



Biotech Daily

Friday May 17, 2019

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.59 percent on Friday May 17, 2019, with the ASX200 up 37.5 points to 6,365.3 points. Sixteen of the Biotech Daily Top 40 stocks were up, 11 fell, eight traded unchanged and five were untraded. All three Big Caps were up.

Neuren was the best, up 15 cents or 14.6 percent to \$1.18 with 1.7 million shares traded.

Osprey climbed 8.3 percent; Impedimed improved 7.7 percent; Oncosil was up 6.35 percent; Antisense and Clinuvel were up more than five percent; Compumedics, Genetic Signatures, Immutep and Pro Medicus were up more than three percent; Cochlear, Nanosonics, Paradigm, Prescient and Universal Biosensors rose two percent or more; CSL and Resmed were up more than one percent; with Cyclopharm and Polynovo up by less than one percent.

Orthocell led the falls, down 4.5 cents or 8.4 percent to 49 cents, with 8.1 million shares traded.

Proteomics lost 7.1 percent; Cynata fell 4.9 percent; Telix and Volpara shed more than two percent; Kazia, Mesoblast and Pharmaxis were down more than one percent; with Ellex, Medical Developments and Starpharma down by less than one percent.

DR BOREHAM'S CRUCIBLE: PRO MEDICUS

By TIM BOREHAM

ASX code: PME

Share price: \$19.95

Market cap: \$2.07 billion

Shares on issue: 103,616,518

Chief executive officer and founder: Dr Sam Hupert

Board: Peter Kempen (chairman), Dr Hupert, Anthony Hall, Anthony Glenning, Dr Leigh Farrell

Financials (December half): revenue \$25.4 million (up 60%), net profit \$9.1 million (up 184%), adjusted profit* \$9.2 million (up 80%), earnings per share 8.7 cents (up 184%) interim dividend per share** 3.5 cents fully franked (up 40%), cash of \$24.7 million (down 2%)

* Adjusts for net currency gain and the impact of revenue recognition accounting rule

** The company also paid a fully franked 2.5 cents special dividend as an advance on this year's expected final dividend

Identifiable major shareholders: Dr Sam Hupert 29.33%, Anthony Hall 29.29%, Bram and Maaïke Vander Jagt 0.82%, Grain Exporters Australia Pty Ltd 0.66%, Peter and Elaine Kempen 0.66%.

Now with a \$2 billion market capitalization, the home-grown radiology digital imaging outfit has crept up on investors having been valued at less than \$100 million five years ago.

Not that Pro Medicus has been an overnight success: Melbourne general practitioner Dr Sam Hupert and technologist and fellow wine buff Anthony Hall formed the company in 1983, when mullets and perms rather than digital imaging were all the rage.

Having evolved its technology and products - but not its intrinsic nature - over that time, Pro Medicus is now a recognized leader in the US and Europe with its proprietary internet cloud-based software for large medical enterprises and individual practices.

In the US, Pro Medicus has signed up five of the top 20 hospitals and won 14 of the last 17 requests for proposals (tenders for new work).

“Truth be known we have gone further far more quickly than most people anticipated,” Dr Hupert says.

About Pro Medicus

Pro Medicus provides diagnostic imaging, practice management and image archiving software to radiology practices. The company is mainly involved in the ‘viewing’ part of the chain: enabling clinicians to call up the images quickly and make better use of them.

The company’s key products are Visage RIS (as in radiology information system) and Visage 7 (enabling users to consolidate information requiring multiple views into a customized single platform).

Pro Medicus has surfed the burgeoning data requirements for modern imaging techniques such as high density multi slice CT (computed tomography) scans, high density breast tomo-synthesis, opto-acoustic breast ultrasounds and total body scans.

With breast imaging, a mammography used to require about 300 megabytes of capacity; now breast tomo-synthesis creates files of four to six gigabytes.

“Now there’s a new high-definition version requiring eight to 10 gigabytes per study,” Dr Hupert says.

Pro Medicus also stands to benefit from new rules in the US mandating electronic health records in all hospitals, with 90 percent of this data related to imaging.

The Pro Medicus ‘Alan Bond’ moment

At the height of the global financial crisis 10 years ago, Pro Medicus acquired the California based Visage Imaging for a knock-down \$5 million.

Then a leader in digital imaging, Visage Imaging otherwise was an unwanted life sciences offshoot of the Nasdaq-listed Mercury Computer Systems.

The purchase price was quickly validated, because Pro Medicus shed Visage Imaging’s unwanted research arm shortly after for \$15 million.

“We were in the right place at the right time,” Dr Hupert says. “It was a company-changing acquisition.”

As the Visage product moniker implies, the acquisition was the foundation of the current business.

The purchase delivered Visage Imaging’s Berlin-based intellectual property as well as its key people, 90 percent of whom are still with the company.

Who's who of clients

Pro Medicus has managed to attract a book of big-name hospitals, including two of the top four in the US.

Locally, the company provides Visage RIS to the two biggest radiology providers, Healius (formerly Primary Healthcare) and I-Med.

US clients include the esteemed Mayo Clinic and Yale New Haven Health (the state of Connecticut's second-biggest employer).

In its biggest contract, Pro Medicus last year signed Massachusetts' largest health system Partners Healthcare for a \$27 million, seven-year deal.

Initially the deal covers the Massachusetts General Hospital (part of Harvard Medical School) and the Brigham and Women's Hospital.

(Memo to anyone: why do US hospitals have such odd names?)

In late April, North Carolina's biggest health system Duke Health signed a \$14 million deal over seven years to roll out Visage 7 across all of its radiology departments. Revenues are also transaction based, but with a guaranteed minimum.

In Germany, the company extended a three-year contract with a big government hospital network.

Britain is a notable exclusion to the company's coverage, because the National Health System (much loved as it is) involves too much bureaucracy.

The size of the prize

Dr Hupert says about 410 million radiology tests are undertaken in the US each year and the sector is growing at about three to four percent each year.

"We think we have around four to five percent of the market but we are never going to address the full 100 percent because some sectors are not economic to service," he says.

"We are a premium product and we hope to be the best product."

Currently most radiology is not in the internet 'cloud' because of fears about patient privacy and data breaches.

"But the pendulum is swinging because some cloud providers have better security," Dr Hupert says.

Pro Medicus currently services large multi-facility providers who don't want to run their own infrastructure, but smaller providers without the wherewithal to do so are also a target.

The company competes with equipment makers such as Philips and Siemens, as well as the old film (imaging) houses such as Fuji and Clearstream (formerly Kodak). It also competes with other independent software houses.

The ASX-listed Mach7 also makes for an interesting comparison.

Based in Burlington Virginia, Mach7 provides cloud-based enterprise software for hospitals and clinics that aggregates an individual's medical records so that they are readily available for healthcare professionals.

In reality, Mach7 plays more in the archiving than the 'viewing', so Pro Medicus doesn't bump into them too often.

But given Mach7 has former Pro Medicus (and Visage Imaging) CEO David Chambers on the board, Dr Hupert certainly knows who they are.

Finances and performance

In the six months to December 31, Pro Medicus posted a net profit of \$9.2 million, up 80 percent on revenue of \$25.3 million (up 60 percent).

"The result was particularly pleasing in that we saw growth in all three major jurisdictions," Dr Hupert says.

In the first half, Pro Medicus gleaned half of its revenue from examination licences (\$12.1 million, up 31 percent), one quarter derived from support and baseline fees and one quarter from capital payments and professional services.

Pro Medicus derives 64 percent of turnover from North America and 18 percent each in Europe and Australia.

While the US is obviously the key market, the North American reliance has reduced from 70 percent in the previous half, reflecting stellar European growth.

Pro Medicus's profit margins have expanded to 51 percent in the first half, compared with 49 percent in 2017-'18 and 45 percent in 2016-'17.

Unusually, Pro Medicus is both debt free and dividend paying.

On top of the interim payout of 3.5 cents a share, the company advanced a 2.5 cents full year divvie to beat Labor's proposed abolition of cash franking credits.

The company has shareholder approval to carry out a share buyback. But apart from an early foray when the stock traded at 20 cents, it is yet to repurchase stock in earnest.

On the flipside, the company has never done a capital raising beyond the initial public offer, but would consider doing so if a compelling add-on opportunity came along.

Pro Medicus's share base of a tad over 103 million shares is not much more than its 100 million shares when it listed in September 2000 (at \$1.15 a share).

Pro Medicus shares have traded in a 12-month range of \$20.52 (late April) and \$6.85 (late June 2018).

Dr Boreham's diagnosis:

Dr Hupert says the company has had a record number of requests for proposals in the current half, while other opportunities abound in other 'ologies' such as cardiology and ophthalmology.

At a pinch, the company might consider expanding into non-health sectors.

Pro Medicus is also poised for the much-vaunted advent of artificial intelligence, by engineering its platform to allow algorithms developed by third parties.

"We see it becoming mainstream but we don't know when," Dr Hupert says.

"Currently there's no reimbursement and using a new algorithm requires separate regulatory approval."

With Pro Medicus stock trading on an earnings multiple of 110 times, the valuation looks stretched. But Dr Hupert notes the contracts in place are generating annuity revenue, with \$160 million of examination revenues locked in over the next five years.

Revenue and earnings then compound with every additional deal.

Dr Hupert says Pro Medicus is a technology company that happens to be in healthcare and is thus classed in the healthcare/biotech space by investors.

Never mind about the classification: we herald Pro Medicus for becoming the fourth-biggest listed 'biotech' behind CSL, Resmed and Cochlear – a feat that catapulted Dr Hupert and Mr Hall on to this year's Rich List with a combined worth of \$860 million.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is yet to feature on the Rich List and feels he may have left his run too late.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that research in mice shows that a well-tolerated blood cancer drug GSK126 could be used to target the cause of asthma.

The Institute said that the enzyme Ezh2 was found to be critical to the immune system's inflammation allergy response, which caused asthma.

The Institute said that an Ezh2 inhibitor drug, used in current blood cancer clinical trials, could be used to reverse the inflammation response in the lungs by 'switching off' the allergic reaction.

WEHI said current asthma medicine treated symptoms, whereas this drug targeted the cause of the disease.

The research, titled 'Polycomb repressive complex 2 is a critical mediator of allergic inflammation' was published in the Journal of Clinical Investigation Insight, and is available at: <https://insight.jci.org/articles/view/127745/pdf>.

WEHI said that the Dr Rhys Allan, Dr Christine Keenan and Prof Stephen Nutt led the research in collaboration with the University of Newcastle.

"Our early research identified that the enzyme Ezh2, which is an essential component of the epigenome, was critical to the immune system's ability to drive inflammation in response to allergens," Dr Allan said.

"This indicated that an Ezh2 inhibitor drug could effectively suppress inflammation in an allergic response," Dr Allan said.

"Because the drug is already well tolerated in humans, it's reasonable to expect that the transition from oncology to treatments for inflammation should be smooth," Dr Allan said.

NEUREN PHARMACEUTICALS

Neuren says that NNZ-2591 has shown efficacy for Angelman syndrome and Pitt Hopkins syndrome in mice.

Neuren said that a mouse model of Angelman syndrome was treated with NNZ-2591 for six weeks, normalizing deficits in anxiety, daily living, sociability, motor performance and cognition, and eliminated seizures.

The company said that mouse model of Pitt Hopkins syndrome showed that mice treated with NNZ-2591 for six weeks normalized hyperactivity, daily living, learning and memory, sociability, motor performance and stereotypy.

Neuren said both preclinical tests were statistically significant.

In April, Neuren said that following positive mouse data on NNZ-2591 for Phelan-McDermid syndrome it would submit applications to the US Food and Drug Administration for orphan drug designation and a trial (BD: Feb 18, Apr 26, 2019).

Today, Neuren executive chairman Dr Richard Treagus said the company was "excited that NNZ-2591 has clearly demonstrated positive and wide-ranging effects in all three of these disorders".

"These promising results further confirm the potential of this unique neurotrophic drug across a number of neurodegenerative and neurodevelopmental conditions," he said.

Dr Treagus said Neuren was focussed on neurodevelopmental disorders with a high unmet need where NNZ-2591 was most likely to have the greatest impact on outcomes.

"Each of them is caused by a mutation or deletion in a different specific gene or chromosomal region; however typically they share many common symptoms and an underlying impairment in the connections and signaling between individual brain cells."

"Restoring the normal connectivity and signaling between brain cells is considered to be a central property of NNZ-2591," Dr Treagus said.

Neuren was up 15 cents or 14.6 percent to \$1.18 with 1.7 million shares traded.

IMMUTEP

Immutep says three of six patients have shown an overall response rate in part B of its phase I Tactimel trial of IMP321 with Keytruda for metastatic melanoma.

Last year, Immutep said that after three months of IMP321, or eftilagimod alpha, with Keytruda, three of six patients in part B of the trial had a partial response, and it had shown safety from all six patients (BD: Nov 12, Nov 28, 2018).

Today, Immutep said the six patients in Part B who received 30mg of IMP321 and Keytruda continued to reduce tumor size after nine months.

The company said that three of six patients had an overall response and four of six had disease control

Immutep was up 0.1 cents or 3.45 percent to three cents with 1.6 million shares traded.

RHINOMED

Rhinomed says its Pronto technology has been registered as a class I device with the US Food and Drug Administration and Australian Therapeutic Goods Administration.

Rhinomed said the Pronto device was a rechargeable, dual action vapor release technology to improve nasal airflow, clear a stuffy nose or help users sleep with a using a blend of essential oils.

Rhinomed said it would include a recharging and storage case.

The company said it would begin shipping new products by June 2019, sold online and through retail partners.

Rhinomed fell half a cent or 2.3 percent to 21 cents.

ORTHOCELL

In four related notices, Australian Super says it became substantial in Orthocell, sold shares and director Matt Callahan is a related party through a trust company.

Orthocell chief executive officer Paul Anderson told Biotech Daily that Mr Callahan had not sold any of his personal holding in the company.

Australian Super said it had become a substantial shareholder in Orthocell with 7,570,000 shares (6.20%) through Stone Ridge Ventures Tech Trust.

In his Appendix 3Y Director's Interest Notice Mr Callahan said he was a founder and director of Stone Ridge Ventures Pty Ltd which was the manager of the SRV Trust.

Mr Callahan said the Trust sold 1,960,382 shares for \$1,062,294 or 54.2 cents a share.

Biotech Daily understands that the shares sold were Australian Super shares.

Australian Super said that it became substantial in Orthocell with 4,619,190 shares or 5.60 percent in 2014 and in 2016 said that it was diluted below the five percent in a \$4,000,000 placement at 40 cents share (BD: Aug 14, 2014; Dec 13, 16, 2016).

Orthocell fell 4.5 cents or 8.4 percent to 49 cents, with 8.1 million shares traded.

LBT INNOVATIONS

LBT has requested a trading halt "pending an announcement to the market in relation to the results of its submission to the US Food & Drug Administration".

Last year LBT filed an FDA 510k application for its automated plate assessment system (APAS) Independence instrument (BD: Dec 21, 2018).

Trading will resume on May 21, 2019 or on an earlier announcement.

LBT last traded seven cents.

AIRXPANDERS

Airxpanders has requested a further extension for its suspension to “finalize its review of financial and strategic alternatives and provide the market with an accurate update”.

Earlier this month, Airxpanders requested an extension to its voluntary suspension, following its March 29 “debt agreement” trading halt (BD: Mar 29, Apr 2, May 3, 2019).

The company said it expected the suspension to last until July 1, 2019.

Airxpanders said its annual general meeting would be postponed.

Airxpanders last traded at 3.5 cents.

SUDA PHARMACEUTICALS

Suda says David Phillips will replace Joseph Ohayon as a director, with Mr Ohayon continuing as chief financial officer and company secretary.

Suda said it appointed David Phillips as an executive director and chief business officer, with Andrew Curtis continuing as head of business development and alliance management in the US and Europe.

Earlier this week, the company said Paul Hopper was appointed chairman, replacing Steven Carter who would continue as chief executive officer (BD: May 15, 2019).

Suda was unchanged at half a cent with 26.7 million shares traded.