dark aspect to the opioid trade and it’s America’s startling addiction to the euphoria-inducing substance.

Much of the addiction problem stems from prescription medication, but the powerful synthetic opioid fentanyl illegally sourced from China is a huge issue as well.

According to the US Centres for Disease Control and Prevention, 46,802 Americans died from opioid overdoses in 2018, two-thirds from the synthetic variety.

Opioid drug makers have been subject to a barrage of litigation and the plaintiffs are chalking up huge wins.

In October, the maker of Oxycontin (oxycodone), Purdue Pharma agreed to pay $US8.3 billion of damages and plead guilty to criminal charges relating to payments made to doctors and healthcare companies to encourage prescriptions (paid for by public health programs). The family-owned company entered bankruptcy protection last year.

In a landmark civil case in August last year, an Oklahoma court ordered Johnson & Johnson to pay the state $US572 million over opioid misuse.

Plenty of other cases are in progress and there will be more pain to come.

Dr Boreham's diagnosis:

The US opiate crisis aside, Mr Ritchie notes that opioids remain the most effective and affordable treatment for acute and chronic pain - but are inaccessible to three-quarters of the world's people. Palla has partnered with agents in Africa, South America and Asia to increase the availability of opioid-based pain relief in hospitals.

"Morphine remains the gold standard for acute pain relief and palliative care globally and is listed on the World Health Organisation's Model List of Essential Medicines," he says.

"With now over 5.5 billion people with limited or no access to pain relief treatment because of international drug controls, it is becoming imperative that we provide quality and affordable pain relief to those who cannot easily access it."

His view is backed by Australian Ethical, which owns 6.3 percent of Palla.

Palla has kept a low profile since listing, partly because of the nature of the product and partly because the stock is tightly held. Long-time backer Washington H Soul Pattinson accounts for 19.9 percent, while Thorney Investments has dibs on 18.7 percent.

More recently Sydney value investor Wentworth Williamson joined the register with an 8.3 percent stake.

The company is focused on Britain because it's easily the biggest codeine phosphate market in Europe. But the company is also eyeing "opportunities" in Spain and France, the second and fourth largest European markets respectively.

If British prices hold up, Palla's 'farm to pharma' strategy should start reaping financial benefits from next year - and start to get its balance sheet into better shape.

As broking firm CCZ Equities aptly notes: "Palla is a business in transition recently undergoing short term pain."

If all else fails, Palla does a nice side-line in poppy seeds for the culinary market.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. If pain persists, see your real doctor.

VICTORIA GOVERNMENT

The Victoria Government says it will invest $60 million into a genomics research hub run by the University of Melbourne and the San Diego, California-based Illumina.

The media release from Victoria Treasurer Tim Pallas said that the $60 million project aligned with the state's international investment strategy and was the first university project to secure funding from the Victorian Higher Education State Investment Fund developed in response to the impact of the Covid-19 pandemic on Victoria's universities.

Mr Pallas said the Illumina-University of Melbourne genomics hub would be the first in the Asia-Pacific region and bring together the best genomic expertise and technology for better health research and diagnostics, in areas including infectious diseases such as coronavirus.

The media release said the hub would generate hundreds of jobs for medical research staff and interns, boosting links between industry, research and education.

Minister for Higher Education Gayle Tierney said that the "partnership will put Victoria at the forefront of medical research, create jobs and opportunities for businesses, and give students and researchers access to technology and resources not available in any other state."

HEXIMA

Hexima returned to the ASX on December 1, 2020 at 20 cents following its $3.3 million "oversubscribed" initial public offering to fund its HXP124 for onychomycosis.

Previously, Hemixa said it had it raised $40 million in an initial public offer to list on the ASX in 2007 and delisted in 2011 (BD: Nov 22, 2013).

Hexima was previously chaired by Acrux chairman Ross Dobinson and formerly described itself as "an ag-biotech company actively engaged in the research and development of technology for the genetic modification of crops", specializing in fungal resistance technology, insect resistance technology and gene delivery technology.

This week, the company said it had received $5.5 million through a private placement in September 2020 and would use the placement and initial public offer funds to complete a phase IIb trial of HXP124 for onychomycosis, a fungal nail infection.

Hexima said it had 130,857,724 shares on offer following the capital raisings.

The company said it planned to scale-up manufacturing and complete long-term animal toxicology studies for HXP124 to support a US clinical trial.

Hexima said its chief executive officer and managing-director was Michael Aldridge, who was previously the chief executive officer of Peplin.

The company said Dr Nicole van der Weerden was the chief operating officer, with Prof Marilyn Anderson as chief scientific officer and Dr Peter Welburn as chief development officer.

Hexima said the board included chair Prof Jonathan West, executive directors Dr van der Weerden and Prof Anderson, and non-executive directors Justin Yap and Scott Robinson.

Mr Aldridge said that "as a consequence of securing this funding we now have a very clear pathway to deliver the recently initiated Australian phase IIb clinical trial, and beyond that, critically important milestones through to the global phase III clinical program, which is the final stage in the development of this exciting and novel product".

Hexima said Canaccord Genuity Australia was the lead manager for the public offer.

Hexima fell 2.5 cents or 13.5 percent to 16 cents.

USCOM

Uscom says its China-based subsidiary, Uscom China, has been listed as a National High Technology Enterprize by China's Ministry of Science and Technology.

Uscom said High Technology Enterprises were companies identified for significant achievements in research and development, innovations, intellectual property, and transformational outcomes in high technology fields.

The company said the listing entitled Uscom China to benefits including tax exemptions from 15 percent to 25 percent, priority for government contracts, direct regional grants of up to CYN1 million ($A205,564), preferential terms for workspaces, loans and asset depreciation, and better company recognition.

Uscom said that Uscom China was responsible for two thirds of the company's international sales, including the Uscom 1A blood flow monitor, and was growing rapidly.

Uscom executive chair Prof Rob Phillips said that Uscom had been "committed to China for the last 15 years, and this recognition of our technologic, academic, clinical and commercial impact is satisfying".

"This State recognition opens many doors for us and underwrites our future in China, and we look forward to continuing our record growth with the Chinese economy as it leads the world in recovery and expansion," Prof Phillips said.

Uscom was up 1.5 cents or 9.4 percent to 17.5 cents with 1.6 million shares traded.

MEDADVISOR

Medadvisor says its retail rights offer at 38 cents a share has raised $3.2 million of a hoped-for $20 million, taking the total raised for $38.2 million.

Last month, Medadvisor said had raised $35 million in a placement and institutional rights offer to complete the acquisition of Adheris Health, and hoped to raise a further $20 million in the one-for 2.5 share retail rights offer (BD: Nov 12, 2020).

Today, the company said the retail rights offer funds would go towards working capital.

Medadvisor said it held the right to place the shortfall within three months.

Medadvisor was up half a cent or 1.3 percent to 39 cents.

CARDIEX

Cardiex says it hopes to raise $1 million in a share purchase plan at five cents a share.

Biotech Daily calculates the offer prices is a 5.66 percent discount to the last closing share price of 5.3 cents.

Cardiex said that holders at the record date of December 2 would be eligible to buy up to $30,000 worth of shares, with the offer opening on December 7 and closing on December 31, 2020.

The company said it had sufficient cash reserves for its operations, but would undertake the capital raising "to enable our retail shareholders to have the opportunity to participate in the next growth phase of the company at price levels that may not otherwise be available to them".

Cardiex fell 0.1 cents or 1.9 percent to 5.2 cents with 2.5 million shares traded.

ALLEGRA ORTHOPAEDICS

Allegra says the revised design of its spinal fusion cage for bone-neck fusion has double the strength of the previous design and will progress to animal studies.

In August, Allegra said that Covid-19 restrictions delayed the sheep study of its strontium-hardystonite-Gahnite (Sr-HT-Gahnite) spinal fusion cage device, but it had improved the device by implementing advances in 3D printing technology (BD: Aug 7, 2020).

Today, the company said that bench testing of the spinal cage device at the Sydney's Kolling Institute and the results from an unnamed, accredited testing facility in the US had "shown a significant improvement in strength when compared to the previous design".

Allegra said the compressive strength of the spinal cage was 60 kilo-newtons, double the strength of the previous design, and "significantly above" the human physiological loads of 1.2 kilo-newtons and the sheep physiological load of three to four kilo-newtons.

The company said the results showed improved torsional and shear compressive strengths, mechanical integrity "without any signs of fracture or failure".

Allegra said it planned to begin a pilot animal confirmatory study using the revised spinal cage design in January 2021 in Australia which would be followed by a large animal study to comply with US Food and Drug Administration requirements.

Allegra was up 20 cents or 100 percent to 40 cents with 4.3 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it will regain the European marketing authorizations and distribution rights for its Penthrox pain relief from Mundipharma on March 1, 2021.

In 2015, Medical Developments said the Cambridge, UK Mundipharma would pay up to $US54.5 million ($A76.9 million) for the exclusive distribution rights to its Penthrox inhaled methoxyflurane analgesic for pain relief in 39 European countries (BD: Sep 14, 2015).

In October this year, the company said it had "taken back" the Australian distribution rights for its Penthrox from Mundipharma, after appointing Mundipharma as distributor in 2019 (BD: Jun 2, 2019; Oct 30, 2020).

Today, the company said transition arrangements for regaining the European distribution rights for Penthrox were "progressing to plan", including the establishment of legal, corporate, operational and regulatory infrastructure.

Medical Developments chief executive officer Brent MacGregor said that "the opportunity in the EU remains strong and we're revisiting our execution strategy, assessing and building on the foundation work done by Mundipharma, including determining where we can deploy a direct or hybrid selling model which brings enhanced control and margin".

"Europe will be the primary focus … over the coming year", Mr MacGregor said.

Medical Developments fell 21 cents or three percent to $6.71 with 290,314 shares traded.

UNITED NATIONS COMMISSION ON NARCOTIC DRUGS

Yesterday, Biotech Daily reported that the UN Commission on Narcotic Drugs removed marijuana from Schedule IV of the 1961 Single Convention on Narcotic Drugs.

A media release from the Commission said that a vote in Vienna removed marijuana from the Schedule "where it was listed alongside deadly, addictive opioids, including heroin".

Biotech Daily asked the Australian Department of Foreign Affairs how Australia voted, but the Department said the matter was the responsibility of the Department of Health and responses to queries had not been received at the time of publication.

Overnight, the Vienna-based United Nations Commission on Narcotic Drugs told Biotech Daily that Australia voted in favor of easing the restrictions.

EMYRIA

Emyria says it has interest from potential participants for an up-to 200 patient, observational study of its cannabinoid-based EMD-044 for irritable bowel syndrome.
Emyria said irritable bowel syndrome (IBS) affected about 11 percent of the population and was associated with greater levels of anxiety and lower quality of life measures.
The company said the study was based on “real world evidence” data sets collected from irritable bowel syndrome patients at Emyria’s clinical subsidiary Emerald Clinics.
Emyria said the 12-month study would assess patients in Victoria, New South Wales and Western Australia, led by Prof Alistair Vickery and Dr Chris Schneider.
Emyria managing-director Dr Michael Winlo said “IBS can be a challenging condition to manage and the strong interest demonstrates the need for safe and effective options [and] this study will also inform how we can better care for patients with this condition”.
Emyria was up 0.1 cents or 1.2 percent to 8.6 cents.

ALTHEA GROUP

Althea says it has an agreement worth about $650,000 with Africann Pty Ltd and MG Biotech Ventures Pty Ltd to import and distribute medical marijuana in South Africa.
Althea said after attaining all required licences and permits, Africann would import a range of Althea branded marijuana-based products over two and a half years.
The company did not clarify MG Biotech Ventures role in the agreement.
Althea said it expected the first shipment to be delivered by July 2021.
The company said the South African medical marijuana industry would be worth about $US667 million ($A894.6 million) by 2023.
Althea chief executive officer Josh Fegan said that “the agreement with Africann is an exciting development for the company and reinforces our position as one of the world’s leading medicinal cannabis brands”.
Althea fell two cents or 3.5 percent to 55 cents with 1.9 million shares traded.

MEDIBIO

Medibio says the US Food and Drug Administration has denied breakthrough device designation for its MEB-001 heart rate-based depression diagnostic software.
Medibio said it had requested a meeting with the FDA to discuss the issues raised in the notification letter.
The company said that if an agreement could not be reached through the initial discussion, it could request a supervisory review, followed by the filing of an appeal.
Medibio said the denial of the designation had “no impact on the progress of the MEB-001 trial” to validate the medical software device.
The company said MEB-001 used artificial intelligence, algorithms and neural network methodology to identify patterns and markers in overnight heart rate activity to assist in the diagnosis of depression in patients that suffer from sleep disturbance.
Medibio was unchanged at one cent with 8.6 million shares traded.

TALI DIGITAL

Tali has requested a trading halt “pending an announcement regarding a proposed international partnership and equity investment”.
Trading will resume on December 8, 2020 or on an earlier announcement.
Tali last traded at 3.7 cents.

INCANNEX HEALTHCARE

Incannex has requested a trading halt pending an announcement regarding the company "initiating a psychedelic medicine clinical trial".
Trading will resume on December 8, 2020 or on an earlier announcement.
Incannex last traded at 14.5 cents.

INVION

Invion says Unlimited Innovation Group, its largest substantial shareholder with 50.8 percent of the company, has distributed of its Invion shares among group members.
In 2017, the Hong Kong-based Cho Group took control of Invion, investing $5.5 million and licencing the photo dynamic cancer therapy (BD: Aug 31, 2017).
Today, Invion said that the Hong Kong-based Unlimited Innovation Group had conducted an in-specie distribution of 220,682,156 shares to 49 group member, who had agreed to voluntary escrow arrangements ranging from three to 12 months.
The company said that following the distribution, Polar Ventures and NGPDT Greater China would each hold 9.86 percent of the company, Unlimited Innovation director Honsue Cho would hold 5.15 percent and the remaining Unlimited Innovation members would hold smaller percentages.
Invion was unchanged at 1.2 cents.

MEDIBIO

Medibio says 15,000,000 shares will be released from voluntary escrow on December 10, 2020.
Medibio's most recent Appendix 2A new issue announcement said the company had 1,347,662,569 shares available for trading on the ASX, with no shares in escrow.

ESENSE-LAB

Esense says it has appointed Yoav Elishoov to replace chief executive officer Itzik Mizrahi.
Esense said that Mr Elishoov would start on NIS45,000, which the company said was $A220,000 a year, effective from December 7, 2020.
In fact, NIS45,000 is worth about $A18,554.
In March, Esense said it had appointed Mr Mizrahi as chief executive officer starting on $NIS540,000 ($A236,036) a year (BD: Mar 6, 2020).
Today, the company said Mr Mizrahi would remain with the company for a further three-month handover period.
Esense said that prior to joining the company, Mr Elishoov was the chief executive officer of Israeli pharmaceutical company Trima and had established the oncology business unit of Novartis Israel.
The company said Mr Elishoov would be entitled to a yearly bonus of 1.5 percent of Esense's net sales, as well as 6,000,000 shares, pending hurdles.
Esense chairman James Ellingford said the company looked forward "to its next phase of growth under Mr Elishoov's leadership as it looks to pursue commercial development of its terpenes infused hand sanitizers, whilst continuing to progress other promising applications of its terpene technologies".
Esense was in a suspension and last traded at 1.8 cents.

RESAPP

Resapp says it has appointed Stephen Hewitt-Dutton as joint company secretary, joining existing company secretary Nicki Farley.

Resapp was up 0.1 cents or 1.1 percent to nine cents.