



Biotech Daily

Thursday April 13, 2017

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.74 percent on Easter Thursday, April 13, 2017 with the ASX200 down 44.1 points to 5,889.9 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and one was untraded.

ITL was the best, up 2.5 cents or 5.4 percent to 48.5 cents with 53,777 shares traded.

Ellex and Oncosil climbed more than four percent; Compumedics and Neuren improved more than three percent; Pro Medicus rose 2.3 percent; Atcor, Bionomics, Clinuvel, Medical Developments, Opthea and Pharmaxis were up more than one percent; with Cochlear, CSL, Psivida, Starpharma and Viralytics up by less than one percent.

Benitec led the falls, down 1.5 cents or 7.7 percent to 18 cents with 98,380 shares traded.

Dimerix lost 6.25 percent; Orthocell fell 4.1 percent; Cellmid and Living Cell were down more than three percent; Actinogen, Resmed, Sirtex and Universal Biosensors shed more than two percent; Admedus, Airxpanders, Factor Therapeutics, Impedimed, Mesoblast, Nanosonics and Prana shed more than one percent; with Reva down 0.9 percent.

DR BOREHAM'S CRUCIBLE: LBT INNOVATIONS

By TIM BOREHAM

ASX code: LBT

Market cap: \$45 million; **Share price:** 32 cents; **Shares on issue:** 140m

Chief executive officer: Brent Barnes

Board: Robert Finder (chairman), Brent Barnes, Catherine Costello, Stephen Mathwin, Caroline Popper

Financials (December quarter 2016): revenue nil, cash \$5.28 million*, cash from operating activities \$800,000 (previously outflow of \$195,000); estimated current quarter cash outflows \$3,336,000.

*Includes \$3.54 million from two-tranche capital raising and Federal R&D Tax Incentive of \$1.1m. Further \$3.47 million from placement received in January

Shareholders: Biomérieux 7%, B Moran & Morcap 4.8%, Robert Finder 4.6%, Lusia Guthrie 3.2%

The path to market for device and diagnostics is mercifully shorter relative to drug development, as evidenced by the fine work at the likes of Nanosonics and Airxpanders.

"I like devices because they are a lot more predictable than drugs," says LBT chief Brent Barnes. "The challenge lies with the regulatory pathway and what product claims you want to make."

Having listed in mid-2006, LBT has been at it for some time but now looks to be gaining traction with its automated processing of microbiological samples (urine, poo, swabs and blood samples smeared on Petri dishes).

While the bigger commercial pathology labs process thousands of samples a day, plate streaking and diagnosis has remained a stubbornly manual activity.

LBT's first product Microstreak, was for automated streaking of the samples on the culture plates. The device was invented by the Adelaide-based company's scientific director John Glasson in 1979.

LBT licensed Microstreak to Biomérieux in 2007. But the Gallic diagnostics giant changed its mind and handed back the franchise in August 2015. The gall of them!

LBT has since changed focus and expanded its intellectual property to the reading of culture plates, with its automated plate assessment systems (APAS).

This is by way of a 50-50 joint venture with the Zurich based Hettich AG, called Clever Culture Systems, with former LBT chief executive officer Lusia Guthrie, the chair of Clever Culture.

APAS is being used in two iterations: the most advanced to commercialization is APAS Independence, which handles, reads and interprets up to 200 plates per hour (everything after the streaking and incubation).

In contrast, a toiling lab technician will do 40 to 60 plates an hour (depending on the type of sample).

The second device in development, APAS Incubot, also automates the incubation process.

While more efficacy data is pending, clinical results to date confirm APAS can identify pathogens with more accuracy than a human.

These results relate to the accurate diagnosis of 10,000 urine samples at the pathology arm of Sydney's St Vincent's Hospital, which is no wee feat.

As a case study of the rise of the machines, this is a classic. Reassuringly for the last Luddites of the medical profession, the human hand and eye is still involved in testing the identified pathogen to determine the best drug and dose.

First to market is APAS Independence, which has FDA regulatory approval.

Having been showcased in Melbourne last March, a working APAS Independence device is due to be unveiled at the European Congress of Clinical Microbiology and Infectious Diseases in Vienna, later this month.

The machines sell for around \$US300,000 up front, with "material" annual licencing fees for the software as well as service and spare parts revenue.

The joint venture will sell through a global distributor or regional intermediaries, with these arrangement expected to be settled later this year.

"Now we have a working demo model we believe all of these options might be possible," Mr Barnes says.

LBT expects to ship its first batch of APAS Independence units "to fulfil open orders by global alliance and distribution partners" by the end of 2017.

With Microstreak, bean counting firm Deloitte is leading a process to sell or licence the rights, with an outcome expected by October 2017.

Mr Barnes admits it's a "tough sell" because the devices remain Biomérieux branded (as Previ Isola) and the buyer would need to invest further to develop the intellectual property.

But Microstreak more than wiped its face, generating handy upfront and milestone payments from Biomérieux, culminating in a \$7.9 million "divorce settlement" recognized in LBT's December 2015 half-year accounts.

LBT has also opened a third product front with a hand-held device called Woundvue, which helps doctors and nurses record the progress of long term chronic wound sufferers.

LBT cites “significant interest in the US where we have undertaken encouraging baseline studies among wound care practitioners”.

Woundvue was cleared by the FDA in October under the 510(k) protocols in a de novo (new device) process. But it’s very much a work in progress.

Intrigue on the register:

A talking point at LBT’s Adelaide HQ is that Biomérieux remains its biggest shareholder, even though there is no longer any strategic reason to be on the register. In the LBT camp, it’s a case of ‘je ne sais rien’ (I know nothing) when it comes to the intentions of Biomérieux, but let’s assume a sell-down in the near future.

LBT is well cashed up after a \$7 million placement in two tranches, one of which required shareholder approval.

LBT shares have given investors a wild ride, streaking to \$1.09 in October on news of the tie up with Hettich.

By March, the shares had sunk to 26 cents. The placement was done at 31 cents, with attached options (on a one-for-two basis) exercisable at 44.25 cents by December 2018.

Dr Boreham’s diagnosis:

Your humble (faux) practitioner is wary of biotechs that portray the partnering process as a parade in which the company rates a conga line of beauties.

Desperate and dateless is the more usual scenario.

But in this case maybe LBT really is the belle of the ball as it is not after an injection of funds.

“We don’t need to be pushed around by people giving us money to get the distribution deal done,” Mr Barnes says.

Mr Barnes says potential partners are waiting to see APAS Independence in action, which makes the show-and-tell in Vienna (and a subsequent microbiologists’ confab in New Orleans in June) more than just romps among the alps and the levees.

Viewed under the microscope, LBT is teeming with promise.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His understanding of culture does not extend beyond a tub of probiotic yoghurt.

VISIONEERING TECHNOLOGIES

The Alpharetta, Georgia Visioneering has raised \$33,333,333 to list on the ASX to further the design, sale and distribute its US-approved Naturalvue contact lenses.

Visioneering said that through the initial public offer it issued 79,365,079 Chess depository interests (CDIs) at 42 cents each and had 118,996,552 class A US shares with each US share equivalent to one CDI, giving a total number of shares or CDIs on offer of 198,361,631 shares or CDIs.

The company listed on the ASX under the code VTI on March 28, 2017, opening at 45 cents, climbing to 46 cents and closing at 44.5 cents with 1.6 million shares traded.

Visioneering chairman Fred Schwarzer said that the Naturalvue multifocal one day Naturalvue MF) contact lens had “substantial performance improvements and superior patient outcomes for patients with presbyopia [age-related long-sightedness and was] excited by the early levels of adoption of Naturalvue MF contact lenses by eye care practitioners treating children with myopia [short sightedness] another large and important patient population”.

Mr Schwarzer said that Naturalvue contact lenses were cleared by the US Food and Drug Administration in 2014 and an initial pilot US launch began in 2015.

“For presbyopia, clinical trials have shown that Naturalvue MF contact lenses are strongly preferred to other widely used presbyopia solutions, providing superior near, intermediate and distant vision as compared to currently marketed contact lenses, while being much easier to fit by eye care professionals,” Mr Schwarzer said.

“For paediatric myopia, clinical trials in children have found that Naturalvue MF contact lenses correct vision and address the generally recognised optical risk factors thought to lead to the worsening of myopia in children over time,” Mr Schwarzer said.

The company said it had commercial scale manufacturing, warehousing and fulfilment arrangements in place which positioned it “to drive a broader commercial roll-out of its Naturalvue MF contact lenses across the US”.

Visioneering said that over time it planned to enter non-US markets.

The prospectus named Dr Stephen Snowdy as chief executive officer, with non-executive directors including the US-based Gary Stevenson and Christine Van Heek with Australia based Zita Peach, who was also a director of Starpharma, Monash IVF Group and Airxpanders.

The prospectus said Dr Sally Dillehay was its chief medical officer, Rosa Lee was the manufacturing and engineering executive director, with Judith Vitale the chief financial officer.

In substantial shareholder notices the major shareholders included the Mountainview, California-based Charter Life Sciences II, Charter Life Sciences (Ohio) II and CLS II Annex Fund hold, (25.67%) Sydney’s Regal Funds Management (9.80%) Memphis Biomed Ventures II (7.58%), and the Sydney-based Renaissance Smaller Companies Pty Ltd (6.22%).

Today, Visioneering fell one cent or 2.4 percent to 40 cents.

PRIMA BIOMED

Prima says it has received \$492,144, from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Prima said the rebate related to research and development expenditure for the year to June 30, 2016, mainly related to its ‘Two active immune-therapeutics in melanoma’ or ‘Tactimel’ phase I study of IMP321 for melanoma.

Prima was unchanged at 3.1 cents.

UNILIFE CORP

Unilife has requested a voluntary suspension following the filing of an application for relief under Chapter 11 of the US Bankruptcy Code.

Unilife said the application was filed to the US Bankruptcy Court for the District of Delaware and had begun proceedings “to restructure its balance sheet or to sell its assets as a going concern in order to better position the business for the future” and to facilitate the restructuring or sale, it had filed voluntary petitions under chapter 11 of the US Bankruptcy Code.

Last week, Unilife said it did not have “sufficient liquidity to fund ... operations past the week ending April 7, 2017” and was faced with sacking staff and closing its facilities, because at March 31, 2017 its unaudited cash balance was about \$US6.3 million (\$A8.3 million), including \$US2.4 million of restricted cash, but by April 7 it would fall “below the minimum cash and restricted cash balance requirements of \$US5.1 million under its debt facilities” (BD: Apr 5, 2016).

In 2016, Unilife said it had a strategic collaboration with Amgen for its wearable injectable drug delivery systems worth up to \$US75 million and Amgen had purchased a \$US30 million “senior secured convertible note” with an option for a further \$US25 million in convertible notes over the next two years (BD: Feb 23, 2016).

Unilife last traded at 0.5 cents having traded as high as \$1.78 on February 15, 2010 and as low as 0.3 cents on April 3, 2017.

REPRODUCTIVE HEALTH SCIENCE

Reproductive Health says that a University of Ghent, Belgium study of single-cell, whole genome amplification kits confirms that its “Doplify is world leading”.

Reproductive Health said the study results were presented at the Needham, Massachusetts-based Cambridge Healthtech Institute’s molecular diagnostics meeting in Lisbon, Portugal April 10 to 13, 2017.

The company said that in the “independent benchmarking comparison against three other modern single-cell [whole genome amplification] kits, Doplify excelled with 100 percent accuracy, sensitivity and specificity, for the detection of deletions and duplications from whole chromosomes down to 5Mb, matched only by Rubicon’s Picoplex DNA-seq”.

Reproductive Health said the level of resolution was “important for pre-implantation screening and circulating tumour cell applications” and Rubicon was acquired in December 2016 by Takara Bio for [about] \$US75 million”.

The company said that while the Ghent study rated its Doplify equivalent to Picoplex DNA-seq, it was “strongly of the view that the ease of use, robustness and flexibility of Doplify make it a superior product”.

Reproductive Health said it intended to change its name which would be an agenda item at the May 26, 2017 annual general meeting.

Reproductive Health jumped 19.5 cents or 260 percent to 27 cents with 16.8 million shares traded.

According to ASX Commsec data, Reproductive Health has 79,206,198 shares on issue.

BIOXYNE

Bioxyne has requested a trading halt pending “an announcement to the market in relation to an acquisition and capital raising”.

Trading will resume on April 19, 2017 or on an earlier announcement.

Bioxyne last traded at 2.3 cents.

[POLYNOVO](#)

Polynovo says it will release 4,185,095 shares from voluntary escrow on April 15, 2017. Polynovo said that following the release there would be 559,163,915 shares available for trading, with a further 3,368,200 shares in voluntary escrow until October 4, 2017 and 516,895 in voluntary escrow until December 26, 2017. Polynovo was unchanged at 25.5 cents.

[CRESO PHARMA](#)

The Kuala Lumpur, Malaysia-based Mohd Razali Abdul Rahman says he has become substantial in Creso with 7,000,000 shares or 8.06 percent. The initial substantial holder notice said Mr Abdul Rahman bought the shares on March 31 and April 12, 2017 for \$4,820,000 or 68.9 cents a share. Creso fell six cents or 8.05 percent to 68.5 cents with 2.9 million shares traded.