Biotech Daily

Friday June 12, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: UNIVERSAL BIO UP 5%; MESOBLAST DOWN 8%**

*** DR BOREHAM'S CRUCIBLE: ALCIDION GROUP**

*** S&P INDICES: 14 BIOTECHS, AUSTRALIAN ETHICAL UP; 4 DOWN**

*** SCOPUS: CITY OF HOPE DRUG, PAUL HOPPER'S BIOSCIENCE ONCOLOGY**

*** TBG: 'FDA APPROVES SARS-COV-2 TEST EMERGENCY USE'**

*** EXOPHARM LICENCES NY STATE, SANTA CLARA UNI EXOSOME IP**

*** MACH7 PLACEMENT, INSTO RIGHTS RAISE $23.4m; $11.4m TO GO**

*** ELLEX: LUMIBIRD $100m LASER, ULTRASOUND SALE BY JUNE 30**

*** RACE REQUESTS 'TRIAL RESULTS' TRADING HALT**

*** ESENSE REQUESTS 'JOINT-VENTURE' TRADING HALT**

MARKET REPORT

The Australian stock market fell 1.9 percent on Friday June 12, 2020, with the ASX200 down 112.8 points to 5,847.8 points. Just three of the Biotech Daily Top 40 stocks were up, 29 fell, seven traded unchanged and one was untraded. All three Big Caps fell.

Universal Biosensors was the best of the three, up one cent or five percent to 21 cents, with 57,378 shares traded. Impedimed improved 4.7 percent; with LBT up 3.2 percent.

Mesoblast led the falls, down 32 cents or 8.2 percent to $3.60, with 8.9 million shares traded. Opthea lost 8.05 percent; Actinogen, Nanosonics and Polynovo fell more than seven percent; Avita, Compumedics, Cyclopharm, Genetic Signatures, Patrys and Pharmaxis lost six percent or more; Paradigm and Resonance fell more than five percent; Next Science, Telix, Uscom and Volpara fell more than four percent; Dimerix, Immutep and Neuren were down more than three percent; Orthocell and Starpharma shed more than two percent; Antisense, Clinuvel, Cochlear, Ellex, Medical Developments, Prescient, Pro Medicus and Resmed lost one percent or more; with CSL and Cynata down by less than one percent.

DR BOREHAM'S CRUCIBLE: ALCIDION GROUP

By TIM BOREHAM

ASX code: ALC

Share price: 16 cents; **Market cap:** $158.5 million; **Shares on issue:** 990,694,052

Financials (December half 2019): revenue $8.2 million (up 12%), net loss after tax $1.8 million ($568,000 deficit previously)

March quarter 2020: receipts $3.97 million, cash outflows $1.2 million, cash on hand $15.9 million, number of quarters of available funding 13.2

Chief executive officer: Kate Quirke

Board: Rebecca Wilson (chair)*****, Kate Quirke, Prof Malcolm Pradhan, Nick Dignam, Ray Blight, Simon Chamberlain

***** Assumed the chair from Ray Blight in August 2019

Identifiable major shareholders: Malcolm Pradhan 13.6%, Ray Blight 10.15%, Isle of Wight Pty Ltd (Colin MacKinnon) 7.1%, Caledonia Nominees (Donald Kennedy) 6.1%, Kate Quirke 5.7%.

In the current corona-crisis, what bedside doctor or nurse wouldn't like to know a bit more about the current status of a patient and the availability (or otherwise) of beds across a sprawling hospital?

In providing such tools, the Adelaide-based Alcidion taps the zeitgeist although it's been beavering away for the best part of a decade on developing its digitized clinical organization tools. (The folk who devise share market indices certainly think so, promoting Alcidion into the All Ordinaries, just this morning.)

In short, Alcidion's decision support products help hospitals to understand where there is excess demand for services - and who to treat as well as how and when.

"Hospitals are at a real advantage if they can look at the totality of what's going on and identify the hot spots," says Alcidion CEO Kate Quirke.

We can't argue with that. Most western health systems are well behind the curve on digital delivery, which threatens the quality of healthcare delivery when it most counts.

Like now.

"We have had more engagement with existing customers to cope with the tsunami ahead of them," Ms Quirke said ahead of the expected flood of intensive care patients - that thankfully did not happen in Australia.

Miya my, what useful products

Alcidion was founded by director Ray Blight, the erstwhile head of the South Australian Health Commission and Prof Malcolm Pradhan, a general practitioner and health informatics buff.

The company back-door listed in February 2016 via the shell of Narracoota Resources, which obviously had little luck tapping the Earth's riches. Alcidion developed a product called Miya, which consolidates data from multiple sources in one spot for the clinicians.

But the company's hue changed in 2018 when it bought a private mob called MKM Health from a group of ex Deloitte consultants, for a headline $12 million. MKM has an established product called Patientrack, which ensures that doctors and nurses have the full patient information from different departments. If a patient takes a turn for the worse, the nurses are alerted at the central nursing station.

Notably, MKM has a presence in Britain, which Alcidion is targeting as its preferred expansionary geography. MKM's Ms Quirke was anointed Alcidion CEO in July 2018, with then executive chair Mr Blight stepping back to a non-executive director role.

Building a better mousetrap

Currently about 250 hospitals are using Alcidion's products or services in some way or other. About 15 have taken up its core product, Miya, while a further 40 use Patientrack.

Alcidion's latter day efforts have revolved around a next-gen version of Miya, called Miya Precision and Miya Memre. Miya Precision is an internet cloud-based version of the original product, while Miya Memre is fully mobile phone based.

In April, Alcidion said it had struck a deal with the Murrumbidgee Local Health District to supply both Miya Precision and Memre for 12 months. The use includes monitoring patients at home with the coronavirus.

In March, Alcidion said its established client ACT Health had rolled out Miya Precision across two sites, accounting for 600 beds: Canberra Hospital and the University of Canberra Hospital.

Ms Quirke says: "The platform at ACT Health is all about looking at patient flow and logistics: who is taking up beds and how quickly we can move patients through the system. Hospitals are at a real advantage if they can look at the totality of what's going on and identify the hot spots."

Fewer patients, better hospitals

As attested in the famous Yes Minister episode, the most efficient hospital is the one without any patients. While achieving wards full of neat empty beds is beyond the reach of health bureaucrats, what hospital would baulk at sending patients home if they could?

Alcidion's Next Big Thing is the home-testing of patients via devices and Bluetooth connectivity. Of course, this tech is already widely available but the art lies in reliable remote monitoring of the patients.

Unrelated to Covid-19, Alcidion has been running a pilot program with an unnamed South Australian house of healing, relating to monitoring patients after a cardiac episode.

"It's a longer-term play," Ms Quirke says. "I would expect a lot of hospitals would be looking at how to keep more patients at home."

Ms Quirke expects the company will roll out the home version of Miya Precision "fairly quickly".

Hands across the seas

The Miya products are the growth driver for Alcidion, with the more mature Patientrack still delivering significant contracts especially in Britain and New Zealand. The company also has a side product, a speedy messaging service called Smartpage.

Geographically, the Old Blighty is appealing because it has a similar publicly-funded health system to Australia (the National Health Service, NHS, or The 'Ealth). For example, the company has rolled out Miya Precision to the Dartford and Gravesham NHS Trust, in a $1.9 million contract.

During the March quarter, NHS Fife (a Scottish health board) renewed and expanded a contract to use Patientrack for another five years, covering at least 10 of its hospitals. The deal is worth $1.47 million over the period.

"Patientrack already has a 10-year track record there, so for these reasons it's a more attractive market than the US," Ms Quirke says. "The UK is also more receptive to non-UK tech; the US is more insular."

Covid-19 aside, the UK market has settled down since last year's general election, with a greater focus on digitized healthcare emerging. One example is the NHSX Tech Plan, which is the NHS's boffin-y but earnest push to instill digital health across the system.

Financials and performance

In the December 2019 (first) half, Alcidion booked revenue of $8.2 million and had "total sold revenue" of $15.4 million so far for the 2019-'20 year.

By the end of the March quarter 2020 the company claimed sold revenue of $17.2 million for the year (the figure would have been about $600,000 higher without the coronavirus affecting the clients). Of this $17.2 million, $9.8 million is classed as recurring. The company also cites sold (contracted) revenue of $41.6 million to the 2024-'25 year.

At the end of March, the company had $15.9 million in cash, bolstered by a $16.2 million placement last November. The company had cash outflows of $1.2 million, compared with a net loss of $1.8 million for the half.

In the year to June 30, 2019, Alcidion was merely $70,000 in the red and Ms Quirke argues it would have broken even by now had it not expedited its growth spending.

“We made a decision to go for it, now, rather than go slow,” she says. “We are not cash flow positive because of the lag between making the investment and showing revenue.”

Ms Quirke showed her faith by splashing out $137,500 for one million Alcidion shares in mid-March, as the market rout set in. So that’s how she spent the pay rise the grateful board endowed her in January, when her base salary rose to $413,461. (In the 2018-’19, Ms Quirke pocketed a base $249,820, bearing in mind she was executive director from July 3, 2018 to January 25, 2019 and then head honcho thereafter).

The share splurge takes Ms Quirke’s direct and family holding to 27.79 million shares, just under six percent of the register. Company chair and PR queen Rebecca Wilson also set a good example by splurging $29,750 on 250,000 shares.

Dr Boreham’s diagnosis:

Ever a traditionalist, your columnist likes to see companies that are chalking up meaningful revenue increments while not haemorrhaging cash at the same time.

When we last put Alcidion over the Bunsen burner in July 2018, the company had reported March quarter receipts of $519,000 and it ended up recording $4.1 million of revenue for the full 2017-’18 year. Fast forward two years and the sold revenue of $41.6 million over the next four years looks like the sort of decent logarithmic growth we don’t want to see on a Covid-19 infection rate chart.

On a downbeat note, Alcidion back then claimed 15 hospitals had signed up to Miya and that number doesn’t appear to have moved. Selling to hospitals will always be difficult because (a) they’re perennially cash strapped and (b) spending decisions have to go through the sort of laborious committee process so beloved of Sir Humphrey Appleby.

But Alcidion has a decent suite of products to sell, while the MKM merger doesn’t seem to have created the management friction that besets most integrations.

The company’s vital signs look robust, in our view.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he is replete with useful facts, such as Miya being pronounced ‘Myer’ and Alcidion’s market cap now being not much less than that of the once esteemed department store that was once worth billions.

Disclosure: Both Dr Boreham and Biotech Daily editor David Langsam own shares in Alcidion.

STANDARD & POORS DOW JONES INDICES

Standard & Poor's Dow Jones Indices say that along with Australian Ethical, 14 biotechs have been promoted, two removed and two marijuana companies demoted.

In its June quarter indices rebalance S&P said that Mesoblast was promoted into the S&P ASX200, with Mayne Pharma removed.

Standard & Poor's said that Medical Developments, Opthea and Paradigm had been added to the ASX300, along with Australian Ethical Investment, a substantial investor in a number of ASX-listed biotechnology companies.

S&P said that additions to the All Ordinaries Index included Alcidion, Atomo, Genetic Signatures, Next Science, Probiotec, Painchek, PYC (formerly Phylogica), Resapp, Somnomed and Telix.

Standard & Poor's said that Auscann and Cann Group were removed from the All Ordinaries Index.

S&P said that Avita had been removed from the ASX All Australian 200 Index.

In April, Avita said it intended to move its operations to the US, which was approved by the Federal Court of Australia in May (BD: Apr 21, May 11, 2020).

The S&P Dow Jones Indices said the changes were based on market capitalization alone, and would be effective from June 22, 2020.

SCOPUS BIOPHARMA INC

New York's Scopus Biopharma says it has acquired an immuno-oncology gene therapy drug from City of Hope along with Paul Hopper's Bioscience Oncology.

In a media release Scopus said the related transactions meant that it would acquire the Los Angeles-based City of Hope invented gene therapy drug, CpG-STAT3siRNA, a STAT3 inhibitor, to silence the activity of the STAT3 gene with RNA interference while stimulating the TLR9 receptors to activate the body's immune defence to recognize and kill cancer cells.

The company said that in pre-clinical testing, the drug reduced growth and metastasis of various pre-clinical tumor models, including melanoma, colon and bladder cancers, as well as leukemia and lymphoma and a first-in-human phase I trial in B-cell lymphoma patients was expected to begin at the City of Hope by the end of the year.

Scopus said it had acquired all the shares of Bioscience Oncology, headed by Paul Hopper, who joined Scopus as co-chairman and a director.

"I am delighted to develop City of Hope's exciting STAT3 technology with Scopus," Mr Hopper said.

"Pre-clinical data suggests that the technology has a promising future in the fight against cancer," Mr Hopper said.

Mr Hopper was formerly the chair of Viralytics, which was sold to Merck Inc for $502 million for its Cavatak oncolytic immunotherapy and continues as Imugene executive chair and Life Science Portfolio Managers Trust chair (BD: Feb 22, 2018).

Scopus did not disclose the commercial terms but said it would pay City of Hope an upfront licence fee payable in cash, shares and warrants, annual maintenance fees and performance-based payments linked to the clinical development and commercialization milestones, as well as sales-based royalty payments and sub-licencing fees.

The company said the acquisition of Mr Hopper's Bioscience Oncology included an up-front cash payment, a deferred cash payment due on the first anniversary of the closing of the acquisition and the issue of shares, a majority of which was subject to development milestones, and warrants.

TBG DIAGNOSTICS

TBG says it has US Food and Drug Administration “emergency use authorization” for its Exprobe Sars-Cov-2 nucleic acid test kits.
TBG said the approval was through its Taiwan-based wholly-owned subsidiary TBG Biotechnology Corp, which manufactured the test.
The company said that the Exprobe RNA-based diagnostic kit used real time polymerase chain reaction (PCR) technology with multiplex design to detect distinctive segments within RdRP, N and E genes of the severe acute respiratory syndrome coronavirus 2 (Sars-Cov-2) virus in a single reaction.
TBG said that the Exprobe test kit was “commonly used to confirm active infection of the Sars-Cov-2 virus from a specified range of upper and lower respiratory samples”.
TBG said that emergency use authorization was supported by the US Secretary of Health and Human Service’s declaration “that circumstances exist to justify the emergency use of in-vitro diagnostics for the detection and/or diagnosis of the virus that causes Covid-19”.
The company said the test kit had “not undergone the same type of review as an FDA-approved or cleared [in-vitro diagnostic]”.
TBG said the approval was for the duration of the Covid-19 declaration, unless terminated or revoked.
The company said that under the emergency use, the Exprobe test was “only authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 USC Section 263a, to perform high complexity tests”.
TBG said its kit was one of 100 in-vitro diagnostics test kits for detection and/or diagnosis of the novel coronavirus which received FDA emergency use authorization.
TBG was in an ASX suspension and last traded at 27 cents.

EXOPHARM

Exopharm says it has licenced new intellectual property to aid development of engineered exosomes for cancer, rare diseases and neurological conditions.
Exopharm said it licenced the intellectual property of Load, a technology for loading selected nucleic acids to the carrying capacity of engineered exosomes from the Buffalo-based State University of New York.
The company said that nucleic acids, including messaging ribonucleic acid (mRNA), RNA interference (RNAi) and small interfering RNA (siRNA) could modify how cells operated.
Exopharm said it licenced EVPS from California’s Santa Clara University to attach custom proteins to the surface of engineered exosomes to target specific cell types.
The company said the new licences joined its portfolio of engineered exosome products, including Leap for the isolation and purification of engineered exosomes.
Exopharm said that both licence agreements included “non-material annual commitments to keep each licence and associated patents in good standing as well as standard commercial royalties on product sales”.
Exopharm managing-director Dr Ian Dixon said that Leap, Load and EVPS were “a powerful set of tools that enable us to design and make a range of important and novel [engineered exosome] products to treat a number of medical problems”.
“The synergy of these three technologies is harnessed in our new proto type product, Fortrexo Cov, for fighting coronavirus infection by delivering virus-specific RNAi into at-risk cells, arresting virus replication in the cell,” Dr Dixon said.
Exopharm fell half a cent or 1.9 percent to 26 cents.

MACH7 TECHNOLOGIES

Mach7 says its placement and institutional rights offer at 68 cents a share has raised $23.4 million, with a fully underwritten retail rights offer to raise a further $11.4 million.
Earlier this week, Mach7 said it hoped to raise $34.8 million to buy the Waterloo, Ontario-based Client Outlook for $CA38.5 million ($A40.8 million) (BD: Jun 10, 2020).
Today, the company said the placement raised $3.7 million and the institutional rights offer raised $19.7 million, with the 68 cents offer price a 13.9 percent discount to the last traded price of 79 cents on June 9, 2020.
The company said the retail offer would give eligible shareholders the option to buy one new share for every four shares held at the record date of June 12, 2020.
Mach7 said the retail offer would open on June 17, 2020 and close on June 26, 2020.
The company said Morgans Corporate was the sole manager and underwriter.
Mach7 was up 15 cents or 19.0 percent to 94 cents with 5.5 million shares traded.

ELLEX MEDICAL LASERS

Ellex says it and Lumibird Group SA expect to complete the sale of the Ellex laser and ultrasound business on June 30, 2020.
In December, Ellex said the Lannion, France-based Lumibird would pay $100 million in cash for its lasers and ultrasounds business (BD: Jan 19, 2020).
Yesterday, the company said the Australian Competition and Consumer Commission (ACCC) would “not oppose” the acquisition (BD: Jun 11, 2020).
Today, Ellex said there “to the extent there are conditions outstanding they are minor in nature and within control of the parties”.
Ellex said a revised timetable would be provided to the ASX “in the upcoming days”.
Ellex fell one cent or 1.6 percent to 60.5 cents.

RACE ONCOLOGY

Race has requested a trading halt “pending an announcement regarding the release of results from the clinical trial conducted at Sheba Medical Centre, Tel Aviv, Israel”.
Trading will resume on June 16, 2020 or on an earlier announcement.
Race last traded at 31.5 cents.

ESENSE-LAB

Esense has requested a trading halt pending the release of “an announcement regarding the commercial joint-venture update”.
Trading will resume on June 16, 2020 or on an earlier announcement.
Esense last traded at two cents.