Biotech Daily

Friday July 13, 2018

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was flat on Friday July 13, 2018 with the ASX200 up 0.1 points to 6,268.4 points.

Nineteen of the Biotech Daily Top 40 stocks were up, 10 fell, seven traded unchanged and four were untraded. All three Big Caps were up.

Prescient was the best, up one cent or 10.5 percent to 10.5 cents with 135,911 shares traded. Avita, Impedimed and Optiscan climbed six percent or more; Dimerix improved 4.2 percent; Bionomics, Cochlear and Factor Therapeutics were up more than three percent; CSL, LBT, Nanosonics and Oncosil rose two percent or more; Airxpanders, Mesoblast, Nanosonics, Neuren, Opthea, Pharmaxis and Telix were up one percent or more; with Clinuvel, Resmed, Sirtex and Volpara up by less than one percent.

Benitec led the falls, down 1.5 cents or 6.8 percent to 20.5 cents with 3.3 million shares traded. Compumedics, Imugene Polynovo and Prana were down more than three percent; Immutep and ITL shed more than two percent; with Cynata, Medical Developments and Pro Medicus down by less than one percent.

[DR BOREHAM'S CRUCIBLE: CARDIEX (FORMERLY ATCOR MEDICAL)]

By TIM BOREHAM

ASX code: CDX (formerly ACG)

Share price: 2.8 cents; **Shares on issue*** 531,018,793; **Market cap:** $14.9 million

Chief executive officer: Craig Cooper

Board: Donal O'Dwyer (chairman), Craig Cooper, Niall Cairns, Randall King Nelson

Financials (half year to Dec 31, 2017): revenue $1.96 million (up 7%), net loss $1.08 million (down 42%), net tangible assets 0.5 cents (1.2 cents previously), cash $720,000**

Major identifiable holders: C2 Ventures 14.1%***, Paul Cozzi 6.2%, CB Co (The Curran Superannuation Fund) 2.91%, Safari Capital 2.28%, Jane Greenslade 2.07%

***** Includes 250,000,000 shares issued in June's $5 million capital raising
****** Ahead of the capital raising
******* C2 is held equally by Craig Cooper and Niall Cairns

Adopting the philosophy of the (now late) Artist Formerly Known as Prince, Cardiex in June joined a swelling club of biotechs changing their name.

Think Avita (Clinical Cell Cultures), Immutep (Prima), Respiri (Isonea and Karmelsonix), Immuron (Anadis), Factor Therapies (Tissue Therapies) and Kazia (Novogen).

In the case of the blood pressure (BP) monitoring group Cardiex, the new moniker seems fair enough as it switches focus to the 'wearables' and digital health sectors - markets with the claimed potential to increase sales 30-fold.

Central to the repositioning is a deal with the Silicon Valley wearable device outfit Blumio Inc, which could see Cardiex's pulse wave analysis (PWA) diagnostic technique incorporated into Blumio devices.

Star studded board

Your columnist will dwell to an unusual extent on the impressive credentials of the Cardiex board, which in the main relate to the non-health sectors.

CEO Craig Cooper is a Kiwi-born, Australian-raised and now Californian-domiciled entrepreneur. Mr Cooper co-founded NRG Asia Pacific, Australia's biggest "independent" energy producer.

A one-time Blake Dawson senior associate, Mr Cooper also founded Private Energy Partners and was CEO of software house E-world Technologies.

But wait, there's more: in the US he co-founded Boost Mobile, was managing-partner of The Action Fund and has invested in new media including the Huffington Post and the irreverent Buzzfeed.

Mr Cooper is also co-host and investor in CBNC's Adventure Capitalists, so is there anything this guy can't do?

Chairman Donal O'Dwyer is (among other things) on the boards of Cochlear, Mesoblast and NIB Health.

Recent board addition Niall Cairns is a director of the ASX-listed Comops and Chantwest Holdings and managing partner of the Kestrel Growth Fund.

The US based Randall (or R as he prefers) King Nelson was prezzo and CEO of Uptake Medical, Kerberos Solutions and Venpro Medical.

Story to date

Atcor was born founded in 1994, based on the core Sphygmocor platform developed by co-founder Prof Michael O'Rourke. Prof O'Rourke was a heart doc at Sydney's St Vincent's Hospital and professor of medicine at the University of New South Wales.

The company listed in November 2005 after a $15 million raising at 50 cents apiece. Co-founder Ross Harrick, a medical devices dude with experience at companies including Resmed, became inaugural CEO.

Marketed as Xcel, Sphygmocor is the only non-invasive, pulse wave analysis-based blood pressure device cleared by the US FDA as a 510(k) medical device. This means the regulator deems it to be substantially equivalent to the current standard-of-care of an intra-aortic catheter pressure sensor insert.

The company claims Sphygmocor is the only device that can predict pre-hypertension and arterial stiffness, the main precursors to organ damage. Effectively, the software takes a reading from the wrist or upper arm and measures central heart pressure and arterial stiffness.

"You might have great BP, but your arterial stiffness might be off the charts," Mr Cooper says.

Heart failure still accounts for 30 percent of mortalities and snuffs out 20 million folk, annually.

To date, Cardiex has sold more than 4,400 Sphygmocor systems, mainly to pharma companies for research (the likes of Glaxosmithkline, Novartis and Astra Zeneca). It also sells to hospitals (including the hospital affiliates of the Atlanta, Georgia-based Emory University and the Morrisville, North Carolina Sun Tech Medical) and has a licensing agreement with New York University.

Cardiex's operations are based in Sydney and Illinois.

The new direction

Mr Cooper, who joined the company in early December 2017, says shareholders had tired of the company and many were disappointed when US reimbursement for the Sphygmocor Xcel was less than expected.

“My mandate is to turn the company around and refresh it,” he says.

A key focus of Cardiex’s new direction is on wearables and the blood pressure (BP) home-testing market. With readmissions for BP tests clogging up hospital slots, health tsars understandably are keen to see more home testing. Even now, seven of 10 Americans track health indications for themselves or a loved one - or their spouse - at home.

Cardiex’s new deal also entails a “direct to practitioner” push to a wider audience of GPs, executive health centres and naturopaths. The company tugs at the purse strings rather than the heart strings by converting a “non-billable event” (brachial or standard upper arm cuff testing) into a billable one for these users.

Over time Cardiex has sold 4,400 of the devices, which sell for between $10,000 and $17,000 apiece (a leasing alternative is available). While that cost might be OK for the specialist cardiologists, it’s not for the wider target audience and the company needs to reduce unit costs.

“We can’t go into a naturopath like the way we walk into a specialist cardiologist,” Mr Cooper says.

While Cardiex’s current slant is on cardiovascular disease, it also plans to target obesity, orthopaedic health, diabetes and urology.

Jump-starting clinical trials

To kick off the wearables effort, Cardiex has announced a 15-patient trial, to be carried out at Macquarie University’s Faculty of Medicine and Health Sciences.

Over eight weeks, the Cardiex funded trial will assess the Blumio sensors’ responses to varying patient manoeuvres and the amount of cardiovascular data available.

“Basically, we are using our Sphygmocor technology as a predictive device alongside Blumio's sensor for comparison of outputs in order to show that we can get acceptable blood pressure readings from the sensor,” Mr Cooper says.

The Macquarie effort is independent of Blumio’s US studies.

Financials and performance

Like a thirsty camel after a Sahara trek, Cardiex sure needed a decent drink with a December 31 cash balance of well under $1 million.

Luckily, the well - a placement and rights offer announced in April - was not a mirage and provided abundant water.

The “heavily oversubscribed” offer raised $2.37 million through a placement and $1.12 million from a rights issue (oversubscriptions of $907,882 had to be returned to shareholders). A related party, C2 Ventures has a binding commitment to chip in a further $1.5 million.

Both the placement and rights issue were done at two cents a share, a 23 percent discount to the average one-month trading price and increased shares on issue by 89 percent.

Cardiex has also acquired 7.5 percent of Blumio for $US600,000 by way of convertible notes, with the first tranche of $US150,000 paid in June (the balance is due before the end of November).

Blumio is backed by Peter Thiel, who co-founded Paypal and was an early investor in Facebook.

Not the guy you would want to un-friend.

Over the last 12 months Cardiex/Atcor shares have traded as high as 4.9 cents (July last year) and as low as 2.0 cents (April 30 this year).

The shares peaked at 27 cents in October 2015.

Dr Boreham’s diagnosis

It’s understandable why management is entranced by the wearables sector, which is forecast to grow to $US8 billion by 2023.

The BP home testing space is also expected to grow to $US1.1 billion over this period.

With 2016-’17 sales of $4.32 million - which management forecasts to be $4.52 million this financial year - Cardiex remains a modest concern despite its fancier name. Take away the cash and the market is valuing the company at a mere $7 million, which Mr Cooper describes as “crazy”.

Cardiex ostensibly is similar to Uscom (ASX code: UCM), which is also in the central blood pressure measuring game (your columnist covered Uscom on February 16 this year). A key difference is that Uscom is more focused on the Chinese market than the US and had several other technologies on the market or in development.

As well-credentialed as it is, Cardiex management still needs to prove its chops and get more revenue through the door.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Any arterial stiffness belies a soft heart of gold.

FEDERAL GOVERNMENT

The Federal Government says it will provide more than $22 million over five years from the Medical Research Future Fund to the Biomedical Translation Bridge program.

A media release from Federal Health Minister Greg Hunt and Small Business Minister Craig Laundy said the funds were intended to “help Australian businesses move from early-stage health and medical research discoveries to commercial success”.

Mr Hunt said the funding aimed “to improve health outcomes … through the development of preventative interventions, cures and treatments for diseases”.

“This program will provide our world class health and medical researchers with financial support and mentoring to fast-track their breakthroughs to commercially-relevant outcomes,” Mr Hunt said.

“They will also work to secure third-party co-investment in the projects to boost the Government’s commitment,” Mr Hunt said.

“A competitive grants process will be used to select the organizations that will oversee the research projects,” Mr Laundy said.

“Up to $1 million in Commonwealth support will be provided to individual projects,” Mr Laundy said.

More information about the Biomedical Translation Bridge program is available at: www.business.gov.au/biomedical-translation-bridge.

ADALTA

Adalta says it has raised $4,250,000 through a placement at 30 cents a share and hopes to raise more funds through a share purchase plan.

Adalta said the proceeds would fund manufacturing and pre-clinical studies of AD-214, as well as the research and development of its I-body technology and help cover corporate costs.

Adalta chief executive officer Sam Cobb previously told Biotech Daily that I-bodies were proteins from the “intermediate” group of immunoglobulin or immunoglobulin-like domains (BD: Jul 7, 2016).

The company said its directors intended to subscribe for 522,450 shares, subject to shareholder approval.

Adalta said the record date for the share plan was July 12, with eligible shareholders able to apply for up to $15,000 worth of shares at 30 cents a share.

Ms Cobb said that “combined with our existing cash position and anticipated refundable [Federal Research and Development] Tax Incentive, the company now believes it has the necessary funds to take our lead program, AD-214, through to the end of manufacturing, an important milestone for the lead I-body candidate”.

Adalta fell four cents or 11.4 percent to 31 cents.

SIRTEX MEDICAL

Sirtex says it has paid Varian Medical Systems a $15.8 million break fee, for cancelling the proposed $1.56 billion bid, which CDH Genetech and partners has reimbursed.

Last month, Sirtex said it would terminate the Varian scheme implementation deed in favor of a $1.87 billion binding scheme with CDH Genetech and China Grand Pharmaceuticals, requiring the company to pay the break fee (BD: Jun 15, 2018).

Today, the company said it confirmed that it had received cash reimbursement from CDH Genetech and China Grand Pharmaceutical.

Sirtex was up 10 cents or 0.3 percent to $32.05 with 435,878 shares traded.

KAZIA THERAPEUTICS (FORMERLY NOVOGEN)

Kazia says it will divest its anti-tropomyosin cancer antibody discovery research program to the Beecroft, New South Wales-based Trobio Therapeutics.

Kazia said it would release all interests in the research program to Trobio, in return for a 12 percent equity interest in the company, protected from dilution for 12 months, and said that Trobio would assume all future costs of the program, with Kazia to provide limited support to Trobio during a transition period.

According to ASIC documents Trobio was registered on June 28, 2018, giving an address of Beecroft, New South Wales, but there were no other details of the company.

Last year, the then Novogen said it had terminated further development of ATM-3507, or Anisina, but retained its anti-tropomyosin program (BD: Apr 6, 2017).

The company said the research program, which began as a partnership between Kazia, the University of New South Wales and Sydney-based contract research organization ICP Firefly in early 2017, was substantially funded through a Federal Government department of industry, innovation and science Co-operative Research Centre project (CRC-P) grant.

Kazia said it had deprioritized the program in March, 2018, to concentrate on its clinical portfolio and that it supported providing the CRC-P grant to Trobio, subject to approval by the Government, with no further financial obligations.

Kazia chief executive officer Dr James Garner said that while the company considered the "next generation [anti-tropomyosin] program to be of significant scientific interest and therapeutic potential, our strategy has been to focus the company's resources on those activities which we believe represent the best opportunity to build value for shareholders in the near-term".

"We have two promising assets in clinical trials, GDC-0084 for glioblastoma multiforme and Cantrixil for ovarian cancer, and our attention is wholly focused at present on driving those programs forward," Dr Garner said.

Kazia was untraded at 49 cents.

STEMCELL UNITED

Stemcell says it has a $US10 million ($A13.5 million) five-year deal to supply Daemonorops draco blume resin to China's Zhejiang Forest Rainbow Medical.

Stemcell said the agreed unit price of the resin, also known as Dragon's Blood, was $US200,000 ($A269,582) a tonne, and that it expected to make a profit of about $US40,000 for each tonne sold, or $US2,000,000 in total.

In its prospectus of June 29, 2015, Stemcell (then On Q Group) said it would extract Resina from Daemonorops draco blume or Dragon's Blood for traditional Chinese medicines, saying that "whether or not [traditional Chinese medicine] is believed, studies have shown that Chinese herbal medicine can be successful in treating a range of disorders" (BD: May 18, 2017).

Today, the company said the contract was signed June 1, 2018, pending compliance with Chinese import regulations and safety standards and an initial one tonne shipment was received by Zhejiang Forest Medical on July 9, 2018.

Last month, Stemcell said China had granted an industrial hemp licence to its partner Yunnan Hua Fang Industrial Hemp Co allowing it to grow, process and sell hemp product, with Stemcell saying it could use cannabis seeds for research into traditional Chinese medicine cosmetic products (BD: Jun 7, 2018).

Stemcell was up half a cent or 20 percent to three cents with 102.5 million shares traded.

SIRTEX MEDICAL

On Wednesday, Sirtex founder and former chief executive officer Dr Bruce Gray said he had returned to a substantial holding with 2,812,822 shares (5.04%).
A substantial shareholder notice from Hanate Pty Ltd signed by director Dr Gray said that between June 20 and July 8, 2018 the company bought 799,850 shares for $29,217,650, or $36.53 a share, but according to Sirtex trade history on Commsec, during that period the maximum share price was $31.68.
Biotech Daily attempted to contact Dr Gray several times to verify the data, but the calls were not returned.
Today, Dr Gray filed an amended notice saying he had bought 1,080,662 shares for $34,133,789 or $31.59 a share.

MGC (MEDICAL GRACE CANNABIS) PHARMA

MGC says its European production and compounding facility has good manufacturing practice (GMP) certification and a licence to produce GMP grade medical marijuana.
Earlier this year, MGC said it had been granted interim good manufacturing practice certification for its European medicinal cannabis production facility (BD: Jan 25, 2018).
Today, the company said the manufacturing licence allowed it to commence production for pharmaceutical grade products.
MGC was up 0.6 cents or 9.5 percent to 6.9 cents with 43.9 million shares traded.

MMJ PHYTOTECH

MMJ says its 30.7 percent subsidiary Harvest One Cannabis will supply recreational cannabis to British Columbia through its wholly-owned subsidiary United Greeneries.
MMJ said the British Columbia-based United Greeneries had a memorandum of understanding with the Canada’s British Columbia Liquor Distribution Board for the deal.
MMJ was up half a cent or 1.6 percent to 31.5 cents.

GENETIC TECHNOLOGIES

Renaissance Technologies says it has reduced its holding in Genetic Technologies from 148,392,000 shares (6.09%) to 123,751,200 shares (5.08%).
In a substantial shareholder notice, the New York-based Renaissance said it sold 2,700 American depository receipts (ADR) on the Nasdaq, equivalent to 24,640,800 Australian shares.
Genetic Technologies told Biotech Daily that the ratio of ADRs to Australian shares was 150-to-one.
Renaissance said it sold the ADRs on July 11, 2018 at prices ranging from $US1.03 to $US1.06.
Genetic Technologies is currently trading around one Australian cent a share.
Renaissance said that the registered holders of the shares included GF Trading LLC, Ridge Master Trading LP, RIEF RMP LLC and RIEF Trading LLC.
Genetic Technologies was unchanged at one cent with 2.55 million shares traded.