Biotech Daily

Friday August 16, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: ALCIDION UP 10%; ATOMO DOWN 8%**

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

*** IMMURON WINS $3.5m TRAVELAN US MILITARY GRANT**

*** DE MOTU CORDIS WELCOMES FDA ARS NASAL EPINEPHRINE OKAY**

*** LTR: 1st SPONTAN 'AUTHORISED PRESCRIBER SCHEME' SCRIPT**

*** CHIMERIC MANUFACTURES CHM CDH17 FOR PHASE I/II TRIAL**

*** ARCHER: 'VTT TO MANUFACTURE 200mm DIAMETER WAFERS'**

*** PERENNIAL TAKES 8.7% OF MEDADVISOR**

*** LBT M-D BRENT BARNES TAKES 6%**

*** UIL, UTILICO TAKE 8% OF STARPHARMA**

*** SYNTARA: TIM LUSCOMBE CFO, DAVID MCGARVEY CO-SEC**

MARKET REPORT

The Australian stock market was up 1.34 percent on Friday August 16, 2024, with the ASX200 up 105.6 points to 7,971.1 points. Sixteen of the Biotech Daily Top 40 companies were up, 16 fell and eight traded unchanged.

Alcidion was the best, up 0.7 cents or 9.7 percent to 7.9 cents, with 1.7 million shares traded. Opthea improved 8.9 percent; Avita, Immutep, Nova Eye, Paradigm and Telix climbed more than four percent; Mesoblast and Polynovo were up more than three percent; Resonance and Starpharma rose more than two percent; Compumedics, CSL, Nanosonics, Pro Medicus, and Resmed were up more than one percent; with Clinuvel and Cyclopharm up by less than one percent.

Atomo led the falls, down 0.2 cents or 8.3 percent to 2.2 cents, with 143,679 shares traded. Clarity fell 4.3 percent; Actinogen, Amplia, Aroa and Universal Biosensors lost more than three percent; Cochlear, Curvebeam and Percheron shed more than two percent; Emvision, Genetic Signatures, Impedimed, Imugene, Medadvisor and Micro-X were down by more than one percent; with Neuren and Proteomics down by less than one percent.

DR BOREHAM'S CRUCIBLE: ALCIDION

By TIM BOREHAM

ASX code: ALC

Share price: 7.9 cents; **Shares on issue:** 1,342,473,221; **Market cap:** $106.1 million

Financials (Year to June 30, 2024): receipts $43.9 million, positive cash flow $5.64 million, cash of 11.8 million.

Chief executive officer: Kate Quirke (a.k.a. Katrina Elizabeth Doyle)

Board: Rebecca Wilson (chair), Ms Quirke, Simon Chamberlain, Danny Sharp, Victoria Weekes

Identifiable major shareholders: Prof Malcolm Pradhan 10.6%, Australian Super 9%, Ray Blight 5.98%, Salter Brothers 5.11%, Smallman family 2.35%, Kate Quirke 3.5%

The resounding message across the seas that Great Britain used to rule is that the state of the Old Blighty is not at all healthy, with the country just exiting recession.

But what resiliently remains healthy is the 'growth' prospects for the beloved public National Health Service (NHS), as it creaks and groans into the modern era of electronic patient records and streamlined patient flows.

One of the few ASX life-science plays to focus on the UK, Alcidion has developed technology that manages patient flows and integrates data across multiple healthcare facilities and functions into the one handy digital repository. The result, hopefully, is more useful information for doctors and nurses - such as the correct leg to amputate.

After a few years in intensive care, Alcidion looks to be turning the corner with a revenue spurt and positive cash flow.

CEO Kate Quirke says it's been a challenging year for growth, with slower than expected tender processes and lengthier procurement cycles. "Regardless of that, we continue to sign new customers and significant long-term renewals that continue to underpin our long-term financial strength."

Taking on the world from Adelaide

Alcidion's products are used by 400 hospitals and 87 healthcare organizations in the UK, New Zealand and Australia.

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

Starting out with its foundation product Miya Precision, Alcidion back-door listed in February 2016, having raised $2 million at 3.1 cents a share. In 2018, Alcidion bought the private MKM Health for around $12 million. MKM owned Patientrack, which ensures that doctors and nurses have the full patient information from different departments.

MKM's chief, Ms Quirke became Alcidion CEO in mid-2018. Then chairman and executive director Mr Blight became a non-executive director, before quitting in June 2021. Prof Pradhan retired in 2022 but remains a 10.6 percent shareholder.

In April 2021, Alcidion acquired UK mob Extramed, which manages the flow of patients from the emergency department to outpatient services. This opened the way for Alcidion to sell its products to additional hospital sites.

In December 2021, the company paid $55 million for Silverlink Software, "one of the largest and few remaining specialist patient administration systems in the UK NHS".

Miya my, what a good idea

Alcidion's flagship product, Miya Precision, augments a customer's existing information technology (IT) systems. Beneath Miya Precision, 16 modules cover functions including patient flow and bed management, vital signs recording and - of course - patient records.

In short, the platform "transforms inputs from multiple systems to present consolidated, meaningful information". Now known as Miya Assessments and Observations, Patientrack is all about nursing care at the bedside. Silverlink is non-clinical patient administration, but the Silverlink name is no longer used.

Winning deals in the UK …

In July, Alcidion become preferred electronic patient record (EPR) supplier for the North Cumbria Integrated Care NHS Foundation Trust, providing hospital and community care for half a million people at two acute care hospitals and eight community-based hospitals.

Won via tender, the deal extends an existing relationship for patient administration systems to the total Miya suite. While the deal is being negotiated, it is expected to be the Alcidion's biggest with total contract revenue of $30 million to $40 million over 10 years.

Earlier in the year, the company won a contract extension with the South Tees NHS Trust, an existing EPR customer, worth $23.3 million over 10 years. But with extra product and contract extension options, the deal could be worth as much as $54 million over 15 years.

Miya Precision also went live at the Hampshire Hospital Trusts emergency department division, creating 2,700 documents over three hospitals in the first 12 hours. Because emergency departments operate under stress, the Hampshire assignment was important for cementing Alcidion's street credibility.

Earlier sign-ons included University Hospital Southampton and the Herefordshire and Worcestershire Health and Care NHS.

And here …

Let's not forget that in the December 2023 half year, Alcidion still derived 58 percent of its revenue from Australia and New Zealand.

Locally, the Shepparton, Victoria-based Hume Rural Health Alliance said it would adopt Miya Precision to consolidate data across several health services and locations into a single regional platform. The deal is worth $4 million over five years.

Other local contracts include with the Northern Territory health system, Melbourne's Western Health and Alfred Health and home-care contracts with the Sydney and Murrumbidgee local health districts.

In 2022, Alcidion was selected as part of a global consortium to build a new 'health knowledge management' platform for the Australian Defence Force (ADF).

Execrable jargon aside, this means consolidating the health records of all 100,000 or so ADF personnel, no matter whether they are fighting in the trenches or confined to barracks.

The $11 million delivery phase of the program is nearly complete, after which it will deliver annual recurring revenue (for software licencing) of about $3 million a year. The program is in the third year of a five-year contract, with three likely five-year extensions.

Fixing a 'broken' system

As soon as Keir Starmer's Labour Party won office in the UK on July 4, health minister Wes Streeting appointed a healthcare expert, Prof Ara Darzi - aka Baron Darzi of Denham - to run a "raw and honest" review of the "broken" NHS.

To be completed by September, the lightning review is expected to contain strong prescriptions.

The NHS already is investing GBP1.9 billion ($A3.7 billion) in the NHS Frontline Digitisation Program, mainly aimed at supporting the rollout of EPR systems.

"I believe there will be a continued commitment to digitization, if it is not increased," Ms Quirke says. "In opposition, Wes Streeting talked about use of digital to transform the NHS … and I'm confident they will follow through on the rhetoric we heard before the election."

While the authorities claim the NHS EPR process is 90 percent complete, Ms Quirke believes it is not that advanced, with several NHS trusts yet to tender.

She adds that current non-NHS hospitals that want NHS funding will have to implement an EPR program.

"There's still a bit to be done."

Not just about EPR

Ms Quirke says some investors are under the misapprehension that EPR is Alcidion's key market.

"Alcidion is a platform with many modules on it," she says. "If you buy all the modules, you can implement it as an electronic patient record. But that is one small moment in time for us."

The Australian EPR market is mature, with most states implementing EPR systems 10 to 15 years ago (in NZ they're still almost non-existent).

Ms Quirke notes that even when the company didn't have an EPR product, it still had a circa 30 percent UK market share with products such as Miya Observations.

"Miya Flow is only in about five percent of the market, so you could argue we still have 95 percent of the market we can sell to."

Finances and performance

Alcidion reported record receipts of $18.6 million in the three months to June 30, 2024, 5.7 percent better year-on-year and 82 percent better than the March quarter.

The fourth quarter traditionally is the strongest for the company.

Operating cash flow of $5.6 million compared with a March quarter deficit of $1.3 million. Full year cash flow was $7.1 million, taking into account $8.1 million of outflows in the first (September 2023) quarter.

"We have a very lumpy cash situation, so it is very difficult to say every quarter will be positive," Ms Quirke says. "But over a year we are aiming to be cash flow positive and profitable."

Staff costs fell to $6.3 million in the March quarter, from $8.1 million previously.

The company made new sales of $5 million in the quarter and $35.3 million for the year, of which $6.2 million was recorded as revenue during that period.

The company reports $130 million of contract and renewal revenue "recognizable" over the next four financial years. This does not consider the ability to expand current jobs, or the revenue from the NCIC contract.

"We have seen an increase in tendering activity in the first half, compared with the prior year … and that has translated to an additional pipeline activity but it will take time to move through the processes," Ms Quirke says.

Ahead of the full-year results later this month, the company guided to unaudited revenue of $37.0 million to $37.5 million.

Currently, about three-quarters of revenue is from recurring subscriptions and the remainder from services such as product implementation and technical advice.

The revenue skew between the UK and Australia and New Zealand is expected to settle at 50:50 over time.

With cash of $11.8 million and no debt, Alcidion looks self-sufficient as long as it can generate surpluses.

Over the last 12 months Alcidion shares have blipped between 4.0 cents (an all-time low) in mid-April this year and 13 cents in late August last year. The shares peaked at 44 cents in June 2021, before a heavily-discounted $55 million raising to fund the Silverlink purchase sent the shares plunging.

Dr Boreham's diagnosis:

A criticism of Alcidion is that it competes with established larger providers, including Nervecentre Software, Dedalus Global, Epic Systems and Cerner Corp in the UK.

"In Australia we come up against Telstra Health. They don't compete with us in everything, but we also don't compete with them in areas such as aged care, community pharmacy or primary care," Ms Quirke says.

But the NCIC win in the UK shows that Alcidion is the little engine that can, albeit with some heavy grunting as it navigates the cumbersome UK health system.

"Because we are a platform with 16-plus modules we have quite a bit of differentiation," Ms Quirke says. "While we might not be their size, we are focused on what we do."

CG Capital Markets (Canaccord Genuity) notes that NHS procurement delays have been an issue for the last two years and have affected the company's "growth cadence".

"Despite the lumpiness of the past, we continue to like Alcidion given (albeit heavily delayed) tailwinds in digitizing systems across the NHS, [opportunities] for improved total contract value and customer upselling and a differentiated and well-regarded product."

Long-suffering investors who have seen their shares halve in value over the last five years will be reassured that management is committed to making Alcidion profitable, as evidenced by its cost-cutting initiatives.

What's more, Alcidion is addressing a clear unmet need.

"Demands for healthcare have never been greater … and we see greater interest in tech to support efficient care delivery and improved patient flow," Ms Quirke says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. So, he can't diagnose your skin condition and you will have to join the NHS queue

IMMURON

Immuron says the US Department of Defense has approved a $3.5 million grant for it to continue developing Travelan for additional endemic military-relevant diarrheal pathogens.
Immuron said the funding was part of a research agreement with the Naval Medical Research Command (NMRC) and the Silver Spring, Maryland-based Walter Reed Army Institute of Research (WRAIR).
The company said the research would use the experience of the US Department of Defense human infectious disease vaccine programs and "target key protective antigens of the major enteric bacterial pathogens Campylobacter, Shigella and entero-toxigenic [Escherichia] coli strains", not present in Travelan's current product formulation.
Last year, Immuron said the US Army approved a 60-patient trial of Travelan in healthy adults for infectious diarrhoea from entero-toxigenic Escherichia coli (BD: May 30, 2023).
Today, the company said it would negotiate a sub-award for collaboration with the NMRC and WRAIR to advance the research.
Immuron said the US Department of Defense has recognized the benefits of its commercial, over-the-counter bovine colostrum, or cow stomach-derived, product Travelan "for its specificity and effectiveness against diarrheal pathogens".
The company said as an extension of its current research programs the award was intended to further research "to identify and define pathways to formulate, characterize and perform pre-clinical testing of a military-relevant combined colostrum product".
Immuron was up 0.4 cents or 4.2 percent to 10 cents.

DE MOTU CORDIS

De Motu Cordis says it "commends" the US Food and Drug Administration's approval of the San Diego, California-based ARS Pharma's Neffy intra-nasal epinephrine device.
In July, Brisbane's De Motu Cordis said it had appointed Catalant Pharma to manufacture its DMC-IH1 inhaled epinephrine for anaphylaxis (BD: Jul 17, 2024).
Today, De Motu Cordis chief executive officer Peter O'Neill told Biotech Daily that the company's inhaled epinephrine, was comparable to the ARS nasal spray formulation.
Mr O'Neill said the company expected to take the FDA 505(b)(2) regulatory pathway for DMC-IH1, but had about two years of clinical work to complete and was in ongoing discussions with FDA.
The company said the FDA's approval of "the first-ever, needle-free, intra-nasal epinephrine delivery device for the treatment of anaphylaxis" was a significant step forward in expanding emergency treatment options for anaphylaxis patients.
De Motu Cordis said the approval was "a pivotal confirmation of the applicability of the 505(b)(2) regulatory pathway for anaphylaxis treatments" and the FDA regulatory pathway was "especially critical for emergency indications like anaphylaxis, where extensive phase III clinical studies may not be feasible".
The company said the approval strengthened its commitment to advancing its own clinical program and underscored "the importance of providing more patient-friendly alternatives".
Mr O'Neill said De Motu Cordis expected "further growth in approvals of improved treatments for anaphylaxis indications over the next three to five years, primarily driven by continuing innovation in and approvals of improved delivery technologies."
"With these advancements, we expect the addressable patient market to expand by a factor of two to three," Mr O'Neill said. "Currently, in the US alone, only eight percent of individuals with type 1 severe allergic reactions have an active auto-injector prescription, highlighting a significant unmet need."
De Motu Cordis is a private company.

LTR PHARMA

LTR says the first patients have been prescribed its Spontan nasal spray for erectile dysfunction under the Therapeutic Goods Administration's authorized prescriber scheme.
Last week, LTR said two medical practitioners had been approved to prescribe its Spontan nasal spray formulation of vardenafil, marketed as Levitra, under the Australian TGA's special access scheme (BD: Aug 5, 8, 2024).
Today, the company said that the authorized prescriber scheme allowed registered medical practitioners to prescribe Spontan to a broader class of patients with erectile dysfunction, compared to the case-by-case approach of the special access scheme.
LTR said the patients were prescribed Spontan by chief scientific advisor and authorized prescriber Prof Eric Chung, who said the scheme allowed "us to offer Spontan to a wider range of patients who may benefit from its rapid onset of action".
"This innovative nasal spray has the potential to significantly improve quality of life for men struggling with [erectile dysfunction] and offers a new treatment option, particularly for those seeking a more spontaneous solution," Prof Chung said.
LTR executive chair Lee Rodne said the TGA authorized prescriber scheme was "an important milestone".
LTR fell 11.5 cents or 8.4 percent to $1.26 with 1.9 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says it has manufactured the required chimeric antigen receptor T-cells CHM CDH17 for its phase I/II trial in colorectal cancer, gastric cancer, and intestinal tumours.
In May, Chimeric said it opened the phase I/II trial of CHM CDH17 chimeric antigen receptor (CAR) T-cells, or CHM2101, for gastrointestinal cancers at the Nashville, Tennessee-based Sarah Cannon Research Institute (BD: May 22, 2024).
Today, the company said it had collected a clinical trial participant's cells from the Sarah Cannon Cancer Centre and transported the cells to the contract manufacturing site.
Chimeric said the T-cells passed specification testing and quality assurance review and were currently back in transit to the clinical trial site for infusion into the participant.
The company said additional trial sites were expected to open in the second half of 2024.
Chimeric head of technical operations Dr Kelly Thornburg the company was "delighted to have a successful manufacturing run for our first clinical trial participant …[with the] milestone … the culmination of more than two years of focused effort".
Chimeric was unchanged at 1.7 cents.

ARCHER MATERIALS

Archer says the VTT Technical Research Centre of Finland Ltd will manufacture 200mm diameter wafers of its Biochip graphene field effect transistors.
Earlier this year, Archer Materials said it had developed a computer chip to detect the electronic signals from genetic sequence reactions, enabling the potential detection of multiple diseases (BD: Jan 23, 2024).
Today, the company said it had sent a re-design of its graphene field effect transistor for is Biochip to be included in a multi-project wafer run conducted by the Espoo, Finland-based VTT Technical Research Centre of Finland.
Archer said the run would integrate its device "directly onto the silicon complementary metal-oxide semiconductor (CMOS) chip" to measure how effective its sensors could be electrically accessed, controlled and read-out by a conventional silicon CMOS circuity.
Archer was up one cent or 4.3 percent to 24.5 cents.

MEDADVISOR

Sydney's Perennial Value Management Ltd says it has increased its substantial holding in Medadvisor from 40,409,181 shares (7.34%) to 48,187,368 shares (8.74%).
Perennial said between July 9 and August 13, 2024 it bought and sold shares on-market, with the single largest purchase 2,623,624 shares for $1,156,905, or 44.1 cents a share.
Medadvisor fell half a cent or 1.1 percent to 45 cents.

LBT INNOVATIONS

LBT managing-director Brenton Barnes says he has become substantial in the company with 98,713,606 shares, or 6.10 percent.
Mr Barnes said that with Hawkeye Self-Managed Superfund and Barnes' Love Work Live he bought 33,000,000 shares on August 16, 2024 for $165,000, or 0.5 cents a share.
LBT fell 0.15 cents or 9.1 percent to 1.5 cents with 2.1 million shares traded.

STARPHARMA HOLDINGS

UIL and Utilico Emerging Markets Trust PLC say they have increased their substantial holding in Starpharma from 27,566,682 shares (6.69%) to 33,066,682 shares (8.02%).
The Surrey, England and Bermuda-based UIL said it bought, sold and transferred shares between June 28 and August 15, 2024, with the single largest purchase 1,031,476 shares on July 24 for $97,693, or 9.5 cents a share.
Starpharma was up 0.2 cents or 2.2 percent to 9.2 cents.

SYNTARA (FORMERLY PHARMAXIS)

Syntara says Tim Luscombe will replace David McGarvey as its chief financial officer, with Mr McGarvey to continue as company secretary, effective from August 31, 2024.
Syntara said Mr Luscombe was a director at financial services firm Bio101 Financial Advisory, as well as chief financial officer and company secretary for several companies.
The company said Mr Luscombe held a Bachelor of Commerce from the University of Melbourne.
Syntara said Mr McGarvey was retiring after more than 20 years as chief financial officer of the company and would continue to give "special attention to concluding financial and legal arrangements associated with the sale of the mannitol business unit".
Syntara chief executive officer Gary Phillips thanked Mr McGarvey for "his steadfast commitment, sound advice and support … over many years".
"We are delighted that David has agreed to continue his engagement with the board as company secretary, where his in-depth knowledge of our business will prove invaluable as we finalise the restructuring of our business following the sale of the mannitol business unit last year," Mr Phillips said.
Last year, the then Pharmaxis said it had sold its mannitol respiratory business to Sydney's Arna Pharma which has taken over day-to-day operations (BD: Oct 19, 2023).
Syntara was unchanged at 3.2 cents with 1.35 million shares traded.