Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: OPTISCAN UP 13%; PRANA DOWN 8%**

*** DR BOREHAM'S CRUCIBLE: IMUGENE**

*** SIRTEX DROPS $1.6b VARIAN OFFER FOR CDH, CHINA GRAND $1.9b BID**

*** ALL CHANGE AS BENITEC LOSES CEO GREG WEST, CSO DR DAVID SUHY**

*** PARADIGM: '75 OA PATIENTS REPORT AVERAGE 50% PAIN REDUCTION'**

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*** PRIVATE PORTFOLIO MANAGERS BELOW 5% IN BIONOMICS**

*** JP MORGAN CHASE DECREASES, DILUTED TO 6% OF BENITEC**

*** ANALYTICA CHAIR DR MICHAEL MONSOUR INCREASES, DILUTED TO 23%**

*** PETER CORR, INOV8 INCREASE, DILUTED TO 11% OF ANALYTICA**

*** MERCHANT GROUP TAKES 7% OF RHYTHM**

*** TDM INCREASES TO 19.97% OF SOMNOMED**

MARKET REPORT

The Australian stock market climbed 1.29 percent on Friday June 15, 2018 with the ASX200 up 77.4 points to 6,094.0 points. Seventeen of the Biotech Daily Top 40 stocks were up, nine fell, 12 traded unchanged and two were untraded.

Optiscan was the best, up 0.9 cents or 12.9 percent to 7.9 cents with 245,895 shares traded. LBT climbed 12.2 percent; Impedimed was up 8.3 percent; Immutep rose 5.9 percent; Actinogen and Sirtex were up four percent or more; Factor, Mesoblast, Oncosil and Orthocell rose more than two percent; Admedus, Compumedics, Ellex, Resmed, Starpharma and Telix were up more than one percent; with Cochlear, Nanosonics and Pro Medicus up by less than one percent.

Yesterday's 13.95 percent best, Prana, led the falls, down 0.4 cents or 8.2 percent to 4.5 cents with 326,666 shares traded. Airxpanders lost eight percent; Pharmaxis fell 7.5 percent; Benitec shed 6.7 percent; Prescient was down 4.2 percent; Opthea lost 3.9 percent; Neuren and Reva shed more than two percent; with CSL and Medical Developments down by more than one percent.

DR BOREHAM'S CRUCIBLE: IMUGENE

By TIM BOREHAM

ASX code: IMU

Share price: 2.6 cents

Shares on issue: 2,854,882,382*****

Market cap: $74.2 million

Chief executive officer: Leslie Chong

Board: Paul Hopper (executive chairman), Charles Walker, Dr Axel Hoos, Leslie Chong

Financials (March quarter): revenue nil, cash used $1.46 million, cash at end of quarter $10.4 million*****, estimated current quarter cash outflows $1.4 million

Identifiable holders*: Platinum Asset Management 5.57%, Private Portfolio Managers 4.39%, Paul Hopper 2.49%, Sarah Cameron 2.1%.

***** Ahead of the $20m capital raising that will result in up to 744,950,463 additional shares being issued.

Earlier this year, Imugene managing director Leslie Chong asserted the cancer vaccine minnow did not want to be a "me too" company.

"We want to be innovative and come at it from a different angle," she told a biotech confab.

As it happens, Imugene's "different angle" was a $20 million licencing deal to acquire a family of 16 patents from the Ohio State University and Minnesota's Mayo Clinic.

Hence, Imugene has swooped on the world's biggest repository of B-cell patents and know-how.

The acquisition taps the 28 years of research expertise of Ohio University's Prof Pravin Kaumaya, one of the godfathers of cancer vaccine research.

Ms Chong says Imugene cottoned on to the opportunity when chief technical officer Nick Ede chaired a conference president by Dr Kaumaya.

"We understood Prof Kaumaya was doing similar things but we didn't know how far ahead he was," she says.

Like a whirlwind romance, one thing led to the other and within seven weeks the Ohio-Mayo camp decided Imugene was its preferred partner.

The deal details

Overall the deal provides Imugene with six additional cancer targets.

To fund the shebang, Imugene is in the throes of a $20 million capital raising, by way of a $12 million placement and an $8.1 million rights issue, both at 2.7 cents a share.

Investors also receive one free option for every three shares held, exercisable at four cents each by November 2021.

The licence entails a small (six figure) upfront payment, milestone and royalty or royalty-style payments.

The raising is underwritten by Bell Potter so the funds are as good as through the door, although the deal requires shareholder assent at an EGM scheduled for July 9.

From poultry to immune-oncology

A classic Aussie battler, Imugene listed on the ASX in 2002, emerging from the shell of an outfit called Vostech.

Speaking of shells, Imugene initially was pushing vaccines for poultry (and pigs) and then turned its sights to a bird 'flu vaccine, but that opportunity flew away.

In 2012 Axel Hoos and Prof Ursula Weidermann identified the HER-vaxx technology at the Medical University of Vienna. The technology was incorporated as Biolife Science, which was initially private funded but then reverse-listed into Imugene (by then a shell company) in 2015.

Unusually, Dr Hoos remains on the Imugene board but he hasn't given up his day job as vice president for oncology R&D at Glaxosmithkline (GSK).

Dr Hoos played a key role in developing the immune-oncology treatment Yervoy, a.k.a. the drug that saved Hawthorn AFL star and melanoma sufferer Jarryd Roughead.

Prof Weidermann is Imugene's chief scientific officer.

Then Imugene's chief operating officer, Ms Chong took over as CEO in 2016, replacing former Alchemia chief Charles Walker (who remains on the board).

In March, Ms Chong was elevated from CEO to managing director (in other words, she got a board seat but sadly no pay rise).

Ms Chong previously was senior clinical lead at Genentech, which developed the blockbuster breast and gastric cancer Herceptin before being acquired by Roche.

Chairman and gun negotiator Paul Hopper also chaired Viralytics, which Merck has just acquired for $502 million.

What's the fuss about?

The Ohio-Mayo programs cover B-cell peptide vaccines and are closely linked to Imugene's existing work. Its most advanced program is in phase II, covering solid tumors such as breast, colon and ovarian.

But the purchase also strengthens the prospect of developing so-called programmed death-1 (PD-1) checkpoint inhibitor drugs, in the same vein as the monoclonal antibodies Keytruda and Opdivo. A combination therapy is also a likely outcome.

Imugene's lead molecule HER-Vaxx targets the same cancer receptors as the $US7 billion a year Herceptin - but Imugene hopes that it can do so more cheaply and with better efficacy.

HER-Vaxx is a mimotope: a small molecule, often a peptide, which mimics the structure of an epitope (the specific target the antibody binds to). The mimotopes cause the B-cells to produce a copy of the desired antibodies.

In non-nerdy terms, the vaccine wakes up the B-cells to produce millions of antibodies that fight the good fight. The mimotopes work in the same way as Herceptin, but they are naturally produced and supposedly more efficacious.

Trial progress

Imugene's story to date on the clinical front is a phase I breast cancer trial, completed at the Medical University of Vienna. The trial enrolled 10 patients with late-stage HER-2+/++ cancers, in combination with traditional chemotherapy. HER-2 is a hair-like receptor found on the surface of 20 to 30 percent of breast and gastric cancer cells.

The results indicated a strong vaccine response, with the induced antibodies showing "potent anti-tumor activity".

Attention has turned to a phase Ib/II trial for gastric cancers showing the HER-2+ mutation. The lead-in open label trial enrolled up to 18 patients, who were treated in combination with standard chemotherapy. Early patient data is expected this month.

A phase II study is expected to expand the patient cohort to 70 subjects across sites in Asia (the largest market for gastric cancer).

The Ohio-Mayo acquisition brings programs including a US National Cancer Institute funded, phase II HER-2 breast cancer trial, as well as a PD-1 checkpoint inhibitor for a phase I solid tumor trial.

The latter is described as ready for a US Food and Drug Administration investigational new drug application (IND).

The difference between the Imugene and Ohio-Mayo studies is that the latter carried out more academic investigator sponsored trials, while Imugene's are structured more as commercial studies.

“Having parallel programs provides synergies and ergo that’s why we acquired [the assets],” Ms Chong says.

Financials and performance

Imugene shares have traded between 1.2 cents and 3.6 cents over the last 12 months, having spurted from 1.9 cents to 2.5 cents after Merck swooped on Viralytics in February.

Late last year, Imugene raised a chunky $8.7 million in a placement and rights issue. Given the earlier raising was struck at 1.8 cents, it presumably delivered investors more than happy to pony up for the latest $20 million (which should be enough to fund the company for up to three years).

Imugene’s prospects were bright enough to attract Platinum Asset Management - which normally only invests in global companies - to the register.

It will be interesting to see what newbie investors crop up as a result of the raising, which will be completed next month following the shareholder vote.

Dr Boreham’s diagnosis:

Many biotechs have tried to develop cancer vaccines, but the Gardasils of the world (Prof Ian Fraser’s wonder cervical cancer vaccine) are few and far between.

With the company now tapping the world’s best B-cell brains, it has a fighting chance of getting somewhere.

Some pundits have questioned why Imugene is ASX-listed, with its HQ in Melbourne, when the development work to date has taken place in Johann Strauss’s old waltzing ground.

So far, the company has regarded a Nasdaq listing as too expensive. For the time being, the company will remain as Australian as Vegemite (which unlike most of our supposedly dinky-di brands is actually locally owned).

“It’s a great time to be an Australian biotech, there are lots of things happening in the sector,” Ms Chong says.

Given the early nature of the combined programs it’s hard to say what Imugene should be worth, but it’s real value will become apparent as the programs either progress or stumble.

“If you follow the science, the dollars will come,” Ms Chong promises.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he is as Australian as imported Holden cars.

SIRTEX

Sirtex says it has terminated the $1.56 billion Varian Scheme and has a $1.87 billion binding scheme deed with CDH Genetech and China Grand Pharmaceuticals.

Last month, Sirtex said it received an unsolicited proposal from China's CDH Investments to buy Sirtex for $33.60 a share, but said its board backed the Palo Alto, California-based Varian Medical Systems' offer of $28 a share, which was to be voted on by shareholders three days later (BD: May 4, 2018).

On May 4, the company said the offer from CDH Investments, an alternative asset fund manager with more than $US20 billion of committed capital, was non-binding, indicative and was subject to conditions including approval by CHD's investment committee following due diligence and formal documentation, as well as approval from Australia's Foreign Investment Review Board.

On May 22, Sirtex said CDH Genetech, an entity wholly-owned by funds advised by CDH Investments, had made "an offer capable of acceptance" to acquire Sirtex through a scheme of arrangement at $33.60 a share, but that Sirtex's directors continued to "unanimously support and recommend the Varian scheme" (BD: May 23, 2018).

Today, Sirtex said the proposal from CDH Genetech had been changed to a joint offer from CDH Genetech and its partner China Grand Pharmaceutical and Healthcare Holdings, both of which would be liable to complete the acquisition, with terms and conditions similar to the May 22 offer.

The company said it had issued a notice to Varian providing it with a right to submit a matching or superior proposal, as required under the terms of the scheme implementation deed, although Varian said it would not submit a matched or superior proposal.

Sirtex said its board unanimously supported the CDH Genetech and China Grand Pharmaceutical proposal over the Varian scheme, having investigated its merits and risks as well as seeking specialist advice regarding regulatory, legal and funding risks, and recommended Sirtex shareholders vote in favor of the new proposal, subject to the company not receiving a superior proposal and an independent expert concluding that the scheme was in the best interests of shareholders.

The company said termination of the scheme required it to pay Varian a break fee of about $16 million, but said CDH Genetech and China Grand Pharmaceutical had agreed to indemnify Sirtex for this fee.

Sirtex chief executive officer Andrew McLean said the new scheme was an "exciting opportunity to enhance the growth of the Sirtex business, including through entry into new geographies, and we look forward to working with [CDH Genetech] and [China Grand Pharmaceutical] to implement the transaction".

Sirtex climbed $1.36 or 4.6 percent to $31.00 with 1.6 million shares traded.

BENITEC

Benitec says chief executive officer Greg West and chief scientific officer Dr David Suhy have resigned, with chairman Dr Jerel Banks and director Megan Boston promoted.

Benitec said Mr West's resignation was effective immediately, after seven years working for the company rising from company secretary and chief financial officer to chief executive officer, while Dr Suhy's resignation was effective from June 22, 2018, and he would continue as a consultant.

The company said Dr Banks was the chief investment officer of Nant Capital LLC, which held 34 percent of Benitec and had been appointed executive chairman, with Ms Boston appointed an executive director and head of Australian operations.

Benitec fell one cent or 6.7 percent to14 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says 75 osteoarthritis (OA) patients treated with pentosan polysulfate sodium under a special access scheme had an average 50 percent pain reduction.

Paradigm said it had data on a further 30 patients treated with injectable pentosan polysulfate sodium under the Australian Therapeutic Goods Administration program.

The company said that of the 75 patients, 63 (84.0%) responded with both a reduction in joint pain and an improvement in knee function.

Paradigm said that the 50 percent reduction in pain scores was “considered superior than the typical 15 percent pain reduction scores reported for opioid treatments for chronic pain in [osteoarthritis] of the knee and hip” and a clinically meaningful reduction of chronic pain was defined as 25 to 30 percent pain reduction.

Paradigm said the special access scheme patients were treated under a similar dosing regimen as those in its up-to 100-patient, phase IIb, randomized, double-blind, placebo-controlled osteoarthritis trial, which was expected to release results by the end of the year.

In May, the company said the trial was 80 percent recruited (BD: May 17, 2018).

Today, Paradigm said that the 75-patient “real-world” data could be used in combination with trial results to support product registration for repurposed pharmaceuticals under the US Food and Drug Administration 505(b)(2) regulatory pathway.

The company said there might be more than 150 patients in total reported under the special access scheme before the phase IIb clinical trial results.

Paradigm said the 75-patient self-reported data was a pooling of results from 24 patients in October 2017, 21 patients between November 2017 and February 2018 and 30 patients treated and assessed between March 2018 and June 2018.

Paradigm said the group included 38 males and 37 females with a median age of 57.8 years in a range from 31 years to 84 years, who had been clinically diagnosed with osteoarthritis and subchondral bone marrow lesions or bone bruising.

The company said that all patients were symptomatic with pain for at least six months and had failed current standard of care, which involved treatment with analgesics, non-steroidal anti-inflammatory drugs (NSAIDs) or cortico-steroids.

Paradigm said that 70 percent of the patients had moderate to severe bone bruising with lesions ranging from five millimetres to more than 20 millimetres in diameter and 30 percent had lesions less than five millimetres in diameter.

The company said the patients were administered with two injections of pentosan polysulfate sodium per week for three to six weeks depending on the severity of the lesions and followed up at four to six weeks following the last treatment, during which patients did not receive NSAIDs or cortico-steroid treatment.

The company said that 68 of the 75 (90.6%) patients showed improvement in knee function and the average improvement in knee function “was clinically meaningful at 67.4 percent compared to pre-treatment function.

Paradigm chief executive officer Paul Rennie said the company was “very pleased to see the third group of real world evidence patients report results that are consistent with the first and second groups of patients we treated under the program”.

“The number of patients seeking treatment via the [special access program] is accelerating, which we believe is a strong indication that the patients are receiving a clinical benefit from the … treatment,” Mr Rennie said.

“Given these patients have a very similar treatment regimen to subjects being treated under the current phase IIb osteoarthritis … trial and these patients have failed current therapies to treat [osteoarthritis], we feel particularly confident regarding a positive clinical trial outcome,” Mr Rennie said.

Paradigm was up half a cent or 0.7 percent to 68.5 cents.

SUDA PHARMACEUTICALS

Suda says that Magna Pharmaceuticals has licenced its Zolpimist for insomnia to the Englewood, Colorado-based, Aytu Bioscience Inc for the US and Canada.
Suda said it had licenced Zolpimist, or zolpidem tartrate oral spray, from Magna for all territories other than the US and Canada.
The company said that Zolpimist was an US Food and Drug Administration-approved, proprietary, oral spray formulation of zolpidem tartrate indicated for the short-term treatment of insomnia, characterized by difficulties with sleep initiation.
Suda chief executive officer Stephen Carter told Biotech Daily that Suda had licence and distribution deals in place with Israel's Teva Pharmaceuticals for Latin America and with Eddingpharm for China, and the company was in discussions with other companies for the rest of the world.
Mr Carter said that Aytu would raise the profile of Zolpimist, which in turn would benefit Suda's sales and distribution.
In a media release to the ASX Mr Carter said the company was "pleased that Magna Pharmaceuticals has licensed Zolpimist to Aytu Bioscience in the US and Canada".
"Aytu is well placed to build further awareness of this novel oral spray for insomnia and to grow prescription demand in the US market through its direct sales force," Mr Carter said.
"The success of Zolpimist in the US enhances our efforts to secure partners and commercialize the product in the rest of the world," Mr Carter said.
"We look forward to working with the team at Aytu," Mr Carter said.
Suda was up 0.1 cents or 12.5 percent to 0.9 cents with 1.65 million shares traded.

MEDADVISOR

Medadvisor says it has a three-year agreement with Ebos subsidiary Zest to provide a digital communication channel for Zest's healthcare programs.
Last year, Medadvisor said the Melbourne and Christchurch, New Zealand-based Ebos group has invested $10.5 million in the company for a 14.1 percent stake and through its community pharmacy division, Ebos had interests in or operated pharmacy chains and brands including Terry White Chemmart, Pharmacy Choice, Good Price Pharmacy Warehouse and Healthsave Pharmacy, as well as providing software and services to community pharmacies (BD: Oct 24, 2017).
Today, Medadvisor said the agreement with Zest would enable better connections with manufacturers and the community.
The company said that Zest had a "track record of implementing programs for leading healthcare and pharmaceutical companies".
Medadvisor said it expected to earn fees for delivery of programs by the two parties.
Medadvisor fell 0.2 cents or 4.8 percent to four cents.

NANOSONICS

JCP Investment Partners says it has reduced its substantial shareholding in Nanosonics from 28,210,101 shares (9.42%) to 25,078,032 shares (8.38%).
The Melbourne-based JCP said that between May 25 and June 12, 2018 it bought and sold shares, with the single largest sale of 2,000,000 shares for $6,168,545, or $3.08 a share, while the largest purchase was 190,131 shares for $504,871, or $2.66 a share.
JCP said its shares were held by National Nominees, HSBC Custody Nominees, BNP Paribas Nominees, JP Morgan Nominees and UBS Nominees.
Nanosonics was up two cents or 0.65 percent to $3.09 with 1.7 million shares traded.

BIONOMICS

Private Portfolio Managers says it has ceased its substantial shareholding in Bionomics, buying and selling shares between February 9 and June 8, 2018.
In 2017, the Sydney-based Private Portfolio Managers said it became substantial with 26,403,534 shares (5.48%) (BD: Feb 24, 2017).
Private Portfolio Managers previously became substantial in Bionomics in 2015 but was diluted below 5.0 percent in a series of issues of shares in employee share schemes (BD: Oct 29, 2015).
Today, Private Portfolio Managers said its single largest sale was 528,498 shares for $301,243, or 57 cents a share on June 8, 2018.
Private Portfolio Managers said it held 23,985,659 shares in Bionomics, which Biotech Daily calculates to be 4.97 percent of the company.
Bionomics was unchanged at 54 cents.

BENITEC BIOPHARMA

JP Morgan Chase says it has decreased its shareholding and has been diluted in Benitec from 15,444,020 shares (7.00%) to 15,420,800 shares (6.00%).
The New-York based JP Morgan Chase said that on June 13, 2018 it sold 1,161 American depositary shares (ADS) equivalent to 23,220 Australian shares for $54,567, or $2.35 per ADS or 11.75 cents per Australian share, through its subsidiary Highbridge Capital Management LLC.
JP Morgan Chase said an “ISC change” on June 4, 2018 diluted it from seven to 6.01 percent of Benitec.
In April and May, Benitec said it had raised $8.8 million in a placement and rights offer at 17 cents a share (BD: Apr 30, Jun 1, 2018).

ANALYTICA

Analytica chairman Dr Michael Monsour has increased his shareholding and been diluted from 705,614,893 shares (25.06%) to 776,176,379 shares (23.36%).
Dr Monsour said in his substantial holder notice that the shares were acquired through the exercise of options of options and participation in a rights issue directly and through MPMM Pty, Ms A Monsour, MP Monsour Medical Practice Super Fund and Halonna Pty.
The substantial shareholder said the shares were bought for 0.5 cents a share.
Analytica was unchanged at 0.5 cents with 4.4 million shares traded.

ANALYTICA

Inov8 LLC and Peter Corr have increased their holding and been diluted in Analytica from 320,702,362 shares (12.58%) to 360,790,157 shares (10.81%).
In a substantial shareholder notice signed by owner and director Peter B Corr, the St Thomas, US Virgin Islands-based Inov8 said the 46,949,153 shares were bought on April 24, 2017 for $277,000 or 0.59 cents a share.

RHYTHM BIOSCIENCES

Merchant Funds Management says it has increased its substantial shareholding in Rhythm from 5,060,000 shares (5.02%) to 7,060,000 shares (7.01%).
The Perth-based Merchant said it bought the shares on market and was diluted through the exercise of options on June 13, 2018, acquiring 2,000,000 shares for $449,561 or 22.5 cents a share.
Rhythm was up 1.5 cents or 6.8 percent to 23.5 cents.

SOMNOMED

The New York-based TDM Asset Management says it has increased its shareholding in Somnomed from 11,407,561 shares (18.34%) to 12,422,014 shares (19.97%).
TDM said that between June 11 and June 14, 2018 it bought 1,014,453 shares, at an average of $2.26 but did not disclose individual purchases.
TDM said its associated entities included TDMAM Pty Ltd, Madleowill Investments Pty Ltd, Zoolander Investments Pty Ltd, Thomas Cowan, Rebecca Cowan, Hamish Corlett and Benjamin Gisz.
Somnomed fell 11 cents or 4.7 percent to $2.25.