Biotech Daily

Friday May 6, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: AMPLIA UP 4%; RESONANCE DOWN 9%**

*** DR BOREHAM'S CRUCIBLE: PRO MEDICUS**

*** RHINOMED PLACES $455k SHORTFALL; TOTAL $4.9m**

*** OPTHEA: 'OPT-302, LUCENTIS IMPROVES PCV'**

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MARKET REPORT

The Australian stock market fell 2.16 percent on Friday May 6, 2022, with the ASX200 down 159.1 points to 7,205.6 points.

Five of the Biotech Daily Top 40 stocks were up, 29 fell, four traded unchanged and two were untraded.

Amplia was the best, up 0.5 cents or 4.35 percent to 12 cents, with 14,255 shares traded, followed by Polynovo up 4.05 percent to 90 cents with 7.3 million shares traded. Genetic Signatures and Opthea were up one percent or more; with Resmed and Starpharma up by less than one percent.

Resonance led the falls, down one cent or 8.7 percent to 10.5 cents, with 198,419 shares traded, followed by Patrys down 8.3 percent to 2.2 cents with 12.4 million shares traded.

Cyclopharm, Micro-X, Oncosil and Universal Biosensors lost seven percent or more; Pro Medicus shed 6.7 percent; Avita, Clinuvel, Cochlear, Impedimed and Proteomics fell more than four percent; Alcidion, Dimerix and Nanosonics were down three percent or more; Compumedics, CSL, Cynata, Mesoblast, Orthocell and Pharmaxis shed more than two percent; Actinogen, Emvision, Immutep, Medical Developments, Neuren, Next Science, Paradigm and Volpara were down more than one percent; with Kazia and Telix down by less than one percent.

DR BOREHAM'S CRUCIBLE: PRO MEDICUS

By TIM BOREHAM

ASX code: PME

Share price: $42.63; **Shares on issue:** 104,355,753; **Market cap:** $4.449 billion

Chief executive officer and co-founder: Dr Sam Hupert

Board: Peter Kempen (chairman), Dr Hupert, Anthony Hall (co-founder), Anthony Glenning, Dr Leigh Farrell, Deena Shiff, Alice Williams

Financials (December half 2021): revenue $44.7 million (up 40.9%), net profit after tax $20.7 million (up 53%), earnings per share 19.7 cents (up 52%), dividend per share 10 cents (up 43%), cash and investments $57.0 million (up 11.8%)

Identifiable major shareholders: Dr Sam Hupert 26.04%, Anthony Hall 26.01%

If Melbourne's US-focused radiology digital imaging house is running out of steam after an enormous five years of growth, co-founder and CEO Dr Sam Hupert isn't letting on.

These days the company commands a valuation of just under $4.7 billion and is the fourth biggest ASX-listed life sciences play behind the 'big three' of CSL, Cochlear and Resmed.

Dr Hupert says the last 18 months have been the busiest ever for the company, "not just in terms of sales, but implementation".

In the equal biggest deal to date, last October, the company signed up Novant Health for a $40 million contract over seven years. The transaction expands the company's presence away from the traditional 'sandstone' colleges and into the non-academic sector. Last month, Pro Medicus signed North Virginia not-for-profit Inova Health in a $32 million deal over eight years.

Renewed contracts include Europe's Allegheny Healthy, New York University's health network, the Baltimore and Washington-based Medstar and Utah's Intermountain.

"The market is very active at the moment, there's an increased cadence with RFPs (requests for proposals)," Dr Hupert says. "A lot of them require the option to work in the [internet] cloud or are mandating the cloud, which favors us."

Image-in that

Pro Medicus provides diagnostic imaging, practice management and image archiving software to radiology practices.

The company was founded by Melbourne general practitioner Dr Hupert and his technologist friend Anthony Hall in 1983.

Back then, ‘digital deployment’ referred to rude hand gestures from drivers of beaten-up Kingswood panel vans, rather than technological revolution. The cloud, of course, was that puffy thing in the sky leading to precipitation and dongles were … just plain rude.

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.

Pro Medicus has surfed the burgeoning data requirements for modern imaging techniques such as high-density multi-slice CT (computed tomography) scans, 3-dimensional breast ‘tomo’-synthesis, opto-acoustic breast ultrasounds and total body scans.

The company’s key products are Visage RIS (as in radiology information system) and the cornerstone Visage 7 (enabling users to consolidate information requiring multiple views into a customized single platform). The image storage tool Visage Open Archive was introduced in 2017, with Visage Workflow Management emerging in 2020.

In 2019, 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.

Executed during the global financial crisis, this acquisition turned out to be both a bargain and a company maker, as the Visage products are core to the company’s offerings.

Along the way, Pro Medicus signed up the Mayo Clinic, the Connecticut-based Yale New Haven Health, North Carolina’s Duke Health and Partners Healthcare, Massachusetts’ largest health system that includes Harvard’s Massachusetts General Hospital.

Amassing firepower for the battle of the gigabytes

Dr Hupert says the computer “firepower” (data) required for computed tomography (CT) and magnetic resonance imaging (MRI) is increasing all the time.

“The best analogy is consumer [digital] photography,” he says. “I remember the days when three megabits was pretty good, now it’s in the 20s and 30s.”

Similarly, a decent CT scan used to require 150 to 300 megabytes but now the requirement is measured in gigabytes.

“They take 5,000 slices and each one is half a megabyte. It’s not just the resolution, the volume of images is growing as well,” he says.

“Much bigger datasets are becoming the norm. The traditional way of moving images around, compressing them and uncompressing them and manipulating them at a work station is starting to crack at the seams.”

The other key driver of modern imaging is the migration to the cloud, which has not been as rapid in the rarefied radiology world as one might expect. That said, the last five Pro Medicus deals were all internet cloud-based.

Antipodean upstart snares leading US market share

Dr Hupert estimates that Pro Medicus has the lion's share of the traditional academic market, having signed up nine of the top 20 US institutions ('top' is determined not just by size, but perceived quality).

"We have more than double [the market share] of our nearest competitor," he says. "Given we have only been in that market for six or seven years, no-one has been able to do that."

The company is also making inroads into what our American friends call IDNs, or integrated delivery networks. These are non-academic, non-teaching hospital chains, generally not-for-profit. Intermountain and Novant Health fit this category.

Dr Hupert notes that about 500 million tests are done in the US annually, which come to think of it is 1.5 for every man, woman and child. He estimates Pro Medicus has around six percent of that broader market.

"That doesn't sound too much, but not too many players have been able to achieve that to date."

Sizing up the rivals

Traditionally, Dr Hupert says, the company's competition came from the equipment vendors such as GE Health, Siemens and Philips. When camera film became redundant, the likes of Agfa, Fujifilm and Carestream also sashayed into the sector.

Dr Hupert claims these providers are losing market share at the expense of up-and-coming independent providers steeped in the digital way of doing things. Many of these providers are being subsumed by private equity 'roll up' plays.

The internet cloud allows Pro Medicus to sell to a Mayo or a five-person radiology clinic in Airport West (an unprepossessing Melbourne suburb proximate to Essendon Airport).

"Cloud has made a huge difference. If a five-person practice had to buy its own hardware and organize a data centre and hire a data manager, it would be too much. The beauty of the cloud is that it matches our billing model by which you only pay for what you use."

Naturally, Pro Medicus has a weather eye on ASX counterpart Mach 7, which is based in Burlington, Virginia.

With a far more modest $150 million market capitalization, Mach 7 services smaller hospitals and focuses on image storage (archiving) rather than viewing.

Intriguingly, Mach 7 is chaired by David Chambers, who ran Pro Medicus for a while.

"We tend to swim in different ponds," Dr Hupert says.

Who’s best in breast?

Pro Medicus also overlaps with the Kiwi based, ASX-listed Volpara Health Technologies, which specializes in imaging interpretations and practice management for breast cancer clinics. Volpara has a sharper focus on breast density imaging and reporting.

In conjunction with Yale’s breast imaging centre, Pro Medicus mucked about with its own breast-imaging platform,

“It worked so well that we got it approved by the [US Food and Drug Administration] and got it commercialized,” he says.

Dr Hupert envisages expanding this capacity to “all the major body parts”, most likely in joint developments with the Mayos and Yales of the world.

He notes that tumors are not “uniform round little golf balls or marbles” - they are more unwieldy with tissue growing in all directions. Artificial intelligence (AI) enables these tumors to be better segregated from the surrounding tissue and viewed in glorious 3D.

“AI is not as ingrained in radiology as people would believe, it’s just emerging,” he says.

Coping with covid

On balance, The Plague was helpful for Pro Medicus because it sheeted home the applicability of its cloud-based products for remote working.

“The key selling point of software is that you can work remotely,” Dr Hupert says.

In March and April 2020, examination volumes dropped “precipitously”, but was short lived. “In May to July 2020, we saw volumes return and they were back to near normal by the end of the year,” he says.

Now, in some areas, volumes are higher, such as for breast examinations.

The company is buffered from the risk of a sharp downturn because its contracts are based on the take-or-pay principle. Typically, a new client must pay for 80 percent of the number of exams carried out in the previous year and then pays extra for usage beyond this level.

Dr Hupert says no client dipped below these minimums.

Finances and performance

Pro Medicus reported a net profit of $20.6 million for the first (December 2021) half, up 53 percent, on a 41 percent revenue boost to $44.7 million. Investors were rewarded with a 10 cents per share dividend, fully franked, up 43 percent.

Revenue wise, 85 percent of turnover derived from the US, where transaction (examination) revenues rose 37 percent as new customers came on stream.

The company's profit margin increased to 65 percent on an underlying earnings basis, having risen from 51 percent to 59 percent in the 2020-'21 year.

This was somewhat unexpected, given costs rebounded from the Covid era when they were constrained because no one was travelling anywhere.

"So even though our cost base has increased in line with our projections, our revenue growth has outstripped that," Dr Hupert says.

Unusually, the debt-free Pro Medicus has not done a capital raising since its initial public offer and seeing the company is accruing cash, it doesn't expect to do so.

Pro Medicus shares peaked at $70 a share in late August 2021, valuing the company at a hefty $7.3 billion. The shares attained a 12-month low of $39 in mid-May of that year.

Dr Boreham's diagnosis:

While Pro Medicus shares have declined about 20 percent over the last six months and three percent year-on-year, they've fared better than most other US-oriented life sciences stocks.

"We are an unusual mix but that's always been part of our DNA," Dr Hupert says. "We are a hybrid in that we're a growth stock but we make money, pay dividends and accrue cash.

"Our industry is insulated from interest rates and inflation because it is largely non-discretionary. Our clients are incredibly well-funded and we don't have any debt."

The tougher funding conditions also means that valuations in the sector are waning, posing the opportunity for the company to engineer some bolt-on acquisitions.

When we last covered Pro Medicus in May 2019, we opined the valuation looked stretched given the stock traded on an earnings-multiple of 110 times.

Well guess, what? The company still trades on a similar earnings-multiple, yet shareholders have pocketed handy gains indeed - given the company back then was valued at a 'mere' $2 billion.

The current valuation looks more modest given the $360 million of contracted revenue locked-in over the next five years - with the probability of more fresh deals to come.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He was certainly not smart enough to buy Pro Medicus shares at 50 cents, which he reminds himself before his daily descent down the salt mine.

RHINOMED

Rhinomed says it has placed a $455,000 shortfall from its rights offer at 19 cents a share, taking the total raised with the institutional rights offer to $4,923,000.
In April, Rhinomed said it had completed a $3.37 million underwritten institutional one-for-9.87 rights offer at 19 cents a share, and hoped to raise a further $1.63 million in a retail rights offer at the same price (BD: Apr 7, 8, 2022)
Earlier this week, Rhinomed said it had raised $1,098,000 in the retail entitlement offer and would seek to place a shortfall of about $532,000 (BD: May 4, 2022).
Rhinomed fell 1.5 cents or 7.7 percent to 18 cents.

OPTHEA

Opthea says OPT-302 with ranibizumab (Lucentis) significantly improves vision in patients with polypoidal choroidal vasculopathy (PCV).
In 2019, Opthea said its 366-patient phase IIb trial of OPT-302 for wet age-related macular degeneration met its primary endpoints (BD: Aug 7, 2022).
Today, the company said the study dosed patients with ranibizumab as monotherapy, or ranibizumab with either 0.5mg or 2.0mg of OPT-302.
Opthea said that in the evaluation of a sub-set of 66 patients from the trial who had polypoidal choroidal vasculopathy, those receiving 2mg OPT-302 and 0.5mg ranibizumab achieved an additional 6.7 letter gain on a standard eye chart compared with those receiving ranibizumab monotherapy ($p = 0.025$).
The company said that the study, titled ‘Efficacy and Safety of OPT-302 in combination with Ranibizumab for Polypoidal Choroidal Vasculopathy’, was presented to the Association for Research in Vision and Ophthalmology meeting on May 1, 2022, and was available on its website: https://bit.ly/3w51fDf.
The presentation said that 20 of 22 patients (90.9%) dosed with 2mg OPT-302 and 0.5mg ranibizumab had an increase of five or more letters, compared to 12 of 19 patients (63.2%) in the ranibizumab alone group.
The poster said 17 of 22 patients (77.3%) dosed with 2mg OPT-302 and 0.5mg ranibizumab saw an increase of 10 or more letters, compared to nine of 19 patients (47.4%) in the ranibizumab alone group.
The presentation said nine of 22 patients (40.9%) dosed with 2mg OPT-302 and 0.5mg ranibizumab saw an increase of 15 or more letters, compared to six of 19 patients (31.6%) in the ranibizumab alone group.
Opthea chief executive officer Dr Megan Baldwin said the company had “received positive feedback on the potential utility of OPT-302 combination therapy for patients with [polypoidal choroidal vasculopathy] lesions and we look forward to evaluating additional data which is being obtained from the ongoing OPT-302 phase III … trials which are expected to enrol a significant number of treatment naïve patients with [polypoidal choroidal vasculopathy],” Dr Baldwin said.
According to the American Academy of Opthalmology ‘Eyewiki’ website, polypoidal choroidal vasculopathy was a disease of the choroidal vasculature, present in men and woman of many ethnicities, characterized by sero-sanguineous detachments of the pigmented epithelium and exudative changes that could commonly lead to subretinal fibrosis.
The website said that evidence supported the concept that symptomatic patients could have complete regression without severe vision loss with photodynamic therapy and anti-vascular endothelial growth factor (VEGF) treatment.
Opthea was up one cent or one percent to $1.02 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says that Dr Emma Ball, George Kenley and Prof Lauren Ayton have won the three Women in Leadership awards.
The Bio-Melbourne Network said that the Victoria Minister for Innovation, Medical Research, and the Digital Economy Jaala Pulford presented the 2022 awards yesterday.
The Network said that Illumina's Dr Ball won the distinguished leadership award, Seer co-founder and chief operating officer Ms Kenley won the inspiring leadership award, and the emerging leadership award went to the Centre for Eye Research Australia's Prof Ayton.
The industry organization said the three women "helped spark industry advancement and inspire others to follow their lead at a critical time in health - all took risks to pursue their goals and advance the sector".
Bio-Melbourne Network chief executive officer Jeff Malone said the three winners were "helping to ensure that Victoria's [health technologies] industry continued to innovate and lead the way".

OSPREY MEDICAL

Osprey says it will reduce its workforce across all areas, effective from today.
In its most recent Appendix 4C, the company said it had receipts from customers for the three months to March 31, 2022 of $US411,000 ($A578,424), a cash burn for the three months of $US2,724,000, with cash and cash equivalents of $US2,616,000.
Osprey said in the Appendix 4C that it was evaluating its "strategic and funding options including a possible sale of assets".
Last week, Osprey said it had requested a trading halt "as it considers its strategic and funding options" and on Tuesday requested a voluntary suspension to follow the trading halt (BD: Apr 29, May 3, 2022).
Osprey last traded at 20 cents.

INCANNEX HEALTHCARE

Incannex has requested a trading halt pending an announcement regarding results of its "pre-clinical study assessing IHL-216A in a sports concussion model".
Trading will resume on May 10, 2022, or on an earlier announcement.
Incannex last traded at 38 cents.

IMMURON

Immuron says it has appointed Steven Lydeamore as its chief executive officer, effective from June 27, 2022.
Yesterday, Anatara said Mr Lydeamore would resign as its chief executive officer, effective from June 26, 2022, to pursue "other business interests" (BD: May 5, 2022).
Today, Immuron said Mr Lydeamore had more than 30 years' experience in the Australian, US, and Canadian pharmaceutical industries, including 11 years at the Toronto's Apotex, four years at Mayne Pharma, and most recently at Anatara.
The company said that on Mr Lydeamore's commencement, interim chief executive officer Dr Jerry Kanellos would resume his role as chief operating officer.
Immuron was unchanged at 10.5 cents.