Biotech Daily

Friday July 14, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: DIMERIX UP 36%, CELLMID DOWN 7%**

*** DR BOREHAM'S CRUCIBLE: UNIVERSAL BIOSENSORS**

*** PROTEOMICS, BIOSANAPHARMA TEST ASTHMA BIO-SIMILAR**

*** IDT LOSES DR PAUL MACLEMAN, GONE A-DROVING DOWN THE BASS**

*** REVA BOARD, EXECUTIVE CHANGES; 10 STAFF GO**

MARKET REPORT

The Australian stock market climbed 0.49 percent on Friday July 14, 2017 with the ASX200 up 28.3 points to 5,765.1 points.

Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, 10 traded unchanged and four were untraded.

Dimerix was the best, up 0.4 cents or 36.4 percent to 1.5 cents with 51.0 million shares traded, followed by LBT up 12.5 percent to 31.5 cents with 778,519 shares traded.

Ellex and Osprey climbed more than four percent; Nanosonics was up 3.4 percent; Atcor and Pharmaxis rose two percent or more; Acrux, Compumedics, Neuren, Oncosil and Viralytics were up more than one percent; with Cochlear up 0.8 percent.

Cellmid led the falls, down 0.2 cents or 7.4 percent to 2.5 cents with 300,322 shares traded.

Prana and Psivida lost five percent or more; Airxpanders, Bionomics and Prima fell more than three percent; Clinuvel, Impedimed and Orthocell shed more than two percent; Admedus, Avita, CSL and Universal Biosensors were down more than one percent; with Mesoblast, Resmed and Sirtex down by less than one percent.

[DR BOREHAM'S CRUCIBLE: UNIVERSAL BIOSENSORS]

By TIM BOREHAM

ASX Code: UBI

Market cap: $73.8 million; **Share price:** 42 cents; **Shares on issue:** 175.8 million

Executive chairman and acting chief executive officer: Andrew Denver

Board: Andrew Denver, David Hoey, Denis Hanley, Judith Smith, Marshall Heinberg, Craig Coleman

Financials (March quarter): revenue $7.9 million***** (up 56%), net profit $2.5 million (previous $1.6m loss), operating cash flow -$1.1 million (-$2.3m), cash $17.8 million, expected current quarter cash outflows $7.2 million.

***** Includes $872,000 of Xprecia Stride sales.

Major shareholders: Viburnum Funds/Wyllie Funds Management 15.5%, KFT Investments 10.2%, Denis Hanley 3.77%, Talu Ventures (CM Capital) 3.6%.

We've all heard of Brexit, a.k.a. the 'Theresa May or May not survive' debacle.

Here's another one: Strexit, as in 'strip exit'. In this case the Strexit decision is not in the hands of the people, but diagnostic group Universal Biosensors' partner on the blood sugar testing side of its business, Johnson & Johnson offshoot Lifescan.

In the near future - and we're deliberately being vague - Lifescan must decide whether to pay Universal a lump sum, in return for ceasing the profit-sharing deal on Universal's single-use Onetouch Verio blood testing strips.

The strips are based on a proprietary electrochemical sensing system.

Should Lifescan choose to Strexit rather than to Stremain, Universal will pocket a lump sum on future quarterly service fees (QSFs) estimated at $80-90 million. Under a complex formula, the Strexit decision is crystallised when cumulative Onetouch Verio QSFs reach $US45 million ($58 million).

Universal earns a royalty of 1.25 US cents for the first 500 million strips sold every year and then 0.75 US cents per strip thereafter.

Lifescan sold 1.4 billion strips in calendar 2016. This year, Lifescan expects to sell around two billion strips, so at this rate the $US45 million threshold should be attained later this year.

Universal's management assumes Lifescan will avail of the Strexit option, because if Onetouch Verio sales continue at the current momentum it will be up for a lot more than $80-90 million lump sum.

"The rational decision would be to exercise that right," Mr Denver says.

If the union remains intact, broker Veritas Securities values Universal's blood glucose business at up to $361 million, or $2.05 a share.

Another broker, Taylor Collison estimates just under $US60 million ($A78 million) paid in January 2018 as "one potential scenario". However given Lifescan is free to decide any time in 2018, payment may not be received until 2019.

The firm notes that demand for the Verio strips has been "robust" since being launched in early 2010 - and is likely to remain so.

For the history buffs, Universal listed in December 2006 after raising $22 million at 50 cents apiece. For a while, the stock traded above $1 until the usual setbacks and delays occurred. But the company's core story is little changed over the decade.

Coagulation thickens the plot

The Universal story gets even more interesting because there are two sides to the business, the other being measuring the effectiveness of the anti-coagulation (blood thinning) drugs, like warfarin.

Universal has a separate deal with Siemens to market these strips, called Xprecia Strides.

With the blood testing, J&J owns the intellectual property, even though Universal Biosensors has the technical knowledge and retains the commercialization rights.

The Siemens deal is different in that Universal controls the intellectual property and is the exclusive manufacturer. "We make money by selling the strips," Mr Denver says.

The Xprecia Strides won US Food and Drug Administration approval in October last year and have only been marketed since January. But they are also sold in Europe, the Middle East, the Asia Pacific, Canada and Latin America - which just about covers the world.

By the numbers

At Universal's recent annual general meeting, Mr Denver said the March quarter Xprecia Stride sales of $872,000 were five times the value of sales in the whole of 2015-'16.

"We expect to see Xprecia Stride test strips make an increasingly important financial contribution to Universal's financial position in 2017," he said.

The company, of course, is working off a low base.

Encouragingly, Universal's bottom line is looking plumper: after reporting a cumulative $28 million of net losses over four years, the company posted a $1.3 million net profit in calendar 2016 and this was augmented with a $2.4 million surplus in the March quarter.

The company has also been net cash flow positive for the last four years.

Dr Boreham's diagnosis:

Universal's current $70 million market valuation makes for an interesting disconnect with the implied underlying value of both sides of the business.

Brokers value the coagulation side around $100 million and this does not include the emerging home testing market, over which Universal retains the full rights.

The company values the US blood glucose home-monitoring market at $US12 billion, with anti-coagulation monitoring worth a further $US1.3 billion.

The latter is a "quasi monopoly market" dominated by Roche.

In theory, Universal should be worth $200 million or more taking the diabetes and coagulation sides into account.

So why the yawning valuation gap? "I wouldn't be doing what I'm doing if I knew why," Mr Denver says.

Fair enough, Andy.

There are a few possible reasons: one is that the expected growth in the coagulation side is over-stated; the second is that competition on the blood thinning side is under-rated.

The third is that warfarin therapy has been declining as other novel drugs (that don't require the same level of monitoring) are developed. But warfarin has been the standard-of-care since 1954 and clinical behaviour won't change overnight.

The fourth explanation for the valuation chasm is that investors are simply stupid.

Dr Boreham believes investors are never dumb, but possibly sometimes a bit slow on the uptake.

The Strexit vote (around the J&J boardroom table in this case) eventually will determine whether this discrepancy is justified or not.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He wouldn't be doing what he does if he knew why the market behaves so erratically.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has a partnership with Biosanapharma to test a bio-similar treatment for allergic asthma, expected to generate more than $200,000 in revenue.

Proteomics said it would conduct characterisation analysis of the Haarlem, Netherlands-based Biosanapharma's asthma treatment over a period of 12 months, including long-term and accelerated stability testing, assessing long-term storage under different temperature conditions to verify safety and efficacy.

The company said that the partnership was "the start of a new service in release testing and long-term and accelerated stability testing for bio-similars".

Proteomics managing-director Dr Richard Lipscombe said the treatment to be tested was "an antibody drug that controls moderate to severe allergic asthma".

"It's a great example of the new breed of bio-similars, complex generic drugs that copy existing biological medicines," Dr Lipscombe said.

Proteomics said it was its largest bio-similars contract to date and worth more than $200,000.

The company said that the global bio-similars drug market surpassed $US3.3 billion in 2016 and was expected to triple in size to reach $US10.5 billion by 2022 as pharmaceutical companies sought "to replicate a host of blockbuster drugs coming off patent".

Dr Lipscombe said that stability and accelerated testing for bio-similars was a new area of importance for Proteomics, with the long-term service attracting long-term clients.

"Only specialist laboratories are able to take on this work because if a fridge or freezer fails, due to a power cut for instance, you could lose six months of testing data," Dr Lipscombe said. "Our extensive ISO 17025 laboratory certifications set us apart as the most accredited protein testing laboratory in the world.".

Biosanapharma chief operating and chief scientific officer Dr Jaap Wieling said that "the quality and reliability of service was key to choosing Proteomics International as a partner for [our] exciting new drug".

"Australia's advanced [research and development] environment supports our desire to make antibody bio-similars efficiently and affordably," Dr Wieling said.

Proteomics climbed 1.5 cents or 9.1 percent to 18 cents.

IDT AUSTRALIA

IDT says managing-director Dr Paul MacLeman will resign "to advance new business initiatives and to pursue … non-executive board roles" effective from August 31, 2017.

IDT said that Dr MacLeman would resign as a director from today.

Dr Macleman joined IDT in 2013 and later that year the company filed its first US Food and Drug Administration abbreviated new drug application for generic temozolomide for cancer, followed in 2014, by the acquisition of 23 previously marketed US generic drug products from Sandoz (BD: Apr 3, Nov 18, 2013; Nov 3, 2014).

Dr Macleman told Biotech Daily he intended to spend more time with his Gippsland-based beef cattle business, Avoch Highlands, on the Bass River, and was looking to expand his board positions.

IDT chairman Graeme Kaufman said that Dr Macleman had "correctly identified the limited growth opportunities in IDT's traditional markets and the need to capture more of the value chain, leading to the development of our generics business".

"We will miss him and wish him well in his future endeavours," Mr Kaufman said.

IDT said it was conducting a search for a replacement.

IDT was unchanged at 9.5 cents with one million shares traded.

REVA MEDICAL

Reva says it will replace chief financial officer Katrina Thompson, hire a head of European sales, replace two directors with one and reduce total staff by 10 people.

Reva said the changes “signal the shift in focus to commercial roll out of Fantom, which has commenced in Europe”.

The company said that Brandi Roberts would replace Ms Thompson as chief financial officer, effective from August 28, 2017.

Reva said that president and chief operating officer Robert Schultz would retire along with founding director Gordon Nye with Ray Larkin appointed a director in their place.

The company said that Carmelo Mastrandrea would be appointed head of European Sales, effective from August 1, 2017.

Reva said that 10 employee positions “were eliminated in connection with the transition to commercial operations” reducing the total employment from 60 to 50 staff.

The company said that Ms Roberts had more than 20 years of public accounting and finance experience, including 18 years at publicly traded pharmaceutical, medical technology, and life science companies, most recently as Mast Therapeutics chief financial officer.

Reva said that Ms Roberts held a Bachelor of Science in business administration from the University of Arizona and a Master of Business Administration from the University of San Diego.

The company said that Mr Mastrandrea had 17 years’ experience in sales, including more than 10 years in cardiovascular medical devices and was most recently Biosensors Europe’s general-manager for Germany, Austria and Switzerland.

Reva said that Mr Mastrandrea held Swiss Federal diplomas in machine engineering from the Mitecha Engineering School in Aarau and in business form the KV Business School in Basel.

The company said that Mr Larkin had operating and board expertize and currently served as chair of Align Technology and was recently the chair of Heartware, prior to its acquisition by Medtronic.

Reva said that Mr Larkin held a Bachelor of Science in industrial management from the Philadelphia Pennsylvania-based LaSalle University and was formerly a captain in the United States Marine Corps.

Reva chief executive officer Dr Reggie Groves thanked Ms Thompson, Mr Schultz and Mr Nye for “the significant contributions they have made to Reva over the years”

“Their leadership and resourcefulness were instrumental in helping to put us in the exciting position of commercializing Fantom,” Dr Groves said.

Reva was untraded at 80 cents.