Biotech Daily

Friday February 9, 2018

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.89 percent on Friday February 9, 2018 with the ASX200 down 52.7 points to 5,838.0 points. Nine of the Biotech Daily Top 40 stocks were up, 23 fell, six traded unchanged and two were untraded. All three Big Caps fell.

Benitec was the best, up one cent or 4.55 percent to 23 cents with 280,962 shares traded. LBT climbed 2.6 percent; Admedus, Airxpanders, Clinuvel, Medical Developments, Optiscan and Psivida were up more than one percent; with Neuren up 0.3 percent.

Telix led the falls, down 5.5 cents or 9.8 percent to 50.5 cents with 306,810 shares traded. Opthea lost seven percent; Impedimed shed 6.3 percent; Avita was down 5.2 percent; Ellex, Immutep (Prima) and Mesoblast fell more than four percent; Oncosil, Pharmaxis, Prana, Starpharma and Universal Biosensors were down more than three percent; Acrux, Compumedics, Polynovo and Pro Medicus shed more than two percent; Cochlear, CSL, Nanosonics, Orthocell, Osprey, Resmed and Volpara were down more than one percent; with Viralytics and Sirtex down by less than one percent.

DR BOREHAM'S CRUCIBLE: CYNATA THERAPEUTICS

By TIM BOREHAM

ASX code: CYP

Share price: 82 cents

Shares on issue: 90,057,248

Market cap: $73.8 million

Chief executive officer: Dr Ross Macdonald

Board: Dr Paul Wotton (chairman), Dr Ross Macdonald, Dr Stewart Washer, Dr John Chiplin, Peter Webse

Financials (December quarter): revenue nil, cash generated $145,000, cash balance $8,839,000*****, estimated March quarter cash burn $1,753,000

***** The company received a $1,328,649 R&D Tax Incentive in December

Identifiable major holders: Fujifilm 8.98 percent, Prof Igor Slukvin 3.39 percent, John W King Nominees 2.64 percent, Celtic Capital 2.39 percent.

The stem cell play has just passed its first day of reckoning, with early results from a phase-one trial of its treatment for graft versus host disease (GvHD).

While there's a long way to go, the results support Cynata's core approach to the production of mesenchymal stem cells (MSCs).

Investors certainly liked it, pushing the shares from 56 cents to 92 cents before this week's overall market 'bondcano' stole some of the gains.

Crucially, further positive trial results could prompt partner Fujifilm to exercise an option over the technology, thus delivering a $US3 million upfront payment and milestones worth up to $US60 million and ongoing double-digit royalties.

The key point here is that Fujifilm would also cover the cost of developing the drug further.

Plan B - scrounging for another party - is not so picturesque.

"But we are not against the burden of coming up against this cold," says ever-optimistic chief executive officer Dr Ross Macdonald.

"We know that MSCs work clinically."

As an ASX entity, Cynata derived from Eco Quest, which sold green-friendly disposable nappies before getting into the poo.

The nappies were then consigned to the smelly garbage bin and Eco Quest relisted as Cynata in October 2013.

The stem cell dilemma

Along with proving the efficacy of the technology to treat specific diseases, the big challenge with stem-cell therapeutics is procuring enough of the raw material in the first place.

In short, Cynata claims to be the only stem cell play in the world that can produce MSCs on a commercial scale without requiring multiple donors.

“We have taken a product that is pretty darned good but said here’s a better way of manufacturing it,” Dr Macdonald says.

To date, the precursor material has been derived either from embryos, or a process called bone marrow aspiration.

For bone marrow aspiration multiple donors are required and the coveted MSCs are only present in small amounts.

MSCs are adult stem cells which can be isolated from human and animal sources and can produce more than one kind of specialist cell.

An invasive surgical procedure, bone marrow aspiration sounds painful because it is painful.

As for tapping embryos, the practice is controversial because some people see a fertilised embryo as a human in its own right.

Under pressure from the religious right, George W Bush outlawed harvesting spare embryos from in-vitro fertilization (IVF) procedures, only for Barack Obama to rescind the measure. Trump, meanwhile, is yet to tweet his official stance.

“While many others strongly disagree with that view, especially within the scientific community, the vociferous opposition from some quarters continues to hamper progress with embryonic stem cell research,” says Cynata co-founder Prof Igor Slukvin.

... and Cynata’s answer

Cynata hopes it has the solution with its patented Cymerus manufacturing process.

The technology is based on induced pluripotent stem cells (IPSCs), from which MSCs are derived and don't require embryos or bone marrow aspiration.

The 'pluripotent' bit means the IPSCs have the ability to develop into any type of adult cell. They can be derived from anywhere in the body - typically skin and blood - and grown in limitless quantities in the lab.

IPSCs derived from the work of Prof Slukvin, from the University of Wisconsin-Madison as well as Japanese research.

University of Wisconsin-Madison is a global leader in stem cell research, while Japanese researcher Prof Shinya Yamanaka won a Nobel Prize in 2012 for his work in the area.

The MSC sector is certainly active, with 650 trials currently taking place including for cardio vascular, lung disease (such as asthma) and strokes.

Just to be clear though, Cynata doesn't intend to be a mere factory that supplies the material to others: it aims to develop drugs, starting with its putative graft versus host disease remedy CYP-001.

An immunological disease, GvHD afflicts bone-marrow recipients and is usually fatal in the case of candidates resistant to steroid treatment. It's also a key target for Mesoblast, which is running a paediatric trial in the US.

One GvHD drug has already been brought to market: JCR Pharma's Temcell, licenced from Mesoblast and originally acquired from Osiris.

But Dr Macdonald says Fujifilm still believes a new drug would be worth $US300 million in annual sales, which would deliver at least $US30 million in annual royalties to Cynata.

Cynata's less advanced therapeutic targets include heart attacks, acute respiratory disorder syndrome, glioblastoma and critical limb ischemia.

DSMB says CYP-001 for GvHD is AOK

On January 22, Cynata proclaimed that the independent data safety monitoring board had recommended that it treat the second cohort of GvHD patients with CYP-001, after all eight patients in the first (lower dose) treatment group showed a partial response to the treatment.

This was measured by an improvement of at least one grade form the baseline on the GvHD scale. One patient subsequently died of pneumonia, but this was deemed not to be trial-related.

A further eight patients will be treated with a higher dose across seven treatment sites here and in the UK, with results expected later this year.

The trial is significant because it is the first time globally any patient has been treated with an IPSC derived MSC product of any description, the patients' own cells or otherwise.

"A successful outcome will support the application of CYP-001 in many medical and commercially significant targets where therapeutic MSCs have shown promising results," Dr Macdonald says.

In both groups, the patients haven't responded to traditional cortico-steroid treatment and are most unwell.

Dr Boreham's diagnosis:

We're loath to say something as hackneyed as the $73 million market cap Cynata is the poor man's version of the $600 million market cap Mesoblast. But we'll say it anyway.

Success is far from guaranteed. As the company acknowledges, there's a lot of time and money going into IPSC research globally and scalable products have already been achieved (including blood, heart, vascular and connective tissue cells).

Cynata is confident that in the next decade several IPSC products will be approved for clinical use and become commercially available.

Like every self-respecting chief executive officer, Dr Macdonald believes the stock is undervalued but at least he offers some solid evidence: in early January Japanese pharma giant Takeda bought Belgian stem-cell developer Tigenix for $US620 million.

"This creates a fear of missing out among all other drug companies including Fujifilm," he says.

Fujifilm aside, Cynata's register is oriented to retail investors, with the stock featuring regularly on the Hot Copper tattle site (much to Dr Macdonald's chagrin). A notable holder is John King, founder of the Storage King empire and a keen investor in speccie techies.

The stock is not well covered. But US research house HC Wainwright & Co (formerly Rodman & Renshaw) takes a stab at a $1.50 a share valuation, "based upon the valuation of the platform on collaboration-based revenue only".

With cash of $8.8 million Cynata is self-sufficient until 2019, but every time Crucible says that about a biotech the company then passes around the hat for funds.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort – or even the early precursor of a Nobel Prize, as far as he knows.

MTP CONNECT

MTP Connect says biotechnology manufacturing exports are up 30 percent to $5.2 billion and jobs increased by 10 percent to 62,109 for the year to December 31, 2016.

The Federal Government-funded MTP Connect, formally the Medical Technology, Biotechnology and Pharmaceutical Industry Growth Centre, said that data produced by it and the Australian Bureau of Statistics showed that the 62,109 jobs was the highest level since 2011.

The organization said that manufacturing exports continued to rise, having reached $5.2 billion in 2016 and the combined MTP sector was the tenth largest Australian export by value.

MTP Connect said the Federal Government had identified the MTP sector as "one in which Australia could lead the world".

MTP Connect chief executive officer Sue MacLeman said the centre was "delighted to share new data that reveals the immense positive impact the MTP sector makes to Australia's healthcare and economic future."

"The MTP sector today continues to be a significant contributor to the Australian economy, creating new jobs and increasing export revenue," Ms MacLeman said.

"This growth is set to continue, especially with the recent rapid growth in medicinal and pharmaceutical product exports, combined with steady growth in medical device exports" Ms MacLeman said.

"Clinical trials are at the fore, with approximately 1,360 new clinical trials starting in Australia in 2015, driven by the quality of our research infrastructure and output, our medical experts, and financial incentives that support cost competitiveness such as the R&D Tax Incentive," Ms MacLeman said.

"The Medical Research Future Fund and Biomedical Translation Fund will result in significant increases in grants, co-investment funds and capital equity from 2017, with [circa] $250 million in funds already allocated," Ms MacLeman said.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that its methoxyflurane inhaled analgesic Penthrox has been approved for sale in Latvia.

Medical Developments said that the State Agency of Medicines of the Republic of Latvia issued the marketing authorization on January 25, 2018.

Medical Developments chief executive officer John Sharman said the company had received five approvals in the last three weeks.

"We expect the remaining [European] 17 countries will issue marketing authorizations to approve the sale of Penthrox … over the coming months," Mr Sharman said.

Medical Developments was up 10 cents or 1.3 percent to $7.57.

RESONANCE HEALTH

Resonance says it has received $451,904 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Resonance said the rebate related to research and development expenditure for the year to June 30, 2017

Resonance was untraded at two cents.

TELIX PHARMACEUTICALS

Telix says that 2,937,500 shares will be released from ASX escrow on March 5, 2018.
Telix said that is 51,635,586 shares were in voluntary escrow, with 12,692,308 shares escrowed until February 15, 2018, 32,918,663 shares were subject to voluntary escrow until November 15, 2018, 384,615 shares were in voluntary escrow until November 15, 2019 and 5,640,000 shares were subject to voluntary escrow for up to 48 months from listing, decreasing by 1,410,000 shares on November 15 of each year.
The company said that it had 197,437,500 shares on issue of which 127,108,087 shares were quoted on the ASX.
Telix fell 5.5 cents or 9.8 percent to 50.5 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says 63,346,700 shares will be released from escrow on February 23, 2018.
The company's most recent Appendix 3B new issue announcement said MGC had 1,054,901,640 shares quoted on the ASX and following the release it would have 1,118,248,340 shares available for trading.
MGC was unchanged at 10 cents with 9.1 million shares traded.

IMMUTEP (FORMERLY PRIMA BIOMED)

Immutep says the combination of eftilagimod alpha with pembrolizumab is "safe and well tolerated at doses up to 30mg per subcutaneous injection".
Immutep said the data safety monitoring board confirmed the safety in the 18-patient, phase I trial of two active immunotherapies in melanoma (Tacti-mel) combining eftilagimod alpha (LAG-3Ig or IMP321) pembrolizumab (Keytruda) in unresectable or metastatic melanoma patients, using doses of IMP321 at 1mg, 6mg and 30mg.
The company said that results presented at the Society for Immunotherapy of Cancer meeting in November, 2017 resulted in plans to expand the study by six patients at 30 mg of IMP321 in combination with pembrolizumab.
Immutep chief scientific and medical officer Dr Frédéric Triebel said "the positive results now provide the basis to safely extend the clinical trial to start at cycle one with the recommended phase II dose and for a 12-month duration, meaning patients could benefit earlier and for longer from the combination".
Immutep fell 0.1 cents or 4.35 percent to 2.2 cents with 2.8 million shares traded.

IMUGENE

Imugene says it will host a meeting of investigators involved in the trail of its HER-Vaxx IMU-131 cancer vaccine in Bangkok, Thailand, this Sunday, February 11, 2018.
Imugene said the meeting would host investigators from Hong Kong, Thailand and Taiwan to review early data from the current phase Ib trial of the HER-Vaxx cancer therapy.
This week, the company said that researchers in their 18-patient trial reported no safety, toxicity or tolerability issues with IMU-131 (BD: Feb 7, 2018).
Imugene said that chief executive officer Leslie Chong would provide a "strategic update and overview of plans to build on the work to date and expand Imugene's clinical pipeline".
Imugene was up 1.7 cents or 0.1 percent to 6.25 cents with 31.9 million shares traded.

ONCOSIL MEDICAL

Regal Funds Management says it has reduced its substantial shareholding in Oncosil from 41,853,223 shares (8.59%) to 36,625,525 shares (7.51%).
The Sydney-based Regal Funds substantial shareholder notice said that between October 25, 2017 and February 6, 2018 it sold 5,227,698 shares at prices ranging from 13 cents to 16 cents.
Oncosil fell half a cent or 3.6 percent to 13.5 cents with 2.1 million shares traded.

ANALYTICA

Analytica chairman Dr Michael Monsour has increased his shareholding in the company from 564,491,918 shares (22.1%) to 705,614,893 shares (25.06%).
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 0.6 cents with 2.4 million shares traded.

GI DYNAMICS

The Crystal Amber Fund says it has increased its holding in GI Dynamics and been diluted from 258,559,341 shares (46.35%) to 262,245,605 shares (44.73%).
The London and Guernsey Island-based Crystal Amber Fund said that between November 24, 2017 and February 6, 2018 it bought 2,253,109 shares for $54,474 or an average of 2.4 cents a share.
In January, the company said that it binding commitments to raise $2,057,321 in a private placement at 3.5 cents per Chess depository instrument (BD: Jan 23, 2018).
GI Dynamics was unchanged at 2.8 cents.

ESENSE-LAB

Esense says Ilan Saad will replace chairman Brendan de Kauwe effectively immediately, and Benjamin Karasik has been appointed as a director.
Esense said that Mr Saad had been a director since October 2016.
The company said that Mr de Kauwe continued as a director.
Esense said that Mr Karasik was a founding investor and one of the largest shareholders in the Company.
The company said that Mr Karasik had more than 40 years' experience in business development in many segments and industries and was a founder of more than 20 medical start-ups.
Esense said that it had cancelled the annual general meeting planned for February 15, 2018 and would convene the annual general meeting and the board spill extraordinary general meeting on March 29, 2018.
In January, Esense said it had received a request under Israeli Companies Law from shareholders Romfal Sifat Pty Ltd, Buzz Capital Pty Ltd and Attollo Investments Pty Ltd calling for a meeting to remove directors Haim Cohen, Eran Gilboa and Ilan Saad; and appoint as directors current chairman Dr Brendan de Kauwe, if he is not re-elected at the annual general meeting, as well as MMJ Phytotech chief executive officer Andreas Gedeon and Faldi Ismail (BD: Jan 29, 2018).
Esense fell 1.5 cents or 7.1 percent to 19.5 cents.

CRESO PHARMA

Creso has requested a trading halt “pending an announcement in relation to a proposed issue of securities and discussions with [the] ASX, and a company update”.
Trading will resume on February 13, 2018, or on an earlier announcement.
Creso last traded at 88.5 cents.

SIMAVITA

Simavita says that Emma Lawler will replace Sarah Prince as joint company secretary, effective from today, February 9, 2018.
Simavita said that bothMs Lawler and Ms Prince worked for Company Matters Pty Ltd.
The company said that chief commercial officer Peta Jurd continued as company secretary.
Simavita was up 0.1 cents or 6.7 percent to 1.6 cents.

BRAIN RESOURCE

Brain says it has appointed Matt Resteghini as chief marketing officer and Pablo Sanchez as the head of user experience.
Brain said that Mr Resteghini had 20 years’ experience online and offline businesses, specializing in marketing automation strategy, technology implementation and scalable digital marketing operations and was most recently Monster Worldwide’s head of marketing.
The company said that Mr Sanchez had more than 20 years’ experience in “user experience design” at Western Digital, JP Morgan Chase and Yahoo and was most recently employed by Tivo as its director of user experience.
Brain was untraded at 5.5 cents.