Biotech Daily

Friday January 24, 2020

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH DOWN: AMPLIA UP 11%**
- IMPEDIMED, RESONANCE DOWN 8%

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

*** RESMED PAYS $60m TO RESOLVE US 'KICKBACK' ALLEGATION**

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*** NEUROTECH REQUESTS TGA REGISTRATION TRADING HALT**

MARKET REPORT

The Australian stock market edged up 0.04 percent on Friday January 24, with the ASX200 up 2.5 points to 7090.5 points. Eleven of the Biotech Daily Top 40 stocks were up, 19 fell, and 10 traded unchanged.

Amplia (Innate) was the best, up 0.8 cents or 11.1 percent to eight cents, with 20,300 shares traded.

Medical Developments and Universal Biosensors climbed more than eight percent; Paradigm improved four percent; Dimerix, Imugene and Oncosil were up three percent or more; CSL, Opthea, Proteomics and Telix rose more than one percent; with Next Science up 0.45 percent.

Impedimed and Resonance led the falls, both down 7.7 percent to 12 cents and 24 cents, respectively, with 2.3 million and 2.5 million shares traded, respectively.

Actinogen lost 5.1 percent; Antisense, Cyclopharm, Nanosonics, Osprey and Prescient fell more than three percent; Avita, Clinuvel, Ellex, Neuren and Orthocell two percent or more; Cynata, Immutep, Kazia, Pro Medicus, Resmed and Volpara were down more than one percent; with Cochlear and Starpharma down by less than one percent.

DR BOREHAM'S CRUCIBLE: POLYNOVO

By Tim BOREHAM

ASX code: PNV

Market cap: $1,870.8 million

Share price: $2.83

Shares on issue: 661,088,044

Chief executive officer: Paul Brennan

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

Financials (year to June 30 2019): revenue $13.7 million (up 128%), sales revenue $9.35 million (up 435%), loss of $3.2 million (previous $6.0 million deficit), cash $13.9 million

Identifiable major holders: Moggs Creek Pty Ltd (David Williams) 2.4%, Lateral Innovations (David Kenley) 1.6%, Monash Investment Holdings 1.4%, Trust Company Australia (The Merchant Group) 1.4%, Dr John Greenwood 1.4%.

As with fellow ASX listed burns house, Avita Medical, the decade ended on a high for Polynovo after European regulators in December gave the nod to its lattice-style device to treat serious burns and other horrendous wounds.

So far, the Twenties have been roaring for Polynovo as well, with its shares surging 11 percent to a fresh record high on January 22.

The catalyst was German artificial skin outfit Polymedics Innovations lodging first orders for Polynovo's lead product, the Novosorb Burns Temporising Matrix (BTM) and the first German use of the product.

The company also said it had wined and dined 70 top burns surgeons at the DAV***** Burns Conference in Austria, with many of them promising to use the product "in the near future".

Further validating the technology, Novosorb was used to treat several burns patients from New Zealand's White Island volcano disaster.

The US Food and Drug Administration approved Novosorb way back in 2015 and the product is also available in Australia, New Zealand, South Africa, India, Malaysia, Singapore and Israel.

Lest we forget

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 a joint venture with Xceed Biotechnology.

Metabolic bought 60 percent of this venture in 2008. (Metabolic was infamous for a failed obesity trial using the peptide AOD9604, later made even more infamous in the Essendon and Cronulla drug scandals. Then CEO Dr Roland Scollay corrected Biotech Daily at that time: “Oh, no, David. The trial was very successful. It showed that our drug didn’t work.”)

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 director David Kenley’s Lateral Pharma Pty Ltd for $1.5 million.

Chairman Williams is also well known as chair of Medical Developments, which is successfully selling the Penthrox (green whistle) front-line pain relief product. He also runs advisory company Kidder Williams with Bega Cheese as a major client. On the clinical side, leading burns surgeon and 1.4 percent shareholder Prof John Greenwood is a certified Polynovo fan.

Novosorb explained

Novosorb is a 2.0mm thick biodegradable polymer foam wound scaffolding that is claimed to provide a better result than rival lattice products, or skin grafts. The material can be produced as a fibre, a cardiac stent or films and foams.

Novosorb looks like a piece of foam but 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.

As a dermal scaffold, the foam-like material is placed in the wound area where it forms a closed protective zone. Eventually, the material biodegrades and is excreted via the usual channels (urine or respiration).

You Barda believe it

As with Avita, Polynovo is receiving support from the US Biomedical Advanced Research and Development Authority (BARDA), the agency that stockpiles medicine and medical equipment for use in a disaster.

“They are keen to make sure the product works and also make sure we are commercially viable so their investment in getting it to market is safe,” Mr Brennan says.

The BARDA-funded full thickness burns feasibility trial in the US involves 19 patients across four hospitals, with four enrolled so far. While plenty of US surgeons have used Novosorb for full-thickness burns, the use is off-label which means that Polynovo can’t promote it.

BARDA is stumping up about $US18 million ($A22 million) for the trial, with a further $US35 million to $US40 million for a pivotal trial.

Results from six sites participating in the feasibility trial are expected in March, with the pivotal trial expected to kick off in June.

“They are our friends,” Mr Brennan says of BARDA. “We have a very good relationship with them, they help us in all sorts of ways.”

Approved for use where it counts

The US Food and Drug Administration 510k (device) clearance was for use in reconstructive and surgical wounds.

The CE mark approval covers broad indications: full thickness burns, reconstructive surgery, scar revision, venous leg ulcers, diabetic foot ulcers and “any loss of dermis needing repair”. That just about covers the world

Mr Brennan estimates the European market at $300 million to $330 million, one-third the size of the US market. The reason for this is that reimbursement is limited to hospital use, whereas in the US private insurers will fund out-of-hospitals use.

Notably, the approval covers the Europhobic Brits, as well as Ireland. The reason for this is that while Britain has executed its Brexit along with Megxsit, the Poms have decreed they will accept European registration for the next three years.

Polynovo has also done the rounds of European burns conferences and is girded to launch in Austria in January.

The distributor for Germany, Austria and Switzerland, Polymedics Innovations says it has 14 hospitals ready to evaluate Novosorb.

The European approval also enables fast track approval in a number of South East Asian geographies, with applications also lodged in South Korea, Taiwan, Mexico and Kuwait.

Finances and performance

Polynovo doesn’t intend to issue quarterly statements but in early January management trumpeted December as its first $2 million month sales-wise.

The company hit $1 million of monthly sales last April, “which gives some feel for the acceleration of sales in the US, Australia and New Zealand.”

The first (December) half results on February 26 will show revenue of $8.57 million, 129 percent better than the previous $3.75 million.

The company achieved $9.35 million of product sales in 2018-’19, 435 percent higher and narrowed its loss from $5.97 million to $3.19 million.

At its November annual general meeting management advised the company was “on track” to more than double sales in the current (2019-’20) year: “however cash flows will continue to be reinvested to drive growth”.

The company expects “accelerated” revenue from its direct marketing in the US, UK, Ireland, Australia and New Zealand.

But Mr Brennan cautions sales will continue to be “lumpy” as new staff are signed on, with “natural disasters such as fires and volcanoes” adding to the unpredictability.

Broker Baillieu Holst forecasts current-year revenue of $24 million and net earnings of $2.2 million (earnings per share of 0.3 cents).

Polynovo shares have climbed from 61 cents to a peak of $2.83 over the last 12 months, a 364 percent increment. Just over three years ago they were trading at a mere 19c and the company was more worried about cash burn than third degree burns.

In September 2019, the ASX bestowed Polynovo its highest honor - well, almost - by elevating the stock to the ASX200 index.

So, investors are smiling like the proverbial moggies from Cheshire. But hang on - why the long faces at active stock picker Regal Funds Management?

The answer is that Regal certainly picked Polynovo - but as a short-sold position. This means the fund was betting on the share price declining rather than soaring with the gods.

Oops.

What’s next?

Polynovo’s next target is the hernia repair market, with a planned entry into the US and New Zealand markets in 2021 (the Kiwis recognize US registration).

“The hernia market is twice the size as the skin market and that’s where we see a real transformation of Polynovo,” Mr Brennan says. “We move from being a one-shot-in-the - locker company to a platform technology.”

The company’s Port Melbourne facility is currently a construction site, as an extension is built to accommodate production of the hernia variant.

The hernia product is based on the same foam as Novosorb, but otherwise is a complete rebuild.

As with Novosorb, a key selling point is that the device is dissolved by the body, unlike the permanent current standard-of-care meshes that are sutured on to the offending area where the bowel is trying to push through.

The company plans to run post-marketing trials in the US over the next two years, to assess the longer-term progress of the patients.

Beyond hernias, Polynovo is eyeing applications for type two diabetes, involving transplanting pancreatic islet cells into the dermal depot created by the matrix.

The company also mentions breast reconstruction and - intriguingly - breast augmentation which implies potential cosmetic applications (boob jobs).

Polynovo's technology platform might also be relevant for repairing bone fractures and damaged cartilages and for subcutaneous drug delivery.

Dr Boreham's diagnosis:

It's tempting to compare Polynovo and Avita, both of which have won US Food and Drug Administration approval and have enjoyed powerful price rallies.

Both bear beefy market valuations: $1.8 billion for Polynovo and circa $1.5 billion for Avita (which we covered on December 20, last year).

In truth, there's room for both, in that Avita's Recell spray-on skin is more suitable for less severe burns. Novosorb and Recell have also been used alongside each other.

A corporate match made in heaven? Just sayin'.

We agree with Regal that Polynovo's valuation looks toppish relative to its current revenues and there's no margin for error.

We'll get a better feel when it starts selling in European markets.

The hernia roll-out will also establish whether the company's valuation is strained, or merely the beginning.

(***** DAV is an abbreviation of Jahrestagung der Deutschsprachigen fur Verbrennungsbehandlung. Thanks for asking.)

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His grasp of German is pretty scheiβe as well.

RESMED

Resmed says it has paid $US41.2 million ($A60.17 million) in litigation costs, mostly to the US Government, to resolve allegations relating to US False Claims Act violations.

A Resmed spokesperson told Biotech Daily the $US41.2 million included $US37.5 million paid to the US government, about $US2 million to US state governments, and associated legal and processing fees; and the company “denies the allegations and maintains that it has committed no wrongdoing”.

A statement from the US Department of Justice said the allegations were unproven but related to “allegedly causing false claims related to the sale of equipment for sleep apnoea and other sleep-related disorders”.

The Department of Justice said the payment resolved “alleged False Claims Act violations for paying kickbacks to … suppliers, sleep labs and other health care providers”.

The Resmed spokesperson said the matter had been mentioned in the 2018-’19 quarterly report and earnings call.

In its July 26, 2019 fourth quarter results, Resmed said it spent $US41,199,000 on "litigation settlement expenses", along with a mention on page 23 of the annual report.

Resmed revenue for the year to June 30, 2019 was up 11.4 percent to $US2,606,600,000 with net profit after tax up 3.6 percent to $US526,400,000 (BD: Jul 26, 2019).

The company’s annual report said that from 2016 to 2019, the US Department of Health and Human Services had sent “subpoenas, informal requests and a civil investigative demand, requesting documents and other materials that relate to our business practices, marketing programs, promotional activities, and leasing programs with home medical equipment providers, medical providers, sleep labs, and physicians”.

“Responding to investigations can be time-and resource-consuming and can divert management’s attention from the business,” the company said. “We have tentatively agreed with the government to civilly resolve the 2016 to 2019 government investigations described above for a payment of $US39.5 million.”

In a transcript of the fourth quarter earnings call, Resmed general counsel David Pendarvis said there were four categories relating to “how we made the resupply programs available on a trial basis … marketing programs, issues about financing and issues about making some apnoea links available”.

“Importantly, we're not going to be required in this resolution to admit any wrongdoing,” Mr Pendarvis said. “In fact, we believe that we've handled ourselves appropriately, but like in a lot of situations, you resolve matters on a consensual basis to get it behind you and we feel it's the best resolution for our customers, our patients and for the company and our shareholders.”

In a media release, Department of Justice assistant attorney general Jody Hunt said that “paying any type of illegal remuneration to induce patient referrals undermines the integrity of our nation’s health care system”.

The Department applauded the whistle-blower for coming forward and said the settlement resolved allegations that Resmed provided distributors with free call center services, patient outreach services; provided sleep labs with free and below-cost masks and diagnostic machines; arranged and guaranteed payments on interest-free loans for equipment; and provided non-sleep specialist physicians free home sleep testing devices.

The media release said Resmed had a Corporate Integrity Agreement with the US Department of Health and Human Services to implement additional controls on product pricing and sales and conduct monitoring of its arrangements with referral sources.

The media release said that the claims resolved by the settlement were “allegations only, and there has been no determination of liability”.

Resmed fell 31 cents or 1.3 percent to $23.60 with 765,840 shares traded.

IMMVIRX

Immvirx co-founder and former Viralytics chief executive officer Dr Malcolm McColl says the team is back to develop a new virus-based cancer immunotherapy.

In 2018, the Branchburg, New Jersey-based Merck Inc paid $502 million for Viralytics, for its Coxsackievirus A21-based Cavatak oncolytic immunotherapy (BD: Feb 22, 2018).

The company said Cavatak was being evaluated in multiple phase I and phase II trials, both as an intra-tumoral and intravenous agent, including in combination with Merck's Keytruda, or pembrolizumab, an anti-programmed cell death protein 1 (PD-1) therapy.

In 2015, Viralytics said it had an agreement with a Merck Sharp and Dohme subsidiary investigating the use of the Cavatak and Keytruda combination in melanoma, prostate, lung and bladder cancers (BD: Nov 6, 2015).

Several Viralytics staff members continued working for Merck on the project.

Today, Dr McColl told Biotech Daily the "team is back", including co-founder and chief scientific officer Prof Darren Shafren, regulatory and quality affairs head Dr Jennifer Rosenthal, chief financial officer and company secretary Robert Vickery, with directors Peter Turvey and Dr Len Post, and key members from the Newcastle laboratory.

Dr McColl said that Immvirx would take the same approach as Viralytics, but a new target virus had been identified to develop "an agent combined with an immunotherapy to treat cancer.

Dr McColl said the company was at the early stages of start-up with work at the laboratory bench stage.

Dr McColl said that the company had completed an undisclosed seed funding round that would cover expenses for 18 months.

Immvirx is a private company.

NUHEARA

Nuheara says it has a 24-month $2.5 million Lind Partners draw-down equity facility and will issue Lind 24,264,706 options, exercisable at 5.0 cents within four years.

Nuheara said shares issued to the New York-based Lind Partners would be restricted for the first 120 days with the first tranche set at a conversion price of 6.0 cents a share.

The company said the conversion price after 120 days would be the lessor of 6.0 cents a share or 90 percent of the average of the five lowest daily volume weighted average prices in the 20 days prior to conversion.

Nuheara said the proceeds would be used to fund mass production and marketing of its Iqbuds Max and for working capital.

The company said it would issue Lind a "secured redeemable convertible security with a face value of $3 million … [and had the] right to redeem at any time without penalty, which, if repaid within 180 days, the face value will be reduced to $2.85 million

Nuheara fell 0.2 cents or 6.1 percent to 3.1 cents with 4.7 million shares traded.

NUHEARA

Nuheara says Silverstream will purchase its 1.5 percent royalty of the Mt Ida Gold Project mines near Leonora, Western Australia for $US200,000 ($A292,141).

Nuheara said the Cayman Islands-based Silverstream would pay half the consideration in $US100,000 worth of Silverstream shares once it commences trading on the Toronto Stock Exchange, with the other half to be paid in cash within seven days of listing.

UNIVERSAL BIOSENSORS

Universal Biosensors says receipts from customers for the year to December 31, 2019 were up 149.1 percent to $59,943,000.
Last year, Universal Biosensors said it had received $US31,503,880 ($A44,036,123.46) as a lump sum payment from Johnson & Johnson's Lifescan to buy-out its obligation to pay quarterly service fees for its Verio blood sugar test strips (BD: Feb 18, 2019).
Today, the company said it received $US4 million from Siemens in November 2019 as prepayment for strip sales and Xprecia Stride strip revenue was $4.9 million for the year.
Universal Biosensors said it had cash and cash equivalents of $37,193,000 at December 31, 2019 and expected a cash burn for the three months to March 31, 2020 of $3,554,000.
Universal Biosensors was up 1.5 cents or 8.6 percent to 19 cents.

SIENNA CANCER DIAGNOSTICS

Hong-Kong's Jeffrey Emmanuel says he has increased his substantial shareholding in Sienna from 25,000,000 shares (7.43%) to 33,571,428 shares (8.49%).
Mr Emmanuel did not say how much he paid for the shares, as required under the Corporations Act 2001.
Earlier this week, Sienna said it raised $3.7 million in a placement and rights issue at 3.5 cents a share (BD: Jan 21, 2020).
Sienna was unchanged at 3.9 cents.

CRESO PHARMA

Jamber Investments says it has reduced its substantial shareholding in Creso from 20,369,753 shares (11.73%) to 15,825,250 shares (9.09%).
The Substantial shareholder notice signed by Jamber director James Schwarz for the Amber Schwarz Family account said that between January 17 and 21, 2020 it sold 4,544,503 shares for $899,453 or an average of 19.8 cents a share.
Creso was unchanged at 17.5 cents.

NEUROTECH INTERNATIONAL

Neurotech has requested a trading halt pending an announcement "in relation to the registration of its Biofeedback system" with the Therapeutic Goods Administration.
Trading will resume on January 29, 2020 or on an earlier announcement.
Neurotech last traded at 1.8 cents.