Biotech Daily

Friday April 3, 2020

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 1.68 percent on Friday April 3, 2020, with the ASX200 down 86.8 points to 5,067.5 points. Eleven of the Biotech Daily Top 40 stocks were up, 25 fell, one traded unchanged and three were untraded.

Kazia was the best, up six cents or 15.6 percent to 44.5 cents, with 134,668 shares traded. Optiscan climbed 15 percent; Cyclopharm was up 10.5 percent; both Dimerix and Prescient were up 7.1 percent; Opthea was up 5.3 percent; Actinogen was up 4.8 percent; Orthocell and Universal Biosensors improved more than three percent; Compumedics and Resmed rose more than two percent; with Neuren up 1.5 percent.

Genetic Signatures led the falls, down 21 cents or 10.7 percent to $1.75, with 590,585 shares traded. Pharmaxis fell 9.1 percent; Clinuvel, Immutep, Next Science and Volpara lost eight percent or more; Medical Developments, Mesoblast, Oncosil and Resonance retreated more than seven percent; Impedimed, Nanosonics and Osprey were down six percent or more; Avita and Imugene were down five percent or more; Cochlear, LBT and Proteomics fell four percent or more; Ellex, Pro Medicus and Uscom were down more than three percent; Antisense shed 2.3 percent; Amplia, CSL, Cynata and Telix were down more than one percent; with Starpharma down 0.6 percent.

DR BOREHAM'S CRUCIBLE: TBG DIAGNOSTICS

By TIM BOREHAM

ASX code: TDL

Share price: 27 cents (trading suspended)

Market cap: $58.74 million

Shares on issue: 217,587,289

Executive chairman: Indrajit Solomon (Jitto) Arulampalam

Board: Jitto Arulampalam, Dr Stanley Chang, Emily Lee, CK Wang

Financials (calendar 2019 year): Revenue (continuing operations) $3.3 million (up 6%), net profit $620,137 (previously $4.4 million loss), loss on continuing operations $11.2 million (previously $2.53 million deficit), cash of $5.2m (down 8%).

Major shareholders: Medigen Biotechnology Corp 48.68%, Eternal Materials Co 18.48%.

As could be expected, the molecular diagnostics house's announcement of European approval of its Chinese investee company's Covid-19 test was greeted with a powerful share rally.

The trouble is, some investors appear to have developed psychic powers and weighed in before the European regulator's approval was announced to the market on Wednesday March 18.

TBG Diagnostics stock was suspended the previous day, but not before surging from 2.6 cents on February 26 to 27 cents - a rise of 938 percent.

As they say, the early bird catches the worm! If only these seers had had the foresight to predict the Covid-19 plague itself and helped us all avoid it.

TBG Diagnostics shares are now frozen in time (suspended) as the ASX makes "further enquiries" about the heavy volumes and irregular trading leading up to the announcement.

In a reply to an ASX query, management explained that Taiwan based director Dr Stanley Chang became aware of the assent informally on Saturday March 14.

This was via the investee company TBG Biotech Xiamen, which is 46.65 percent owned by TBG Diagnostics.

TBG Diagnostics argues the delay ensued because management needed to sight the official Conformité Européenne (CE) mark paperwork and that it reasonably believed the news would be confidential until then.

“We expected (the announcement) would give us good exposure but being suspended is not a good look,” rues executive chairman Jitto Arulampalam.

TBG who?

While the disclosure probe is an unwelcome distraction, at least the European approval highlights the existence of one of the bourse’s lower key biotechs.

Indeed, one figure in the molecular diagnostics sector told your columnist he had never heard of the company! But possibly he might recall a long brawl over cash in 2008 (see history, below).

TBG Diagnostics is already revenue generative and profit making, with approved products in Taiwan and China via TBG Xiamen and its fully-owned subsidiary TBG Taiwan.

Ready to go

The European approval relates to TBG Xiamen’s nucleic acid diagnostics kit, which uses real time polymerase chain reaction (PCR) technology to detect distinctive genetic segments of the Covid-19 virus.

More specifically, the test uses RNA (ribonucleic acid) to detect the RDRP, N and E genes of the virulent lurgy.

The in-vitro diagnostic (IVD) kit will be available for “immediate validation and purchase”.

Mr Arulampalam said TBG Xiamen had the advantage of working on ’flu diagnostics, with these efforts pivoting to the coronavirus as soon as the bug emerged in Wuhan province in November.

“The result was much better than expected,” he said.

TBG Xiamen is now preparing to ship its first batch of 20,000 kits to Europe this week, with a vaunted selling price of $US15-25 ($A20-30) per test.

“It’s now a question of how quickly we can scale up and manufacture the product in larger batches,” he said.

TBG Xiamen has also received a “substantial order” from the US and was lodging a fast-track application with the US Food and Drug Administration.

“We hope to get into the US, given it’s the country likely to be at the epicentre of it all,” Mr Arulampalam said. “It’s clear that more testing needs to be done quickly.”

The company is also eyeing local Therapeutic Goods Administration approval.

Tracking Covid-19's genetic footprint

Initially focused on the in-vitro fertilization market, TBG markets numerous products and services from its certified core facility at Xiamen, a port city on the southeast coast in Fujian province.

Clients include hospitals, independent reference labs, blood centres and bone marrow registries. The purpose of the tests includes detecting infectious diseases, viral load testing and genotyping (used to detect a person's genetic variants).

For the boffins, the products include Exprobe (typing kits based on polymerase chain reaction technology) and HL Assure (human leukocyte antigen genotyping based on sequence-based typing). With the look and size of an air conditioner, the Q6000 PCR instrument will be the basis of a fully automated system in development.

Pay attention - you will be tested

Older - and of course venerable - readers will remember TBG Diagnostics as Progen Pharmaceuticals, the antecedent firm that listed in 1990.

Progen eventually came a cropper when it cancelled its seminal liver cancer trial, having raised a total of $150 million.

To cut a long and sometimes litigious story short, the current technology was vended into the group in 2016 via Taiwanese major shareholder Medigen, which had earlier acquired Texas Biogene (yep - TBG).

Around that time Progen changed its name to TBG Diagnostics.

In 2014, the company founded TBG Xiamen to address the Chinese government's requirements for foreign entities carrying out a genetic testing business.

In 2019, TBG Xiamen acquired Zhangsha Zhang Ye Medical Laboratory Corps, which provides medical lab testing services in Chairman Mao's old stamping ground of Hunan.

In the process, TBG Diagnostics' stake in TBG Xiamen was reduced to 46.65 per cent. The deal also involved a private equity firm injecting $2.25 million into TBG Xiamen.

Put in context, all the coronavirus testing action is taking place in Zhang Ye's certified lab.

In 2016, TBG Diagnostics' contract manufacturing arm, Pharmasynth, was acquired in a management-led buyout and renamed Luina Bio Pty Ltd. Luina continues Covid-19 related activity as well (see below).

In the same year, TBG sold its PG500 assets - in effect Progen's old oncology business - to the Brisbane based Zucero Therapeutics for $6 million in a cash and scrip deal.

Financials and performance

A key point is that the Covid-19 test activity is under the auspices of TBG Xiamen, not TBG Diagnostics.

Hence, TBG Diagnostics investors benefit not so much from direct revenues, but the value of TBG Biotechnology on its books ($3.14 million as of the end of December).

TBG Diagnostics revenues currently derive from TBG Taiwan, which is responsible for Asian sales outside of China.

TBG Xiamen serves as the company's sales distributor in mainland China (except Hong Kong and Macau) and is the only provider of sequence-based testing products approved by the China Food and Drug Administration.

Of the $3.34 million of revenue in 2019, 81 percent derived from products - mainly the sequence-based typing and sequence-based primer products.

A further eight percent of revenue was derived from technical services.

TBG Diagnostics reported an operating profit of $712,000 a sharp turnaround on the $3.5 million deficit in 2018.

But the number is confounded by a $2.85 million share of net loss of associates, a $6.38 million impairment loss and an $11.8 million credit mainly relating to the TBG Xiamen transaction.

Also clouding the picture is a $5.99 million gain from deferred settlement of the PG500 deal.

Meanwhile ...

The Brisbane-based Luina Bio has made it clear that it remains open for business during the pandemic.

"If you are working on a drug, a vaccine or a diagnostic to help battle Coronavirus, please contact us now for a fast consultation to see how we can work together for fast response to scale up and manufacturing."

One such venture is a tie-up with Griffith University's Centre for Cell Factories and Polymers, to marry Luina's contract manufacturing expertise with the learning institution's expertise in vaccine platforms.

Griffith has developed a rapid response vaccine platform technology that allows for low cost, large scale manufacturing of new pilot vaccine candidates ready for pre-clinical and clinical testing against an emerging viral threat.

Sounds topical, but can't quite pin down why ….

Luina chief executive officer Les Tillack told Biotech Daily that with optimal conditions the vaccine candidate could be ready for human clinical trials in six to 12 months.

Mr Tillack said that the importance of the Griffith University-Luina process was that it could produce the vaccine “quickly and at a fraction of the cost of normal vaccines”.

Meanwhile, Zucero reckons its immune-oncology programs might also be relevant in the fight against Covid-19.

Dr Boreham’s diagnosis:

Just to show how much has changed in a short space of time, stock analysis site Simply Wall Street had this to say about TBG Diagnostics in early December 2019, when the shares traded around four cents.

“We don’t think TBG Diagnostics’ revenue of $3.42 million is enough to establish significant demand,” the site said. “So, it seems shareholders are too busy dreaming about the progress to come than dwelling on the current (lack of) revenue. For example, they may be hoping that TBG Diagnostics comes up with a great new product, before it runs out of money.”

These hopes have now been satiated, big time.

TBG’s test joins a growing array of Covid-19 assays, ranging from fairly basic swabs to the more accurate nucleic acid testing.

“Our scientists are telling us that even though a swab test is negative it can turn out to be positive later, whereas [polymerase chain reaction] results are very accurate,” Mr Arulampalam said.

“Hence the larger labs and path organizations are preferring PCR machines and our testing is built on that methodology.”

In our humble view, TBG’s imperative is to surf the Covid-19 potential while the bug remains an epidemic and before the market is swamped with various other tests.

But with the European paperwork in its back pocket, TBG has a head start.

TBG is also not just about Covid-19 assays. As of December, TBG had 24 products in development, with six in clinical trial or development stage for transfusion, immunity and infectious diseases.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort – or any psychic abilities beyond predicting the end of daylight savings this weekend.

ATOMO DIAGNOSTICS

Atomo says its $30 million initial public offering was over-subscribed raising $30 million, and it has a deal with NG Biotech SAS for its Covid-19 rapid antibody test.
Last month, Atomo said it hoped to raise $30 million at 20 cents a share to list on the ASX and commercialize its rapid tests, including HIV tests (BD: Mar 5, 2020).
The company said it was working with device and manufacturing customers to develop rapid self-tests for Covid-19, using its device to collect and deliver blood to test for the presence of antibodies generated in response to the virus (BD: Mar 19, 2020).
Today, Atomo said the oversubscriptions would be scaled back and it expected to list on the ASX in mid-April under the ASX ticker code AT1.
The company said the funds raised would be used to accelerate an expansion of its production capacity to meet the demand for its Covid-19 tests.
Atomo said that major shareholders included property developer Lang Walker, former Macquarie Bank chief executive officer Allan Moss, the Bill and Melinda Gates Foundation-backed Global Health Investment Fund and the Government of Canada's Grand Challenges Canada fund and Canaccord Genuity was the offer's lead manager.
Atomo said it would supply the Guipry, France-based NG Biotech its devices for NG's Covid-19 test, which had Conformité Européenne (CE) mark approval.
The company said NG had placed an initial order for 397,200 devices and would be able to buy up to 2,465,000 devices during 2020, after which it intended to enter into a binding purchase agreement for its products beyond 2020.
Atomo is a public unlisted company.

IMPEDIMED

In yesterday's news of its $25 million rights offer, Impedimed also said that directors and executives would have a pay cut and said a US investigation would take no action.
Impedimed said that chief executive officer Richard Carreon would have a temporary pay cut of 30 percent and with 20 percent of his pay being in shares it was a total cash reduction of 50 percent.
The company said that executive cash salaries would be temporarily reduced by 10 percent along with the 20 percent in stock and non-executive directors' fees, currently paid in shares, would be reduced by 25 percent, with further staged reductions, if necessary, pending a review of Covid-19 affected business conditions.
Last year, and also at the end of an announcement of a rights issue - to raise $13.9 million at 11 cents a share - Impedimed said it recognized revenue from European distributors of about $130,000 in the year to June 30, 2016 and about $430,000 in the year to June 30, 2017, and recognized an impairment of about $390,000 in the year to June 30, 2018 most of which related to the European distributors (BD: Jun 27, Jul 19, 2019).
The company said at that time that the information was disclosed in its 2017 and 2018 annual reports and the US Securities and Exchange Commission began "a non-public, fact-finding inquiry in relation to the revenue recognized and the impairment".
Impedimed said at that time that it did not expect any matters in relation to the inquiry to be material to its current or any prior period financial statements.
Yesterday, Impedimed said that the US SEC had concluded its inquiry and did "not intend to recommend an enforcement action".
The company said it was "in early discussions with a variety of counterparties to explore different opportunities … [varying] from a joint development agreement, a licence agreement and a sales and marketing agreement".
Impedimed fell 0.4 cents or 10 percent to 3.6 cents with 18.2 million shares traded.

IMPEDIMED

Impedimed says it has raised $10 million in the institutional component of its rights offer at 3.75 cents a share and hopes to raise a further $14.9 million in the retail offer.
Yesterday, Impedimed said it hoped to raise up to $24.9 million through a partly underwritten, non-renounceable, 13-for-10 rights offer at 3.75 cents a share, including a $10 million institutional component and $14.9 million retail component (BD: Apr 2, 2020).
Today, the company said $8 million was underwritten by lead managers Canaccord Genuity Australia and Wilsons Corporate Finance, with Morgans Financial as co-manager.

OSPREY MEDICAL

Osprey says it hopes to raise up to $15.5 million through a partly-underwritten, three-for-one entitlement offer at 1.2 cents per Chess depositary interest (CDI).
Osprey said the issue price was a 20 percent discount to its closing price on March 31, 2020 and it would issue one attaching option for every new share, exercisable at 1.4 cents and expiring on February 15, 2021.
The company said the offer would include a top-up facility for eligible holders on the record date of April 8 to buy new CDIs and free attaching options beyond their entitlement.
Osprey said the offer would open on April 15 and close on April 24, 2020.
Osprey said its largest shareholder Brandon Capital Partners would take up its entitlement for $3,196,744 and Brandon funds underwriting the shortfall, for up to $4,453,692.
The company said the funds would be used to continue commercial expansion in the US, to support GE Healthcare's commercial efforts in Europe, Russia, the Middle East, Africa, Central Asia and Turkey, to support generation of clinical evidence and the multi-hospital Dyeminish registry and for ongoing product portfolio development.
Osprey fell 0.1 cents or 6.7 percent to 1.4 cents.

TELIX PHARMACEUTICALS

Telix says it has acquired a Seneffe, Belgium-based radiopharmaceutical production facility from Berlin's Eckert & Ziegler Strahlen und Medizintechnik AG.
In October, Telix said it would buy the facility for a nominal cash sum and assume future decommissioning liabilities, estimated to be up to EUR5.2 million ($A8.5 million), as payment for the 35,000 square metre site (8.6 acres) (BD: Oct 3, 2019).
Today, the company said it paid a nominal sum of EUR1, had assumed the future decommissioning liability and the site's active radiation licence had been transferred to Telix, approved by Belgium's Federal Agency for Nuclear Control.
Telix said commercial benefits of the acquisition included the class IIa radiation licence, expansion of its existing research and development and product development in Belgium, ownership of a fully licenced production site "in the heart of Western Europe", access to a key isotope supply and the ability to produce a range of radio-isotopes.
Telix chief executive officer Dr Chris Behrenbruch said the facility had "one of the most extensive private sector medical isotope licences in Europe".
"This provides significant operations flexibility to Telix and the ability to deliver the company's production needs for its product portfolio in Europe for the long-term," Dr Behrenbruch said.
"The timing of this acquisition is significant, given Telix expects to launch its prostate cancer imaging product TLX591-CDx as well as its kidney cancer imaging agent TLX250-CDx in Europe over the next 18 months," Dr Behrenbruch said.
Telix fell two cents or 1.8 percent to $1.09.

DIMERIX

Dimerix says it will borrow $1,024,128 from Radium Capital against its Federal Research and Development Tax Incentive

Dimerix said the loan was equivalent to 80 percent of its accrued Tax Incentive for the period for the period from July 1, 2019 to February 29, 2020 and would allow for a second advance payment at June 30, 2020.

The company said the advance would accrue interest at 1.25 percent per month and repayment would coincide with receipt of its Research and Development Tax Incentive for the year to June 30, expected by September 30, 2020.

Dimerix was up one cent or 7.1 percent to 15 cents.

EMVISION MEDICAL DEVICES

Emvision says the Covid-19 pandemic has halted enrolment at 15 of the 30-patients in its six-month pilot trial of its portable brain scanner for stroke patients

In December, Emvision said it had completed testing and key checks for its portable, non-invasive brain scanner unit to begin clinical trials, to collect stroke patient imaging data and to advance its imaging algorithms with computed tomography (CT) and magnetic resonance imaging (MRI) scans (BD: Dec 19, 2019).

Today, the company said it had “gathered considerable valuable patient data” and expected to report preliminary images from two months of the trial later this month.

Emvision was up two cents or 3.6 percent to 58 cents.

FACTOR THERAPEUTICS

Factor says it would not recommend a Ramcap proposal for a joint venture.

Factor said it was “made aware of a notice on the Ramcap Ltd website indicating that it has made a [joint venture] proposal”.

The company said it had not entered into any agreement with the Sydney-based Ramcap, it had received preliminary information which was “high level and insufficient … to respond to other than to request further detailed information … [and] “based on the information received to date, [it] would not recommend this proposal to shareholders”.

Factor was up 0.05 cents or 25 percent to 0.25 cents with 6.2 million shares traded.

POLYNOVO

Polynovo has requested a trading halt pending “an announcement on a clinical trial results, trading update and funding”.

Trading will resume on April 7, 2020 or on an earlier announcement.

Polynovo last traded at $1.675.

COCHLEAR

Veritas Asset Management says it has become a substantial shareholder in Cochlear with 3,574,042 shares or 5.57 percent of the company.

The London-based Veritas said that between February 14 and March 31, 2020 it acquired 3,268,300 shares for $504,125,211 or $154.25 a share, with the single largest purchase on March 26 of 2,175,000 at $140 a share, the share price for the $880 million placement and $50 million share plan (BD: Mar 25, 26, 2020).

Cochlear fell $7.98 or 4.2 percent to $182.02 with 456,987 shares traded.

BOD AUSTRALIA

Tribeca Investment Partners says it has ceased to be a substantial shareholder in Bod Australia.
Last July, the Sydney-based Tribeca said it had increased its substantial shareholding in Bod from 4,345,332 shares (6.26%) to 5,595,332 shares (8.06%) (BD: Jul 23, 2019).
Today, Tribeca said that between July 26, 2019 and April 2, 2020 it sold 1,043,161 shares for $451,810 or an average of 43.3 cents a share.
Biotech Daily calculates that Tribeca retains 4,552,171 shares or 4.98 percent of Bod.
Bod was unchanged at 21 cents.

AZURE HEALTH TECHNOLOGY

Azure says it has extended the close of the capital raising to backdoor list Invictus Biopharma to April 15, 2020, and the ASX extended its delisting deadline to April 24.
In February, Azure said it hoped to raise up to $10 million to acquire Invictus for its tocotrienols food additive, supplements and pharmaceuticals business (BD: Feb 5, 2020).
Azure was in a suspension with Commsec reporting its last price was 0.0 cents.

ESENSE-LAB

Esense-Lab says it has a $50,000 working capital loan from Everblu Capital Pty Ltd, repayable at 0.4 cents per Chess depository interest (CDI).
Esense-Lab said it would issue one free attaching option per two CDIs, exercisable at 1.0 cent per CDI, expiring 18 months from issue, pending shareholder approval.
Esense-Lab was in a trading halt and last traded at 0.7 cents.

MGC (MEDICAL GRADE PHARMACEUTICALS) PHARMACEUTICALS

MGC has requested a seventh extension to its voluntary suspension following the trading halt requested on March 19, 2020 for a Covid-19-related joint venture.
On March 19, MGC requested a trading halt pending an announcement on “a material agreement regarding a strategic joint venture with a Swiss company in relation to Covid-19” (BD: Mar 19, 2020).
Last week, the company requested its first voluntary suspension, followed by almost daily extensions to the suspension (BD: Mar 23, 24, 25, 26, 27, 31; Apr 2, 2020).
Today, MGC said it expected the suspension to last until April 8, 2020.
MGC last traded at 1.7 cents.