Biotech Daily

Friday March 18, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: OPTHEA UP 10.5%; GENETIC SIGS DOWN 5.5%**

*** DR BOREHAM'S CRUCIBLE: IMMUTEP**

*** REDHILL REVENUE UP 33% TO $116m, LOSS UP 28% TO $133m**

*** IMPEDIMED: ASTRAZENECA EXTENDS SOZO KIDNEY CONTRACT**

*** POLYNOVO SELLS PORT MELBOURNE HQ FOR $6.4m; LEASEBACK**

*** MICRO-X: $1.9m US BAG SCANNER PROTOTYPE MILESTONE**

*** INCANNEX: UP-TO $69m IN-THE-MONEY 'LOYALTY', PIGGY-BACK OPTIONS**

*** IDT MISSES FEDERAL mRNA GRANT, 2nd 'REMAINS LIVE'**

*** JM FINANCIAL REDUCES TO 8.7% OF UNIVERSAL BIOSENSORS**

*** PETERS TAKES 12.7% OF OPTISCAN**

MARKET REPORT

The Australian stock market was up 0.6 percent on Friday March 18, 2022, with the ASX200 up 43.6 points to 7,294.4 points. Eighteen of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and two were untraded.

Opthea was the best, up nine cents or 10.5 percent to 94.5 cents, with 8.4 million shares traded. Immutep and Telix climbed more than six percent; Prescient was up 5.9 percent; Atomo and Starpharma improved four percent or more; Antisense, Avita, Compumedics, Impedimed and Imugene were up more than three percent; Alcidion, Medical Developments, Micro-X and Oncosil rose more than two percent; Actinogen was up 1.2 percent; with CSL, Emvision and Pro Medicus up by less than one percent.

Genetic Signatures led the falls, down seven cents or 5.5 percent to $1.205, with 18,815 shares traded. Mesoblast fell 4.8 percent; Clinuvel, Paradigm and Resonance were down more than three percent; Kazia, Nova Eye, Universal Biosensors and Volpara shed more than two percent; Cynata, Neuren and Polynovo were down more than one percent; with Cochlear, Cyclopharm, Next Science and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: IMMUTEP

By Tim BOREHAM

ASX code: IMM; **Nasdaq code:** IMMP

Share price: 39.5 cents

Market cap: $342.2 million

Shares on issue: 866,239,815

Chief executive officer: Marc Voigt

Board: Dr Russell Howard (chair), Pete Meyers, Marc Voigt, Lucy Turnbull*****
***** Ms Turnbull re-joined the board after the sudden death of director Grant Chamberlain on January 28, 2022

Financials (December half 2021): revenue (research material sales) $21,408 (previously $193,533), net loss $16.2 million (previously $19.8 million deficit), cash of $99.7 million up 64%

(December quarter 2021): revenue $14,000, loss of $6.05 million, quarters of available funding 16.5

Identifiable major shareholders: FIL Ltd (Fidelity) 7.3%, Australian Ethical 4.8%, Marc Voigt 1%, Dr Frederic Triebel 0.9%.

As a developer of a new cancer drug, Immutep knows that it's gaining traction when the world's luminaries gather - virtually at least - to discuss that mode of treatment and nothing else.

Such was the case with immunotherapy play Immutep at the January 26, 2022 confab, the inaugural lymphocyte activation gene-3 (LAG-3) Drug Development Summit.

Immutep CEO Marc Voigt was honored with delivering the opening remarks, while chief scientific officer Dr Frederic Triebel – a.k.a. the godfather of LAG-3 – gave a keynote speech alongside heavy hitters from Roche, Bristol Myers Squibb and Regeneron.

As Basil Fawlty said in a different context: "There's enough material for an entire conference."

Immutep's lead compound is called eftilagimod alpha (efti to friends) and targets the LAG-3, a protein that regulates immune responses. The compound is better known as IMP321.

Mr Voigt says there's a high likelihood the first LAG-3 therapy will win approval this year, with Bristol Myers Squibb eyeing a March 19 'target action date' for a biologics application to the US Food and Drug Administration (FDA).

Bristol Myers Squibb is seeking approval for its LAG-3 antibody relatlimab, to be used in combination with nivolumab (Opdivo) for unresectable or metastatic melanoma.

“As LAG-3 becomes commercial there will be more noise around it,” Mr Voigt says. “We are the only LAG-3 pure play with more programs than anyone else, including big pharma.”

But to get this far, Immutep’s path has been anything but smooth, with some clinical results failing to meet their primary endpoints.

Turnbull wins second term

And now a potted history:

The LAG-3 protein was discovered by French immunologist and now Immutep chief scientific officer Dr Frederic Triebel. In 2001, Dr Triebel founded Immutep SA.

In 2014, ASX plodder Prima Biomed acquired Immutep for $US10.8 million in cash and shares.

In May 2016, Prima divested its original CVac ovarian cancer vaccine program to Sydys Corp of the US, for 9.8 percent of Sydys and $400 million of potential milestones and royalties. Sydys had $US856.00 in the bank at the time.

Nothing has eventuated from that tie-up.

The original CVac program attracted former Sydney lord mayor Lucy Turnbull to the board, which she chaired between October 2010 and November 2017. (Ms Turnbull’s spouse, Malcolm, was Australia’s Prime Minister during some of that period.)

Ms Turnbull has now re-joined the board, the catalyst being January’s sudden death of Grant Chamberlain, an Immutep director since August 2017.

Immutep has been listed on the Nasdaq for the last decade, with the American depository receipts accounting for 28 percent of total shareholders.

What’s all the fuss about?

Immutep’s platform is being furthered as a combination therapy with immune checkpoint inhibitors (such as the blockbuster drug Keytruda).

The idea is that efti (IMP321) “pushes the gas” while the inhibitors release the “brakes” of the immune system.

Immutep’s key program is called Aipac and relates to metastatic breast cancer patients.

Aipac, by the way, stands for “active immunotherapy paclitaxel”.

Aipac tests a new class of products called antigen-presenting cell activators, which the company hopes will be relevant for other solid tumors.

The $20 million phase IIb trial tested IMP321 in combination with paclitaxel - brand name Taxol - a standard-of-care chemotherapy.

The randomized, double-blinded and placebo-controlled trail enrolled 227 hormone receptor positive (HR+) and human epidermal receptor 2 negative (HER2-) metastatic breast cancer patients across 30 sites in Europe.

In March 2020, the company revealed first data from the 227-patient trial, which showed a 63 percent progression-free survival, relative to 54 percent for the control group (paclitaxel plus placebo).

In December 2020, the company followed-up with overall survival data showing a media benefit of 2.7 months, relative to placebo.

In short, the results missed the primary endpoints on progression free survival and overall survival.

But - as you do - the company stressed a “statistically significant overall survival benefit across pre-determined patient sub groups”.

These included those aged under 65 (median benefit 7.1 months) and those with a low starting monocyte count (9.4 months).

Monocytes are a type of white blood cell.

In November last year, Immutep presented at a ‘late breaking’ slot at the Society for the Immunotherapy of Cancer (SITC) pow-wow.

(If management really does burst into these forums screaming ‘hold the front page’ - Jimmy Olsen like - please get us a ticket).

In front of its learned peers, management outlined a revised overall survival benefit of 19.6 months for the under-65s, 19.6 months for the low monocytes and 4.2 months for those with luminal B type cancers.

Constructive feedback

Immutep’s quest to develop efti (IMP321) received a boost earlier this month, with the US FDA providing “constructive feedback” on the company’s plans for a phase III registrational trial for metastatic breast cancer.

In October 2021, the European Medicines Agency also said ‘go for it’ - although not using that exact wording.

Mr Voigt says the new trial will optimize the design of the global trial, focusing on patients most likely to benefit.

“We have learned from Aipac and would not go with the European scheduling of giving paclitaxel for six months and then stopping,” he says. “Instead, the drug will continue to be administered, if tolerated, until the cancer progresses.”

Tacti-002

As in ‘two active immune-therapeutics’, Tacti-002 tests efti in combination with the checkpoint inhibitor Keytruda (pembrolizumab) for non-small cell lung cancer (NSCLC) and head and neck squamous cell carcinoma (HNSCC).

Done in collaboration with Merck & Co of the US, the open label, single-arm trial has recruited 185 patients across 20 centres in the US, Europe and Australia.

Part A relates to a first-line treatment for NSCLS and part B for a patient-derived xenograph refractory version (the tissue containing the non-responsive tumors are taken from the body for treatment in mice).

Part C relates to a second-line HNSCC treatment.

So far, two phase II trials have been completed for both indications. In the case of NSCLC, the company reported an overall response rate of 41.7 percent and two complete responses (the tumors disappeared).

Reported at last November’s SITC chinwag, the HNSCC effort showed an overall response rate of 29.7 percent compared with 14.6 percent for pembrolizumab (for the general patient population).

Recruitment of a 74-patient expansion of part A was completed last year and the company plans to present data in the current half.

Recruitment of part B was also completed last year, with the company due to tell all at the European Lung Cancer Congress that kicks off on March 30.

Tacti-003

Tacti-003 evaluates efti in the “commercially more relevant” setting of a first-line treatment for recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) “in a randomized setting”.

In April 2021, the company won fast-track designation from the FDA, for use of the compound for this purpose.

Immutep has started recruiting a 154-patient randomized, open-label trial across 35 clinical sites in the US, Europe and Australia.

Intriguingly, one of the first sites to open was in Kapitanivka in central Ukraine, where first-line concerns are more about dodging bullets and bombs at one of the front lines of the Russian invasion.

“It’s terrible for people living there and especially terrible for the patients and their families,” he says. “We support the very few patients in Tacti-003 as much as we can.”

Czech out this Covid research

Is there a Covid-19 angle in all of this. Yes, of course!

And with the latest variant of the blight causing renewed problems in China, cracking a genuine treatment remains a lucrative prize.

In Immutep’s case, a Czech research centre asked for some efti to carry out its own Covid trial.

“We are happy to provide that but we are not actively investing. We can’t do oncology as well as infective diseases,” Mr Voigt says.

“But efti is an immune booster, so as a therapeutic against Covid it could make sense.”

For reasons unknown, the Czech program is called ‘Eat Covid’ - and only if it were that easy.

Finances and performance

Following a $67 million raising in June last year, Immutep had a healthy December-end cash balance of just under $100 million.

Immutep’s main financial commitment is of course the efti phase III trial, with the other programs largely funded by partnering deals.

The cost of the registration trial is not mentioned but it could be ‘efti.

“Our funding is strong. The company is in a better financial position than it has ever been since inception in 2001,” Mr Voigt says.

He says Immutep won't be going back to the market for more dosh any time soon, with the funding 'runway' prolonged with a prudent approach to spending.

"I review every invoice, whether it is 50 cents or $500,000," Mr Voigt says. "We spend investors' money very wisely."

Immutep shares are at a similar level to 12 months ago, which is a reasonable performance given the punishment meted out to biotechs in recent months.

Trading has been volatile over the last two years and at one point the stock was the most heavily traded on the Nasdaq.

Immutep shares tumbled to a low of 11 cents in March 2020 after the initial disappointing Aipac results.

Last year, the shares ran up to 70 cents in early June and then again in November, ahead of the SITC prezzo - after which the stock fell again.

Mr Voigt says the shares corrected after a "phenomenal" period of growth: "to take a break from time-to-time is healthy."

Dr Boreham's diagnosis

Mr Voigt says checkpoint inhibitors are typically a "big boy's game", which means that Immutep has discarded its junior school bumfreezers* for proper daks**.

Immutep also has the attention of the institutional big boys, with Blackrock, Fidelity, Karst Peak and local hero Australian Ethical all gracing the register.

With a $300 million market capitalization, Immutep is on the cusp of graduating from junior classes to Big School, having endured the corporate equivalent of Chinese burns, wedgies, nipple cripple and the 'typewriter'*** over the years.

In the next couple of months, investors should look out for further data from the Tacti-002 and updates on Tacti-003 recruitment. Later in the year the company hopes to deliver interim results from Insight-003, the first triple-combination efti trial.

But despite the company's multi-pronged clinical efforts, the Aipac breast cancer trial is likely to determine its fortunes in the rough-and-tumble biotech playground.

***** Shorts; ****** long trousers; ******* advanced juvenile torture techniques

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort, but retains his faculties. Despite the junior school torment of the school bully literally stealing his marbles, he still has some in an idiomatic sense.

REDHILL BIOPHARMA

Redhill says revenue for the year to December 31, 2021 was up 33.2 percent to $US85,757,000 ($A116,258,000) with net loss after tax up 28.3 percent to $US97,744,000 ($A132,508,000).

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

Today, the company said Talicia, formerly RHB-105, for Helicobacter pylori was “the most prescribed branded [Helicobacter] pylori therapy in the US achieving record quarterly prescriptions” with revenue up 78.4 percent compared to the prior corresponding period.

Redhill also said that Movantik, which it bought from Astrazeneca, was the market leader in opioid-induced constipation treatments, with a 73 percent market share.

Redhill did not disclose the amount of revenue from each drug.

Redhill chief executive officer Dror Ben-Asher said the company had “delivered record revenues against a pandemic backdrop …[and] a very strong fourth quarter for both Talicia and Movantik, coupled with disciplined cost-control measures across the business and intensive out-licensing and in-licencing activities, sets us up for continued organic and non-organic growth in 2022 and beyond”.

Redhill chief financial officer Micha Ben Chorin said the company expected commercial operations profitability in the year to December 31, 2022.

Redhill said diluted loss per share was constant at 21 US cents, with cash of $29,474,000 at December 31, 2021 compared to $US29,295,000 at December 31, 2020.

On the Nasdaq, Redhill was up 45 US cents or 24.59 percent to $US2.28 ($A3.09) with 876,185 shares traded.

IMPEDIMED

Impedimed says Astrazeneca has extended by three months its contract to use the Sozo bioimpedance fluid volume system in a phase IIb chronic kidney disease trial.

Last year, Impedimed said Astrazeneca requested the contract be extended from 18 months to 21 months and increased from 175 devices to 211, taking the total contract value to about $5 million (BD: Nov 4, 2021).

Today, the company said Astrazeneca would pay a further estimated $500,000 to extend the contract by a further three months, and increase the required number of devices by 23 Sozo units.

Impedimed said each device would have a monthly licence fee for the duration of the study, and it would retain ownership of the devices at the conclusion of the trials.

The company said that between the separate Astrazeneca heat failure and kidney disease trial and the second chronic kidney disease trial, a combined 434 Sozo devices had been leased across 28 countries by Astrazeneca.

Impedimed managing-director Richard Carreon said that the feedback on Sozo had been “very positive”.

“The trial is providing a significant number of cardiologists and nephrologists, both in the US and globally, first-hand experience with Sozo,” Mr Carreon said.

“Heart failure and chronic kidney disease are two of our three strategic focus areas, and this contract addition provides continued validation of the applicability of our technology in both patient populations,” Mr Carreon said.

“The endorsement is timely, as the company starts enrolment for its renal failure trial and progresses towards an [US Food and Drug Administration] clearance in renal through the breakthrough device designation program,” Mr Carreon said.

Impedimed was up half a cent or 3.45 percent to 15 cents with 1.9 million shares traded.

POLYNOVO

Polynovo says it has sold its Port Melbourne headquarters for $6.35 million, but will lease the offices for 10 years through two five-year options.
Polynovo said $3 million of the proceeds would be used to reduce debt, with the balance as working capital.
Polynovo chair David Williams said that “apart from realizing a profit on the sale, we will use the sale to align the lease arrangements on the adjoining site”.
Polynovo fell 1.5 cents or 1.4 percent to $1.09 with 4.2 million shares traded.

MICRO-X

Micro-X says it has unlocked $US1.4 million ($A1.9 million) from the US Department of Homeland Security, having reached a milestone in its baggage scanner contract.
Micro-X said the Department’s Science and Technology Directorate had accepted for approval a prototype of its miniature computerized tomography baggage scanner, a milestone completed “on-time and on-budget”.
The company said the milestone provided access to $US1.4 million for the remaining eight months of the contract.
Micro-X said the next stage would involve the manufacture of a full prototype, and was expected by the end of 2022.
Micro-X US chief executive officer Dr Brian Gonzales said “successfully meeting the prototype design review milestone represents an exciting achievement for Micro-X as we can now transition into the next phase of fabricating a full [computed tomography] prototype for testing later this year”.
“We are one step closer to the day where we can deploy our miniaturized baggage scanners in airports around the world which will play a critical role in improving passengers’ airport security checkpoint experiences,” Dr Gonzales said.
Micro-X was up half a cent or 2.7 percent to 19 cents.

INCANNEX HEALTHCARE

Incannex says it will offer shareholders one in-the-money option for every 15 shares they hold, plus a second option for every two of the first options exercised.
Incannex said the first options would be offered free to eligible shareholders at the record date on March 23, exercisable at 35 cents each by April 22, 2022.
The company said that shareholders would receive a further one ‘piggyback’ option for every two initial options they exercised, exercisable at $1.00 by April 28, 2023.
Incannex did not disclose how much it hoped to raise from the offer.
The company’s most recent filing said it had 1,210,378,003 shares on issue and Biotech Daily calculates that if all shareholders take up the offer and exercise the free options at 35 cents each, it could raise as much as $28,242,153.
Should all shareholders exercise all the piggy-back options, the company would raise a further $40,345,933.
Incannex said the loyalty option scheme was intended to reward shareholders, particularly after the clinical trial success of its marijuana-based IHL-42X for obstructive sleep apnoea (BD: Mar 10, 2022).
Incannex said the scheme would also facilitate additional funding from existing shareholders for clinical trials, which it said would ramp up this year and in 2023.
Incannex was unchanged at 66.5 cents with 46.3 million shares traded.

IDT AUSTRALIA

IDT says it was unsuccessful in its Federal Government Collaboration Stream Grant bid to produce mRNA vaccines in Australia, but a second application “remains live”.

Last year, IDT said that with Monash University’s Institute of Pharmaceutical Sciences it had manufactured a severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) mRNA vaccine, the drug product “met all specifications” and was progressing through the release process to be supplied to MIPS for their clinical trial (BD: Nov 30, 2021).

In December, the company said its submission to the Federal Government for an onshore mRNA manufacturing capability had not been selected to progress (BD: Dec 16, 2021).

In January, IDT said its Federal Government sterile readiness agreement had ended, but mRNA product translation and manufacturing talks were ongoing (BD: Jan 31, 2022).

Today, the company said that after a six-month tender process, the Federal Government had notified it that its bid for the collaboration stream of the Modern Manufacturing Initiative had been unsuccessful.

IDT said its round two application for the translation stream of the initiative was still live.

IDT chief executive officer Dr David Sparling said: “Whilst we are disappointed in the outcome of the MMI Collaboration Grant process, the company is continuing to progress several alternative strategic options, including IDT’s application to round 2 of the MMI translation stream which remains live.”

“During the more than six months period IDT has waited for an outcome on the MMI Collaboration Stream grant, the Company has secured a sterile manufacturing licence from the Therapeutic Goods Administration and successfully delivered on the Monash-Doherty Institute developed Covid-19 mRNA receptor binding domain vaccine candidate project,” Dr Sparling said.

“This project is Australia’s first locally manufactured … mRNA finished product and the first of its kind in the Southern Hemisphere,” Dr Sparling said.

“IDT is currently the only company in Australia with demonstrated capability in this regard,” Dr Sparling said.

IDT fell two cents or 10.3 percent to 17.5 cents with 3.2 million shares traded.

UNIVERSAL BIOSENSORS

Melbourne’s JM Financial Group says it has reduced its substantial holding in Universal Biosensors from 17,382,413 (9.78%) to 15,402,835 (8.65%).

JM Financial said that in more than 750 transactions between October 27, 2021 and March 8, 2022, it bought, sold, and transferred shares, with the single largest sale 115,209 shares for $97,437 or 84.6 cents a share.

Universal Biosensors fell two cents or 2.3 percent to 86 cents.

OPTISCAN IMAGING

Peters Investments says it has increased its substantial holding in Optiscan from 70,000,000 shares (11.37%) to 78,541,105 shares (12.68%).

The Cottesloe, Western Australia-based Peters said it acquired 8,541,105 shares on various dates to March 15, 2022 for $1,434,068, or 16.8 cents a share.

Optiscan was unchanged at 14 cents.