Biotech Daily

Friday June 8, 2018

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: COMPUMEDICS UP 12.5%;**
- PRESCIENT DOWN 7%

*** DR BOREHAM'S CRUCIBLE: FACTOR THERAPEUTICS**

*** S&P PROMOTES COCHLEAR INTO ASX50**

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*** SANDON CAPITAL TAKES 6.6% OF IDT**

*** LAZARD BELOW 5% IN MAYNE PHARMA**

*** BARD1 RELEASES ESCROW SHARES**

*** OBJ ELECTS ANTONIO VARANO CHAIRMAN**

MARKET REPORT

The Australian stock market fell 0.2 percent on Friday June 8, 2018 with the ASX200 down 12.1 points to 6045.2 points. Fifteen of the Biotech Daily Top 40 stocks were up, 16 fell, six traded unchanged and three were untraded. All three Big Caps fell.

Compumedics was the best, up seven cents or 12.5 percent to 63 cents with 110,467 shares traded. Avita climbed 11.5 percent; Oncosil improved 10.3 percent; Benitec was up 6.45 percent; Nanosonics was up 5.9 percent; Mesoblast and Prana were up more than four percent; Immutep and Imugene were up more than three percent; Actinogen, Optiscan and Universal Biosensors rose more than two percent; Cynata and Ellex were up more than one percent; with Bionomics up 0.9 percent.

Prescient led the falls, down one cent or 7.1 percent to 13 cents with 55,680 shares traded. Admedus lost 5.6 percent; Factor, Impedimed and Polynovo fell four percent or more; Reva fell 3.85 percent; Dimerix shed 2.1 percent; Cochlear, Opthea, Orthocell, Pharmaxis and Volpara were down one percent or more; with Clinuvel, CSL, Medical Developments, Neuren, Pro Medicus, Resmed and Sirtex down less than one percent.

DR BOREHAM'S CRUCIBLE: FACTOR THERAPEUTICS

By TIM BOREHAM

ASX: FTT

Share price: 4.8 cents

Market cap: $40.05 million

Shares on issue: 834,335,633

Financials (March quarter)*: receipts $22,000, cash used $2.02 million, cash on hand $4.62 million, estimated current quarter cash outflows $3.2 million

***** In April the company raised $4.2 million in a rights offer at four cents a share and in May it received a $1.23 million Federal R&D Tax Incentive.

Chief executive officer: Dr Rosalind Wilson

Board: Dr Cherrell Hirst (chair), Dr Chris Behrenbruch, Dr Robert Ryan, John Michailidis, Tim Hughes

Identifiable major shareholders: Allan Gray Investment Management 14.7%, Fidelity Investment Management 9.9%, Acorn Capital 4.9%.

In the public Battle of the Diseases, venous leg ulcers (VLUs) are losing the PR war to breast cancer (Pink Ribbon Day), motor neurone disease (Ice Bucket Challenge) and even muscular dystrophy (National Superhero Week).

"Trying to heal wounds is not at all sexy," says Factor Therapeutics chief Dr Rosalind Wilson. "The level of public awareness of venous leg ulcers is a massive problem - they just don't get talked about."

Affecting up to three percent of the populace, VLUs are caused by poor circulation due to blood clots, ageing, injury or obesity. They are notoriously difficult to treat, with the wounds, on average, recurring four times.

The untrendy nature of the affliction is reflected in what Dr Wilson dubs a "stunning" lack of progress in wound care R&D in general.

The last time a key wound care technology was approved for diabetic leg ulcers was in 1997, when Seinfeld episodes (new ones, not repeats) ruled the airwaves.

"When I came into the wound care field I was pretty stunned about how little research was being done in general," Dr Wilson says.

She posits that one reason for this is that wound care products are usually regulated as devices, which requires a lower standard of proof than for a drug.

As a result, the wound care developers don't make the extra R&D effort because they don't have to.

No RDO for Factor

But we are seeing a lot of scaffolding these days - and we're not talking about building sites. Rather the healing technologies to treat wounds and burns based on creating a structure on which cells can regrow.

(The clinicians don't even require a CFMEU ticket, but we doubt whether they would work on their RDO, either)

Factor's clinical work centres on phase II trialling of its scaffolding product for VLUs, dubbed VF001, which is not the first Virgin flight of the day but a liquid, topical treatment that contains two nature-based substances.

The first, a peptide called vitronectin creates a biological scaffold to which the skin cells attach and the second is an insulin-like growth factor-1 (IGF-1) which orders the cells to go forth and multiply. The unguent is applied weekly during standard dressing changes.

Tissue name change nothing to be sniffed at

Until May 2016 Factor Therapeutics was known as Tissue Therapies, but opted to rebrand after a corporate overhaul. As part of the process, Factor dumped the Vitrogro name in favor of the more generic title.

The revamp was spearheaded by then executive director Dr Christian Behrenbruch, who reverted to non-executive director after overseeing the appointment of Dr Wilson in May last year.

Dr Wilson has held senior global roles at companies including Nucleusx (medical communications) and Roche; and more recently was the Australian Lung Foundation's executive officer.

Tissue's technology evolved from work at Queensland University of Technology's Institute of Health and Biomedical Innovation.

About VF00102

Factor's clinical work centres on its phase II VLU trial of VF001 that goes by the equally catchy name of VF00102.

The multi-site, 168-patient trial involves the subjects receiving a dose of the good stuff or a placebo over 12 weeks. They also receive the standard-of-care of moist dressings and compression bandages.

The primary endpoint is simple enough: reduce the size of the wound.

Other endpoints are the proportion of patients with full wound closure, time of wound closure and “improvements in pain and quality of life and safety.”

After long delays, in May Factor reported VF00102 had enrolled 70 percent of its intended 168 patients, with the withdrawal rate lower than expected.

At Factor’s annual meeting last month, management presented preliminary results based on 91 patients that had completed treatment.

By the end, 53 percent were fully healed, with 50 percent healing by week four and 70 percent healing by week 12.

This compared with the standard of care UK trial, called Venus 3. In this 49-patient effort, 41 percent were fully healed, with 50 percent healing at week 10 and 55 percent healing at week 12.

Bear in mind that because the Factor trial is blinded, the rapidly healing patients could well be those taking the placebo.

Top-line results are due in October, with full results early in 2019.

Factor is carrying out early stage work for diabetic leg ulcers, ocular applications and harlequin ichthyosis (a severe genetic condition that causes infants’ skin to turn hard and thick).

In July, Factor plans to start a program for an ocular orphan indication known as persistent corneal epithelial defect (a hole on the surface of the eye).

If you don’t succeed the first time ...

In its Tissue days, Factor failed to win European approval for a VLU device despite a positive 53-patient trial. In 2011, Tissue Therapies said it expected European approval that year along with the start of a US trial and first sales in 2012.

In 2013, the company said that despite assurances from its European Medicines Agency (EMA) responsible entity the British Standards Institute that Vitrogro was a device and the EMA took a further two years to decide that the IGF-1 in the potion’s mixture was actually a drug, requiring a new trial. Chief executive officer Dr Steven Mercer took the fall.

While the previous trial results were promising, the small size of the patient base raised issues which the current larger trial should obviate.

“We should be in a position to return to CE Mark process fairly soon after the final readout,” Dr Wilson says.

“In parallel we will approach the US Food and Drug Administration for an end of phase II meeting.”

As the US process would involve a drug rather than device approval, a phase III trial would be required.

Dr Wilson says European approval could be possible within nine to 12 months, with a product on market by 2020.

Missed by that much ...

Reflecting Factor's US focus, the company this year has changed to a December 31 balance date. This meant shareholders were treated to two "annual" meetings, on November 16 last year and on May 24 this year.

At the most recent one, management narrowly avoided a first 'strike' against its remuneration report: a 23.8 percent protest vote compared with the threshold 25 percent.

Dr Wilson attributes the near miss to institutions unhappy with the options-based incentive scheme for directors. But none of the option tranches was granted below an 11c a share strike price so they're nowhere near in-the-money.

"Some investors were clearly affected by the company's inability to get over the line in Europe last time around," she said. "But there is no other issue."

Dr Boreham's diagnosis:

Factor is in a similar genus to Polynovo (PNV, market cap $392 million), which has an approved scaffolding called Novosorb on the market.

Unlike Polynovo, which can use its Commonwealth Scientific and Industrial Research Organisation-originated product in a range of materials, Factor presents a binary outcome as a one-product company.

Factor's mandatory risk statement - a.k.a. the cup of truth - states there's no assurance a product will be "safe and efficacious" or able to be commercialized.

As the Bard said, it's a case of VF001-2B, or VF001-NOT-2B.

At least Factor is reasonably well cashed-up, having last month raised $4.17 million in a non-renounceable rights issue at four cents apiece.

Three institutions (Allan Gray, Fidelity and Acorn Capital) are major shareholders. So, if Factor does need a wee top up, management knows who to turn to first.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He awaits a National Canker Sore Week, no doubt in vain ...

COCHLEAR, STANDARD & POOR'S

The Standard & Poor's Dow Jones Indices has included Cochlear to the S&P ASX50, demoting Incitec Pivot (formerly Imperial Chemical Industries).
Standard & Poor's previously told Biotech Daily that the inclusions reflect market capitalization meaning that Cochlear is one of the 50 largest companies listed on the ASX. (BD: March 10, 2017)
Standard & Poor's said that changes in the indices would be effective from the open of trading on June 18, 2018.
No other biotechnology companies were affected by the review of the rebalance, which included the S&P ASX 200 and the S&P ASX All Australian indices.
Cochlear fell $2.34 or 1.2 percent to $198.63 with 125,273 shares traded.

NUHEARA

Nuheara says it has raised $6 million in a placement at 9.5 cents a share, the same price as the 20-day volume weighted average price.
Nuheara said the funds would be used to increase sales and marketing of its hearing devices Iqbuds and Iqbuds Boost, increasing inventory levels of Iqbuds Boost and the mass production and launch of Liveiq, a new hearing device to be launched later this year.
Nuheara chief executive officer Justin Miller said that "due to strong initial consumer and retail demand, we have now had to increase our June production levels".
"In light of the popularity of Boost, as well as our continued geographical retail expansion into new major markets such as Japan, Nuheara has now needed to add more financial resources," Mr Miller said.
Nuheara said that existing shareholder Farjoy Pty Ltd "cornerstoned the equity raising", with the Sydney-based APP Securities Pty Ltd the bookrunner and lead manager.
Nuheara was up half a cent or 4.8 percent to 11 cents with 12.85 million shares traded.

IDT AUSTRALIA

IDT says it began remediation activates immediately following a US Food and Drug Administration warning regarding its facilities in December 2017 (BD: May 29, 2018).
IDT said it had changed its quality and operational personnel, as well as its internal processes and systems.
The company said it had organized a team of personnel from quality, operations and microbiology, along with several technical specialists, to "compile the response, drive remediation activities and effect improvements to the ongoing quality and operational systems at IDT".
The company said it had hired Seerpharma's Andrew Giles, who previously worked for the Australian Therapeutic Goods Administration as a consultant on good manufacturing practice to assist the changes.
IDT said its response to the Food and Drug Administration was due within 15 working days of receipt of the warning letter and the company would formally respond to the warning letter within the stated timeframe.
The company said that the FDA warning letter did not contain any enforcement conditions limiting or preventing the import or sale of its products in the US and its order book for the financial year to June 30, 2018 was strong.
IDT was up 0.9 cents or 12.7 percent to eight cents.

IMUGENE

Imugene says it has told the ASX that an “external consultant to the company” advised it to provide embargoed information to the Australian Financial Review.
The ASX asked how information regarding its $20 million capital raising and B-cell acquisition from Ohio State University and the Mayo Clinic was published in the Australian Financial Review on June 7, 2018, prior to the release of the news to the ASX at 9.43am on that date (BD: Jun 7, 2018).
Imugene said it had provided the “background information” under an embargo and that a quote was sought from the company on that basis.
The company said “the situation was compounded by time zone issues relevant to key parties”.
Imugene said that the wording of the newspaper article reflected that at the point of publication no definitive information existed and that it had remained in a trading halt at all relevant times.
The ASX said “Listing Rule 15.7 prohibits an entity from releasing information which is for release to the market to any person, including the media, even on an embargoed basis, until it has given the information to [the] ASX and received an acknowledgment that [the] ASX has released it to the market”.
The ASX said “Listing Rule 3.1 states “Once an entity is or becomes aware of any information concerning it that a reasonable person would expect to have a material effect on the price or value of the entity’s securities, the entity must immediately tell ASX that information”.
Imugene said it “regrets that its actions, whilst taken in good faith and based on external consultant’s advice, have resulted in these concerns being raised … [and] now understands that it is not appropriate to provide information to the media on an embargoed basis”.
The company said it would “conduct further training on Listing Rules 3.1 and 15.7 with its directors and senior management”.
Imugene said it would “ensure its terms of engagement with external consultants and professional advisers are appropriate to achieve compliance with the ASX Listing Rules”.
Imugene was up 0.1 cents or 3.6 percent to 2.9 cents with 13.2 million shares traded.

BIOTECH DAILY COMMENT

Biotech Daily has previously written about the need for companies to adhere to the ASX Listing Rules for the stock market to be “a level playing field” (BD: Oct 11, 2017).

Some public relations companies think it is clever to selectively leak a news item to a favored reporter, so they can claim to have a “scoop exclusive”.

But a media release can never be a “scoop”, which requires original research, and it is not very exclusive if the whole world will be told the same news a little bit later.

Apart from the breach of ASX Listing Rules, the leaking to one reporter may curry favour with that person, but it means every other journalist will know they have been deliberately excluded.

Some might question the wisdom of doing so for a dozen paragraphs on page 23 of any publication, no matter how prestigious.

David Langsam, Editor

OVENTUS MEDICAL

Oventus says the US Patent and Trademark Office has granted a patent covering its integrated airway technology, providing coverage until May 18, 2032.
Oventus said that the patent, titled 'Breathing Assist Device' covered its integrated airway or Oventus airway technology which is used in its O2vent devices for sleep apnoea and snoring.
The company said it had already been granted an Australian patent and had received a notice of allowance from the European patent office for its Oventus Airway Technology.
Oventus chief executive officer Neil Anderson said the patent protected "the fundamental invention of the use of an airway from the front to the back of the mouth".
"It is the reason why our appliances work so well compared to the existing mandibular advancement devices…[and] is also the platform for which our additional [patent] families are based," Mr Anderson said.
Oventus fell 1.5 cents or 3.95 percent to 36.5 cents.

MONASH UNIVERSITY, BIOTECH RESOURCES

Monash University says it has been issued a US patent for a malaria diagnostic developed by one of its chemists as part of a research collaboration.
Monash University said the patent, titled 'Attenuated Total Reflectance (ATR)' would provide intellectual property cover, for a rapid and low-cost test for malaria which used spectroscopy to diagnose the disease, until February 5, 2034.
The University said the patent was licenced to Melbourne-based Biotech Resources, which would commercialise the product, to be known as 'Aimalux'.
Monash University said patent applications were pending in Australia and nine other countries, with the US the first to be granted.
Prof Bayden Wood said the patent "covers the extraction of the parasites from the blood sample, spectroscopic analysis of the sample and cloud-based diagnosis based on the infrared lipid signatures from the parasite".
Biotech Resources is a private company.

IDT AUSTRALIA

Sandon Capital says it has increased its substantial shareholding in IDT from 12,885,055 shares (5.3%) to 16,102,505 shares (6.6%).
In a substantial shareholder notice signed by director Gabriel Radzyminski, the Sydney-based Sandon Capital said that between March 13 and June 6, 2018 it bought 3,217,450 shares for $237,065 or 7.4 cents a share.

MAYNE PHARMA

The Sydney-based Lazard Asset Management Pacific Co says it has ceased its substantial shareholding in Mayne Pharma.
In February, Lazard filed an initial substantial shareholder notice saying it held 79,563,230 shares or 5.22 percent of Mayne Pharma (BD: Feb 28, 2018).
Today, Lazard said that between February 2 and June 5, 2018 it bought and sold shares, with the single largest sale on June 5 of 9,578,390 shares for $8,318,676, or 86.9 cents a share.
Mayne was up 2.5 cents or 2.9 percent to 89 cents with 12.2 million shares traded.

BARD1 LIFE SCIENCES

Bard1 says it will release 229,503,236 shares and 217,003,236 performance shares from ASX mandatory escrow on June 20, 2018.

In its most recent Appendix 3B new issue announcement, Bard1 said it had 599,159,161 shares quoted on the ASX and with the release of the escrowed shares would have 828,662,397 shares tradeable on the ASX, with the performance shares subject to meeting milestones.

Bard1 fell 0.1 cents or 6.7 percent to 1.4 cents with 9.2 million shares traded.

OBJ

OBJ says its board has elected New-York based Antonio Varano as chairman, replacing interim chairman Steven Schapera effective from July 1, 2018.

Last month, OBJ appointed Mr Varano as a non-executive director (BD: May 7, 2018).

OBJ was up 0.1 cents or 4.8 percent to 2.2 cents with 3.7 million shares traded.