Biotech Daily

Friday April 26, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: RESMED UP 10%; PRESCIENT DOWN 10%**

*** DR BOREHAM'S CRUCIBLE: OPTHEA**

*** RESMED 9-MONTH REVENUE UP 12% TO $5.3b; PROFIT UP 17% TO $1.3b**

*** CONTROL BIONICS 9-MONTH RECEIPTS UP 5% TO $4m**

*** GENETIC SIGNATURES 9-MONTH RECEIPTS DOWN 50.5% TO $8m**

*** ADHERIUM: $1.6m PLACEMENT; $7m RIGHTS OFFER TO FOLLOW**

*** IMEX DIRECTOR PLACEMENT RAISES $250k; TOTAL $1.5m**

*** VICTORIA $2m FOR POLYNOVO $4m EXPANSION**

*** RECCE 4,000mg 30-MIN R327 DOSE FOR UTI**

*** ECHO IQ TELLS ASX 'AWARE FOR 1 DAY; CEO CULTURAL FIT'**

*** VITURA: CODE4 CANNABIS ORDERED TO NOT WITHDRAW SERVICES**

*** CRYOSITE DIRECTOR ANDREW KROGER REDUCES TO 41%**

*** CRYOSITE CHAIR MARK KERR, LINDMARK TAKES 15%**

*** AVECHO APPOINTS EX-J&J KATHY CONNELL DIRECTOR**

MARKET REPORT

The Australian stock market fell 1.39 percent on Friday April 26, 2024, with the ASX200 down 107.1 points to 7,575.9 points. Fourteen of the Biotech Daily Top 40 stocks were up, 18 fell and eight traded unchanged.

Resmed was the best, up $2.76 or 9.6 percent to $31.50, with 5.6 million shares traded. Next Science improved 7.9 percent; Percheron and Syntara both climbed 6.25 percent; Actinogen was up 3.45 percent; Micro-X and SDI rose more than two percent; Alcidion, Amplia, Mesoblast, Nova Eye and Pro Medicus were up more than one percent, with 4D Medical, Cochlear, Genetic Signatures and Telix up by less than one percent.

Prescient led the falls, down 0.6 cents or 10.3 percent to 5.2 cents, with 1.8 million shares traded. Universal Biosensors shed 9.1 percent; Opthea lost 7.4 percent; Immutep was down 6.7 percent; Avita, Curvebeam and Paradigm were down more than five percent; Dimerix, Impedimed, Imugene and Polynovo fell more than four percent; Medical Developments was down 3.6 percent; Clarity, Clinuvel and Emvision shed more than two percent; CSL, Neuren and Orthocell were down more than one percent; with Nanosonics down 0.4 percent.

DR BOREHAM'S CRUCIBLE: OPTHEA

By TIM BOREHAM

ASX and Nasdaq code: OPT (eight ASX shares = 1 American depositary share)

Share price: 62.5 cents; **Shares on issue:** 662,808,634; **Market cap:** $414.3 million

Chief executive officer: Dr Frederic Guerard

Board: Dr Jeremy Levin (chair), Dr Megan Baldwin (founder and executive director), Lawrence Gozlan, Dr Julia Haller, Dr Susan Orr, Quinton Oswald, Sujal Shah, Anshul Thakral

Financials (half year to December 31, 2023): revenue $US60,798 ($A93,200) (up 17%), loss of $US96.1 million (previous deficit $US79.1 million), cash $US157 million (up 76%).

Identifiable major shareholders: Regal Funds Management 22.96%

One doesn't have to be a Madison Avenue 'Mad Man' to know that it's more effective to have a credible third party spruik a product or service, rather than the advertiser itself.

Opthea has taken this lore to heart, having rolled out three key opinion leaders - eye clinicians - to spread the message about the company's proposed drug for wet age-related macular degeneration (wet AMD) - the leading cause of blindness in the over 50s. In a recent online clinical seminar, investors were told the company's proposed treatment for wet AMD would be the first new one in 15 years.

"This is the only program in late-stage development designed to have better visual acuity outcomes for patients and that is what matters," said Dr Arshad M Khanani, founder of Sierra Eye Associates. Indeed!

University of Illinois retinal specialist Dr Veeral Sheth chimed in: "this program has the potential to transform how we treat wet AMD in our daily clinical practice."

After years of development, D-day is approaching as the company carries out two pivotal phase III combination trials for its drug candidate sozinibercept - OPT-302 to friends.

Eye-catching history

Opthea's corporate history goes back to the days of Circadian Technologies, which toyed with melatonin for jet lag.

Founded by biotech doyen Leon Serry, Circadian incubated companies including the Victoria state-founded Amrad, (later renamed Zenyth and sold to CSL). Other companies in its portfolio were Metabolic (which became Calzada before morphing into Polynovo), Antisense and Optiscan.

Circadian acquired the eye portfolio - based on vascular endothelial growth factor (VEGF) inhibitors - from the University of Helsinki in 2008. The company changed its name to Opthea in December 2015.

With a Doctor of Philosophy in VEGF, Dr Megan Baldwin joined the company in 2008 and was anointed CEO in February 2014.

In October last year, the company appointed Dr Guerard as CEO and Peter Lang as chief financial officer, both US-based.

Dr Baldwin assumes a new role of executive director and chief innovation officer, responsible for 'forward looking' programs such as co-formulation and pre-filled syringe development and clinical studies beyond wet AMD.

Dr Guerard was CEO of the clinical stage Graybug Vision Inc, where he led the development of a late-stage wet AMD candidate. Before that, he was worldwide business franchise head of ophthalmology for Novartis.

In October 2020, the company raised $US128 million by way of American depositary shares and listed on the Nasdaq Global Select Exchange.

Opthea's vision statement

The leading cause of vision impairment in people over the age of 50 years, wet age-related macular degeneration is linked with blood vessel dysfunction in the macular region. Blood vessels grow abnormally under the retina, resulting in leakage of fluids, lipids and blood from the vessel; and patients can lose vision in as little as 10 weeks.

A so-called 'trap inhibitor', OPT-302 is a fusion protein that blocks the activity of two VEGF proteins: VEGF-C and VEGF-D.

Opthea is developing OPT-302 as a wet AMD combination therapy with the existing drugs Lucentis (ranibizumab) and Eylea (aflibercept), which only block VEGF-A.

Currently about 60 percent of patients have sub-optimal results, because the disease process is more complex than just blocking VEGF-A. About half the market is treated off-label with Avastin, an old cancer drug.

Eye see more letters

In August 2019, Opthea released "statistically significant and clinically meaningful" results of its keenly-awaited 366 previously-untreated patient, phase IIb trial, which tested a combination of OPT-302 with the standard-of-care Lucentis.

The primary endpoint was the ability of patients to read more letters on an eye chart after 24 weeks of treatment. Aged on average in their mid-70s, the 'combo' group read 14.2 letters, a mean 3.4 more than those on the standard-of-care therapy alone.

Coast and Shore trials launched, but company not at ‘see’

The market’s attention is now focused on the two phase III wet AMD trials, nautically dubbed Coast and Shore, in combination with Lucentis and Eylea respectively.

The company recently enrolled its last patient in Coast, while Shore is 96 percent enrolled.

Both trials each enrol 990 treatment-naïve patients, with one-third allocated to a sham (placebo) group.

The primary endpoint is the mean change in the eye chart reading at week 52, with the secondary endpoints of an improvement of either more than 15 letters (three lines), or ten letters (two lines). There are also “anatomical” endpoints, including fluid measures at the back of the eye.

As of December 2023, Shore had 198 active trial sites in 22 countries, while Coast had 219 sites in 30 nations.

Enrolment had been challenging because of the pandemic, inflation, supply chain issues and the old railways excuse of “lack of qualified staff”.

Trial recruits include patients with a form of hard-to-treat wet AMD called polypoidal choroidal vasculopathy (PCV), by which fluid leaks and bleeds from abnormal blood vessels.

PCV is common in people with Asian background.

In the phase IIb trial,18 percent of the 366 treatment-naïve patients had PCV and the results for this cohort were impressive.

Dr Baldwin says some of the phase III patients have completed the 100th week of treatment, well beyond the week-52 milestone for the top-line data.

“Of course, the company hasn’t seen the data because it is masked and they will only get a look see when all patients have completed week-52,” she says.

Opthea will move swiftly to file a US Food and Drug Administration application - if the 2025 trial read-out is positive - and probably within six to 12 months of the results.

The company has fast-track approval, which enables it to submit a biologics licence application (BLA) on a module-by-module approach.

Eyeballing the competition

Some changes to the wet AMD competitive landscape have unfolded since we last covered Opthea in May 2022.

Last October, the FDA approved a Roche drug, Vabysmo (faricimab). The subsequent launch was spectacular and the drug now outsells previous market leader Lucentis.

Vabysmo is a bi-specific molecule targeting ANG2 and VEGF-A. But Dr Baldwin says there's no efficacy benefits over the other anti VEGF-A drugs (Eylea and Lucentis).

"We view it as another standard-of-care molecule, with a view that we would be able to add on it to just in the same way as we plan to with Lucentis, Eylea, Avastin or a biosimilar."

(A biosimilar is a cheaper copy of an existing drug).

"The fact the uptake has been so fast shows the clinicians are willing to try new drugs," Dr Baldwin says.

Meanwhile, Regeneron recently won approval for a high-dose form of Eylea, which is likely to be more competitive with Vabysmo.

In 2019, the FDA approved a Novartis wet AMD drug called Beovu (brolucizumab).

The subsequent launch flopped after evidence emerged of side effects including retinal vasculitis, which can cause profound vision loss.

Talk about the cure being worse than the disease!

Glory or bust

In August 2022, Opthea unveiled a share placement and a novel non-dilutive deal with US outfit Launch Therapeutics (an offshoot of global investment giant Carlyle and its acquired life sciences franchise, Abingworth).

Launch agreed to provide $US120 million over three unconditional instalments, with an option to tip in a further $US50 million.

If OPT-302 is approved in a major market, Opthea repays Launch through a quasi-royalty of 7.0 percent on annual net sales.

The unusual aspect is that these payments are capped at four times the invested amount: a tidy $US510 million profit.

But if OPT-302 is not approved Launch gets yada, zip and a donut.

Opthea keeps the full rights to the drug and is only obliged to repay the funding - let's call it quasi debt - if successful.

Technically, the arrangement is called a structured financing royalty deal, which are common in the US but not here.

The deal was accompanied by a $US90 million placement - a prerequisite for Launch's involvement - struck at $1.15 a share (a 12.5 percent discount).

Finances and performance

In December 2023, Opthea pocketed the last scheduled $US35 million from the deal, with Launch chucking in another $US50 million with a co-investor.

In August 2023, the company again replenished its coffers with a $73 million placement and rights issue at 46 cents apiece, followed by a rights offer that raised $16.3 million for a total $90 million.

Opthea recorded an ugly-sounding $96 million loss in the December 2023 half, reflecting the cost of rolling out more trial sites.

The (very) modest revenue of $60,798 came from royalty and licencing income.

Opthea has $US157 million in cash, but phase III trials don't come cheaply. According to Opthea's annual report, the company is funded to the third quarter of calendar 2024.

Opthea still has access to an at-the-market equity program, by which the company can issue up to $US75 million of its American depositary shares at a time of its choosing.

Opthea shares peaked at $3.45 in September 2019 and troughed to 20 cents in June 2015.

Dr Boreham's diagnosis:

Despite the stiffening wet AMD drug competition, Dr Baldwin says OPT-302 is still the most advanced product in development that has shown superiority over standard-of-care therapy, as opposed to showing better treatment durability (extended efficacy between injections).

"Only a couple of very early-stage companies are looking at new mechanisms of action so we have a clear runway in terms of that development path," Dr Baldwin says. "We are going to have a lot of commercial interest in our readout and there's huge potential because of that."

By entering phase III, Opthea is in a rare pantheon of ASX-listed biotechs that includes Dimerix, Mesoblast and Paradigm.

Opthea cites the size of the prize as a $US15 billion market: $US9 billion for Lucentis and Eylea and $US5 billion for the off-label Avastin and other biosimilars.

"Any way you cut and dice the market, it is a multi-billion-dollar opportunity even on conservative estimates of the proportion of clinicians administering it initially," Dr Baldwin says.

Disclosure: Any way you cut and dice it, Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His vision is to get one eventually.

RESMED

Resmed says that revenue for the nine months to March 31, 2024 was up 11.6 percent to $US3,462.1 million ($A5,305.5 million), with net profit up 16.6 percent to $US833.0 ($A1,273.4 million).

Resmed said three-month revenue rose 7.2 percent to $US1,197.0 million with increased demand for its respiratory care devices and software, with North America sales up 9.3 percent to $US687.5 million, Europe and Asia sales up 3.0 percent to $US361.6 million.

The company said it provided US generally accepted accounting principles (GAAP) and non-GAAP data, and it "uses non-GAAP information internally in planning, forecasting, and evaluating the results of operations in the current period and in comparing it to past periods ... [and] believes this information provides investors better insights".

This report quotes the non-GAAP data.

The company said an unfranked dividend of 4.8 US cents per share would be paid on June 13 to shareholders at the record date of May 9, 2024.

Resmed said diluted earnings per share for the three months to March 31 2024 were up 26.8 percent to $US2.13 and that it had cash and cash equivalents of $US237,910,000 at March 31, 2024, compared to $US227,894,000 at March 31, 2023.

Resmed was up $2.76 or 9.6 percent to $31.50 with 5.6 million shares traded.

CONTROL BIONICS

Control Bionics says receipts from customers for the nine months to March 31, 2024 were up 4.6 percent to $4,341,000, compared to the previous corresponding period.

Control Bionics said receipts were from sales of its electro-myography wireless wearable device for motor neuron disease and amyotrophic lateral sclerosis patients, with US sales impacted by the seasonal insurance deductibles reset and Australian sales performance impacted by "significant delays experienced by the [National Disability Insurance Scheme] in approving submissions for assistive technology".

The company said it had a cash burn of $1,068,000 for the three months, with cash and cash equivalents of $883,000 at March 31, 2024 compared to $1,312,000 at March 31, 2023, leaving the company with about 0.83 quarters cash.

Control Bionics said it that expected to resolve the NDIS funding approval delays that had led to deferred sales revenue for the three months, had an increased cash outflow due to "substantial funding for the Drove and Neurostrip projects" and believed it could raise capital if required.

Control Bionics was unchanged at 4.3 cents.

GENETIC SIGNATURES

Genetic Signatures says receipts from customers for the nine months to March 31, 2024 fell 50.5 percent to $7,740,000, compared to the previous corresponding period.

Genetic Signatures said receipts were from sales of its portfolio of Easyscreen detection kits for respiratory viruses, impacted by "seasonally reduced sales of the Easyscreen respiratory pathogen detection kit and reduced shipping while modifications to the kit were under review by the Australian Therapeutic Goods Administration".

The company said non-Covid-19-only sales were $1.4 million for the three months, with about 16 percent of sales coming from outside of Australia.

The company said it had a $4,333,000 cash burn for the three months, with cash and equivalents of $20,355,000 at March 31, 2024 compared to $21,627,000 the prior year.

Genetic Signatures was up half a cent or 0.7 percent to 68.5 cents.

ADHERIUM

Adherium says it has “binding commitments” to raise up-to $1.57 million in a placement at 2.0 cents a share, followed by a $6.8 million underwritten, one-for-one rights offer.
Adherium said the issue price was a 60 percent discount to the 30-day volume weighted average price.
The company said investors would receive one attaching option for every share subscribed, exercisable at three cents each by June 30, 2025, subject to shareholder approval.
Adherium said chair Lou Panaccio and director George Baran had agreed to subscribe for a total of $250,000 in the placement, with Trudell Medical Ltd, a company related to Mr Baran, subscribing for $220,000, and chief executive officer Dr Paul Mastoridis subscribing for $100,000, subject to shareholder approval.
The company said the entitlement offer was fully-underwritten by lead manager MST Financial Services Pty Ltd.
Adherium said the rights offer had a record date of May 2, would open on May 6, and close on May 20, 2024.
Adherium fell half a cent or 17.2 percent to 2.4 cents with 7.3 million shares traded.

IMEX HEALTH SERVICES

Imex says it has raised $250,000 at 55 cents a share through a conditional placement to “certain directors” taking the total raised to $1,500,000.
In March, the company said it had raised $1,250,000 in a placement at 55 cents a share, with a further $250,000 to be raised in a placement to directors, subject to shareholder approval (BD: Mar 11, 2024).
On Tuesday, the company said its annual general meeting voted up-to 44.1 percent against management options and 27.03 percent voted for a remuneration report first strike, with 97.93 percent of votes passing the issue of shares to directors under the conditional placement (BD: Apr 23, 2024).
Imex was up 2.5 cents or 4.6 percent to 57 cents.

VICTORIA GOVERNMENT, POLYNOVO

Polynovo says the Victoria Government has grant it up to $2,000,000 “to assist in expanding its advanced tissue engineering polymer capability”.
Polynovo said that the grant from Victoria’s Industry Research and Development Infrastructure Fund would support the estimated $4,000,000 expansion, due to be completed by July 2025.
The company said the project included capital expenditure for expanding laboratory infrastructure, including analytical and research and development equipment.
Polynovo chair David Williams said the grant would “significantly increase our product development capabilities while preserving our capital light balance sheet”.
“I would also like to thank the Victorian Government for the grant and for recognizing the jobs and technology we have brought to Port Melbourne and Victoria,” Mr Williams said.
Polynovo chief executive officer Swami Raote said that Novosorb BTM had healed more than 40,000 patients in 37 countries.
“With the support of the Victorian Government and our talented team of scientists, we are enhancing our research capabilities, allowing us to expand the Novosorb product range to include implantable products on top of the current graftable range,” Mr Raote said.
Polynovo fell 10 cents or 4.8 percent to $1.99 with 1.9 million shares traded.

RECCE PHARMACEUTICALS

Recce says it has approval to dose six-patients in its phase I/II urinary tract infection trial at a high dose of intra-venous 4,000mg of R327 over 30-minutes.
Last month, Recce said it began dosing at a 20-minute infusion rate, having tested 15, 30, 45 and 60-minutes (BD: Mar 12, 2024).
The company said recruitment was underway and it expected to begin dosing soon.
Recce said it had achieved "minimum inhibitory concentration activity" and identified 30 minutes as "the potential optimum infusion time and increased to a higher concentration … to investigate R327's high concentration potential".
Recce chief executive officer James Graham said the "high concentration potential to administer a broad-spectrum, anti-infective underscores the potential of a novel treatment for millions of patients worldwide … [with] urinary tract infection [and, or] urosepsis."
Recce fell 1.5 cents or 2.2 percent to 67 cents.

ECHO IQ

Echo IQ has told the ASX it became aware of a US reader study the day before publication and had "cultural fit" concerns with chief executive officer Kimber Rothwell.
The ASX asked Echo IQ when it became aware of the completion of its US reader study, whether it regarded the information as material, when Mr Rothwell had acquired 500,000 shares in the company and to provide "further details of the circumstances giving rise to Mr Rothwell stepping down" (BD: Apr 2, 2024).
Echo IQ said it believed the information was material and that it had made periodic announcements on the completion of the study in its half yearly, quarterly and annual reports and became aware of the completion of the study on March 26, 2024.
The company said it held a meeting regarding the information on March 26 from 2pm to 4pm (AEST), and once approved, released its announcement on March 27, 2024.
Echo IQ said Mr Rothwell had "requested clearance to purchase between 200,000 and 500,000 shares in the company on March 7, 2024" which were bought in orders on March 18, 21, 22 and 25, and settled on March 20 and 27, 2024.
The company said "its board had concerns regarding Mr Rothwell's cultural fit within the organization and the impact of this on the executive team at the company" and agreed he would leave the company in a meeting held on March 28, 2024.
Echo IQ said "Mr Rothwell was not aware of the information regarding the completion of the US Reader Study at the time of his transactions in the company's securities".
The ASX noted the company's share price rose 33.33 percent from a close of 11.25 cents on March 26 to a close of 15 cents on March 28, 2024.
Echo IQ was unchanged at 10.5 cents.

VITURA HEALTH

Vitura says wholly-owned subsidiary Canview Pty Ltd has stopped its software licensor Code4 Cannabis from terminating their services agreement early.
On Tuesday, Vitura said it had taken legal action against Brisbane's Code4 Cannabis following confirmation that Code4 intended to terminate its services agreement on April 29, 2024 (BD: Apr 23, 2024).
Today, the company said Code4 had consented to an injunction order made by Justice Kelly in the Supreme Court of Queensland stopping it "from disabling Canview's access to the software until the proceedings are determined, or until further order".
Vitura was up one cent or 9.5 percent to 11.5 cents with 1.55 million shares traded.

CRYOSITE

Cryosite director Andrew Kroger says he has decreased his substantial shareholding in the company from 21,043,702 shares (43.11%) to 20,043,702 shares (41.07%).
The London-based Mr Kroger said that with Melbourne's Austen Bay Pty Ltd and Daltonvale Pty Ltd on April 23, 2024 he sold 1,000,000 shares off-market for $830,000, or 83 cents a share.
Cryosite fell two cents or 2.3 percent to 85 cents.

CRYOSITE

Cryosite chair Mark Kerr says he has increased his substantial shareholding in the company from 6,154,494 shares (12.61%) to 7,154,494 shares (14.66%).
The Melbourne-based Mr Kerr said that with Lindmark Investments staff superannuation fund he bought 1,000,000 shares on April 23, 2024 for $830,000, or 83 cents a share.

AVECHO BIOTECHNOLOGY

Avecho says it has appointed Kathy Connell as a non-executive director of the company, effective from April 26, 2024.
Avecho said Ms Connell had worked for Johnson & Johnson and Sanofi, co-founded Medicines Australia's Pharmaceutical Australia Inclusion Group, was a partner at Korn Ferry's Australia healthcare and life-sciences practice, won the Bio-Melbourne Network's Woman of the Year Award in 2018 and was currently a director of Bio-New South Wales.
According to her Linkedin profile, Ms Connell held a Bachelor of Applied Science from Melbourne's La Trobe University and a Bachelor of Psychology from Melbourne's Swinburne University of Technology.
Avecho said Ms Connell would receive 3,993,644 sign-on options, exercisable at a 25 percent premium to the 30-day volume weighted average price on April 24, 2024 within 42 months after the grant date.
Avecho chair Dr Greg Collier said as Avecho entered a phase III clinical trial of its tocopheryl phosphate mixture (TPM) marijuana for insomnia its "ongoing business development and licensing discussions are entering a defining phase of execution".
"The board is delighted to welcome a director of Ms Connell's calibre… she will be in a position to leverage significant licensing experience in some of the world's largest pharmaceutical companies and maximize our chances of securing high value future licensing agreements," Dr Collier said.
"This executive appointment is a significant achievement for our company and we look forward to working closely with Ms Connell in the years to come," Dr Collier said.
Avecho was unchanged at 0.4 cents with 1.4 million shares traded.