Biotech Daily

Friday August 25, 2017

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: NANOSONICS UP 14%, ACTINOGEN DOWN 6%**

*** DR BOREHAM'S CRUCIBLE: SIENNA CANCER DIAGNOSTICS**

*** BOEHRINGER PHASE II NASH TRIAL TRIGGERS PHARMAXIS $27m**

*** MESOBLAST $51m 1-FOR-12 RIGHTS OFFER, TRADING HALT**

*** ELLEX REVENUE DOWN 2% TO $72m, PROFIT TO $894k LOSS**

*** MAYNE REVENUE UP 114% TO $573m, PROFIT UP 137% TO $89m**

*** PROBIOTEC REVENUE DOWN 5% TO $63m, LOSS TO $4m PROFIT**

*** NANOSONICS, GE SIGN RESALE DEAL TO 2022**

*** ALLEGRA SHEEP TRIAL TAKES SR-HT–GAHNITE TO NECK SPINE CAGES**

*** GENETIC TECHNOLOGIES 'STRATEGIC REVIEW'**

*** CHINA, SINGAPORE PATENTS FOR VISIONEERING CONTACT LENSES**

*** CANN LICENCES CANNAKORP VAPORIZING SYSTEM, MARIJUANA PODS**

*** LBT APPOINTS RAY RIDGE CFO, DAN HILL TO CO SEC**

MARKET REPORT

The Australian stock market slipped 0.03 percent on Friday August 25, 2017 with the ASX200 down 1.6 points to 5,743.9 points. Ninetween of the Biotech Daily Top 40 stocks were up, 12 fell, six traded unchanged and three were untraded.

Yesterday's inexplicable worst on excellent results, Nanosonics, was today's best, up 31 cents or 14.2 percent to $2.50 with 5.4 million shares traded. Prima climbed 10 percent; Polynovo was up 8.1 percent; Compumedics climbed 6.3 percent; Clinuvel was up 5.6 percent; Airxpanders, Neuren, Pharmaxis and Psivida improved three percent or more; Admedus, Oncosil and Starpharma rose more than two percent; Impedimed, Osprey, Pro Medicus, Sirtex and Universal Biosensors were up more than one percent; with Cochlear, CSL and Medical Developments up by less than one percent.

Actinogen led the falls, down 0.3 cents or 6.1 percent to 4.6 cents with 312,501 shares traded. Uscom lost 5.9 percent; Benitec and Ellex fell more than four percent; Acrux, Atcor and Cyclopharm were down more than three percent; ITL shed 2.4 percent; with Avita, Factor Therapeutics, LBT and Opthea down more than one percent.

DR BOREHAM'S CRUCIBLE: SIENNA CANCER DIAGNOSTICS

By TIM BOREHAM

ASX Code: SDX

Share price: 15 cents

Shares on issue: 180,262,327

Market cap: $27.0 million

Chief executive officer: Matthew Hoskin

Board: Dr Geoffrey Cumming (chairman), Dr David Earp, Carl Stubbings, Dr John Chiplin

Financials (December half 2016): revenue $935,793, net profit $354,702

Major shareholders: David Neate 9.4 percent, Traoj Pty Ltd (Trent Barry) 7.7 percent, Geron Corp (San Francisco biotech) 7.68 percent, University of Texas 2.56 percent.

For investors adhering to the 'follow the money' dictum, the path to Sienna's recent initial public offer should have led to prosperity.

After all, it was a route followed by two monied investors in the guise of ex Macquarie Group chief Allan Moss and rag trader tycoon David Neate.

Instead, Sienna shares closed at 14c on the day – well shy of the 20 cent offer price – because parties in a pre-IPO offering saw the opportunity to take profits.

We have to say at the outset the reaction is not commensurate with the reasonable success of the IPO – $4.6 million of the targeted maximum of $6 million - or, more importantly, the enormous potential of Sienna's simple diagnosis tool for pathology labs.

We're sure the aforementioned monied gentlemen are in it for the long haul, but check the exits for any strands of fine Armani cotton thread nonetheless.

Sienna's test

In short, Sienna has developed an in-vitro test to detect the biomarker telomerase, which is prevalent in 85 percent of all epithelial (tissue-based) cancers.

In other words, most of them.

A biomarker is a natural occurring item (such as a molecule) that identifies the presence of a disease.

Sienna's product goes by the snappy moniker of Anti-hTERT antibody (SCD-A7), because it detects the suspect telomerase component h-TERT in abnormal cells.

(We hate to bat for the marketing industry, but spending a few bob on a branding agency wouldn't go astray).

Telomerase naturally occurs in white blood cells– so it's not much chop good for detecting leukaemia or brain cancers - and is a natural agent for cell repair.

The trouble is, it also the evil weapon cancer cells use to multiply. Telomerase repairs the telomere caps at the ends of chromosomes, but cancer cells use telomerase to replicate immortally.

The role of telomerase in cancer won Melbourne's Prof Elizabeth Blackburn a Nobel Prize in 2009.

Founded by medical entrepreneur David Lance in 2006 as Sienna Capital and looking for a biotech investment, Sienna cottoned on that there was no telomerase-based test. After three years of failed efforts, it cracked a test able to 'stain' the suspect cells that line the urinary tracts.

The test was advanced by former chief executive officer Dr Kerry Hegarty and later approved in the US, Europe and Australia.

Focus on bladder cancer

Sienna's initial commercial focus is on testing for bladder cancer with urine samples.

Currently, says CEO Matthew Hoskin, samples from patients presenting with cancer symptoms (such as blood in their urine) are tested for abnormal cells under a microscope.

"With all urine cytology tests up to 10 percent will be positive for an identifiable malignancy," he says.

"Our tests won't add much value for that 10 percent, but for the rest they do, because they are not definitive."

Bear in mind that up to a quarter of urine test results will be indeterminate.

In an ideal world of daisies and fluffy kittens, every relevant sample would be double-tested with Sienna's kit. But as Americans would attest, healthcare boils down to money and preferably someone else's.

In the US, Sienna is achieving an average reimbursement of $US108 ($A137) per test. This compares to the list price of around $US40, which means a decent margin for the path labs even taking sundry costs such as labor into account.

Sienna's target markets are both path labs and the doctors (typically oncologists) who order the tests.

While the path labs generally do tests as ordered by the docs, they have the discretion to do extra biomarker tests in the case of those indeterminate results. That makes the path labs a key target for Sienna's US distributor, Statlab Medical Products.

But insofar as the clinicians need to be comfortable prescribing the tests, the path labs' own extensive sales forces that target the docs are a friend of Sienna as well.

Sienna generates revenue because for two years before the product was approved it sold to Bostwick Laboratories for internal use.

"This was a busy private lab using the test every day and also receiving reimbursement ," Mr Hoskin says.

Dr Boreham's diagnosis:

On the raw economics, Statlab needs to penetrate 15 percent of the bladder cancer market for Sienna to become profitable.

"We obviously want more than 15 percent but won't kid ourselves we will get to 100 percent," Mr Hoskin says.

Indeed.

In the US 1.3 million to 1.6 million urine cytology tests are carried out every year, implying a market value of at least $US140 million annually. Globally, around 3.5 million such tests are undertaken and Sienna is on the hunt for distributors to cherry pick this vast market.

While Sienna's current FDA, EU and TGA approvals relate to bladder cancer and urine, management is working on developing protocols for other cancers (in other words, other bodily samples).

Another measure of Sienna's potential is that the overall US cancer diagnostics market is worth $US5.6 billion. On your columnist's metaphorical wee test, this one ain't just pissing into the wind.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort – nor an Armani suit.

PHARMAXIS

Pharmaxis says that Boehringer Ingelheim's 150 patient trial of BI 1467335 for non-alcoholic steato-hepatitis triggers an EUR18 million ($A26.9 million) milestone payment.
Pharmaxis said the first patient had been dosed in the Ingelheim, Germany-based Boehringer multi-centre, European and North American, double-blinded, randomized phase IIa trial of BI 1467335 for non-alcoholic fatty liver disease, formerly known as PXS-4728A, acquired from the company in 2015 (BD: Mar 12, 2015).
Pharmaxis chief financial officer David McGarvey told Biotech Daily that Boehringer was expected to pay an EUR10 million milestone for a second unnamed indication phase II trial expected to begin later this year.
The company said that PXS-4728A was an oral inhibitor of amine oxidase, copper containing 3 (AOC3) and worked by blocking leucocyte adhesion and tissue infiltration in inflammatory processes underlying non-alcoholic fatty liver disease.
Pharmaxis said non-alcoholic fatty liver disease was the most common liver disorder in Western industrialized nations and was highly prevalent in patients with type 2 diabetes.
The company said non-alcoholic steato-hepatitis (NASH) was a major cause of liver fibrosis and cirrhosis and was a high unmet medical need with no treatments available.
Pharmaxis said that in 2016 Boehringer obtained US fast track designation for the development of BI 1467335 in NASH and the primary objectives of the dose-escalation phase IIa trial were to establish proof of clinical principle, investigate suitable dosing, and to evaluate the safety of BI 1467335.
The company said that a subsequent phase IIb study would seek to confirm and extend the findings.
Pharmaxis chief executive officer Gary Phillips said the start of the trial was "excellent news and is very significant for Pharmaxis".
"It triggers the payment of an EUR18 million milestone … and opens the path to a total of EUR195 million in milestone payments as the drug progresses through development and approval for this indication," Mr Phillips said.
"The initiation of phase II trials in a second indication later this year by Boehringer Ingelheim can bring the total potential value of the partnership with Boehringer Ingelheim to EUR418.5 million plus sales milestones and high single digit earn-out payments on annual net sales," Mr Phillips said.
Pharmaxis was up one cent or 3.7 percent to 28 cents with 3.5 million shares traded.

MESOBLAST

Mesoblast says it is in a trading halt for a fully underwritten one-for-12 rights issue to raise $50.7 million at $1.40 a share.
Mesoblast said that the funds would cover the costs of its "tier 1" clinical programs, including cardiac and arthritis programs, along with manufacturing requirements expansion of our manufacturing capabilities and resources, general and administrative expenses, working capital and other general corporate purposes.
The company said that the record date would be August 29, the offer would open on September 1 and close on September 12, 2017, with retail investors able to apply for additional shares beyond their entitlement..
Mesoblast said the institutional entitlement offer would be conducted between August 25 and 28, 2017.
Mesoblast said that Bell Potter securities had underwritten the offer.
The company said it expected the trading halt to be lifted on August 29, 2017.
Mesoblast last traded at $1.61.

ELLEX MEDICAL LASERS

Ellex says revenue for the 12 months to June 30, 2017 fell 1.75 percent to $71,635,000 taking last year's $3,027,000 net profit after tax to an $894,000 loss.
Ellex said the results were "materially impacted" by expanding sales and marketing, with $2.5 million spent on promotion of its Itrack and 2RT laser systems.
The company said the Itrack was a minimally invasive glaucoma surgery device with the market expected to increase from $US200 million to $US1 billion by 2021, offering "a significant growth opportunity for our business".
Ellex said that net tangible asset backing per share was up 64.8 percent to 29.0, although last year Ellex reported net tangible asset backing per share of 25.0 cents.
The company said that last year's diluted earnings per share of 2.77 cents turned to a diluted loss of 0.76 cents per share and it had $9,244,000 in cash and equivalents at June 30, 2016 compared to $7,283,000for the previous corresponding period.
Ellex fell four cents or 4.1 percent to 93 cents.

MAYNE PHARMA GROUP

Mayne Pharma says that revenue for the 12 months to June 30, 2017 was up 114.2 percent to $572,595,000 with net profit after tax up 137.1 percent to $88,567,000.
Mayne said that in June 2016 it acquired 37 approved and five US Food and Drug Administration-filed products from Teva and Allergan with the deal transforming "the scope and breadth of the company's generic products division" and expected to take Mayne into the top 25 retail generic pharmaceutical companies in the United States.
The company said that in August 2016, it acquired a portfolio of on-market dermatology foam assets from Glaxosmithkline for $US50.1 million, including US rights to Fabior and Sorilux, Canadian rights to Luxiq and Olux-E and Mexican rights to betamethasone foam.
Mayne said that net tangible assets per share fell 16.7 percent to 5.0 cents, with diluted earnings per share up 31.2 percent to 6.06 cents and cash and cash equivalents of $63,027,000 at June 30, 2017, compared to $47,481,000 at June 30, 2016.
Mayne fell 3.5 cents or 4.9 percent to 67.5 cents with 27.0 million shares traded.

PROBIOTEC

Probiotec says that sales revenue for the year to June 30, 2017 was down 4.7 percent to $62,546,000 with net profit after tax down 43.6 percent to $2,264,162.
Probiotec said it would pay a fully-franked 1.5 cents a share dividend for shareholders at the record date of September 5, 2017.
The company said that sales revenue was below the prior period "predominantly as a result of sales growth from new contract manufacturing business being offset by the rationalization of a number of low-margin service lines within the contract manufacturing division … the removal of licence fees for the Impromy and declines in the group's Europe operations".
Probiotec said that operating margins had increase significantly and the strategy to remove low margin, capacity hungry volume left the group "well positioned to take advantage of the significant growth opportunities in the contract manufacturing space".
The company said it had "a clear focus on the core pillars of the business into the future, being contract manufacturing, branded pharmaceuticals and obesity and health.
The company said diluted earnings per share fell 43.4 percent to 4.3 cents and it had cash and cash equivalents of $321,624 at June 30, 2017 compared to $505,622 last year.
Probiotec was up two cents or four percent to 52 cents.

NANOSONICS

Nanosonics says it has a new three-year Trophon EPR reselling agreement with GE Healthcare which will come into effect at the end of the current agreement on July 1, 2019.
Nanosonics said the agreement provided the Chicago-based GE Healthcare “capital reseller” rights as part of its ultrasound program, providing GE customers access to its Trophon EPR ultrasound probe cleaning system in North America.
The company said it would “gain a material increase in both sales and margin on consumables in North America as of and beyond July 2019”.
Nanosonics said the risk of cross contamination with ultrasound procedures was leading to more international guidelines being implemented and the two companies had introduced a framework that would allow them to continually assess and implement international capital reseller opportunities as new markets develop.
Nanosonics chief executive officer Michael Kavanagh said that the three year deal was “a great testimony not only to the excellent value proposition of the technology but also the excellent support GE Healthcare has provided as a leader in ultrasound solutions over the last six years”.
“We very much welcome the opportunity to continue our relationship with GE beyond the existing agreement as we continue to further establish Trophon as standard-of-care not only in North America but across international markets,” Mr Kavanagh said.
Nanosonics climbed 31 cents or 14.2 percent to $2.50 with 5.4 million shares traded.

ALLEGRA ORTHOPAEDICS

Allegra says that 12 month data from an eight-sheep trial of Sr-HT–gahnite bone substitute shows bone in-growth and some complete defect bridging.
Allegra said that Sr-HT–gahnite was composed of strontium, hardystonite (a calcium-zinc-silicate) and gahnite,a zinc-aluminium-oxide (BD: Jun 8, Sep 20, 2016; Feb 10, 2017).
The company said the histology report indicated that all the samples containing the Sr-HT gahnite scaffolds showed bone in-growth through the scaffold and the bone formed was interconnected and integrated with remaining tibial bone.
Allegra said that bone structure was more mature near the defect edges indicating that bone formation was progressing from the defect edges, through the scaffold, toward the centre of the defect, and there was no evidence of inflammation or formation of fibrous tissue indicating good biocompatibility of the Sr-HT Gahnite.
Allegra said it would begin interbody cervical spinal cages as the initial product.
The company said the bone substitute had “the potential to be the world’s first fully synthetic spinal cage that can regenerate bone under spinal load … conditions and be completely absorbed, leaving the body free of foreign materials”.
Allegra said it was establishing a pilot manufacturing facility in Sydney, with capability to manufacture the three-dimensional printed spinal cages, which would allow it to develop and optimize the manufacturing process ahead of commercial volume manufacturing.
The company said it had engaged Melbourne’s Boron Molecular to produce large scale Sr-HT powder as the raw material to the finished product and was working with the University of Wollongong’s Australian National Fabrication Facility to optimize the design of a three dimensional printer suitable for the material.
Allegra chief executive officer Jenny Swain said the company was “extremely pleased with the progress of this unique technology and we are very focused on establishing our advanced manufacturing facility and getting the first product, the cervical spinal cage, to market as a custom device”.
Allegra was untraded at 12 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has initiated a strategic review and retained the Newport Beach California-based Roth Capital Partners as a financial advisor in the process.
Genetic Technologies said alternatives included a business combination or strategic merger, reverse merger, sale of the company or its assets, in-licencing assets, an acquisition, or other transactions to maximize near and long-term value for shareholders.
The company said it did not have a defined timeline for the review.
Genetic Technologies was unchanged at 0.7 cents with 2.8 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says that China has allowed a patent protecting its contact lens optical designs when used for myopia progression control.
Visioneering said that the patent, entitled 'Method of Treating Myopia Progressions' would provide protection until 2036 and had previously been allowed in Singapore, Taiwan and Australia, with patents pending in other territories.
The company said that Singapore recently allowed a patent entitled 'Induced Aperture Lens and Method' that would broadly protect the use of its multi-focal designs in any vision care application until 2036.
Visioneering said that patent was also pending in additional jurisdictions.
The company said that Asia was a large potential market, with about 90 percent of the youth in some Asian countries suffering from progressive myopia.
Visioneering chief executive officer Dr Stephen Snowdy said that "successful protection of our innovations through intellectual property is an important accelerant in our growth and creation of value".
"These patent allowances layer on top of the other patents in our extensive portfolio of intellectual properties, and have expiries that provide very long protection in key geographies," Dr Snowdy said.
Visioneering was untraded at 40 cents.

CANN GROUP

Cann says it has a licencing and distribution agreement with Cannakorp Inc to import and sell Cannakorp's proprietary vaporizing system and produce the device pods.
Cann said that the Boston Massachusetts-based Cannakorp was "simplifying and improving the inhalation process for medicinal cannabis patients".
The company said that Cannakorp had designed and developed vaporization technology, with a desktop vaporizer using single-use pods containing prepared ground cannabis.
Cann said its wholly-owned subsidiary Cannproducts was granted a licence to import and sell the system in Australia and New Zealand, as well as manufacturing rights which includes an initial nine month exclusive right following regulatory approvals.
The company said that sales would be subject to necessary regulatory approvals.
Cann chief executive officer Peter Crock said the agreement was "an important development".
Cann said the patent-pending vaporizing system had "a hygienic, one-way valve mouthpiece … detachable for convenient cleaning" with a microprocessor controlling the system for optimal performance including temperature, time and air pressure.
The company said that the pod system allowed doctors to prescribe appropriate strains of medicinal cannabis to suit patient requirements.
Cann was up 12 cents or 11.4 percent to $1.17.

LBT INNOVATIONS

LBT says it has appointed Ray Ridge as its chief financial officer effective from today.
LBT said Mr Ridge had been a consultant to the company since December 2016 and had worked closely with the previous chief financial officer Dan Hill as part of a transition, planned due to Mr Hill's increased commitments to other business interests.
The company said that Mr Hill would continue as company secretary.
LBT said that Mr Ridge had held senior management positions in finance, compliance and commerce across a range of industries and was currently chief financial officer and company secretary for Thor Mining PLC, RHS and chief financial officer for Southern Gold.
The company said that Mr Ridge was previously an executive with Parsons Brinckerhoff, Elders and Arthur Andersen.
LBT said that Mr held a Bachelor of Accounting and Finance from the University of South Australia.
LBT fell half a cent or 1.7 percent to 29.5 cents.