Biotech Daily

Friday November 10, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PSIVIDA UP 12%; LIVING CELL DOWN 81%**

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*** G MEDICAL: 'FIRST CHANNEL $527m TAIWAN, INDIA DISTRIBUTION DEAL'**

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*** ESENSE REQUESTS 'INVESTMENT, COLLABORATION' TRADING HALT**

*** JM FINANCIAL TAKES 8% OF MACH7**

MARKET REPORT

The Australian stock market fell 0.33 percent on Friday November 10, 2017 with the ASX200 down 20.0 points to 6,029.4 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and one was untraded.

Psivida was the best, up 19.5 cents or 12.4 percent to $1.765 with 29,792 shares traded. Clinuvel climbed 7.25 percent; Opthea and Volpara were up five percent or more; Avita and Compumedics improved more than four percent; Osprey was up 3.5 percent; Impedimed and ITL rose more than two percent; Polynovo and Reva were up more than one percent; with Nanosonics, Resmed and Sirtex up by less than one percent.

Living Cell led the falls, losing as much as 88.8 percent to 2.3 cents, before closing down 16.5 cents or 80.5 percent at four cents with 86.95 million shares traded. Genetic Signatures lost nine percent; Prima shed 6.9 percent; Prana was down 5.7 percent; Admedus and Neuren fell more than four percent; Dimerix, Mesoblast and Starpharma shed more than two percent; Actinogen, CSL, Ellex, LBT, Orthocell, Pharmaxis, Pro Medicus and Universal Biosensors were down more than one percent; with Airxpanders, Cochlear and Medical Developments down by less than one percent.

DR BOREHAM'S CRUCIBLE: NANOSONICS

By TIM BOREHAM

ASX code: NAN

Share price: $2.92; **Shares on issue:** 299,263,438; **Market cap:** $873.8 million

Chief executive officer: Michael Kavanagh

Board: Maurie Stang (chairman), Marie McDonald, Michael Kavanagh, Dr David Fisher, Richard England, Steven Sargent

Financials (2016-17 year): sales $67.5 million (up 58%), net profit $26.2 million (previously $100,000), earnings per share 8.79 cents (up 2200%), cash $63 million (up 29%)

Identifiable Holders: JCP Investment Partners 8.4%, Fidelity Management 7%, Maurie Stang 7.59%, Bernard Stang 6.3%, Steve Kritzler 2.85%.

The rise and rise of the Trophons sounds like something out of a Dr Who episode, but we're referring to the global adoption to date of Nanosonics' automated medical probe sterilizing units, the Trophon EPRs.

When opened, the wall-mounted units bear a passing resemblance to a urinal (or maybe that's just Crucible's lurid imagination).

The only resemblance to a Dalek is that all germs will be exterminated within seven minutes and at the press of a button.

One of Australia's greatest medical device success stories so far, Nanosonics has sold 14,100 units to date including 12,400 in the US. The company cites a global addressable market of 140,000 units, which means that Nanosonics is only 10.07 percent into its quest to make Trophon the bug-busting standard-of-care.

How they work

As with clothes pegs and Liquid Paper, simplicity is the key to the Trophon invention.

The probes are inserted into the 'urinal' and sprayed with biocidal micro droplets derived from canisters containing hydrogen peroxide.

No golden staph will live to tell the tale in this pissoir.

The process compares with the routine of taking the probes to a central facility and spraying and wiping them with a compote of toxic chemicals. They're so harmful that the room must be isolated and staff need to don hazardous clothing and even then, the part of the probe being held may not be sterilized.

In contrast, Trophons emit water and oxygen as a by-product - two elements the world could do more with, along with buttercups and daisies.

At the forefront of germ warfare

Driving the take-up of the Trophon are stricter hospital infection guidelines enforced by august bodies such as the World Federation of Ultrasound in Medicine and Biology.

Yes – there really is one.

Increasingly, those in-the-know are demanding high-level disinfection to apply to all semi-critical procedures, whether bodily insertion is involved or otherwise. This includes anything from organ and breast biopsies, tumor ablation, venous access and abscess and foreign body removal.

The company has screeds of clinical evidence, most recently pointing to a six-year Scottish study on the infection rate of patients after undergoing semi-invasive ultrasound procedures. The gist is that those subject to probes not treated with high-level disinfection were more likely to be prescribed antibiotics because of “positive microbiological reports”.

The moral of the story? What the Scots wear under their kilts is not as important as what’s put up ’em.

Razor blade model

Nanosonics sells the units outright to hospitals for about $10,000 each as a capital item, but over time the company expects to derive more revenue from a list of consumables and accessories that would make even Apple’s product folk blush.

These include the hydrogen peroxide canisters, probe covers, printers and printer rolls, log books, wall-mounted Trophon carts and the mounts to mount the Trophon carts.

In five years’ time, the company expects about 25 percent of revenue to derive from equipment sales, with 50 percent gleaned from consumables and a further 25 percent from servicing.

In the US, the Trophons are distributed directly by the company and by GE Healthcare. In August, Nanosonics and GE inked a new re-seller agreement for a further three years after the current compact expires on June 30, 2019.

“As a result of the new agreement Nanosonics will gain a material increase in both sales and margin on consumables in North America,” the company says.

In the UK, Nanosonics has rolled out a variant called the managed equipment service (MES) model, by which the company continues to own the equipment.

The hospital pays an all-inclusive price for use and servicing, which obviates the need for the cash-strapped healing institutions to buy the equipment as a capital item.

In June, Nanosonics also struck a deal with sterilization specialist Sakura Seiki to sell its Trophons in germ-phobic Japan, the world's second biggest healthcare market, with an addressable market of 2,000 units, subject to ongoing clinical trials.

Clean financials

From a standing start of nil a decade ago, Nanosonics turned over $67.5 million of revenue last year. Having recorded small losses between 2012-'13 and 2014-'15, Nanosonics struck a maiden $100,000 surplus in 2015-'16 and a healthy $26 million profit for 2016-'17.

At its recent AGM, Nanosonics top brass affirmed that current (first) half sales were likely to be similar to the second (June) half uptake, but also warned that uncertainties around the US health care reform process could delay capital purchases.

UK purchases are expected to grow by 75 to 100 percent, with 90 percent of orders subject to the MES model. Nanosonics is also about to enter the Middle Eastern market and commence pre-marketing in Japan.

Dr Boreham's diagnosis:

To the naysayers, Nanosonics' $800 million-plus market cap doesn't take into account the likelihood that the company has reaped the low-hanging fruit and that sales growth will slow.

Nanosonics stock has traded between 14 cents and $3.60 since listing in May 2007 at 50 cents apiece. At current levels, the shares are trading on an earnings-per-share multiple of 34 times, based on 2016-'17 earnings.

Expensive? Perhaps - but not for a growth stock in the healthcare sector.

Nanosonics' fan base points to the market being only 10 percent penetrated and the disinfection guidelines that will force many hospitals to adopt the Trophons.

Nanosonics expects to spend a hefty $14 million on research and development this year compared with $9.5 million last year, partly on product extensions in the sterilization sector.

In fact, management targets the launch of two new products over the next two years, "subject to expected regulatory approvals".

Management is mum about the target markets, but the products could prove bigger than the Trophons.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He does his bit for the sterilization cause by washing his hands before eating.

LIVING CELL TECHNOLOGIES

Living Cell tumbled as much as 88.8 percent to 2.3 cents on news there was no statistical significance for the efficacy of its NTCell treatment for Parkinson's disease.

Living Cell said that three of the four primary endpoints were met in its phase IIb trial, with no product or procedure adverse events and no evidence of xenogeneic infection in patients and their partners.

The company said that at 26 weeks post-implant, there was "not a statistically significant difference between the groups who received the encapsulated pig choroid plexus brain cell NTCell and the patients who had sham surgery, as measured by the change in the unified Parkinson's disease rating scale (UPDRS).

Living Cell said the study was designed to confirm the most effective dose of NTCell, define any placebo component of the response and identify the initial target Parkinson's disease patient sub-group.

The company said that the study consisted of three groups of six patients, with two patients from each group having sham surgery with no NTCell implanted, while the active cohorts received 40 microcapsules, 80 microcapsules and 120 microcapsules of NTCell implanted on each side of the brain.

Living Cell said that the trial protocol allowed for the controls to receive treatment but the data safety monitoring board had recommended that no treatment be given to the control patients.

Auckland City Hospital principal investigator Dr Barry Snow said "the next step is to analyse the data in depth and continue to monitor patients in accord with the study extension protocol, particularly for the efficacy movements at longer time points".

Living Cell chief executive officer Dr Ken Taylor said the study was "very good … from a safety viewpoint, we are disappointed that the efficacy primary endpoint has not been met".

"It is encouraging that some efficacy data is positive and that the treatment was well tolerated and safe," Dr Taylor said.

"More data analysis and input from our advisors is required but at this time we cannot proceed with a regulatory application," Dr Taylor said.

Dr Taylor told an investor conference call that the company would be holding a strategy meeting and its annual general meeting next week and would discuss future directions at that time.

Dr Taylor said that with $5 million in cash the company was in a good position to progress its pericytes and neuroscience assets (BD: Nov 7, 2017).

In 2013, Living Cell implanted four patients in a phase I/II trial of NTCell for Parkinson's disease, later reporting that at 42 weeks post-implant, NTCell "stopped the progression of Parkinson's disease" and was safe and effective at 58 weeks with all patients showing statistically significant improvement (BD: Sep 20, 2013; Oct 27, 2015; Jan 27, 2016).

The company began the 18-patient, phase IIb trial of NTCell in 2016 (BD: Mar 24, 2016).

Living Cell closed down 16.5 cents or 80.5 percent at four cents with 86.95 million shares traded.

INVITROCUE

Invitrocue says it has raised $1,132,400 through the placement of 14,155,000 shares at eight cents a share.

The company said the funds would be used for the development of its oncology patient-derived organoid (Onco-PDO) business and for working capital.

Invitrocue fell 0.4 cents or 4.65 percent to 8.2 cents.

G (GEVA) MEDICAL INNOVATIONS

G Medical says it has an agreement worth $US405 million ($A527.3 million) over three years with First Channel Ltd to distribute its products and services in India and Taiwan.
G Medical said that the British Virgin Islands-registered First Channel was a subsidiary of the Hong Kong-based Union Bridge Holdings and had agreed to purchase a minimum quantity of Prizma medical smartphone cases, which monitor medical vital signs, within the first year, with minimum total payments expected to be $US90 million.
The company said that First Channel was in discussion with partners including Vodafone India, Reliance Communications and BSNL Mobile with agreements to be finalized, providing additional support for the distribution and financial commitments to G Medical.
G Medical said that it had met the partners and was satisfied they intended to enter into definitive arrangements, but this had not been formalized and it could not provide expected revenues until the arrangements had been formalized.
The company said that once completed, a letter of credit would be exchanged with an Israel Government insurance company, to provide protection in the case of customer default, freezing of proceedings, creditor arrangements or appointment of liquidator.
G Medical said that First Channel had agreed to purchase and distribute the Prizma medical smartphone case through existing networks, infrastructure and customers in India and Taiwan and be responsible for marketing, product launch, commercialization and sales.
G Medical's chief executive officer Dr Yacov Geva said First Channel's "extensive reach and market know-how … [would] allow for true remote medical solutions offered to millions of patients and consumers in India and Taiwan".
G Medical was up 13.5 cents or 34.6 percent to 52.5 cents with 11.3 million shares traded.

REDHILL BIOPHARMA

Redhill Biopharma says it has completed enrolment of 331 patients in its phase III study of RHB-104, formerly Myoconda, for Crohn's disease.
In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
Redhill said the phase III, randomized, double-blinded and placebo-controlled study assessed the safety and efficacy of RHB-104 in patients with moderate to severe Crohn's disease, defined as patients measured by the Crohn's disease active index between 220 points and 450 points.
Redhill said the primary endpoint of the study was disease remission at week 26, with a Crohn's disease active index at or below 150, with top-line results to be released announced in mid-2018.
In August, Redhill said that safety and efficacy data from the first 222 patients was reviewed and the data safety monitoring board gave a unanimous recommendation to continue, but the company did not detail the interim results (BD: Aug 2, 2017).
The company said that a separate on-going, open-label, extension, phase III study was evaluating RHB-104 in patients with continued active Crohn's disease beyond the 26-week endpoint.
Redhill said worldwide sales of Crohn's disease therapies was more than $US7.6 billion in 2016.
The company said it would initiate a phase III study with RHB-104 for the treatment of non-tuberculous mycobacteria infections by July 2018.
On the Nasdaq, Redhill was up eight US cents or 1.52 percent to $US5.36 ($A6.98) with 382,676 shares traded, following a capital raise at $US5.50.

PHOSPHAGENICS

Phosphagenics says its partner Terumo is advancing the tocopheryl phosphate mixture (TPM) anaesthetic propofol injection to pre-clinical development.
Phosphagenics said that under the present agreement, Terumo was responsible for a set of agreed-upon rat studies to begin this year and extend into 2018, comparing the efficacy and safety of the candidate formulation with the current propofol formulation, Diprivan.
In 2016, Phosphagenics said it had an agreement with Terumo to develop a transparent formulation of propofol, using its TPM technology (BD: Jul 29, 2016).
The company said that it held the rights to Australia and New Zealand while Terumo held the rights for Japan.
Phosphagenics said that earlier this year it performed in-vitro assays of a propofol formulation which indicated the potential for a two-year shelf life and the formulation was compatible with “several common diluents used during the infusion process”.
The company said that with Terumo it had generated two patent applications for the use of TPM in a range of injectable formulations, and a joint TPM-propofol formulation.
Phosphagenics fell 0.1 cents or 6.25 percent to 1.5 cents.

PARADIGM

The Paradigm annual general meeting voted 20.5 percent against the issue of 210,000 loan shares at 62.9 cents each to director Paul Rennie.
Paradigm said that 1,582,516 proxy votes (20.5%) opposed Mr Rennie’s loan shares, with 6,065,831 proxy votes (78.7%) in favor and 0.8 percent at the proxy’s discretion.
The company said that all other resolutions, including the adoption of the remuneration report, re-election of director Chris Fullerton, approval of increased placement capacity and ratification of a prior issue were passed overwhelmingly.
The company’s most recent Appendix 3B new issue announcement said that Paradigm had 101,925,220 shares on issue, meaning that the 1,582,516 votes against Mr Rennie’s loan shares amounted to 1.6 percent of the company’s total shares on issue, which is not sufficient to requisition extraordinary general meetings.
The Corporations Act (Section 250U) provides for a ‘two strikes and re-election’ process if a company’s remuneration report is opposed by more than 25 percent of votes on two consecutive occasions, taking the company to a vote on a board spill motion.
Paradigm said that all resolutions were passed “on a show of hands” but did not disclose the number of votes available.
Paradigm was unchanged at 33.5 cents.

MMJ PHYTOTECH

MMJ has requested a trading halt “pending an announcement regarding a material investment and collaboration arrangement”.
Trading will resume on November 14, 2017 or on an earlier announcement.
MMJ last traded at 44.5 cents.

ESENSE TECHNOLOGIES

Esense has requested a trading halt pending an “investment and collaboration agreement”.
Trading will resume on November 14, 2017 or on an earlier announcement.
Esense last traded at 27 cents.

MACH7 TECHNOLOGIES

JM Financial Group says it has increased its substantial shareholding in Mach7 from 7,970,368 shares (6.74%) to 10,037,753 shares (8.49%).

The Melbourne-based JM Financial said it held the shares with No Plan B Pty Ltd, buying and selling shares between June 19 and September 29, 2017 with the largest purchase 1,557,520 shares for $233,628 or 15 cents a share.

Mach7 fell half a cent or 2.2 percent to 22.5 cents.