Biotech Daily

Friday February 24, 2023

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: AVITA UP 20%; OPTHEA DOWN 6%**

*** DR BOREHAM'S CRUCIBLE: COCHLEAR**

*** PROBIOTEC H1 REVENUE UP 25% TO $107m; PROFIT UP 23% TO $5.5m**

*** CLINUVEL H1 REVENUE UP 19% TO $29m; PROFIT UP 94% TO $11m**

*** AVITA REVENUE UP 4% TO $50m, LOSS UP 7% TO $40m**

*** ALCIDION H1 REVENUE UP 48% TO $19m, LOSS DOWN 52% TO $3m**

*** MEDICAL DEV H1 REVENUE UP 45% TO $14m, LOSS TO $2.7m PROFIT**

*** NEUREN POSTS $14.6m REVENUE, $184k PROFIT**

*** CANN GROUP H1 REVENUE UP 83% TO $5.8m, LOSS UP 128% TO $19m**

*** IMPEDIMED H1 REVENUE UP 9% TO $5.7m; LOSS DOWN 15% TO $9m**

*** COGSTATE: 'FAILED TAKEOVER, REVENUE' TO ASX 29% FALL QUERY**

*** MAYNE TO SUPPLY GENERIC ORACEA FOR ROSACEA LESIONS IN US**

*** DR SIMONE SCOVELL REPLACES VITURA CHAIR DR MARCIA WALKER**

MARKET REPORT

The Australian stock market was up 0.3 percent on Friday February 24, 2023, with the ASX200 up 21.6 points to 7,307.0 points. Fourteen of the Biotech Daily Top 40 stocks were up, 13 fell, 11 traded unchanged and two were untraded. All three Big Caps rose.

Avita was the best, up 53 cents or 20.15 percent to $3.16, with 1.6 million shares traded. Medical Developments climbed 14.2 percent; Uscom was up 7.3 percent, Pharmaxis rose 6.4 percent; Dimerix and Kazia climbed more than four percent; Genetic Signatures, Imugene, Next Science and Prescient were up more than three percent; Actinogen and Paradigm rose more than two percent; with Cochlear, CSL, Emvision, Neuren and Resmed up by less than one percent.

Opthea led the falls, down five cents or 5.6 percent to 85 cents, with 795,524 shares traded. Antisense and Compumedics lost five percent or more; Atomo fell 4.1 percent; Micro-X and Impedimed were down more than three percent; Clinuvel, Mesoblast, Nanosonics and Polynovo shed more than two percent; Cyclopharm and Proteomics were down more than one percent; with Pro Medicus down by 0.06 percent.

[DR BOREHAM'S CRUCIBLE: COCHLEAR]

By TIM BOREHAM

ASX code: COH

Share price: $226.19; **Shares on issue**: 65,781,532; **Market cap:** $14.9 billion

Chief executive officer: Diggory 'Dig' Howitt

Board: Alison Deans (chair), Mr Howitt, Yasmin Allen, Glen Boreham, Andrew Denver, Prof Bruce Robinson, Michael Daniell, Christine McLoughlin, Michael del Prado, Karen Penrose

Financials (first half to December 2022): revenue $885.2 (up 8%), earnings before interest and tax $185.7 million (down 22%), net profit $141.6 million (down 16%), dividend per share $1.55 (steady), net cash $505.4 million (down 14%)

Identifiable major shareholders: Blackrock Inc 6.4%, State Street Corp (5.7%), ABP (Algemen Burgerlijk PSF) 5.5%.

Cochlear's ostensibly downbeat half-year numbers show that when it comes to corporate results, the raw figures usually need a decent explanation.

At face value, the hearing implant leader's results show that a healthy growth in implant and volumes is not being reflected in earnings - either the reported number or the underlying figures that management prefers.

One explanation is that the company is building inventories as hospitals re-open and surgeries recover to more normal levels. Another is that the previous comparative half simply was better than expected, so the bar was raised in the first place.

In any event, Cochlear chief Diggory Howitt didn't give the impression of a man under pressure as he fronted analysts, post results. (Ironically, the questions were hard to hear because of a technical glitch).

Another sign of Cochlear's corporate health is that it is launching a share buyback to soak up some of its $500 million of excess cash.

In contrast, at the onset of the pandemic the company raised $1.32 billion in an upsized institutional issue and share purchase plan at a heavily discounted $140.00 a share.

"We can see that uncertainty receding," Mr Howitt declares.

We'll defer to the investor reaction as the final arbiter: a six percent share boost in immediate response to the results.

Ear’s a bit of history

The Cochlear name refers to the cochlea spiral tunnel of the inner ear that receives vibrations and sends them to the brain for interpretation, as well as the adjacent cochlear canal or duct and cochlear nerve. The Cochlear implant is implanted in the cochlea.

Cochlear, by the way, is Latin for ‘snail shell’.

But how did the devices come about?

While idling his time on a beach in 1977, otolaryngologist Graeme Clark (later to become Prof Clark) fiddled with a shell and a blade of grass - as you do - and realized there was a safe way to insert electrodes into the inner ear. His Eureka moment was inspired by his pharmacist father who profoundly deaf.

After wiping the sand off his thongs, Prof Clark partnered with a mob called Nucleus Group to commercialize an implant.

The first device was the Nucleus 22 “the first multi-channel cochlear implant”. The device is said to have been the only real hearing advancement since the 17th century ear trumpet (hearing aids included).

Nucleus Group was acquired by the conglomerate Pacific Dunlop but morphed into Cochlear, which listed on the ASX in 1995.

To date, Cochlear has sold more than 700,000 implants and has a circa 60 percent market share.

The company has spent more than $2 billion on research and development since listing. But for one device, it should have spent a little more: in 2011, the company recalled its Nucleus CI500 implants for a moisture-related defect - costing of more than $100 million.

Headquartered at Sydney’s Macquarie University, Cochlear employs about 4,500 people and sells to more than 180 countries, with a direct presence in 30 countries.

Long-running CEO Dr Chris Roberts stepped down in September 2015, to be replaced by the Denver-based Chris Smith. Mr Smith quit in July 2017 for family reasons and Mr Howitt - then chief operating officer - took over.

Staying a step ahead

Cochlear’s products include the implants, the sound processors and other bits and pieces such as spare coils and cables, remote controls, repairs and shake-awake alarm clocks.

As with home-grown medical device giant Resmed, Cochlear needs to stay one step ahead of competitors with constant product tweaks and iterations.

The lion’s share of the company’s revenues derives from implants and services (such as sound processors and upgrades).

But acoustics (bone conduction implants) are becoming more important. They are more suited to patients with mixed, or single-sided, hearing loss. Typically, they have functioning cochleae, but a middle ear problem prevents sound transmission from the outer ear to the cochlea.

The resounding fortunes of acoustics were driven by the western European rollout of the core Osia 2 device, following recent approval (Osia, by the way, stands for ‘osseo integrated steady state implant’).

The new Baha 6 Max Sound Processor - as in bone-anchored hearing aid - is “driving strong demand for sound processor opportunities across all regions”.

In October 2022, the company launched the Nucleus 8 sound processor, which the company dubs “the smallest on the market by far”. With features such as Bluetooth connectivity and background noise suppression, Nucleus 8 is expected to be a key short-term revenue driver for the company.

Hear’s a good acquisition

As with CSL - another home-grown bio-giant - Cochlear has discovered its acquisitive juices after a long period of relying on organic growth.

In April 2022, Cochlear announced the purchase of Oticon Medical for around $170 million.

Oticon consists of the implant business of the Danish-based, Nasdaq-listed Demantis Group, which wanted to shed its Oticon implant business in favor of other stuff (such as hearing aids).

Cochlear’s rationale is that while it is clearly the leader in implants, it doesn’t get much custom from the hearing loss segment “where hearing aids remain the primary treatment option”.

With 75,000 clients, Oticon generates $75 million to $80 million of revenue a year, but is currently loss-making.

The transaction was meant to have been sealed by the end of 2022, but has been delayed because of preliminary concerns raised by Australian and British competition regulators.

In Australia, Cochlear and Oticon are two of only three providers of non-surgical bone conductors and bone anchored devices.

The UK Competition and Markets Authority is undertaking a further review, as is the Australian Competition and Consumer Commission. The latter has nominated a March 16 decision date which, come to think of it, is not far off.

While it’s common for the takeover gatekeepers to raise competition concerns, it does not mean a deal is likely to be kyboshed. Cochlear is engaging with authorities, but maintains the deal will not diminish competition and will go ahead.

Oticon is Cochlear’s biggest purchase since paying paid $US78 million ($A115 million) for Sycle LLC, the world’s dominant supplier of audiology practice management software, in 2017.

Finances and performance

Cochlear posted a statutory net profit of $141.6 million for the first (December) half, down 16 percent and ahead of consensus expectations of $136 million.

Implant volumes increased by 14 percent to 21,249 million, but revenues rose only 9 percent to $9 million.

Mr Howitt attributes the gap to flat pricing in developed markets. But deferred revenue rose sharply, the result of the company shipping Nucleus 8 units ready for users of the current Nucleus 7 units to upgrade.

Implant sales rose 12 percent and now account for 57 percent of revenue.

Services revenue (29 percent of sales) edged up one per cent. Driven by Osia 2 and Baha 6 upgrades, acoustics revenue rose 20 percent and accounted for 13 percent of sales.

Geographically, the Americas account for almost half of Cochlear’s revenue, while Europe, the Middle East and Africa chips in one third. Asia Pacific (notably Australia) accounts for 18 percent.

An interesting quirk was that growth was best in the regions most affected by Covid-19, such as Latin America, India and China. One reason for this is that government tendering for device programs was non-existent during the plague, but this sector has come back to life.

“The company delivered better than expected revenue across all product segments, with significantly higher Cochlear implant and acoustic revenues,” RBC Capital Markets analyst Craig Wong-Pan said.

Over the last 12 months, Cochlear’s share price has varied between $186 (mid-October 2022) and $236 (mid-April 2021). The shares hit an all-time high of $265 in August 2021.

Two decades ago, the stock traded around $40.

Hello buy back

Despite the Oticon acquisition, Cochlear will spend up to $200 million over two years to buy back its own shares, thus modestly improving earnings per share and dividends.

The company intends to spend $75 million in the first year - about 0.5 percent of shares on issue - but as per the norm, the quantum and timing depends on market conditions.

Broker Barrenjoey estimates that even after the Oticon purchase and the buyback, Cochlear will have $60 million of excess cash (over and above management's targeted $200 million buffer).

Outlook

Management has maintained its full-year earnings guidance at $290 million to $305 million on an underlying basis, an increase of five to 10 percent.

At last August's full year results, management referred to "variable" country-to-country performance, with pandemic hospital staffing shortages impacting operating theatre capacity.

Mr Howitt opines that the market continues to improve post lockdowns, but there are still "uncertainties" including surgical backlogs in most markets.

"While it is great to see the reopening, we are still a bit cautious on our outlook."

Dr Boreham's diagnosis:

A year ago, we opined that when investors turn risk averse, they will gravitate to the established big names rather than the pre-revenue wannabes. Cochlear's share price - up 12 percent for the calendar year to date - suggests this is indeed the case.

"Our long-term strategy is absolutely intact," Mr Howitt says. "The need for our products is very clear and if anything [the pandemic] has increased awareness."

(He contends that when people were forced to hear people wearing masks, they realized how deficient their hearing was).

In the long term, Cochlear's game is about accessing the 60 million people who have severe-to-high hearing loss. Of these, only five percent of those suitable for an implant actually have one.

The company also estimates an addressable market of 1.3 million people for acoustic implants, with less than one percent benefiting to date.

In the short term, Nucleus 8 upgrades will play a key role in boosting revenue given the delayed surgeries have constrained the supply of newly-implanted patients.

Another management priority is to boost the low level of referrals from hearing aid practices, with the Sycle and Oticon purchases expected to help the company to achieve this.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But when it comes to finding subject matter, he does keep his ear to the ground and his nose to the grindstone.

PROBIOTEC

Probiotec says revenue for the six months to December 31, 2022 was up 25.4 percent to $106,770,158 with net profit after tax up 22.9 percent to $5,460,776.
Probiotec said despite supply chain and labor shortages which “significantly impacted output” its revenue was up due to an increased demand for its pharmaceutical manufacturing services and price rises.
The company said that a fully-franked interim dividend was up 50 percent to 3.0 cents a share for holders at the record date of March 3 to be paid on March 17, 2023.
Probiotec said diluted earnings per share rose 18.0 percent to 6.62 cents, net tangible assets per share fell from negative 19.9 cents to negative 4.5 cents, with cash and equivalents of $22,768,835 at December 31, 2022 compared to $28,935,289 in 2021.
Probiotec fell seven cents or three percent to $2.29.

CLINUVEL PHARMACEUTICALS

Clinuvel says revenue for the six months to December 31, 2022 was up 19.2 percent to $29,355,042 with net profit after tax up 94.0 percent to $11,387,675.
Clinuvel said revenue came primarily from sales and reimbursements for Scenesse, or 16mg afamelanotide, for erythropoietic protoporphyria, which increased due to a rise in US patient demand and a 10 percent increase in “specialty centres participating in the program willing to administer Scenesse”.
The company said diluted earnings per share rose 93.0 percent to 22.0 cents, net tangible asset backing per share was up 30.0 percent to $2.78 and it had cash and equivalents of $140,703,376 at December 31, 2022 compared to $98,992,349 at December 31, 2021.
Clinuvel fell 62 cents or 2.6 percent to $23.43 with 175,972 shares traded.

AVITA MEDICAL

Avita says revenue for the 12 months to December 31, 2022 was up 3.9 percent to $US34,421,000 ($A50,490,000) with a net loss after tax up 6.8 percent to $US27,098,000.
The company said revenue from sales of Recell for burns was $US34.0 million and other revenue included funding from the US Biomedical Research and Development Authority (BARDA) up 100 percent to $US400,000 compared to previous corresponding period.
Avita said diluted loss per share was up 84.5 percent to $US1.07, net tangible asset backing per share was down 15.8 percent to $US3.47, and it had cash of $US18,164,000 at December 31, 2022 compared to $US55,511,000 at December 31, 2021.
Avita was up 53 cents or 20.15 percent to $3.16 with 1.6 million shares traded.

ALCIDION GROUP

Alcidion says revenue for the six months to December 31, 2022 was up 47.6 percent to $18,984,000 with net loss after tax down 52.4 percent to $2,972,000.
Alcidion said despite “a challenging economic and healthcare environment” revenue increased due to multiple signed and renewed contracts for its hospital and healthcare patient management technologies in Australia, New Zealand and the UK.
Alcidion said diluted loss per share fell 60.7 percent to 0.22 cents, negative net tangible asset backing per share increased 400 percent from negative 0.1 cents to negative 0.5 cents, and it had cash and equivalents of $11,868,000 at December 31, 2022 compared to $18,938,000 at December 31, 2021.
Alcidion was unchanged at 14 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says revenue for the six months to December 31, 2022 rose 45.1 percent to $13,925,000 with last year's loss turned to a $2,658,000 net profit after tax.
Medical Developments said revenue was largely from sales of its Penthrox inhaled methoxyflurane analgesic in Australia, and its respiratory medical devices in the US.
The company said diluted earnings per share was 3.00 cents compared to a previous 10.35 cents loss, net tangible asset backing per share was up 108.7 percent to 52.8 cents and it had cash and equivalents of $37,121,000 at December 31, 2022 compared to $28,275,000 at December 31, 2021.
Medical Developments was up 19.5 cents or 14.2 percent to $1.565.

NEUREN PHARMACEUTICALS

Neuren says revenue for the 12 months to December 31, 2022 was $14,553,000, turning last year's loss of $7,794,000 to a net profit after tax of $184,000.
Last year, Neuren said Acadia Pharmaceuticals has paid a $US10 million milestone payment after the US Food and Drug Administration accepted a new drug application for trofinetide for Rett syndrome (BD: Oct 20, 2022).
Today, Neuren chief executive officer Jon Pilcher said the company "ended 2022 in a very strong position with cash of $40 million and on-track for the transforming catalysts", including a US target action date for trofinetide in Rett syndrome in fewer than six weeks.
Neuren said that last year's diluted loss per share of 6.6 cents was turned to a diluted earnings per share of 0.1 cents, net tangible asset backing per share rose 6.45 percent to 33 cents and it had cash and equivalents of $40,180,000 at December 31, 2022 compared to $36,783,000 at December 31, 2021.
Neuren was up three cents or 0.4 percent to $7.16 with 549,084 shares traded.

CANN GROUP

Cann Group says revenue for the six months to December 31, 2022 was up 83.4 percent to $5,819,000 with net loss after tax up 127.6 percent to $18,844,000.
Cann Group said revenue increased due to "large repeat orders for [marijuana] oil and flower products, and the largest single domestic order for a [marijuana] oil product".
The company said its increased loss was due to "higher than usual administration, corporate and [research and development] costs".
The company said diluted loss per share was up 92.8 percent to 5.34 cents, net tangible assets per share fell 34.8 percent to 18.83 cents and it had cash and cash equivalents of $7,190,000 at December 31, 2022 compared to $10,680,000 at December 31, 2021.
Cann Group was unchanged at 17 cents.

IMPEDIMED

Impedimed says revenue for the six months to December 31, 2021 was up 8.8 percent to $5,655,000 with net loss after tax up 21.2 percent to $10,815,000.
Impedimed said revenue for its Sozo bio-impedance spectroscopy was up 8.5 percent to $5,273,000, with the remainder from its "legacy" L-Dex systems for lymphoedema.
The company said diluted loss per share was constant at 1.0 cent, net tangible assets fell 33.3 percent to 2.0 cents a share, and it had cash and cash equivalents of $26,197,000 at December 31, 2022 compared to $50,807,000 at December 31, 2021.
Impedimed fell 0.2 cents or 3.45 percent to 5.6 cents.

COGSTATE

Cogstate has told the ASX that the termination of "a potential control transaction" may have been the explanation for a 29.3 percent share price fall.
The ASX said the company's share price fell 29.3 percent from $2.32 on February 17, to a low of $1.64 on February 21, 2023.
Yesterday, Cogstate requested a voluntary suspension to follow its Tuesday trading halt to respond to an ASX price query (BD: Feb 21, 2023).
Cogstate last traded at $1.625 a share on Tuesday February 21, falling 27.5 cents or 14.5 percent from a close of $1.90 on Monday, February 20, and down 69.5 cents or 30.0 percent from the close of $2.32 on Friday, February 17, 2023.
Today, the company said it had been "in discussions with a third party in relation to a potential control transaction … [since] late December 2022, with access to due diligence granted in late January 2023".
"At all times, the company considered that the discussions were and remained confidential, non-binding, incomplete and insufficiently definite to warrant disclosure," Cogstate said.
"On February 18, 2023, it was determined that the potential transaction would not proceed, and accordingly, all such discussions have ceased," the company said.
Cogstate said it made a separate announcement today and expected to report clinical trial revenue down 12 percent to $17.1 million for the six months to December 31, 2022 and it expected to report breakeven profit before tax for the six months.
The company said that in releases to the market as part of its November 4, 2022 annual general meeting it advised that revenue and profit for the six months to December 31, 2022, "were expected to be impacted by slower than expected enrolment of patients by pharmaceutical companies in a small number of their large Alzheimer's trials, with such enrolment rates expected to cause delays to Cogstate's revenue recognition".
Cogstate said enrolments had increased and the rate would "not catch up to the initial projections provided by Cogstate's customers and enrolment will continue into 2023-'24".
Cogstate fell 44.5 cents or 27.4 percent to $1.18 with 5.6 million shares traded.

MAYNE PHARMA GROUP

Mayne Pharma says it will supply Galderma's generic 40mg Oracea, or doxycycline, for the treatment of inflammatory lesions related to rosacea in US adults.
Mayne said the Galderma licence and supply agreement provided an exclusive three-year license for the authorized generic, containing 30mg doxycycline immediate release and 10mg doxycycline delayed release for the US.
The company said that in 2022 the Oracea market was valued at about $US210 million.
Mayne chief executive officer Shawn O'Brien said the agreement "provides another example of how we are building on our core strengths and expanding our portfolio of dermatology products".
"We continue to focus on identifying and taking advantage of strategic expansion opportunities, and generic Oracea fits well within our roster of products to help patients have healthier skin," Mr O'Brien said.
Mayne Pharma was up nine cents or 2.9 percent to $3.15.

VITURA HEALTH (FORMERLY CRONOS AUSTRALIA)
Vitura says that director Dr Simone Scovell has been appointed permanent chair replacing acting chair Dr Marcia Walker.
Vitura said that Dr Walker had been acting chair since April 2022 and would continue as an independent, non-executive director.
The company said that Dr Scovell had been a director since September 2022.
Vitura said that Dr Scovell was the founder and chief executive officer of Totium a biotechnology and health services company.
The company said that Dr Scovell was a former director of the Royal Australasian College of Physicians and held a Bachelor of Medical Science, Bachelor of Surgery, Bachelor of Medicine from the University of Sydney and a Master of Occupational and Environmental Health from Melbourne's Monash University.
Vitura was unchanged at 51 cents.