

Biotech Daily

Friday August 24, 2018

Daily news on ASX-listed biotechnology companies

- * ASX FLAT, BIOTECH UP: AIRXPANDERS UP 8%; UNIVERSAL BIO DOWN 6%
- * DR BOREHAM'S CRUCIBLE: VISIONEERING TECHNOLOGIES
- * RESONANCE CLAIMS 2 NEW TRIAL CONTRACTS WORTH \$721k
- * TELIX, MELBOURNE UNI, PETER MAC WORK ON COLORECTAL CANCER
- * SIENNA RIGHTS OFFER RAISES \$3.6m, TOTAL \$5.2m
- * MAYNE REVENUE DOWN 7% TO \$530m, PROFIT TO \$134m LOSS
- * MACH7 REVENUE DOWN 16% TO \$9m, LOSS DOWN 7% TO \$5m
- * ALLEGRA REVENUE DOWN 5% TO \$4.7m, PROFIT TO \$604k LOSS
- * PROBIOTEC SELLS BRANDED PRODUCTS TO INOVA FOR \$13.5m
- * ITL EXTENDS BLOOD BANK CONTRACT
- * ASX IMPEDIMED AWARE QUESTION, IGNORES SHARE JUMP; SEMINARS
- * ADHERIUM CLAIMS TO EXPAND VITALUS DEAL
- * MITSUBISHI, MORGAN STANLEY TAKE 5% OF MEDADVISOR
- * MMJ LOSES JOINT CO SEC ERYLN DALE

MARKET REPORT

The Australian stock market edged up 0.05 percent on Friday August 24, 2018 with the ASX200 up 2.9 points to 6,247.3 points. Nineteen of the Biotech Daily Top 40 stocks were up, 10 fell, 10 traded unchanged and one was untraded. All three Big Caps were up.

Airxpanders was the best, up 0.6 cents or 7.8 percent to 8.3 cents with 1.4 million shares traded. Avita, Compumedics and Impedimed climbed more than six percent; Optiscan and Osprey were up more than five percent; Starpharma improved 4.7 percent; Clinuvel was up 3.3 percent; CSL, Genetic Signatures, Medical Developments, Oncosil and Reva rose more than two percent; with Actinogen, Cochlear, Cynata, Dimerix, Nanosonics, Polynovo, Resmed, Sirtex and Telix up one percent or more.

Universal Biosensors led the falls, down 1.5 cents or 6.1 percent to 23 cents with 240,000 shares traded. Opthea fell 4.1 percent; LBT lost 3.7 percent; ITL, Neuren and Prana shed more than two percent; Mesoblast, Orthocell and Pro Medicus were down more than one percent; with Ellex down 0.8 percent.

DR BOREHAM'S CRUCIBLE: VISIONEERING TECHNOLOGIES

By TIM BOREHAM

ASX code: VTI (Chess depositary instruments)

Share price: 18 cents

Market cap: \$44.3 million

Shares on issue: 246,263,334*

Chief executive officer: Dr Stephen Snowdy

Board: Fred Schwarzer (chairman), Dr Stephen Snowdy, Christine Van Heek, Zita Peach, Tom Dooley, Jean Franchi

Financials (June quarter 2018): revenue \$US607,202 (\$A838,507; up 9%), cash burn \$US5.07 million, cash balance \$US7.09 million*, expected September quarter cash burn \$US4.45 million

Major identifiable holders: Regal Funds Management 13.4%, Charter Life Sciences 12.9%, Memphis Biomed 7.58%, CLS11 Annex Fund 7.4%, Kinetic Investment Partners 6.7%, Lucerne Group 4.7%

* After the \$11.86 million private placement announced in mid-August.

Multifocal contact lenses have a shortcoming that even Blind Freddy can see, yet it took some visionary work from this Atlanta-based mob to rectify the problem.

You see, your typical multifocal contacts have three concentric zones – near, distance and intermediate – but it's virtually impossible to provide seamless clarity across these zones.

Visioneering went back to the future and deployed the principles of a pin-hole camera, which has an infinite depth of focus so that near and distant objects can be viewed without blurriness.

The resulting range of Naturalvue contacts addresses two overlooked conditions: childhood myopia (short-sightedness) and age-related presbyopia (long-sightedness or the inability to see near objects and nothing to do with a Protestant religion).

The story to date

Visioneering was incorporated in Delaware (where else?) in 2008, based on the work of a Dr Richard Griffin. Dr Griffin was an aeronautical engineer who nutted out that a pinhole aperture known for improving depth of field in photography could be applied to make a better contact lens.

We're not sure about the nexus between aviation and optics, but it's all science-y.

Dr Griffin and co mucked about with bench top designs, before a liaison with Taiwanese contact lens maker Pegavision Corp enabled full-scale production.

Two funds, MB Venture Partners and Charter Life Sciences came on as strong pre-initial public offer supporters.

Visioneering listed on the ASX on March 27, 2017, after raising \$33 million in an oversubscribed offer at 42 cents per security.

Visioneering's contacts are approved for sale in the US and are being sold there. The company earlier this year also won local and European assent for childhood myopia.

The company estimates the size of the US market at \$US3.4 billion for presbyopia and \$US2 billion for paediatric myopia.

About the lens

Visioneering's focal point is that the current multifocal lenses on the market are made of three layers that don't interact well with each other. This means that there's always a degree of compromise between the near and distant vision components.

It's like buying those \$10 specs from the chemist on the basis they work well enough - and perhaps they do.

But the pinhole principle means that the Naturalvue lenses are simpler. By inducing a 'virtual pinhole', the lenses enable the eye to deliver the brain clear vision of near, intermediate and distant objects, "all without employing complex zones of near and distance powers".

With a normal multifocal, there are dozens of permutations of lens strength because both the near-distance and long-distance layers vary according to the prescription. This makes fitting the lens a "frustrating and time-consuming experience" for patient and eye care professional alike.

The Naturalvue lenses are much simpler.

In June, Visioneering released two extension lines: traditional spherical contacts and MF contacts in a greater range of strengths.

The company is due to launch lenses for astigmatism in 2018 and for astigmatism with presbyopia, Naturalvue Toric and MF (multifocal) Toric, in the first half of 2019.

Toric lenses have two different curves instead of one and correct both astigmatism and short or long-sightedness. Astigmatism is a defect in the eye which results in distorted images.

Path to market

Visioneering has changed it distribution approach from selling directly to eye care professionals to deploying "fulfilment partners".

The fulfilment partner (a glorified logistics company) handles shipping, returns and credit risk - anything but selling the product.

By piggybacking on deliveries for other optical providers such as industry leader ABB, Visioneering reduced the cost of sending out a consignment of lenses to opticians from \$US15-20 to around \$US6.

The other benefit is that practitioners are highly likely to use only one fulfilment provider, so not being in their delivery truck will put accounts off limit.

One Visioneering multifocal lens sells for \$US1.05 to \$US1.20, bearing in mind that most users have a different prescription for each eye. "They are pitched at the same price as other multi focal lenses," CEO Dr Stephen Snowdy says.

"We don't want to give any optometrist a reason not to use us."

Multifocals are more expensive than standard lenses because of the special design that helps both (myopia and presbyopia) patient populations.

Dr Snowdy says the company didn't move to the fulfilment model because of poor initial sales.

"It's just the opposite," he says. "We were too small when we got started but once sales got bigger they said we would take us on."

Visioneering also supplies standard spherical (non- multifocal) lenses. "We are paying for the sales reps anyway so might as well throw as much in their bags as possible," Dr Snowdy says.

Indeed!

Financials and performance

Visioneering's sales have been gaining traction off a low base, with second (June) quarter revenues increasing by nine percent to \$US607,202 (\$US1.2 million for the first half).

In calendar 2017, the company lost \$US17 million on revenue of \$US1.049 million, so the trend is the company's friend.

Management's favorite measure is net revenue of goods actually shipped to the eye care professionals by the intermediaries. On this basis, revenue gained 40 percent to \$US683,218.

The company cites 1,149 active accounts, a 22 percent increase on the quarter.

Dr Snowdy says Visioneering's sales emphasis is shifting from growing current accounts, rather than deploying more sales staff to sniff out new ones.

The company is targeting \$US5,000 to \$US12,000 of revenue per mature optician account with peak maturity usually within two to four years.

On our sums, that equates to annual revenue of \$US5.7 million to \$US13.8 million.

Perhaps routinely, Visioneering's 2017 accounts said there was substantial doubt about Visioneering continuing as a going concern without raising more moolah.

Lo and behold, in mid-August the company said it had raked in \$8.9 million in a private placement to sophisticated and professional investors, at 18 cents a share.

The company is also undertaking a share purchase plan to raise a further \$3 million.

The funds will take Visioneering's cash balance to \$18 million, "which on current expectations provide the working capital to fund our growth for at least the next 12 months".

Visioneering had accrued \$US42 million of losses as of December 2017, so won't be bugged by the fiscal fiend in the foreseeable future.

Dr Boreham's diagnosis:

A keen licenced pilot, Dr Snowdy took his family up to 11,000 feet in a Mooney four-seater in the Georgian skies, to witness the "zone of totality" in the recent total eclipse.

Similarly, Dr Snowdy says the sky is the limit for Visioneering on market penetration. But we all know how commercial missteps (such as inappropriate pricing) can shade such ambitions.

"Things are growing very rapidly and we don't have to take much of the market to be a very large company," he says.

Visioneering's greater fortunes may lie in Asia, for the simple reason that 80 percent to 90 percent of the vast populace is inherently short-sighted.

Old timers will recall how the Western powers assumed the Japanese couldn't wage aerial warfare for this reason - a tragic underestimation.

Wisely, the company will tackle the key markets of Japan and China in partnership with someone who knows the regulatory wiles of these countries.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he is a man of vision who doesn't see the sector entirely through rose-colored glasses.

RESONANCE HEALTH

Resonance says it has two clinical trial contracts worth \$US522,000 (\$A720,809) with pharmaceutical and therapeutic companies.

Resonance said the multi-year contracts for its Ferriscan and other products and services would be paid throughout the duration of the trials, with full payment subject to the completion of each trial.

The company said that the total amount of clinical trial work contracted in the 2018 calendar year was about \$US1,418,000, with Ferriscan and other services being used by seven pharmaceutical and therapeutic companies in a total of eight clinical trials. Resonance said it "continues to actively pursue additional clinical trial opportunities with pharmaceutical companies as the company looks to further utilise its capabilities to provide contract research organization services".

The company said it had submitted its application to the US Food and Drug Administration for its Ferrismart artificial intelligence tool for the quantification of liver iron concentration. Resonance was unchanged at 2.3 cents.

TELIX PHARMACEUTICALS

Telix says it will collaborate with the University of Melbourne and Peter MacCallum Cancer Centre on molecularly-targeted radiation for colorectal cancer.

Telix said the collaboration would investigate the use of targeted radio-pharmaceuticals or molecularly-targeted radiation to provide improved treatments for colorectal cancer. The company said the collaboration would be led by Prof Frederic Hollande and Prof Alexander Heriot and would explore the role of a tumor-associated antigen, carbonic anhydrase IX, in metastatic colorectal cancer.

Telix said that carbonic anhydrase IX could be used as a potential pathway for new and more targeted diagnostic and therapeutic applications of Telix's TLX250 girentuximab program, currently under development for renal cancer.

The company said that high expression of carbonic anhydrase IX (CAIX) in colorectal cancer tumors was "a prognostic indicator for poor outcomes for patients treated with the currently available therapies".

Telix research and development director Dr Michael Wheatcroft said TLX250 imaging and therapy had "potential in colorectal cancer where conventional radiation oncology strategies can be more limited, particularly for highly invasive disease".

"Using [positron emission tomography] to more accurately stage patients and then deliver molecularly-targeted radiation to very sensitive tissues could prove to be a better option for patients than external beam radiation," Dr Wheatcroft said.

Prof Heriot said that about 25 percent of colorectal cancer patients initially presented with metastatic disease and a further 25 percent would develop subsequent metastases after being originally treated for a local stage of the disease, and more than 80 percent of patients with metastatic disease had unresectable metastases with systemic chemotherapy insufficiently effective, resulting in a very poor survival outlook.

Prof Hollande said the pilot research project would "more precisely explore CAIX expression in patients with metastatic colorectal cancer by correlating

immunohistochemistry and RNA profiles of surgical resection specimens".

"This will enable us to understand how CAIX expression changes as a function of tumor growth, including through the study of organoids grown in the lab from actual patient metastasis samples," Prof Holland said.

Telix was up one cent or 1.2 percent to 83 cents.

SIENNA CANCER DIAGNOSTICS

Sienna says it has raised \$3.6 million through a rights issue offer at six cents a share, taking the total raised with a July placement to \$5.2 million.

In July, Sienna said it had raised \$1.6 million in a placement at six cents a share to Merchant Funds and Medical Developments and Polynovo chairman David Williams, and would offer a rights issue for a further \$3.6 million (BD: Jul 20, 2018).

Today, the company said the non-renounceable rights issue and shareholder top-up offer raised \$1.5 million from existing shareholders, and that the \$2.1 million shortfall would be placed to institutional and sophisticated investors, including Merchant Corporate Advisory and Mr Williams.

Sienna said that shareholders who applied for additional shares under its top-up offer would be allocated those shares to a cap of 100 percent of their rights entitlement offer, with excess shares to be refunded.

Sienna fell half a cent or 5.6 percent to 8.5 cents.

MAYNE PHARMA GROUP

Mayne says revenue for the 12 months to June 30, 2018 fell 7.4 percent to \$530,313,000, with last year's \$86,026,000 profit turned to a \$134,257,000 net loss after tax. Mayne said generics revenue fell eight percent to \$385.7 million, specialty brands lost 19 percent to \$177.4 million but its Suba-itraconazole for fungal infections continued to perform well, "capturing 34 percent volume share of the itraconazole market", with plans to sell the drug in six additional countries.

The company said expenditure on research and development was up \$9.2 million to \$45.3 million, with marketing and distribution expenses up \$11.7 million to \$61.0 million and impairments of \$184.4 million following a review of the company's intangible assets in the first half of the financial year.

Mayne said that net tangible assets per share rose 140 percent to 12 cents, with diluted earnings per share of 6.06 cents at June 30, 2017 was turned to a diluted loss per share of 9.16 cents for the year to June 30, 2018, with cash and cash equivalents of \$87,312,000 at June 30, 2018, compared to \$63,027,000 at June 30, 2017. Mayne was up six cents or 5.7 percent to \$1.11 with 66.7 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says that revenue for the year to June 30, 2017, was down 15.8 percent to \$8,644,345, with net loss after tax down 71.9 percent to \$4,953,396.

Mach7 said that the revenue was a combination of software licence fees, professional service fees, support maintenance fees, subscriptions and three-dimensional printed products, with the decrease attributable to a change in product mix sold, with one large services-based sales order recognized over time in 2018.

The company said that its net tangible asset backing per share decreased 33.3 percent to 2.0 cents, with diluted loss per share down 76.1 percent to 3.9 cents.

Mach7 said that it had cash and cash equivalents of \$2,504,587 at June 30, 2018 compared to \$2,684,225 at June 30, 2017.

Mach7 fell half a cent or 2.2 percent to 22 cents.

ALLEGRA ORTHOPAEDICS

Allegra says revenue for the year to June 30, 2018, fell 5.1 percent to \$4,690,342 with last year's \$501,048 profit turned to a \$604,144 net loss after tax.

Allegra said its orthopaedic goods division performed well but fell 5.9 percent to \$4,698,000, a figure higher than its total revenue, which included "other income". The company said that corporate and administration expenses increased eight percent to \$1,882,140 with research and development expenses up 37 percent to \$1,227,678. Allegra said the loss was due to investment in its innovation division, which was in line with expectations, although a final product was still "several years away".

Allegra said last year's 0.72 cents diluted earnings per share turned to a diluted loss per share of 0.64 cents, with net tangible assets per share up 19.0 percent to 6.27 cents, and \$1,614,937 in cash and cash equivalents compared to \$1,847,647 at June 30, 2017. Allegra was untraded at nine cents.

PROBIOTEC

Probiotec says it will sell its Gold Cross, David Craig and Skin Basics brands to the Singapore-based Inova Pharmaceuticals for \$13.5 million in cash.

Probiotec said the deal included all associated intellectual property and assets, which were subject to a distribution agreement with Inova's Sydney-based subsidiary that would be terminated upon completion of the transaction.

The company said the sale was expected to be completed by about September 30, 2018, subject to satisfaction of conditions and that it would continue to manufacture the products on an "exclusive, long term basis".

Probiotec managing-director Wes Stringer said that "the sale of the assets continues the company's objective of unlocking shareholder value and focusing on Probiotec's core manufacturing business".

The company said it would explore opportunities to unlock shareholder value and the board would consider appropriate capital management strategies for any surplus capital. Probiotec said it was advised by PWC Australia, formerly Pricewaterhousecoopers, and Arnold Bloch Leibler.

Probiotec was up five cents or 3.05 percent to \$1.69.

ITL HEALTH GROUP

ITL says its biomedical division has extended the contract for its Samplock blood sampling kit with an undisclosed "large US community blood-bank" by 12 months.

ITL said it biomedical division was a provider of specialty ancillary products for blood culture testing and that the Samplock kit was used to transfer platelet samples during bacterial detection testing.

ITL fell half a cent or 2.6 percent to 18.5 cents.

ADHERIUM

Adherium says it has expanded its deal with Vitalus Health to provide its Hailie inhaler sensor to patients with asthma and chronic obstructive pulmonary disease.

In May, Adherium said the Houston, Texas-based Vitalus would promote patient use of the Hailie sensor, then called the Smartinhaler (BD: May 1, 2018).

Today, the company said it had expanded the program but did not provide details. Adherium was up 0.1 cents or 1.25 percent to 8.1 cents.

IMPEDIMED

Impedimed has told the ASX that it became aware of its trial results at 10.13pm on the night of August 22, after its share price jumped 27.3 percent.

The company said it drafted, finalized and posted a media release before the market opened on August 23, 2018.

The ASX asked the company when it became aware of the information in the trial results but did not refer to the share price leap the day before.

According to ASX data provided by Commsec Iress, Impedimed's shares opened at 27.5 cents, climbing to 30 cents by 10.21am and fluctuating around 30 cents until 2.21pm, slowly climbing through the afternoon in a very large number of small trades and closing at 35 cents.

Yesterday, Impedimed was up a further 10 cents or 28.6 percent to 45 cents with 2.7 million shares traded.

In a separate announcement Impedimed said that the Prevent trial's principal investigator Dr Sheila Ridner had begun a series of presentations on the trial titled 'Removing the Mystery Around Bioimpedance - Moving Towards a New Standard of Care'.

The company said the purpose of the seminars was to present bio-impedance spectroscopy and the L-Dex technology as the new standard of care for cancer survivors at risk of developing lymphoedema in the US and Australia to encourage clinicians to adopt it as the standard of care in the early detection of lymphoedema.

Impedimed climbed a further three cents or 6.7 percent to 48 cents with 2.5 million shares traded.

MEDADVISOR

Mitsubishi UFJ Financial Group and Morgan Stanley say they have become substantial in Medadvisor with 66,155,142 shares, or 5.02 percent of the company.

The Tokyo, Japan-based Mitsubishi UFJ Financial and the New York and Sydney-based Morgan Stanley filed similar substantial shareholder announcements detailing a number of purchases between April 24 and August 21 2018, with the single largest purchase of 920,900 shares on June 28 for \$43,300, or 4.7 cents a share.

Medadvisor was unchanged at 4.4 cents with one million shares traded.

MMJ PHYTOTECH

MMJ says Erlyn Dale has resigned as joint company secretary, effective from August 25, 2018.

MMJ said chief financial officer Jim Hallam continued as the sole company secretary. MMJ was unchanged at 22.5 cents with 1.2 million shares traded.