Biotech Daily

Friday June 7, 2019

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ORTHOCELL UP 7%; BENITEC DOWN 39%**

*** DR BOREHAM'S CRUCIBLE: MEDICAL DEVELOPMENTS**

*** AXOVANT TERMINATES BENITEC $954m BB-301 OPMD DEAL**

*** BIO-MELBOURNE WOMEN'S LUNCH 'SOLD OUT'**

*** NUHEARA TRADES ON US OTCQB EXCHANGE**

*** CANADA'S PHARMACIELO TO BUY CRESO for $122m IN SHARES**

*** IMAGION TO RELEASE 78m ESCROW SHARES, 9.6m RIGHTS**

*** MMJ 10m SHARE BUY-BACK; EMBARK INVESTMENT MANAGER**

*** MGC, RMIT DIGITAL CANNABINOIDS LIBRARY**

*** NOXOPHARM'S NYRADA RECEIVES $486k R&D TAX INCENTIVE**

*** PAUL ANDERSON, MATT CALLAHAN, SRV DILUTED IN ORTHOCELL**

*** CHAIRMAN DR MICHAEL MONSOUR TAKES 25% OF ANALYTICA**

*** LEVENSON TAKES 7% OF ANTEO**

*** JAMES MIDDLEWEEK TAKES 5% OF ADHERIUM**

*** DEBORAH AMBROSINI REPLACES ACRUX CFO, CO SEC TIM BATEMAN**

MARKET REPORT

The Australian stock market was up 0.95 percent on Friday June 7, 2019, with the ASX200 up 60.9 points to 6,443.9 points. Eleven of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and six were untraded. All three Big Caps were up.

Orthocell was the best, up 2.5 cents or 6.6 percent to 40.5 cents, with 6.2 million shares traded. Patrys climbed four percent; Antisense and Compumedics rose more than two percent; Clinuvel, CSL, Kazia, Medical Developments and Oncosil were up more than one percent; with Cochlear, Cynata, Nanosonics, Pro Medicus and Resmed up by less than one percent.

Benitec led the falls, down 4.7 cents or 39.2 percent to 7.3 cents with 5.1 million shares traded. Imugene lost 11.8 percent; Actinogen retreated 9.1 percent; Avita was down 6.85 percent; Prescient fell 4.65 percent; Immutep and Proteomics were down more than three percent; Dimerix, Paradigm, Polynovo and Telix shed more than one percent; with Mesoblast, Neuren, Starpharma and Volpara down by less than one percent.

DR BOREHAM'S CRUCIBLE: MEDICAL DEVELOPMENTS

By TIM BOREHAM

ASX Code: MVP

Share price: $5.28

Shares on issue: 65,516,746

Market cap: $345.9 million

Chief executive: John Sharman

Board*: David Williams (chairman), Max Johnston, Leon Hoare, Phillip Powell

***** Directors Alan McCallum and Dr Harry Oxer resigned in December last year

Financials (December half 2019): revenue of $9.52 million (up 22%) earnings before interest and tax $136,000 (down 5%), net profit $132,000 (up 3.9%), cash of $32.27 million (up 3400%), dividend 2 cents (steady).

Major shareholders: David Williams 14.5%, M&G Investments 5.0%, Dr Russell Kay Hancock 2.55%, Alistair David Strong 0.99%.

The home-grown Medical Developments is well down the path of fulfilling its charter of making Penthrox the "mainstream analgesic of choice" globally.

After all, Medical Developments has been selling (or is about to sell) its temporary pain relief device - a.k.a. the Green Whistle - in 49 countries.

In Europe, the company sells the device in nine countries, notably the UK (we'll call it Europe for the time being), Ireland, France and Belgium.

Within a year or so, Penthrox should also be available in Germany Italy and Spain and other geographies including that current house of pain, Vatican City.

"It's all about to happen," says CEO John Sharman.

But there's a glaring exception to the company's coverage - the US.

In July last year, Medical Developments revealed the US Food and Drug Administration had put a hold on the company's approval application "pending a letter outlining outstanding issues and concerns".

The news sent the company's shares down 18 percent on the day, although about half of the lost ground has since been regained.

The Brexit process has also slowed the European approval process (see below).

Penthrox through the ages

Medical Developments is all about re-inventing Penthrox - formally known as methoxyflurane - first used here in 1975.

Declaring It's Time for a fast-acting, non-addictive painkiller, prominent anaesthetist Dr David Komesaroff founded Medical Developments in 1972.

Penthrox was (and is) pitched as a rival product to nitrous oxide (laughing gas), morphine, Fentanyl (another opioid) and ketamine (better known as a horse tranquillizer).

Steered by current chairman and biggest shareholder David Williams, Medical Developments listed on the ASX in December 2003, after raising $8.7 million at 25 cents apiece.

Way back then it already had the Victoria Ambulance Service on side, but Medical Developments' more recent history has been one of gradual expansion into overseas geographies from its original Australia and New Zealand base, starting with the UK, Ireland and Saudi Arabia.

In October last year, the company unveiled a tie-up with Daiichi Sankyo to sell Penthrox in China, Thailand and Vietnam. The company pocketed a $21 million up-front payment and is in-line for a further $24.7 million in performance and regulatory related milestones.

Medical Developments has begun a registration process with the China Food and Drug Administration, with an investigational new drug application pending (it takes two months to translate the documents into Mandarin).

Medical Developments generally distributes via partnerships, such as its initial UK-Irish tie up with big pharma house Galen. Mundipharm distributes in Europe and Australia.

The company is also tackling the Russian market in league with JSC Lancet.

Penthrox is also used as a veterinary drug, having been approved a decade ago in the US under the brand name Anafane.

Where's the proof?

Medical Developments has all the clinical proof it needs, because millions of patients have been administered Penthrox safely and effectively.

Still, the company is engaged in a slew of clinical work, either to appease authorities further or to expand the indications of use for Penthrox.

In Europe, interim results from the first 500 patients of a 3,200-patient post-authorization study are due this year.

Medical Developments is also eyeing expanded uses for Penthrox, including as an item in home first-aid kits, for minor surgical procedures, for military purposes and for developing world aid programs.

On the home testing front Medical Developments is developing a next-generation self-administered inhaler, the Selfie.

The company plans to spend $5 million on developing the Epipen-style product, with $500,000 spent so far.

In league with distributor Mundipharma, the company is working on second indications in Europe. These may encompass colonoscopy or gynaecology, cosmetic dentistry, curettes and inter-uterine device insertion.

Overall, the company expects to spend $9.4 million on clinical programs in the current financial year, rising to $12.8 million in 2019-20.

Respiratory arm breathes easily

With products such as Space Chamber and the Breath-a-tech asthma device, acquired for $2.5 million in 2016 from Avita, Medical Developments also has a significant respiratory device business.

Medical Developments has a leading position here, while in the US the devices are sold in 17,000 US pharmacies as well as Walmart, Costco and Kmart.

“It’s an important category because these devices deliver meds 50 percent better (than Ventolin inhalers),” Mr Sharman says.

The division’s revenue was $2.79 million in the December half, one-third of the company’s total sales.

Mr Sharman says the respiratory arm is expected to deliver revenue of $20 million to $22 million “within the next few years”, with an attractive gross margin of 70 percent.

“It’s a very good cash contributor,” he says.

FDA: a tough nut to crack

Perceptions of past use of methoxyflurane may be to blame for the FDA’s reluctance to approve Penthrox.

That’s because the drug was used as an anaesthetic - and it wasn’t that good at keeping patients asleep.

Regulators withdrew approval, leaving Medical Developments the last man standing - Steven Bradbury like - as the only methoxyflurane developer by the end of the 1980s.

The company expects to hold a fireside chat with the FDA about filing a submission, which is expected to happen in 2021 with a view to approval in late 2022.

A trial to satisfy the FDA would likely cost $10 million and involve 700 patients. “It’s pretty straightforward, we have done it a few times,” Mr Sharman says.

Medical Developments maintains it has a strong case. “Seven million people have used the product and we have had no significant adverse signs.”

Brexit brou ha-ha

Mr Sharman concedes the company has been frustrated by Brexit-related regulatory delays, the key issue being the need to find a “qualified person” to replace Britain’s National Health and Medical Research Council.

He says Brexit has produced “insane unintended consequences that don’t cost you an arm and a leg, but cost you time.”

Post Brexit, the NHMRC won’t be the gatekeeper of pan-European drug standards.

Understandable, really.

The company’s solution has been to transfer its files to the smiling eyes of the Irish authorities (Ireland, of course, remaining part of the EU).

“People are jumping out of Britain and looking for a new home, but other regulatory agencies are full,” he says.

“It took us six months to get the Irish to agree to take our files, which meant a six-month hiatus where we couldn’t do anything.”

Finances and performance

Medical Developments has the distinction of being consistently profitable and - shock ! horror ! - it also pays a dividend.

The company reported a net profit for the six months to December 31, 2018 of $132,000, up 3.9 percent, on revenue of $9.52 million (up 22 percent).

December half sales grew by 37 percent, with Europe and UK sales surging 375 percent.

Half of the revenue is still derived from Australia, compared with 62 percent a year previously.

The Kiwis accounted for a further five percent, while the UK and Europe contributed around a quarter (steady).

In August last year, the company went to the well for $17 million by placing 4.25 million shares at $4 apiece. It also raised a further $7.4 million in a share placement.

Management used some of the funds to repay a bank bill facility, reducing debt from $9.5 million a year ago to a mere $181,000.

With cash of $32 million, the board was confident enough to dispense 2.0 cents a share interim dividend, steady on the previous period. A further $7 million in European approval milestones and $50 million in sales milestones are pending.

“There’s plenty of money,” chirps Mr Sharman.

While Medical Developments is making quantum progress, its European launches are also behind schedule because of “regulatory variations”, and management promises “significant sales growth is expected in 2019-20 and beyond.”

Over the last 12 months Medical Developments shares have traded as high as $8 (March 2018) and as low as $3.48 (February this year).

Dr Boreham’s diagnosis

With the ASX ticker MVP, Medical Developments certainly has been a Most Valuable Player in the ASX-listed biotech league.

Can it be the sector’s GOAT*****?

There’s a Groundhog Day element to most biotechs. Indeed, when we wrote about Medical Developments in May 2017, we opined that US approval was the key to justifying the company’s valuation.

Well guess what? FDA approval remains a key driver.

Not that we’re underplaying the company’s ‘rest of the world’ presence.

At the risk of sounding churlish, two years ago Medical Developments reported half year revenue of $8.05 million and a $410,000 profit. In other words, it’s gone backwards earnings wise and hasn’t exactly bounded ahead on the top line.

With the stock trading on a current earnings multiple of around 1,000 times, investors expect this stagnation to abate. And given that investors who weighed in at the 2003 IPO have increased their money 2,400-fold, it’s a case of no pain and all gain.

***** Greatest Of All Time

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has never been named MVP and certainly not GOAT, but has a number of cherished ‘participation certificates’.

BENITEC BIOPHARMA

Benitec says its up-to $US665 million ($A953.6 million) deal with Axovant Sciences for BB-301 for oculo-pharyngeal muscular dystrophy has been terminated.

Last year, Benitec said it would receive a $US10 million upfront cash payment and $US17.5 million in additional cash payments for near-term milestones for BB-301 for oculo-pharyngeal muscular dystrophy (OPMD), from the London and Bermuda based Axovant, and be eligible for milestone payments of $US187.5 million, including the $US17.5 million, as well as 30 percent of the net profits on worldwide sales of the drug, which was renamed AXO-AAV-OPMD. (BD: Jul 9, 2018).

The company said at that time that it would partner with Axovant on five additional gene therapy programs for neurological disorders, receive full research funding for each program and be eligible for $US93.5 million in milestones for each program.

Benitec executive chairman Dr Jerel Banks described the deal at that time as “a milestone for Benitec as we believe this transaction to be transformative for our company”.

Today, Benitec said that the deal would be terminated, effective from September 3, 2019 and it would conduct several exploratory analyses prior to a clinical study of BB-301 for oculo-pharyngeal muscular dystrophy.

Benitec executive director Megan Boston told Biotech Daily that the company would work on further optimization of the compound in preparation for human clinical trials.

The company said that pre-clinical mouse data showed that biological efficacy could be improved by optimizing the delivery method to dose key target tissues that underlie morbidity and mortality associated with oculo-pharyngeal muscular dystrophy.

Benitec said the initial biological efficacy profile from a mouse model of BB-301 for oculo-pharyngeal muscular dystrophy remained unchanged.

The company said completion of the experimental work delayed the BB-301 study beyond the Axovant licence and collaboration agreement timelines.

Last year, Benitec said that Axovant hoped to start a human clinical trial this year.

Benitec said the agreement would be terminated and all rights and licences granted to Axovant would cease.

In 2017 and 2018, the company said it had European and US orphan drug designation, for BB-301 for oculo-pharyngeal muscular dystrophy (BD: Jan 22, 2017; Jan 21, 2018).

Benitec closed down 4.7 cents or 39.2 percent at 7.3 cents with 5.1 million shares traded.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says tickets are sold out for its eleventh annual Connecting Women Lunch on Friday June 21, 2019.

The Network said that the lunch would connect 550 women and men representing all facets of the biotechnology, medical technology and pharmaceutical sector.

Bio-Melbourne Network chief executive officer Dr Julie-Anne White said that the Network was “delighted that the event continues to see such great sector engagement”.

Dr White said that journalist and author Catherine Fox would be the keynote speaker.

The Network said that CSL was the premier sponsor of the Lunch, along with major sponsors Johnson & Johnson Innovation, Deakin University and Syneos Health.

NUHEARA

Nuheara says it has been approved to trade on the US over-the-counter quality B (OTCQB) venture market under the code NUHRF.

Nuheara was up 0.1 cents or 1.3 percent to 7.7 cents with 3.4 million shares traded.

CRESO PHARMA

Creso says the Vancouver, British Columbia-based Pharmacielo will acquire it for $122 million in a share and option scheme.
Creso said shareholders would receive 0.0775 Pharmacielo shares for each Creso share valuing them at 63 cents a share, a 50 percent premium to its June 6, 2019 closing price.
The company said option-holders would receive 0.0185 Pharmacielo shares for each Creso option held as part of the option scheme, valuing each option at 15 cents, which would only proceed if the share scheme proceeded.
Creso said its shareholders would hold 13 percent of Pharmacielo shares, with co-founder and chief executive officer Dr Miri Helperin to be appointed as a director of Pharmacielo.
The company said performance rights holders would be eligible to participate and the schemes would be subject to shareholder and option-holder approval, Australian court approval and Toronto Stock Exchange and TSX Venture Exchange (TSXV) approval to quote new Pharmacielo shares to Creso shareholders.
Creso said there would be a break fee of $1.2 million for either party and a reimbursement fee of $450,000 for Pharmacielo if the share scheme was not approved.
The company said it would receive a $CAD3,500,000 ($A3,390,481) secured bridge loan in advance from Pharmacielo for general working capital, repayable by December 31, 2019 or within four months if the scheme was not approved.
Creso said Everblu Capital was its corporate advisor and would receive a three percent fee and Steinepreis Paganin was its legal counsel.
The company said that Pharmacielo was the largest marijuana producer in Columbia, South America.
Creso was up 13.5 cents or 32.5 percent to 55 cents with 9.05 million shares traded.

IMAGION BIOSYSTEMS

Imagion says it will release 78,099,476 shares and 9,600,000 performance rights from ASX escrow on June 22, 2019.
According to its most recent Appendix 3B new issue announcement, following the release the company would have 322,742,824 shares available for trading.
Imagion was untraded at 2.3 cents.

MMJ GROUP HOLDINGS

MMJ says it has appointed Embark Ventures as its investment manager and will buy-back up to 10 million of its 230,148,985 shares.
In April, MMJ said related party Embark Ventures would manage its marijuana investments, removing the need for a chief executive officer and cancelling a share plan (BD: Jul 16, 2018; Apr 15, 2019).
Today, the company said it had executed the investment management agreement with Embark, subject to shareholder approval for the appointment of Embark and to issue performance rights as renumeration in a July 2019 meeting.
MMJ said it would hold an on-market share buy-back of up to 10 million shares, or 4.3 percent of shares on issue, over the next 12 months.
MMJ was up two cents or 8.9 percent to 24.5 cents with 2.8 million shares traded.

MGC PHARMACEUTICALS

MGC says it has completed the development phase of an international library of cannabinoids digital platform with the Royal Melbourne Institute of Technology.
MGC said the digital platform would connect doctors and patients with clinical research on cannabinoid sequences and potential treatments.
MGC was unchanged at 5.2 cents with 2.1 million shares traded.

NOXOPHARM

Noxopharm says its majority-owned US subsidiary Nyrada has received $486,338 from the Australian Tax Officer under the Federal Government Research and Development Tax Incentive program.
Noxopharm said the rebate related to research and development expenditure for its NYX-330, NYX-242 and NYX-205 compounds for the year to June 30, 2018.
Noxopharm was up half a cent or 0.9 percent to 55 cents.

ORTHOCELL

Orthocell managing director Paul Anderson and Nicole Telford have ceased to be substantial shareholders in Orthocell with 7,032,555 shares or 4.6 percent.
The Nedlands, Western Australia-based Mr Anderson said he acquired 50,585 shares on May 8, 2019 for $17,199 or 34 cents a share and was diluted in the May 30 $10.6 million placement at 40 cents a share (BD: May 30, 2019).
Orthocell director Matthew Callahan said he has increased but been diluted in the company from 8,317,500 shares (6.81%) to 8,610,894 shares (5.63%).
The Haverford, Pennsylvania-based Mr Callahan said that in lieu of director fees, he acquired 293,394 shares on May 21, 2019 for $40,000 or 13.6 cents a share and 19,494 shares on June 6, 2019 for $10,000 or 51.3 cents a share.
The Iluka, Western Australia-based SRV Custodians and SRV Nominees said its 8,219,177 share-holding in Orthocell was diluted from 6.73 percent to 5.49 percent.
Orthocell was up 2.5 cents or 6.6 percent to 40.5 cents with 6.2 million shares traded.

ANALYTICA

Analytica chairman Dr Michael Monsour says he has increased his holding in Analytica from 776,176,379 shares (23.26%) to 879,475,914 shares (24.99%).
The Maryborough, Queensland-based Dr Monsour said that on June 13, 2019, the shares were acquired at 0.5 cents each by MPMM Pty Ltd, Ms Ann Monsour, Halonna Pty Ltd and Dr M Monsour in the $913,000 capital raise (BD: Jun 5, 2019).
Analytica was up 0.1 cents or 25 percent to 0.5 cents with 1.5 million shares traded.

ANTEO DIAGNOSTICS

Levenson Investments says it has become a substantial shareholder in Anteo with 99,126,615 shares or 6.65 percent.
The Caloundra, Queensland-based Levenson said it acquired 43,034,034 shares for $473,374.37 or 1.1 cents a share and Stydon Capital acquired 3,748,281 shares for $41,231.09 or 1.1 cents a share in the $3.65 million placement (BD: Jun 5, 2019).
Anteo was unchanged at 1.3 cents with 8.5 million shares traded.

ADHERIUM

James Middleweek says he has become a substantial shareholder in Adherium with 8,997,000 shares or 5.39 percent.

The Perth, Western Australia-based Mr Middleweek said that between February 19 and June 5, 2019, he bought and transferred shares at prices ranging from 2.3 cents a share to 3.6 cents a share.

Adherium fell 0.2 cents or 8.0 percent to 2.3 cents with 39 shares traded.

ACRUX

Acrux says Deborah Ambrosini will replace Tim Bateman as chief financial officer and company secretary, effective from today.

Acrux said Ms Ambrosini had more than 20 years' experience in accounting and business development for biotechnology, mining, information and communications technology companies and financial services.

The company said Ms Ambrosini had experience in ASX-listed pooled development funds.

Acrux was unchanged at 19.5 cents.