Biotech Daily

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Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market recovered 0.19 percent on Friday June 16, 2017 with the ASX200 up 10.8 points to 5,774.0 points. Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, 13 traded unchanged and one was untraded.

Polynovo was the best, up two cents or 10.5 percent to 21 cents with 346,785 shares traded. Factor Therapeutics climbed 6.35 percent; Cyclopharm and Nanosonics improved more than five percent; Sirtex was up 4.2 percent; Acrux, Impedimed, Starpharma and Uscom rose more than two percent; Orthocell and Pharmaxis were up more than one percent; with Airxpanders and Resmed up by less than one percent.

Benitec led the falls, down 1.5 cents or 10.7 percent to 12.5 cents with 358,117 shares traded. Prana lost six percent; Avita and Viralytics fell more than four percent; ITL and Prima were down more than three percent; Compumedics and Mesoblast shed more than two percent; Actinogen, Bionomics, Clinuvel, Medical Developments and Osprey were down more than one percent; with Cochlear, CSL and Ellex down less than one percent.

DR BOREHAM'S CRUCIBLE: GENETIC TECHNOLOGIES

By TIM BOREHAM

ASX Code: GTG; **Nasdaq Code:** GENE

Market cap: $19.5 million; **Share price:** 0.8 cents; **Shares on offer:** 2,435,282,724

Chief executive officer: Eutillio Buccilli

Board: Dr Malcolm Brandon (chairman), Eutillio Buccilli, Dr Paul Kasian, Grahame Leonard, Dr Lindsay Wakefield

Financials (March quarter): revenue of $195,000 (compared with $184,000 in December quarter), cash burn $1,576,000 ($1,720,000); estimated current-quarter cash burn $2,779,000, cash on hand $12.4 million

Major shareholders (as of 2016 annual report): National Nominees 75%*****, Kentgrove Capital 1.6%, Security and Equity Trustees (0.88%).

***** The National Nominees holding covers the US investors, including Saby Management (6.59%) and CVI Investments/ Height Capital (5.7%).

There's a notable absence on the breast cancer testing outfit's list of key management personnel: British racing driver and breast cancer crusader Pippa Mann.

Peppy Pippa, the company's ambassador, is mentioned in almost every media release and on the company's acknowledgement is the "cornerstone" to its marketing efforts.

So much so that GTG's next generation product, Brevagenplus, was launched at this year's Indianapolis 500 race, in which Pippa competed for the fifth time in her Dale Coyne Racing Honda. She didn't win, but did set a women's record in qualifying laps of a sizzling 230 miles per hour (370kph).

So come on guys, give her a non-executive directorship, at least.

After a tortured recent history – and we'll come to that later – Genetic Technologies' streamlined hopes lie with Brevagenplus, a simple non-invasive predictive test for non-inherited breast cancer.

The test supersedes Brevagen, which had the shortcoming of being applicable to white women and not Blacks and Hispanics. Given Genetic Technologies' target market is the US that removes about one-third of the target audience.

In the March quarter, Genetic Technologies received 162 samples, compared with 278 in the December quarter. But bear in mind Brevagenplus was only rolled-out in earnest in January this year.

Please, no reimbursement

While most companies crave reimbursement - funding eligibility from health insurers or governments - Genetic Technologies' official strategy is to revert to a private pay model.

The test sold for a list price of $US2,795 ($A3,770), but insurers were unwilling to stump up anything like that amount. As a result, patients were presented with surprise bills six to nine months after the event and became somewhat narky. In the company's words: "understandably, they become contentious and this was directed at their physicians".

The new test will be sold for $US349 ($A470). Despite the yawning discrepancy, the company says the price will be in line with what it previously received per test. As with booking a hotel room you never pay the rack rate, do you?

The benefit of not seeking reimbursement is that Genetic Technologies does not have to spend money on clinical trials aimed not at regulatory approval (which it has), but at convincing the insurers to stump up the dough. As a result, two questionnaire-based studies launched last year are being revaluated.

Colorectal expansion

While Brevagenplus is Genetic Technologies' revenue driver, the company has signed an exclusive global compact with the University of Melbourne to develop and commercialize a risk test for colorectal cancer (CRC).

Excluding skin cancer, CRC is the third most common cancer. While the five-year survival rate is an encouraging 92 percent, this plunges to 11 percent when the tumor has metastasized (spread to other organs).

Hence the need for an early risk-based test, which would be similar to the technology underlying Brevagenplus.

From chequered history to chequered flags

Until Pippa motored along, Genetic Technologies was in the headlines for the wrong reasons.

Should we mention founder Dr Mervyn Jacobson? We probably need to.

In November 2014 a Victorian Supreme Court jury found Dr Jacobson guilty of 35 counts of share manipulation, pertaining to trading activity in his GTG holding in 2006 (then 40 percent, now 0.33 percent). Dr Jacobson was sentenced to two years and eight months at Her Majesty's pleasure, with a minimum term of one year, and has since been released.

Then there was the patent litigation over 'ownership' of the mutant gene BRCA1, a leading cause of breast cancer. Myriad Genetics had licenced the patent to Genetic Technologies for use in Australia, but in a case brought on behalf of a Queensland pensioner, the High Court in 2015 ruled that a company could not lay claim to genetic information.

Earlier, Genetic Technologies came under fire for attempting to enforce its exclusive local rights to BRCA1 and BRCA2 screens, thus depriving public research organisations of free use. The company later backed down on its threat to charge royalties.

Operationally, GTG is now a much cleaner business. In November 2014 the company shed its “legacy” animal genomic testing arm to a division of Primary Health for $2 million.

A core activity of this profitable division was assessing the provenance of pooches, a service likely to strike fear into many a dodgy greyhound owner. Until then, the company had gone to the dogs in more ways than one.

Fear not the fiscal fiend

As mentioned, Genetic Technologies’ accumulated losses means it won’t be worrying about a tax bill in the near future. The company has $12 million cash, following an $8.1 million US placement, which saw 4.8 million American depositary shares issued at $US1.25 per ADS, equivalent to 720,000,000 Australian shares at 1.13 cents each.

GTG has a heady 2.4 billion shares on issue, a tell-tale legacy of raising funds at low valuations over the years. The company also has 53.8 million options on issue. Mr Buccilli, who joined the company in June 2014 and was promoted to chief executive officer in February 2015, accounts for 14.2 million of them, exercisable at any time to November 2020 at a strike price of two cents, subject to vesting conditions.

Dr Boreham’s diagnosis:

Can Pippa put the GT stripe back into GTG?

Mr Buccilli and his team (including Pippa) will need to put their feet on the earnings accelerator to realize any value for these securities.

After all, we’re talking about a company with accumulated losses of $109 million and which has chalked up a $42 million cumulative deficit over the last five years ($8.45 million in 2015-’16).

On current trends, the number of Brevagenplus tests carried out is nothing to get excited about, but we stress it’s early days and the target market is capacious.

Not for the first time, the Stating-The-Bleeding-Obvious-Award goes to the auditors: “The extent of any future losses and whether or not the company can generate profits in future years remains uncertain.”

To further state the bleedin’ obvious, the stock is cheap but probably cheap for a reason.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has never competed in the Indi 500 but as a young lad once got his Datsun 1200 to 120kph before the motor blew.

NANOSONICS

Nanosonics says it has signed a strategic relationship with the Tokyo-based Sakura Seiki Co for the distribution of the Trophon EPR ultrasound probe cleaner in Japan.
Nanosonics chief financial officer McGregor Grant told Biotech Daily that the company expected that the total installed base in Japan could be up to 10,000 units.
The company's most recent half-yearly statement said that 10,700 units were installed in the US, generating revenue of $33.9 million for the six months to December 31, 2016.
The company said that Sakura Seiki was "a highly respected brand … [and] a nationally recognized leader in the development, manufacture, sale, and service of washer and sterilizer devices for healthcare, industrial, pharmaceutical and food markets".
Nanosonics chief executive officer Michael Kavanagh said that entering Japan was "an important aspect of our ongoing strategic growth program and partnering with Japan's leading organisation in infection prevention provides Nanosonics a great opportunity to successfully introduce our Trophon technology into this important market".
"It is expected that guidelines in Japan will be reviewed in light of changing global trends in ultrasound probe decontamination and Sakura Seiki is well positioned to participate in and help shape new practices due to their expertise in this area," Mr Kavanagh said.
Nanosonics said that local clinical studies were planned to support the establishment of Japanese specific guidelines on ultrasound probe decontamination and the company would dedicate Japanese staff to support Sakura Seiki with clinical and marketing initiatives over the next six months.
Nanosonics climbed 14 cents or 5.5 percent to $2.68 with 2.98 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says its phase IIa allergic rhinitis trial did not meet its primary endpoints of total nasal symptom score and peak nasal respiratory flow, blaming the formulation.
Paradigm chief executive officer Paul Rennie said that "early indications suggest that the formulation used in the allergic rhinitis clinical trial may need to be optimized".
The company said it was verbally informed by its contract research organization of the top-line outcomes of 80-patient, Swedish, phase IIa trial of Rhinosul for allergic rhinitis, or hay fever, investigated the intra-nasal effect of pentosan polysulfate sodium (PPS) on post-challenge nasal symptoms using the allergen challenge model in subjects with seasonal allergic rhinitis (BD: Nov 22, 2016; Mar 23, May 17, 2017).
"Whilst this is an unexpected outcome, it should be noted that Paradigm conducted the phase IIa clinical trial to the highest possible quality standards and was professionally executed on budget and on time," Mr Rennie said.
"As part of the protocol, extensive clinical and laboratory data was collected and the analysis of this data will provide valuable insights into the effects of PPS and guide our future directions," Mr Rennie said.
"In the coming weeks, Paradigm will receive the final report and the drug master file, allowing for an independent expert to conduct an in-depth investigation, in order to determine the next steps for our allergic rhinitis program," Mr Rennie said.
Paradigm said that its other PPS programs would proceed as planned investigating the compound for bone marrow lesions and viral arthritis following alpha virus infection.
The company said that the injectable form of the drug had been used for more than 60 years and its safety and efficacy had been established.
Paradigm lost 35.5 cents or 50.7 percent to 34.5 cents with 2.6 million shares traded.

REDHILL BIOPHARMA

Redhill says its 321-patient phase III trial of Bekinda, or RHB-102, for acute gastroenteritis and gastritis met its primary efficacy endpoint, is safe and well tolerated.

Redhill said that the randomized, double-blind, placebo-controlled phase III Guard study evaluated Bekinda 24mg in adults and children over the age of 12 years at 21 clinical sites in the US, with patients randomized in a 60 to 40 ratio to receive either Bekinda or placebo, respectively.

The company said that the primary endpoint was the proportion of patients without further vomiting, without rescue medication and who were not given intravenous hydration from 30 minutes post first dose of the study drug until 24 hours post dose, compared to placebo.

New York-based Northwell Health emergency medicine specialist and lead investigator Dr Robert Silverman said that “the positive results of the phase III Guard study demonstrate that Bekinda 24mg is beneficial in the treatment of acute gastroenteritis and gastritis and can provide patients with 24 hours of relief”.

“Gastroenteritis is a very common illness in the US, with approximately 179 million cases annually,” Dr Silverman said.

“If approved by FDA, Bekinda may become the new standard of care helping us treat patients quickly and effectively in both the emergency and outpatient settings,” Dr Silverman said.

Redhill medical director Dr Terry Plasse said that “when looking at results by initial severity of nausea, we see a treatment effect even in patients with very severe nausea at baseline, suggesting that the drug works regardless of the initial severity of gastroenteritis”.

“We continue to analyze the data, with the final clinical study report expected … [by October] 2017,” Dr Plasse said.

‘We look forward to presenting the data to the FDA and discussing the potential path for marketing approval of Bekinda 24mg in the US and whether additional clinical studies are required prior to NDA filing,” Dr Plasse said.

“We are also expecting top-line phase II results from the clinical study of Bekinda 12mg in diarrhoea-predominant irritable bowel syndrome in September 2017,” Dr Plasse said.

Separately, Redhill said it had begun its 444-patient, confirmatory phase III study of RHB-105 for Helicobacter pylori infection, called the Eradicate Hp 2 study.

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

Last year, Israel’s Redhill said a 118-patient, phase III trial of RHB-105 showed safety and superior efficacy for Helicobacter pylori infection over the standard-of-care, meeting its primary endpoint of superiority over standard-of-care eradication rates of 70 percent ($p < 0.001$) and achieving 89.4 percent efficacy in eradicating Helicobacter pylori infection in patients who received at least one dose (BD: Mar 31, 2016).

Today, Redhill said that RHB-105 had been branded as Talicia and was a fixed-dose, oral combination therapy of two antibiotics and a proton pump inhibitor in an all-in-one oral capsule for the eradication of Helicobacter pylori infection.

The company said that subject to a successful outcome and any additional regulatory feedback, the confirmatory phase III study was expected to complete the package required for a potential US new drug application.

Redhill said that the 2015 market potential for Helicobacter pylori eradication was about $US6.3 billion.

On the Nasdaq, Redhill fell 18 US cents or 1.93 percent to $US9.14 ($A12.05) with 157,210 shares traded.

GORDAGEN PHARMACEUTICALS, MONASH UNIVERSITY

Gordagen says it has an option agreement with Melbourne's Monash University to licence "a new drug delivery technology" for use with its vitamin E tocotrienols.

Gordagen said that the technology had "the potential to improve the bio-availability of the tocotrienols that form the basis of [its] prescription medicines portfolio".

Gordagen chief executive officer Dr Glenn Tong told Biotech Daily that the technology was "an oral pro-drug that avoids digestion in the gut and metabolism in the liver".

Dr Tong said that vitamin E was composed of tocotrienols and tocopherols and by removing the tocopherols and administering the tocotrienols sub-lingually, or below the tongue, the company had seen increased pharmacokinetic activity, tocotrienols had shown potential against cancer, inflammatory disease, hypertension and diabetes, but further trials were required, initially for over-the-counter supplements, while identifying compounds for potential regulatory-directed trials (BD: May 29, 2015).

The company said that the new drug delivery technology was developed by researchers at the Monash Institute for Pharmaceutical Sciences (MIPS), with Federal Government funding to MIPS director Dr Chris Porter and his team for a number of tocotrienol-pro-drug analogues to be synthesized and characterized.

Gordagen said that the MIPS team conducted rat studies using the tocotrienol-pro-drug derivatives and blood samples were prepared for further analysis to provide data on bioavailability and pharmacokinetics.

"Completing the next phase of proof-of-concept studies in animals is a very high priority for Gordagen as this will further inform our strategy for the development and commercialization of tocotrienol-prodrugs based on this exciting drug delivery technology platform developed at Monash," Dr Tong said.

Gordagen said it was conducting a capital raising to support its programs.

Gordagen is a private company.

GI DYNAMICS

GI Dynamics says it has a $US5,000,000 ($A6,595,767) convertible note financing with major shareholder Crystal Amber Fund for working capital for 2017.

In its most recent substantial shareholder notice the Saint Peter Port, Guernsey-based Crystal Amber said it held 41.84 percent of GI Dynamics (BD: May 18, 2107).

Today, GI Dynamics said that subject to shareholder approval the principal was convertible into Chess depositary interests (CDIs) at the option of the lender and based on a 5-day volume-weighted average price or automatically on a "qualified financing" of a further equity raising of at least $US10 million ($A13.2 million).

The company said that the loan would carry a compound interest rate of five percent per year but without shareholder approval the loan would not be convertible into CDIs.

GI Dynamics said that repayment would be due by December 31, 2018 or if shareholder approval was not obtained then the earlier of December 31, 2018 and the date six months after the date shareholders withheld approval.

The company said it had been granted a waiver from ASX Listing Rule 10.1 to facilitate the security arrangements and it would need to raise additional capital by April 2018 to continue its current business objectives as planned, to continue to fund its operations, and to repay the note and discharge the security.

GI Dynamics said it was "evaluating a number of fundraising alternatives that could involve any combination of collaborative arrangements, strategic alliances and/or additional equity or debt financing".

GI Dynamics fell 0.1 cents or 1.8 percent to 5.5 cents.

RECCE, LIND PARTNERS

Recce says it has signed a $6.05 million, 24-month equity draw-down facility with the New York-based Lind Partners' Australian Special Opportunity Fund LP.
Recce said the facility would provide capital to take its Recce 327 synthetic antibiotic through its US Food and Drug Administration application and phase I clinical trials.
The company said that Lind would make an initial upfront investment of $300,000 through a $250,000 24-month interest-free unsecured convertible security with a face value of $300,000 and a $50,000 equity investment to be repaid in shares.
Recce said that, subject to condition, subsequent investments would be made in monthly equity tranches of $50,000 that could be increased up to $250,000 by mutual consent.
Recce was unchanged at 20 cents.

ANTISENSE THERAPEUTICS

Antisense says that a post hoc analysis of 2014 brain lesion data from its phase II the ATL1102 multiple sclerosis trial shows a reduction in nerve loss or permanent damage.
In 2008 Antisense said that with its then partner, Israel's Teva Pharmaceutical say that a 76 patient phase IIa trial of ATL1102 "significantly reduced disease activity in patients with relapsing-remitting multiple sclerosis" (BD: Jun 2008).
The company said the randomized, double-blind, placebo-controlled phase IIa study met its primary endpoint showing a significant reduction by 54.4 percent ($p = 0.01$) in the cumulative number of new active brain lesions in patients taking ATL1102 for eight weeks, compared to placebo, as measured by magnetic resonance images.
Teva later handed ATL1102 back to Antisense saying it would "no longer be in line with Teva's preferred product profile" (BD: Mar 24, 2010).
Today, Antisense said that the new analysis showed that ATL1102 significantly reduced the number of active lesions that converted to "black holes" or areas of axonal loss or permanent tissue damage.
The company said that the positive effect of ATL1102 on black holes suggested that along with its action in reducing the number of inflammatory lesions, ATL1102 might be potentially protect the axons in the lesion from degeneration.
Antisense said that ATL1102 was an antisense inhibitor of CD49d, a subunit of very late antigen 4 (VLA-4).
The company said the post hoc analysis of the magnetic resonance imaging data was conducted to assess the effect of ATL1102 on the conversion of the remaining active lesions to black holes and showed there was a significant reduction in active lesions at weeks 8 and 12 converting to black holes at week 16 in the ATL1102 treated patients (13.2%) compared to patients on placebo (27.6%), with the probability of converting to black holes in the placebo arm 2.51 times that of the treatment arm ($p = 0.0376$).
Antisense said a review of the data on the effect of registered multiple sclerosis treatments suggested that ATL1102's reduction of active lesions converting to black holes appeared relatively rapid, with eight weeks of dosing, and potent.
The company said that the post hoc analysis was conducted by the Amsterdam-based University Medical Centre's Dr Frederik Barkhof a co-author on 2014 publication.
Prof Barkhof said that assessing the effect of treatments to prevent lesions evolving into black holes was a relatively new manner to determine neuroprotection .
"Reducing black holes signifies preservation of brain tissue and the slowing of … disease progression," Dr Barkhof said.
Antisense said it had filed a provisional patent application incorporating the new data.
Antisense climbed 0.3 cents or 10 percent to 3.3 cents with 1.7 million shares traded.

NANOSONICS

JCP Investment Partners says it has increased its substantial shareholding in Nanosonics from 17,391,567 shares (5.84%) to 21,829,258 shares (7.33%).
In March, JCP said it had reduced its holding in Nanosonics from 24,829,090 shares (8.39%) to 17,391,567 shares (5.84%), with the single largest sale at $2.705 a share and other significant purchases and sales above $3.00 a share (BD: Mar 2, 2017).
Today, the Melbourne-based JCP said it bought and sold shares between February 28 and June 14, 2017 with the single largest purchase 3,100,000 shares for $7,804,086 or 2.52 a share.
JCP said its shares were held by National Nominees, HSBC Custody Nominees, BNP Paribas Nominees, JP Morgan Nominees and UBS Nominees.

NOVOGEN

Wednesday's edition reported that Michael Abolakian and Hishenk Pty Ltd became substantial shareholders in Novogen with 26,188,670 shares or 5.4 percent of the company.
The Artarmon, Sydney-based Mr Abolakian said he acquired the shares between March 3 and June 13 for $794,581 or 3.03 cents a share.
Yesterday, Mr Abolakian filed a replacement notice saying that between March 3 and June 13 he acquired 11,450,000 shares for $894,581 or 7.8 cents a share.
No sub-editors were hurt in making this clarification.
Novogen fell 0.3 cents or 5.6 percent to 5.1 cents.

SIRTEX MEDICAL

Sirtex says that chief executive officer Andrew McLean has been appointed as an executive director, effective from today June 16, 2017.
Sirtex chairman Richard Hill said that Mr McLean was appointed chief executive officer on May 24, 2017 and "in the short period of Andrew's tenure at Sirtex, he has demonstrated the senior leadership qualities that will make him a valuable contributor to the board's activities moving forward" [sic].
Sirtex climbed 53 cents or 4.2 percent to $13.03 with 1.9 million shares traded.