Biotech Daily

Friday October 5, 2018

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: VOLPARA UP 11%; AIRXPANDERS DOWN 7%**

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*** PRANA: 'PBT434 TARGETS KEY MSA PATHOLOGY' IN MICE**

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*** BENITEC AGM FOR 10m EXECUTIVE CHAIR DR JEREL BANKS OPTIONS**

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*** MEMPHASYS: ALISON COUTTS 16%, ANDREW GOODALL 24.5%**

*** CLINUVEL STAN MCLIESH: 'I'LL RETIRE ON FDA SCENESSE APPROVAL'**

MARKET REPORT

The Australian stock market was up 0.15 percent on Friday October 5, 2018 with the ASX200 up 9.2 points to 6,185.5 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell, six traded unchanged and four were untraded.

Volpara was the best for the second day in a row, on no news, up 12 cents or 11.3 percent to $1.18 with 1.5 million shares traded.

Bionomics and Opthea climbed more than eight percent; Avita and Imugene were up four percent or more; Benitec improved three percent; Immutep and Medical Developments rose two percent or more; Dimerix, Prescient and Starpharma were up more than one percent; with Cochlear, CSL, Nanosonics and Polynovo up by less than one percent.

Airxpanders led the falls, down 0.7 cents or 6.7 percent to 9.8 cents, with 401,642 shares traded.

Actinogen, Cynata and Orthocell fell more than five percent; Mesoblast and Osprey lost more than four percent; Ellex and Genetic Signatures were down more than three percent; Compumedics, Cyclopharm, Neuren, Oncosil and Telix shed more than two percent; with Clinuvel, Factor, Paradigm, Pro Medicus and Resmed down by one percent or more.

DR BOREHAM'S CRUCIBLE: SIMAVITA

By TIM BOREHAM

ASX code: SVA

Share price: 3.3 cents

Shares on issue: 345,944,802 (Chess depositary instruments) pre-$1,975,000 placement at 3.0 cents per CDI; total 411,778,135

Market cap: $13.6 million

Chief commercial officer, company secretary: Peta Jurd

Board: Michael Spooner (chairman), Warren Bingham, Dr Gary Pace

Financials (year to June 30 2018): sales $411,344 (down 55%), loss of $4.94 million (previously $7.75 million loss), cash of $1.36 million ***** (down 34%).

***** This month's $2,975,000 capital raising bolsters the June 30 reported cash balance.

Major identifiable shareholders: (pre-placement) Dussman Group (Damian Haakman) 29%, Chevron Corp 10.7%, WF Asian Reconnaissance Fund 7%, Powell Super Fund (Michael Powell) 8.1%, Inspiration Superannuation Fund 5.3%, Daniel Hegglin 4.8%.

Like most biotech stocks, Simavita boasts a huge addressable market: the $US64 billion a year ($A88 billion) global infant and adult nappy sector.

But like all-too-many biotechs, the incontinence management play has been frustratingly slow in generating revenue, despite regularly returning to investors for top-up funds including a $2.97 million whip around announced on October 3.

The original Simavita business consists of wi-fi enabled products that detect urinary incontinence and then monitors and charts patient progress.

The core premise is that nurses and attendants at aged care facilities spend at least 25 percent of their time dealing with incontinence issues, with 70 percent of residents affected.

The Australian Health and Welfare Institute estimates the condition costs such facilities $1.12 billion a year, with a further $112 million expended on incontinence products annually.

But after a board and management change in 2016 and the Pivot strategy change in early 2017, the company is pinning its hopes on the broader nappy market.

Simavita is predicated on the ‘razor blade’ model by which it makes money out of the consumables (the sensors embedded in the nappy during manufacturing) and not so much out of the one-off hardware and software.

While the world consumes 212 billion infant nappies and 27 billion adult nappies annually, the branded manufacturers are being challenged by the private label market and need a point of differentiation.

Not surprisingly, the market is also price sensitive.

“As long as it doesn’t leak, people will continue to buy the same product,” chief commercial officer Peta Jurd says.

Having sold third-party products previously, Amazon recently launched its own price-sensitive brand and is the third biggest seller in the US.

Simavita’s painful past

Simavita’s technology was devised by an Australian doctor, the late Dr Fred Bergman, while working at a Melbourne residential aged care facility. He filed for a patent in 1996 and by 2008 had developed four iterations of the device.

Along the way, he attracted $28 million of funding from private money and government grants.

Simavita back-door listed via the shell of Genetic Technologies subsidiary Gtech International Resources in February 2014, raising $1.1 million by issuing 2.683 million Chess depositary receipts (CDIs).

Why CDIs? Gtech was actually listed on the Toronto Stock Exchange.

By February 2016 it was clear that things were far from dandy and the board instituted a program to halve costs. This included then chief executive officer Philippa Lewis assenting to a 30 percent pay cut (her salary package of $1.62 million in 2013-’14 - including $734,000 of share-based options - did not exactly go unnoticed by investors).

But by April 2016 Ms Lewis and chairman Michael Brown had agreed to step down, replaced by Mesoblast director Michael Spooner and Resmed and Antisense Therapeutics director Gary Pace.

Around this time three other directors departed: Damian Haakman, Ari Bergman (Fred’s son) and Craig Holland.

As part of the cost purge the company delisted from the Toronto bourse in July 2016.

“The company has had an interesting history, that’s one way of describing it,” Ms Jurd says. “There’s been a lot of money invested in it but we have a very substantial robust patent portfolio.”

Simavita's products

Simavita's first product, SIM (smart incontinence monitor) Clinical was approved in the US in 2013 as a class II medical device. It was also approved in Europe as a class I device.

Based on an inserted sensor, SIM developed an incontinence profile of patients to help with toileting regimens.

In late 2016 the company launched a portable variant for home care and institutional use called Assessplus. The product is approved for funding under the National Disability Insurance Scheme.

Simavita is now developing Alertplus, which monitors wetness via sensors printed into the nappy. The sensors are read by a low-cost, multi-use device that clips on to the nappy and connects to a phone app via Bluetooth.

The company estimated each sensor will cost a mere one cent to make, with the receiver devices also costing one cent per use over a six-month life.

Along the way, the company abandoned its direct sales model, in favor of partnerships. Under the new management, the company stopped trying to sell monitor nappies to aged care homes, changing the business model to embedding monitors in commercial nappy production.

The premise is that the "dumb diaper" market hasn't changed in a quarter of a century and is highly competitive. So, the first maker to introduce smart sensor technology at an affordable price will obtain a key advantage.

In August, Simavita announced its first big marketing tie up, with the Belgian nappy maker Drylock Technologies which specializes in the private label sector.

For a 12 months period, the parties will "use their best endeavors to seek out and identify tender opportunities with large mass market customers and to work exclusively with each other only in relation to agreed tender opportunities."

More specifically, the parties are targeting four mass market customers, accounting for around EUR50 million ($A80 million) each.

The company cites six potential licencing partners who make "billions" of nappies annually.

Value leakage

In its full year accounts, directors opined about the "material uncertainty" of Simavita continuing as a going concern.

Happily, these concerns have been ameliorated by this month's capital raising: a private placement of $1.975 million at 3.0 cents a share (a 20 percent discount to the 15-day average share price) and a $1 million convertible note.

The company also issued $1.35 million of convertible notes in April.

While Simavita is striving to keep nappies intact it's been more a case of value leakage, with its shares losing more than 90 percent of their value since listing five years ago.

Simavita shares have traded as high as 4.6 cents over the last 12 months (in late April) and as low as 1.1 cents (late August).

The company has ploughed $70 million into product development over its corporate life, $12 million of this in the past year.

Dr Boreham's diagnosis

Simavita might fail the smell test – literally.

From your columnist's fading recollection of rearing infants, it was kind of obvious when a nappy change was due - although maybe that was more in relation to "number twos".

Dr Boreham is happy to be proved wrong, if and when Simavita snares a licencing deal with a major nappy maker.

In the aged care context, on paper it makes sense for larger facilities to invest in Assessplus, but given the low take-up it looks like inertia prevails.

Ms Jurd says Alert is a platform technology that in future could add temperature and hydration measurement and GPS tracking of elderly patients.

But without mandatory monitoring requirements for the aged care sector, Simavita is likely to continue to struggle for traction in this market.

Simavita's material, by the way, promises "no more worries ... no more messy diapers" which biologically is a big call indeed.

But if nappy makers can get away with thinner nappies that use less pulp, that's a bottom-line win for the manufacturer, the parents and the environment.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he thinks he has got to the bottom of this one anyway.

PRANA BIOTECHNOLOGY

Prana says PBT434 for multiple system atrophy prevents alpha-synuclein aggregation, preserves neurons, reduces glial cell inclusions and slows motor dysfunction in mice.
Prana said that the data would be presented in a poster at the International Congress of Parkinson's Disease and Movement Disorders in Hong Kong on October 7, 2018.
The company said the poster, titled 'PBT434 prevents the accumulation of glial cell inclusions and insoluble alpha-synuclein in a mouse model of Multiple System Atrophy' showed that "in the most widely accepted animal model of the disease" PBT434 targetted the key pathology in multiple system atrophy and had "excellent potential" as a treatment.
Prana said that multiple system atrophy was a fatal neuro-degenerative disease and an important form of atypical Parkinsonism.
The company said that glial cell inclusions were the key pathological finding in multiple system atrophy (MSA) and contained abundant aggregated alpha-synuclein associated with neuro-degeneration.
Prana said that alpha-synuclein was "of great interest to scientists and clinicians because aggregated forms of the protein are toxic and underlie the pathology of neurological diseases such as MSA and Parkinson's disease".
Prana chief medical officer Dr David Stamler said that multiple system atrophy was "a terrible disease and has no approved treatments".
"Our phase I study in healthy volunteers is ongoing and we look forward to bringing PBT434 to patient studies in the future," Dr Stamler said.
Prana said that PBT434 was the first of a new generation of small molecules designed to inhibit the aggregation of alpha-synuclein and tau, intracellular proteins implicated in neurodegenerative diseases such as Parkinson's disease and atypical Parkinsonism.
Prana was unchanged at 4.9 cents.

GI DYNAMICS

GI Dynamics says it has appointed the London UK-based Intertek as its 'notified body' for Endobarrier Conformité Européenne (CE) mark approval.
GI Dynamics said that a notified body was designated by an EU member country to assess the conformity of products before being placed on the market and undertook tasks related to conformity assessment procedures.
The company has been attempting to commercialize the Endobarrier duodenal insert for obesity and type 2 diabetes.
In 2015, GI Dynamics closed a planned 500-patient US trial, with five of the 325 enrolled patients developing bacterial liver infections (BD: Mar 6, May 6, Jul 30, 2015).
In 2017, the European Union withdrew the Endobarrier conformity certificate and in 2016 the Australian Therapeutic Goods Administration also cancelled the Endobarrier approval (BD: Sep 14, Oct 24, 2016; May 18, Nov 13, 2017).
Today, GI Dynamics said that Intertek was "a leading total quality assurance provider" and would be responsible for Endobarrier conformity requirements "ensure that [its] quality management system is compliant with ISO 13485:2016 requirements".
GI Dynamics chief executive officer Scott Schorer said that "initiating work with Intertek represents a significant step towards achieving an Endobarrier CE mark and brings us closer to commercialization in Europe and the Middle East".
"This is an important step as we continue to develop Endobarrier as the lead implant for the treatment of type 2 diabetes and obesity," Mr Schorer said.
The company said it planned to attain the Endobarrier CE mark by the end of 2019.
GI Dynamics was untraded at 2.2 cents.

BENITEC BIOPHARMA

Benitec will vote to grant executive chairman Dr Jerel Banks 10,000,000 options exercisable at 22.78 cents each by June 26, 2023.
Benitec said the options would vest in three equal annual tranches from June 26, 2019.
The company said the annual general meeting would vote on the remuneration report, the 10 percent placement capacity, the option plan and the re-election of director Kevin Buchi.
In 2015, up to 38.6 percent of Benitec votes opposed the issue of 6,720,000 options to directors, with the remuneration report facing 18.4 percent opposition (BD: Nov 12, 2015).
In 2016 and 2017, the company did not propose issuing options to directors or executives.
The meeting will be held at Grant Thornton, Level 17, 383 Kent Street, Sydney, on November 8, 2018 at 10am (AEDT).
Benitec was up half a cent or three percent to 17 cents.

MMJ PHYTOTECH

MMJ says all resolutions to its divestment and change of activities extraordinary general meeting passed but with up to 25 percent opposition to director Douglas Halley options.
MMJ said that shareholders overwhelmingly voted in favour of divesting Phytotech Therapeutics to Canada subsidiary Harvest One Cannabis for $C8 million ($A8.5 million), change its name to MMJ Group Holdings and change the nature of its activities.
The company said that 3,229,082 votes (24.9%) opposed the issue of 1,000,000 options to Mr Halley (BD: Aug 29, 2018).
MMJ called a trading halt for the results and last traded at 33 cents.

MEMPHASYS

Memphasys executive chair Alison Coutts and director Andrew Goodall have disclosed their post 15-for-one consolidation and $1 million Peters Investment placement holdings.
In separate substantial shareholder notices Mr Goodall said he bought shares and was consolidated and diluted from 1,323,451,390 shares (29.74%) to 89,230,093 shares (24.52%) while Ms Coutts was consolidated and diluted from 884,883,248 shares (19.89%) to 58,992,217 shares (16.21%).
Memphasys was up 0.1 cents or 7.1 percent to 1.5 cents with 2.3 million shares traded.

CLINUVEL PHARMACEUTICALS

In a ‘Letter to shareholders’, Clinuvel chair Stan McLiesh says he will delay his retirement until the US Food and Drug Administration approves Scenesse.
Mr McLiesh said that he had recently stated he would stand down as chair, but after discussion with directors, the management team and some investors, agreed to resign as chair immediately following a successful FDA outcome, expected in 2019.
“A US entry of Scenesse would most likely be [sic] one of the pinnacles of my professional career, a long-fulfilled dream and possibly the most significant event in the history of Clinuvel,” Mr McLiesh.
Clinuvel fell 35 cents or 1.6 percent to $22.07.