Biotech Daily

Friday October 20, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: PRANA UP 23%; AVITA DOWN 7%**

*** DR BOREHAM'S CRUCIBLE: POLYNOVO**

*** AIRXPANDERS Q3 REVENUE 23% ABOVE H1 AT $1.5m**

*** INNATE CLOSES AUCKLAND SCIENCE, DRUG MANUFACTURING**

*** MGC UP 100% ON VARM COSMO $40m PA MARIJUANA COSMETICS DEAL**

*** SIMAVITA RECEIVES $964k FEDERAL R&D TAX INCENTIVE**

*** MEDADVISOR REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** UNNAMED AMERICAN CHAIN COMPLETES RHINOMED MUTE TRIAL**

*** DEUTSCHE BANK TAKES 6% OF AVITA**

*** DAVID SIETSMA TAKES 11% OF PHYLOGICA**

MARKET REPORT

The Australian stock market was up 0.18 percent on Friday October 20, 2017 with the ASX200 up 10.9 points to 5,896.1 points. Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and two were untraded.

Prana was the best on no news but following a 23.75 percent jump on the Nasdaq, up 1.2 cents or 22.6 percent to 6.5 cents with 358,536 shares traded. Benitec climbed 13.3 percent; Airxpanders rose 5.1 percent; Living Cell was up 4.2 percent; Oncosil was up 3.1 percent; Acrux, Starpharma and Volpara rose more than two percent; Compumedics, Factor Therapeutics, Genetic Signatures, LBT, Orthocell and Osprey were up more than one percent; with Cochlear, Nanosonics and Opthea up less than one percent.

Avita led the falls, down 0.4 cents or 6.9 percent to 5.4 cents with three million shares traded. Impedimed lost 6.3 percent; Bionomics fell 5.4 percent; Cellmid and Neuren were down four percent or more; Actinogen was down 3.5 percent; ITL, Mesoblast and Polynovo shed two percent or more; Clinuvel and Pharmaxis were down more than one percent; with CSL, Medical Developments, Pro Medicus, Resmed, Sirtex and Viralytics down less than one percent.

DR BOREHAM'S CRUCIBLE: POLYNOVO

By TIM BOREHAM

ASX Code: PNV

Share price: 36 cents

Market cap: $213.8 million

Shares on issue: 593,974,935

Chief executive officer: Paul Brennan

Board: David Williams (chairman), Bruce Rathie, Dr David McQuillan, Philip Powell, Max Johnston, Leon Hoare

Financials (2016-'17 year): revenue $3.8 million (up 8 percent), loss $5.0 million (up 54 percent), cash $5.5 million (previously $10.7 million).

Identifiable shareholders: The Trust Co (Merchant's Andrew Chapman) 11.6 percent, John Greenwood 2.8 percent, Lateral Innovations (David Kenley) 4.8 percent, Moggs Creek Pty Ltd (David Williams) 1.8 percent, Monash Investment Holdings 1.7 percent, Paul Brennan 1.3 percent.

These days, Polynovo is focused squarely on its non-toxic wound dressing device called the Novosorb biodegradable temporising matrix (BTM), but my, what a circuitous and tortured listed history this corporate has been.

While developed mainly for the $1 billion a year surgical wounds market, Novosorb is intended to be the medical version of the Swiss Army knife in terms of versatility.

Demonstrating Novosorb's multiple uses, the company this week announced a memorandum of understanding with an "innovative global medical device company" to develop devices for the breast reconstruction surgery market.

The potential deal – which is subject to a 90-day exclusive negotiation period – would result in up-front and milestone payments and, ultimately, royalties on any sales.

The news prompted a pneumatic market response, with the shares bounding 25 percent.

Pay attention, you will be tested

Polynovo was previously known as Calzada and, before that, Metabolic Pharmaceuticals.

The Novosorb technology itself was developed by the Commonwealth Scientific and Industrial Research Organisation and spun-off in 2004 as Polynovo Materials, in joint venture with Xceed Biotechnology. Metabolic bought 60 percent of this venture in 2008.

Metabolic was famous (infamous actually), for a massive obesity trial “belly-flop” in 2007 based on the peptide AOD9604.

Or as then chief executive officer Dr Roland Scollay told Biotech Daily at the time: “The trial didn’t fail. The trial was very successful. It showed our drug didn’t work.”

For those who followed the Essendon Football Club (and Cronulla) drugs saga, AOD9604 would be familiar as one of the substances allegedly taken by the unknowing players; and the original target of anti-doping authorities.

In 2009, Metabolic changed its name to Calzada and moved to full ownership of Polynovo in 2010.

Calzada appointed David Williams first as a director and shortly afterwards as chairman and changed its name to Polynovo in 2014.

In 2015, Calzada offloaded the right to AOD9604 – which remains popular with body builders who source the stuff illicitly – to former chief executive officer David Kenley’s Lateral Pharma Pty Ltd.

Lateral Pharma is now developing AOD9604 as an osteoarthritis and osteoarthritis pain treatment, with other pain and repair indications also being explored.

This is apt, given the pain the substance caused Essendon.

“By focusing on Polynovo we have become commercial with proper facilities, staffing and infrastructure,” chief executive officer Paul Brennan says.

It’s all about Novosorb

Novosorb is a 2.0 millimetre thick biodegradable polymer foam wound scaffolding that is claimed to provide a better result than rival lattice products, or skin grafts from the bum.

“We can make it as a fibre, a solid cardiac stent or films and foams,” Mr Brennan says. “It’s all the same polymer but with different end attributes.”

To the lay person, Novosorb looks like a layer of Aussie Post standard parcel packaging but it has three intricate layers: a sealing membrane, a bonding layer and the foam scaffolding that enables integration.

Novosorb provides a ‘home’ for cells to migrate and disrupts the ability of collagen protein fibres to form knots and bundles. Unlike rival products, it covers the full dermis.

Novosorb contains no aromatic isocyanates or solvents (this is a good thing).

It biodegrades through hydrolysis and is excreted via respiration, urine or microphage (blood cell) activity.

Being non-organic, the material is less conducive to infection.

Currently Novosorb is approved for wound and burns use in the US, although burns are only about 10 percent of Polynovo's target market.

As well as breast reconstruction, Novosorb is also being developed for hernia repair and as a "dermal depot" for islet cell transplants (for type 2 diabetes).

The magic foam mat may also be relevant for repairing bone fractures and damaged cartilages and for subcutaneous drug delivery.

The story to date

In 2015, Polynovo gained US Food and Drug Administration 510k (device) clearance for use in reconstructive and surgical wounds.

The first US patient – a trauma victim with a 'degloved' hand and forearm – was treated in February.

The company reports first sales in the US, with good results for trauma, necrosis, burns and reconstructive and plastic surgery.

In short, Polynovo is selling in US, South Africa, Israel, New Zealand and Australia.

The company is progressing through the hospital procurement process at many major US hospitals, with 25 centres of healing nearing the end of their evaluation.

As of September, the company received orders from two large hospitals with a combine invoice value of more than $300,000 and since then has received at least one more, as well as repeat orders.

Polynovo chairman David Williams admits the company had been "over optimistic" about forecast US sales in the past.

"Our conscious decision to build a direct sales model in the world's biggest market is proving the right strategy," he chimes.

This month, Polynovo signed AMI Medical Technologies as Israeli distributor.

The company also has a distributorship in South Africa and is also working other Middle Eastern distributorships, as well as eyeing Indian regulatory approval.

It BARDA be good

Polynovo has the advantage of being backed by US mass disaster agency BARDA (Biomedical Advanced Research and Development Agency).

The BARDA-funded full thickness burns feasibility trial in the US involves 10 patients across four hospitals, with four enrolled so far. The cost? $US18 million, with a further $US30 million for a phase II trial that would involve about 120 patients.

God bless America.

BARDA is also kindly funding a $2.4 million swine study on “degradation and toxicity”.

Off its own bat, the company has commissioned a clinical trial aimed at supporting its application for Conformité Européenne (CE) mark approval, which is expected in 2017.

So far, 18 of 30 patients have been enrolled in the $2.5 million trial, which will take place here and in France.

Dr Boreham’s diagnosis:

Polynovo’s net loss of $5.0 million in 2016-’17 compares with a $3.5 million the year before, but the funds were spent on wholesome development activities.

Polynovo knows how to keep the lights on, raising $13.8 million of equity in 2015 and then $7 million in a recent private placement at 27 cents a share and a share purchase plan is also in train.

Polynovo’s receipts of $3.8 million in 2016-’17 derived mainly from BARDA ($3.5 million) as well as a $700,000 Federal R&D Tax Incentive.

Polynovo has better institutional backing than your normal biotech bear, with The Trust Company (formerly the Merchant Group) an 11 per cent holder.

Chairman David Williams is also well known as chair of Medical Developments, which is successfully selling the Penthrox (green whistle) front-line pain relief product globally. He also runs advisory company Kidder Williams with Bega as a major client.

On the clinical side, leading burns surgeon and 2.5 percent shareholder Prof John Greenwood is a certified Polynovo fan.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has never procured AOD9604, mainly because he has never been seen in a gym.

AIRXPANDERS

Airxpanders says revenue for the three months to September 30, 2017 was $US1,177,000 ($A1,501,020) 23.0 percent more than the six months to June 30, 2017.
Airxpanders said it sold 459 Aeroform tissue expanders for post-mastectomy breast reconstruction in the three months to September 30, 2017, compared to 84 in the three months to September 30, 2016 and more than double the number sold in the three months to June 30, 2017.
Airxpanders was up four cents or 5.1 percent to 83 cents.

INNATE IMMUNOTHERAPEUTICS

Innate says that following the failure of MIS416 for secondary progressive multiple sclerosis its Auckland, New Zealand operations will be closed.
In June, Innate fell 93 percent on news that MIS416 showed no “clinically meaningful or statistically significant” efficacy in the 12-month, 93-patient, phase IIb, randomized, double-blind, placebo-controlled trial of weekly injections (BD: Jun 27, 2017).
Today the company said that “day-to-day scientific and drug manufacturing operations cannot realistically continue”.
Innate said the operations were all based in Auckland and staff involved in the scientific and drug manufacturing activities would be provided with redundancy packages, with plant and equipment disposed in an orderly manner.
The company said the leasehold premises would be vacated by the end of the year.
The directors said they “recorded the company's gratitude to all the New Zealand staff for their loyalty, commitment, and unrelenting hard work over many years”.
Innate said that the outcome of the trial was “a bitter pill to swallow for this dedicated group of researchers and production staff and we commend them for their professional approach to winding up the [secondary progressive multiple sclerosis] related activities”.
The company said that there was promising data to support the use of MIS416 in at least three other therapeutic areas, but it would take “a considerable amount of time and money to reaffirm the preclinical proof of concept data, engage with clinicians, design study(s) and obtain the necessary approvals to conduct a new clinical development program”.
Innate said that raising substantive funds from existing shareholders to pursue a new MIS416 based clinical programme was unrealistic and it was reviewing possible options including the acquisition of a new technology and/or a merger, with a decision to be made by the end of the year.
The company said the final phase IIb clinical study report was due by the end of October but “given the lack of positive efficacy findings, the company has elected to produce an abbreviated [report] which will report only on the study's safety endpoints” which was expected to confirm that MIS416 was generally well-tolerated in patients, with most adverse events mild or moderate in severity, self-limited in duration and often related to the underlying mechanism of MIS416 action.
Innate said that pro-inflammatory related adverse events were associated with MIS416 dosing, but they were generally transient, manageable, not dose-limiting, and did not preclude chronic dosing.
The company said that long-term administration of MIS416 was not associated with cumulative toxicity or perturbations of standard clinical laboratory parameters and in the event that MIS416 might be considered for clinical development in therapeutic indications other than multiple sclerosis, the likely finding that MIS416 was able to be administered long-term in a safe manner would be an important asset.
Innate fell half a cent or 16.1 percent to 2.6 cents with 2.6 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has a $40 million a year binding agreement to supply its marijuana-based cosmetics to South Korea cosmetics manufacturer Varm Cosmo.

MGC said it would the first ASX-listed company "to generate significant revenues, expected to be in excess of $3 million in monthly sales".

The company said that the deal would deliver the revenue to 51.49 percent subsidiary the Ljubljana, Slovenia-based MGC Derma, which was a joint venture with Ashkelon, Israel-based cosmetics manufacturer Dr M Burstein Ltd.

MGC said that five of its cannabidiol cosmetic products would be supplied in bulk and sold by Varm to its consumers and distribution network.

The company said that Varm had committed to a minimum 15,000kg a month delivering "an immediate revenue stream with a strong gross profit margin".

MGC said that $3.3 million would be received shortly after the receipt of the first quarterly purchase order from Varm, expected by the end of October 2017.

The company said that the parties would sign a binding sale agreement in the coming 31 days and examine further expanding the product range and supply volumes.

MGC said that South Korea was among the top 10 global beauty markets and was estimated to be worth more than $US13 billion in 2017.

MGC chief executive officer Roby Zomer said the "watershed milestone supply agreement is transformational for our MGC Derma division and for MGC Pharmaceuticals as a company and importantly for all our shareholders".

"Varm Cosmo are a great company to partner with to bring our cosmetics product to a wider consumer market," Mr Zomer said.

Varm chief executive officer Jung Yoon Hwang said his company produced "the most honest cosmetics in the market".

"Our products contain 1ml of highest purity [cannabidiol] in the world, providing the most effective moisturizing solution while making your skin young and healthy," Mr Hwang said.

MGC climbed 3.8 cents or 100 percent to 7.6 cents with 400.8 million shares traded.

SIMAVITA

Simavita says it has received $964,321 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Simavita said the rebate related to research and development expenditure for the year to June 30, 2017.

Last month, Simavita borrowed $695,039 against its Tax Incentive and today said that the net amount received after paying off the loan was $215,179 (BD: Sep 19, 2017).

Simavita fell 0.2 cents or 9.1 percent to two cents.

MEDADVISOR

Medadvisor has requested a trading halt "pending … an announcement regarding a capital raising and other transactions relating to the capital raising".

Trading will resume on October 24, 2017 or on an earlier announcement.

Medadvisor last traded at 3.6 cents.

RHINOMED

Rhinomed says it has completed a "test and learn" trial of its Mute anti-snoring nasal plugs in 100 shops of an unnamed American pharmacy chain.
Rhinomed said that the trial began in July last year and was part of a program designed for an initial six months (BD: Jul 22, 2016).
In March 2016, Rhinomed said the Mute nasal plugs would be promoted through a 107-shop program in the New York-based Duane Reade chain of drug stores and Mute would be available in 891 Walgreens shops across the US (BD: Mar 29, 2016).
Today, the company said the objective of the trial was to obtain data about consumers who shop within the sleep category in pharmacy.
Rhinomed said that with the retailer it had begun interrogation of the data and discussions were underway.
The company said that completion of the trial followed the recently expansion to more than 4,300 Walgreens shops, with Mute on the shelves of the shops.
Mute is available in the USA, Canada, the UK and Australia.
Rhinomed was unchanged at 18 cents.

AVITA MEDICAL

Deutsche Bank and related bodies corporate say they have become substantial shareholders in Avita with 44,251,600 shares (5.72%).
The Frankfurt, Hong Kong and Sydney-based Deutsche Bank AG said that it bought and sold shares between June 29 and October 17, 2017 at prices ranging between five and nine cents, and acquired 17,777,777 shares at five cents each in the recent placement.
The company said that the registered holders were Bainpro Nominees and Unknown.
Last year Deutsche Bank said it had become a substantial shareholder in Genetic Signatures with 14.24 percent, in 2015 and 2016 it became and ceased its substantial holding in Genetic Technologies and in 2014 it took 12 percent of the then Circadian, now Opthea (BD: Oct 27, 2014; Nov 20, 2015; Mar 10, 15, Oct 21, 2016).
Avita fell 0.4 cents or 6.9 percent to 5.4 cents with three million shares traded.

PHYLOGICA

The Sydney-based David Sietsma says he has increased his substantial shareholding in Phylogica from 199,705,000 shares (9.97%) to 233,643,380 shares (10.99%).
Mr Sietsma said the shares were acquired by Sietsma Holdings and Masali Pty Ltd, between December 19, 2016 and October 17, 2017, but again failed to disclose the price paid, as required under the Corporations Act 2001 (BD: Dec 22, 2016).
Phylogica was unchanged at 3.8 cents.