Biotech Daily

Friday May 12, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ONCOSIL UP 13%, DIMERIX DOWN 14%**

*** DR BOREHAM'S CRUCIBLE: GI DYNAMICS**

*** POLYNOVO, BETA TRIAL BTM PIG ISLETS FOR TYPE 1 DIABETES**

*** EURO PATENT FOR PRESCIENT PTX-200 FOR CANCER**

*** ONCOSIL EX-DIRECTOR MARTIN ROGERS EXERCISES 19m OPTIONS**

*** NEUROTECH CONFIRMS FDA MEETING FOR MENTE AUTISM**

*** BLACKROCK TAKES 6% OF COCHLEAR**

*** PETER REILLY, CHEVRON TAKE 9.5% OF SIMAVITA**

MARKET REPORT

The Australian stock market fell 0.7 percent on Friday May 12, 2017 with the ASX200 down 41.4 points to 5,836.9 points.

Nine of the Biotech Daily Top 40 stocks were up, 14 fell, 10 traded unchanged and six were untraded.

Oncosil was the best, up 1.5 cents or 13.0 percent to 13 cents, with 841,452 shares traded.

Polynovo climbed 4.55 percent; Cyclopharm and Starpharma rose more than two percent; Clinuvel, Mesoblast and Viralytics were up more than one percent; with Ellex and Reva up by less than one percent.

Yesterday's equal best, Dimerix, led the falls, down 0.1 cents or 14.3 percent to 0.6 cents with 1,715 shares traded, followed by Genetic Signatures down 9.1 percent to 40 cents with 155,000 shares traded.

Prima lost 6.25 percent; Factor Therapeutics fell 4.9 percent; Avita and Nanosonics were down more than three percent; Impedimed, Opthea, Orthocell and Psivida shed more than two percent; Actinogen, CSL, Pro Medicus and Sirtex were down more than one percent; with Cochlear, ITL, Medical Developments and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: GI DYNAMICS

By TIM BOREHAM

ASX Code: GID

Market cap: $36 million; **Share price:** 6.5 cents; **Shares on issue:** 558 million CDIs

President and chief executive officer: Scott Schorer

Board: Daniel Moore (chairman), Timothy Barberich, Scott Schorer, Graham Bradley, Michael Carusi, Anne Keating, Dr Oern Stuge

Financials (March 2017 quarter): revenue $US54,000, operating cash outflow $US2.96 million, cash on hand $US5.4 million, estimated current quarter cash burn $US3 million

Major shareholders: Crystal Amber Fund 40%, Medtronics 7%, Advanced Technology Ventures 5.8%, J&J Innovations 5%, Paul Cozzi 4.8%.

As Winston Churchill (sort of) said: "Never in the field of human endeavour has so much been lost by so few on one of the most promising medical device products."

The US annual filing of the Massachusetts-based GI Dynamics tells the story with the sort of bare honesty often lacking in local corporate disclosures: the company has accrued an accumulated deficit of $US248 million ($330 million) and has "incurred net losses in every year since inception".

While the Endobarrier weight-loss device has been approved in Europe and Australia since 2011 (as well as the Middle East and South America), the company has sold 3,500 units, generating underwhelming revenue of $US7.8 million.

GI Dynamics listed its Chess depository instruments (CDIs) here in September 2011, at $1.10 a piece in a $US72 million raising. Overall it has raised $US232 million in equity and has little to show for it, except for some handy tax losses.

The premise of the company's Endobarrier product is as reliable as a gaffe from a bored Prince Phillip at the opening of a Morris dancing festival: beating obesity and type two diabetes.

Usually attributed to lifestyle factors, the incidence of type 2 diabetes is swelling in the Western world, with about 55 percent of patients adequately treated with current drug regimens and little global data available on treatment – if any – of obesity.

Insulin medication leads to higher resistance to diabetes and just exacerbates the problem. Globally, 415 million adults have from diabetes, 90 percent with type 2 diabetes, which some call type 1 obesity or the world's largest preventable epidemic.

Diabetes, if anyone needs reminding, is a leading cause of cardiovascular disease, kidney failure, blindness and lower limb amputation.

Endobarrier is a sleeve that sits in the upper intestine, just below the stomach. It is inserted endoscopically in a 20-minute procedure, with no surgery required.

After 12 months it is similarly painless removed from the hopefully lighter patient.

Crucible's gut feeling would have thought the world's first endoscopically delivered device therapy would have been a no brainer, but it's been no tea party for the Boston boys.

In the US, Endobarrier has only investigational device exemption (IDE) status, which means it can be used for research.

In March last year, the company terminated its 500-patient US trial after 325 patients were enrolled, with the trial failing to meet its primary and secondary endpoints. The stock fell as much as 60 percent on the day.

Seven of the patients suffered liver abscesses; an affliction attributed to the use of proton pump inhibitor drugs. As chief executive officer Scott Schorer noted, the alternative therapies – notably gastric bypass surgery or insulin – aren't without risk either.

In October 2014 European authorities ordered the halt of shipments, pending a review of the company's "reporting and vigilance systems".

Locally the TGA approved Endobarrier in 2011. But last October the authority banished Endobarrier from the Australian Register of Therapeutic Goods, citing compliance issues.

Note though, that no recall was ordered in relation to current users and a local trial of Endobarrier on type two diabetes and non-alcoholic steatohepatitis (NASH) continues.

The company has also re-engaged with the FDA to "address difficult legacy issues in multiple areas."

Probably wisely, management's commercialisation efforts have focused on securing reimbursement in Germany and the UK, bearing in mind the device is not fully reimbursed anywhere.

Financial weight loss:

Endobarrier procedure might not hurt at all, but probing GI Dynamic's financials induces plenty of pain.

In the December half reported revenue of $US500, 000 and a net loss of $US13.1 million. The company's cash balance stands at $US8.3 million. The March quarterly report showed receipts of $US54,000 and cash burn of just under $US3 million, with a cash balance of $US5.4 million.

In what non-executive director Anne Keating's vaguely famous brother (St Paul of Balmain) would have dubbed the cost purge we had to have, last year management instituted measures including replacing every supplier with a "less expensive and more appropriate service provider"

Redundantly, the annual filing states: "We will need to raise capital in 2017."

The GI Dynamics register includes healthcare giants Medtronic and J&J Innovations, who presumably would be willing to donate some small change when the hat is passed around.

But the real intrigue lies with the Crystal Amber Fund, which recently upped its stake by one percent to 40.7 percent. The Guernsey-based entity is described as an activist fund and evidently believes in the story. And if the company's fortunes don't turn for the best, presumably it is also willing to force changes.

Management declares Endobarrier remains ahead of the competition and has not lost its "first mover advantage", which poses the question of how much lead the second movers have in their saddlebags.

GI Dynamics is pondering a listing on London's Alternative Investment Market, to "synchronise" the company's presence with its European commercial activities.

Management also hopes to confirm a new study design for a new Endobarrier obesity and diabetes trial this year.

Management promises to tell more in a so-called 10-Q form to the SEC, to be filed next week.

At the company's annual meeting this month, investors will be asked to vote on granting directors a swag of options, exercisable at either 2.025 cents per CDI or 6.2 cents. Yep, they're currently in the money, but they don't vest for either 12 months or three years.

For those with the time, money and inclination, GI Dynamics' AGM will be held in Boston on May 22.

Endobarrier did win praise at this week's gathering of gastric heavyweights in Chicago at a function called Digestive Diseases Week.

Among the riveting papers was: "Augmentation of Meal-Related Symptoms Following Placement of Duodenal-Jejunal Bypass Sleeve is a Potential Mechanism of Action Inducing Weight Loss".

Ah! To be there …

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he would consider himself a heavyweight in the field of rambling prose.

POLYNOVO

Polynovo says it is exploring the use of its Novosorb biodegradable temporizing matrix (BTM) wound treatment for hosting pig islets of Langerhans for type 1 diabetes.
Polynovo said the collaboration with burns specialist Prof John Greenwood and Prof Toby Coates was through their Adelaide-based Beta Cell Technologies Pty Ltd and was investigating the potential of using Novosorb BTM to host porcine pancreatic islets of Langerhans, which produced insulin, in the skin.
Living Cell attempted to commercialize injected encapsulated pig islet cells, but the project was spun out to a joint venture and following trial results showing safety but "unstable" efficacy, the program was effectively discontinued (BD: Jun 26, Nov 16, 2015).
Polynovo said that Prof Coates and Prof Greenwood identified an opportunity to use the BTM product as an ectopic skin pancreas to treat type 1 diabetes.
The company said that when Novosorb was infiltrated with dermal cells and blood supply, potentially provided an accessible site for the injection and generation of islet cells enabling renewed insulin production in people with type I diabetes.
Polynovo said that Prof Coates and Prof Greenwood told the Juvenile Diabetes Research Foundation meeting in New York this week that pig islets were seeded into Novosorb BTM for 100 days and survived, producing porcine insulin.
The company said that human islets were implanted into Novosorb BTM treated to prevent cellular rejection in pigs and the cells also survived producing human insulin.
Polynovo said the trials were a "proof-of-concept" and a potential step in the development of a dermal depot in the skin, potentially removing the need for insulin injections.
The company said that further pig studies were required with the hope of human trials in the coming years.
Polynovo was up one cent or 4.55 percent to 23 cents.

PRESCIENT THERAPEUTICS

Prescient says it has been granted a European patent providing platform technology protection for its lead compound PTX-200 triciribine phosphate.
Prescient said that the patent was entitled 'Effective treatment of tumors and cancers with triciribine and related compounds' and covereded therapeutic regimens of triciribine phosphate and compositions with reduced toxicity for the treatment of tumors and cancer.
The European Patent Office said the priority date was March 29, 2004, with the University of South Florida as the applicant, and Dr Jin Cheng and Prof Said Sebti as the inventors.
Prescient chief executive officer Steven Yatomi-Clarke said the patent was "a key patent in the PTX- 200 patent estate and it is pleasing to have it granted in Europe".
"PTX-200 is well advanced in the clinic with phase Ib/II studies underway in leukaemia, breast and ovarian cancers in leading US centres," Mr Yatomi-Clarke said.
Prescient was up 0.1 cents or 1.1 percent to 9.3 cents.

ONCOSIL

In an appendix 3B announcement, Oncosil said that former deputy chairman Martin Rogers has exercised 19,000,000 options at five cents each or $950,000.
Oncosil said that the options were issued to Mr Rogers following shareholder approval at a meeting of shareholders on May 22, 2013.
Oncosil closed at 13 cents today, implying that Mr Rogers would make a $1,520,000 gross profit should he sell the shares at current prices.
Oncosil was up 1.5 cents or 13.0 percent to 13 cents.

NEUROTECH INTERNATIONAL

The Malta-based Neurotech says it has confirmed a June 2017 planning meeting with the US Food and Drug Administration for its Mente Autism technology.
Neurotech said the meeting followed the filing of a pre-submission package with the FDA in March 2017 for the Mente Autism electroencephalogram (EEG) device, designed for home use, using neuro-feedback technology to help children with autism spectrum disorder (BD: Nov 4, 2016; Mar 30, 2017).
The company said it expected the FDA to provide targeted feedback on a range of topics, such as product development, planned non-clinical evaluations and proposed data requirements, prior to making a submission to the FDA.
Neurotech said it also expected to clarify the FDA's marketing requirements for the technology at the meeting.
The company said it expected to market its Mente Autism as a class II regulated device in the US, supported by clinical data.
Neurotech was up 2.5 cents or 12.5 percent to 22.5 cents.

COCHLEAR

Blackrock Investment Management has increased its substantial shareholding in Cochlear from 2,876,723 shares (5.01%) to 3,524,456 shares (6.13%).
Blackrock said that October 13, 2016 and May 10, 2917 it bought shares in more than 1,000 separate trades at prices ranging from $113.88 to $148.46 and said the registered holders included Bank of New York melon, JP Morgan Chase, State Street Bank York, Northern Trust UK, RBC Dexia, UBS Zurich, Citigroup, BNP Paribas, Bank of America Merrill Lynch, Goldman Sachs, Morgan Stanley, National Australia Bank and HSBC.
Cochlear fell $1.02 or 0.7 percent to $146.09 with 170,147 shares traded.

SIMAVITA

The Melbourne-based Chevron Corporation Pty Ltd says it has become a substantial holder in Simavita with a holding of 27,500,000 shares or 9.5 percent.
The Chevron notice, signed by director Peter Reilly said the shares were held with Parmelia Pty Ltd and were acquired for $1,100,000 or four cents a share.
Earlier this week Simavita said its recent placement at four cents a share raised $1.5 million with an additional $1.43 expected to be raised in a non-renounceable, one-for-seven rights issue, with Lodge Corporate underwriting the rights issue to $700,000 and Lodge Partners acting as the lead manager to the placement (BD: May 3, 8, 2017).
Biotech Daily has confirmed that Chevron Corporation is the operator of aged care facilities, including the Lifeview group, which uses the Simavita technology.
Simavita is commercializing incontinence monitoring technologies, primarily for use in aged care facilities.
Simavita was untraded at four cents.