Biotech Daily

Friday March 3, 2017

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.81 percent on Friday March 3, 2017 with the ASX200 down 47.0 points to 5,729.6 points. Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, 10 traded unchanged and two were untraded.

Dimerix was the best, up 0.1 cents or 14.3 percent to 0.8 cents with 600,000 shares traded, followed by Compumedics up 12.4 percent to 50 cents with 271,965 shares traded. Mesoblast climbed 6.3 percent; Medical Developments improved four percent; Cellmid and Psivida were up more than three percent; Neuren and Universal Biosensors rose more than two percent; Admedus, Bionomics, Factor Therapeutics, Pro Medicus, Sirtex and Viralytics were up more than one percent; with Clinuvel, CSL and Resmed up by less than one percent.

IDT led the falls, down 1.5 cents or 9.1 percent to 15 cents with 96,043 shares traded. Atcor lost 7.7 percent; Orthocell fell 5.6 percent; Living Cell fell 4.35 percent; Impedimed was down 3.5 percent; Genetic Signatures shed 2.7 percent; with Airxpanders, Cochlear, Nanosonics, Oncosil, Opthea, Pharmaxis, Polynovo and Starpharma down more than one percent.

DR BOREHAM'S CRUCIBLE: VOLPARA HEALTH TECHNOLOGIES

By TIM BOREHAM

ASX code: VHT

ASX Market cap: $36 million; **Share price:** 42 cents

CEO (and co-founder): Dr Ralph Highnam

Board: Roger Allen (chair), Lyn Swinburne, Prof Mike Brady, John Pavlidis, John Diddams, Ralph Highnam

Financials: December quarter revenue of $NZ348,000 ($A325,000, year to date NZ1.846 million); loss of $NZ2.583 million (year to date $NZ6.34 million)

Annual Cash burn: $NZ6.34 million; **Cash at end of quarter:** $NZ21.3m (the company raised $NZ10 million in its April 2016 IPO and $11.3 million in November's one-for-two rights issue).

Major shareholders: Roger Allen (14%), Dr Ralph Highnam (11%), Tina Jennings (8.5%), Prof Mike Brady (5%), Marcus Sarner (4%).

Accosted outside Parliament by a presenter of one of those undergraduate skit shows common in the 1990s, then Australian Labor Party national president Barry Jones was asked about his party's policy on breasts.

"We're for them,'' the erudite Jones dead-panned without a moment's hesitation.

We're for them, too, at Biotech Daily HQ. Specifically, we're for any technology that enhances the effectiveness of breast cancer detection.

That's the remit of the Wellington-based Volpara, which listed here last April with a tool to measure more accurately the degree of a woman's breast density.

In a win for buxom types, women with more breast fat content are at less risk of cancer than those with less squishy mammaries.

Tumors are harder to detect in those with 'denser' breasts, that is, containing more glandular tissue.

Globally, 30 to 40 percent of women are classed as dense-breasted and it is estimated that 20 to 30 percent of cancers are missed in this cohort.

On that well-accepted premise, Volpara developed its diagnostic Volpara Density, based on the lifetime learnings of co-founder Dr Ralph Highnam who even completed an Oxford D Phil on the topic.

Volpara Density last year was included on the globally-accepted Tyrer-Cuzick Risk Assessment Tool.

In Volpara's words: "This is a major validation of Volpara's technology [as] it is the only commercial density score that appears to have been included in the tool."

Volpara generated $NZ2.5 million of revenue from Volpara Density in 2015-'16, under a one-off fee model.

However since listing in April last year, Volpara has emphasised a variant called Volpara Enterprise, which is used by clinics to improve the efficiency, comfort and safety of sites with multiple X-ray machines.

Volpara has both US Food and Drug Administration and Conformité Européenne (CE) mark approval.

Volpara Enterprise is internet "cloud" based and works on a monthly per-patient subscription model.

Volpara Density is now included with this product but according to Dr Highnam "is still an important component of it".

Volpara has also turned to direct distribution rather than an intermediary model, with the proceeds from last year's rights raising earmarked to build the company's US marketing force.

Volpara retains tie-ups with GE Healthcare and Siemens, but the emphasis is now on these distributors introducing subscription clients.

Rather than a one-off product fee, Volpara's revenue model involves an annual licence charge and a fee for each breast screened.

Typical of cloud subscription models, revenue is recognised over the life of the contract which means short-term revenues are more constrained.

But as subscriptions grow, more annuity income is generated.

In an update today, Volpara revealed its book had a total long-term contract value of $NZ3.44 million so far this year, which is expected to generate revenue of $NZ707,000 over the 12 months to March 31, 2018. Volpara's financial year ends on March 31.

Prospects:

Currently, Volpara accounts for only a fraction of the breast imaging market, with 8,744 imaging clinics in the US alone turning over $US7.8 billion a year. The FDA imposes higher quality-control standards through a program called EQUIP.

The company currently boasts nine Volpara Enterprise subscribers, including the 'luminary' sites of Stanford University Hospital (California) and the University of Virginia Medical Centre. Locally, Women's Breast Imaging Perth is also a subscriber.

These sites pay a yearly fee of anywhere between $US12,000 and $US94,800, with an average payment of $US40,000 and the biggest deal worth $US99,000 a year.

Look out for the imminent launch of Volpara Enterprise in Europe this month, as well as appearances at three eminent breast cancer conferences in March and April.

Also watch out for next month's visit of breast cancer survivor Dr Nancy Capello, founder of the public awareness site 'Are You Dense?' (www.areyoudense.org).

Volpara is well-backed, notably by chairman Roger Allen who is an Australian entrepreneur.

The push for better quality imaging is being driven not only by regulator and clinicians, but by the health insurers asked to stump up for wider testing of dense-breasted women.

Dr Boreham's diagnosis:

Volpara shares peaked at 85 cents in November 2016 after the shares listed at 50 cents apiece.

Since then have done a reverse Dolly Parton and are well under water, with Friday's update failing to titillate investors.

At the risk of looking a complete boob, Dr Boreham considers the stock as one to stash away in the bodice with a longer-term view.

As with fellow Kiwi cloud play Xero and its accounting software, Volpara is likely to take some years to produce meaningful revenues.

But it's a happy time for diagnostic products and the share weakness presents an opportunity.

Volpara's catchphrase by the way is We Save Beautiful People, but we're assured they will take all comers.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he assures readers his interest in breasts is purely professional.

PHOSPHAGENICS

Phosphagenics says it is in a legal dispute with Mylan over TPM-daptomycin licenced to Agila Specialties, which Biotech Daily estimates at “tens of millions” of dollars.

Phosphagenics licenced the enhanced generic tocopheryl phosphate mixture (TPM) daptomycin antibiotic for complicated skin infections and staphylococcus aureus bloodstream infections to India’s Agila, a subsidiary of Strides Arcolab (BD: Oct 30, 2012).

Phosphagenics said in its 2016 annual report that in 2013, Mylan Inc announced it had acquired the Agila injectables business from Strides Arcolab for up to $US1.75 billion.

The company said that in purchasing Agila, Mylan acquired the TPM-daptomycin agreements and inherited any associated disputes.

Phosphagenics said it was in arbitration in Singapore over the licence and there had been no reported sales of the TPM-daptomycin and no payments to Phosphagenics despite the original branded daptomycin product Cubicin having sales of about $US1 billion a year prior to competition from generic companies entering the market in September 2016.

The company said it was entitled to single digit royalties on sales of TPM-daptomycin.

In its full year report, Phosphagenics cited two companies daptomycin generic sales, Fresnius earning $US7 million in the three months to September 30, 2016, rising to $US70 million for the three months to December 31, 2016 and Teva Pharmaceuticals earning $US5 million in the three months to September 30, 2016, rising to $US67 million for the three months to December 31, 2016 (BD: Feb 28, 2017).

Phosphagenics said that the TPM-daptomycin licencing agreement signed in 2012 was part of the arbitration dispute with Mylan.

“To date Mylan has not launched the TPM-daptomycin product and Phosphagenics has not been informed by Mylan of either its registration or launch plans,” the company said.

“Therefore Phosphagenics is not aware of when it might begin to receive royalty payments it is entitled to under the licencing agreement,” the company said.

Phosphagenics said it had spent “significant funds” on legal expenses to defend the arbitration claim made against it in the Prophase matter and to lodge a significant arbitration claim against Mylan.

The company said that in January 2016 it lodged a dispute notice in association with the Agila TPM-daptomycin agreements and the dispute was referred to arbitration in Singapore, which would be heard by a single arbitrator.

Phosphagenics said that Mylan was liable for breaches of several provisions under two agreements, misrepresentations, breaches of confidence and/or unjust enrichment in relation to intellectual property amongst others and it had lodged multiple damages claims.

Based on current sales of generic daptomycin by other companies, Biotech Daily believes that the royalties that would have been earned by Phosphagenics amounted to tens of millions of dollars had Mylan assertively marketed the product.

Phosphagenics said that “an assessment of the quantum: had been made, but it was “preliminary and the ultimate value of the claims remain subject to on-going refinement having regard to independent expert input, which is yet to be received in final form”.

“The directors also note that there is no guarantee or certainty in respect of the outcome of these arbitration proceedings and if unsuccessful, the arbitration may not result in any positive result for Phosphagenics and may even result in costs being awarded against Phosphagenics,” the company said.

Phosphagenics said that all costs associated with the litigation to date had been expensed and company intended to investigate the potential for additional funding to cover the remaining costs of this action and had retained Corrs Chambers Westgarth, for the arbitration process, which has a hearing set for October 2017.

Phosphagenics fell 0.1 cents or five percent to 1.9 cents with 1.3 million shares traded.

COMPUMEDICS

Compumedics says it has a $2.3 million sales commitment for its sleep diagnostics, neurological research systems and trans-cranial Doppler systems in China.
Compumedics said the 2017 contract with its German subsidiary DWL was a seven percent increase over the previous year, with $1.3million in sales expected to be delivered before June 30, 2017 and the balance by the end of the year.
The company said that the new contract reinforced its strategy “to expand its core business in major global medical device markets”.
Compumedics executive chairman Dr David Burton said the company had “a significant presence in China and has spent more than a decade with our Chinese partners, building a foundation for future growth in one of the world’s most challenging but highest growth markets”.
“Compumedics is now the number one premium supplier of sleep diagnostic and neurological research systems in China and is carving out a similar position in trans-cranial Doppler systems market,” Dr Burton said.
Compumedics recovered 5.5 cents or 12.4 percent to 50 cents.

VOLPARA HEALTH TECHNOLOGIES

Volpara says that in the 11 months to February 28, 2017, the total sum of capital sales, support agreements and service contracts was $NZ3.44 million ($A3.21 million).
Volpara said that for the 12 months to March 31, 2016 it signed contracts worth $NZ2.5 million.
The company said it had nine signed Volpara Enterprise software-as-a-service contracts, adding three new customers since the start of the calendar year, along with several capital deals.
Volpara said that the largest Enterprise deal for software evaluating, mammography across a centre, was worth US99,000 ($A131,052) a year, with other deals including Stanford Medical Center and the University of Virginia.
The company said that its annual recurring revenue, the amount of revenue expected to be recognized over the next 12 months based on current software service and support contracts was NZ$707,000, a rise of 464 percent compared to the 12 months to March 31, 2016.
Volpara said that software-as-a-service model incorporated an annual licence fee and a fee for each breast screening, with revenue recognized over the life of the contract as the service was delivered, rather than up-front as with a capital sale model, with “the advantage of delivering revenue with every woman screened using Volpara”.
The company said it had released an updated investor presentation ahead of meetings to be held in Sydney, Melbourne and Brisbane in March 2017.
Volpara fell 2.5 cents or 5.6 percent to 42 cents.

OVENTUS MEDICAL

Oventus says that 8,938,975 shares will be released from voluntary escrow on March 17, 2017.
Oventus said that following the quotation of the released shares, there would be 43,929,817 shares available for trading and 28,070,183 shares remaining in escrow.
Oventus was unchanged at 70 cents.

ENGENEIC

The Sydney-based Engeneic says the US Food and Drug Administration granted orphan drug designation for its drug delivery nano-cells for glioblastoma multiforme.
Engeneic joint chief executive officer Dr Jennifer MacDiarmid said that designation for the Engeneic delivery vehicle (EDV) nano-cells was “not only an important US regulatory milestone, but an exciting step towards our US clinical advancement”.
The company said that the nano-cells were non-living, bacterially derived particles which could be loaded with drugs and specifically targeted with antibodies to tumor cells (BD: Jul 14, 2011; Jun 16, 2015).
Engeneic said the technology delivered a toxic payload inside the cancer cell, resulting in cell death and the nano-cells were taken up by cells of the immune system triggering an anti-tumor response.
Engeneic is a private company.

SUDA

Suda says the Japan Patent Office has issued the company’s first Japanese patent for its sildenafil-based products, SUD-003 and SUD-004.
Suda said that the patent was entitled ‘Oral Spray Formulations and Methods for Administration of Sildenafil’, marketed as Viagra.
Suda said the patents provided protection until 2030.
The company said that an application directed to similar subject matter had been approved in Russia and similar patents had been granted in the US, Australia, New Zealand and Singapore, with applications pending in other jurisdictions.
Suda said that the claims covered the administration of sildenafil, the active pharmaceutical ingredient in SUD-003 and SUD-004, through an oral spray for the treatment of sexual dysfunction induced by selective serotonin reuptake inhibitor anti-depressants and for the treatment of pulmonary arterial hypertension.
Suda fell 0.1 cents or 5.6 percent to 1.7 cents with one million shares traded.

NOXOPHARM

Noxopharm says its idronoxil has the potential to promote an “abscopal” response to radiotherapy.
Noxopharm said that an abscopal response was “a rare phenomenon encountered in cancer patients undergoing radiotherapy …with the unexpected disappearance of all cancers in the body following exposure of only a limited number of those cancers to radiotherapy”.
The company said the phenomenon had the potential to be converted into a common event, but the conditions to create an abscopal response were unknown,
Noxopharm said its idronoxil, or NOX66, was being tested in a pre-clinical program in collaboration with an unnamed Australian cancer research institute and in two clinical studies planned to begin by mid-2017 to see if it could produce the abscopal response.
The company said it had five clinical studies testing the anti-cancer effect of idronoxil in the NOX66 dosage form and two of the studies involve combination therapy of NOX66 with radiotherapy, with some tumors exposed to radiotherapy, with at least two other tumors not exposed to radiotherapy.
Noxopharm said the two studies would determine the ability of NOX66 to shrink both the irradiated tumors and the non-irradiated tumors, achieving the abscopal effect.
Noxopharm was up one cent or 2.2 percent to 47 cents.

CRESO PHARMA

Creso has requested a trading halt pending an update on “a binding letter of intent with a high-tech Swiss food and pharma development company”.
Trading will resume on March 7, 2017, or on an earlier announcement.
Creso last traded at 38.5 cents.

ESENSE-LAB

Esense says it has appointed Shaul Schneider as its business development vice-president, with immediate effect.
Esense said that Mr Schneider would be responsible for its marketing and sales strategy, building up distribution channels for its synthetic terpenes plant oils and creating joint ventures with businesses in the different segments of its relevant markets.
The company said that Mr Schneider had more than 25 years’ experience as a manager and director including as the chief executive officer of Israel’s Bezeq Call Communications and the head of business development at Eurocom Communications and was currently a director of Intercure Ltd.
Esense was up two cents or 9.1 percent to 24 cents.