Biotech Daily

Friday February 21, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ALTERITY UP 12%; DIMERIX DOWN 9%**

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

*** MAYNE H1 REVENUE DOWN 17% TO $227m, PROFIT TO $18.6m LOSS**

*** ELLEX H1 RECEIPTS DOWN 6% TO $42m, LOSS DOWN 1% TO $2.7m**

*** MACH7 H1 REVENUE UP 158% TO $9.1m, $675k PROFIT**

*** IDT H1 REVENUE UP 10% TO $7.2m, LOSS DOWN 51% TO $1.2m**

*** ALLEGRA H1 REVENUE UP 26% TO $2.3m, LOSS UP 70% TO $817k**

*** IMMUTEP H1 REVENUE $7.5m, LOSS DOWN 31% TO $6m**

*** CYNATA H1 REVENUE $4.5m, LOSS DOWN 15% TO $2.5m**

*** RESAPP RAISES $5m**

*** SIENNA RIGHTS RAISE $2.1m OF $2.5m; TOTAL $3.8m**

*** PARADIGM MEETS US FDA FOR PPS OSTEOARTHRITIS TRIAL IND**

*** NOXOPHARM: 'FDA APPROVES VEYONDA, COMBO IND FOR SARCOMAS'**

*** TELIX LOSES ODILE JAUME, GAINS CHRISTIAN DAVIS**

MARKET REPORT

The Australian stock market fell 0.33 percent on Friday February 21, with the ASX200 down 23.5 points to 7139 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, seven traded unchanged and two were untraded. All three Big Caps fell.

Alterity (Prana) was the best, up 0.2 cents or 11.8 percent to 1.9 cents with 211,260 shares traded. Oncosil climbed 10 percent; Kazia was up 9.5 percent; Immutep, Imugene and LBT climbed more than three percent; Pro Medicus and Resonance rose more than two percent; Opthea and Uscom were up more than one percent; with Clinuvel, Genetic Signatures and Mesoblast up by less than one percent.

Yesterday's 17.2 percent best, Dimerix, led the falls, down 1.5 cents or 8.8 percent to 15.5 cents with 1.4 million shares traded. Ellex lost 7.5 percent; Osprey shed 5.6 percent; Cochlear, Compumedics, Impedimed, Medical Developments, Pharmaxis and Proteomics fell more than four percent; Cyclopharm and Next Science were down more than three percent; Antisense, Avita, Paradigm and Starpharma shed more than two percent; Nanosonics and Volpara were down more than one percent; with CSL, Cynata, Polynovo and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: COCHLEAR

By Tim BOREHAM

ASX code: COH

Share price: $231.60; **Market cap:** $13.4 billion; **Shares on issue:** 57,829,907

Chief executive officer: Diggory Howitt

Board: Rick Holliday-Smith (chair), Dig Howitt, Abbas Hussain, Yasmin Allen, Glen Boreham*, Alison Deans, Donal O'Dwyer, Andrew Denver, Prof Bruce Robinson, Michael Daniell

Financials (December half): revenue $777.6 million up 9.2%, net profit after tax $157.7 million up 22.6%, underlying profit*** excluding gains on the innovation fund flat at $132.7 million, earnings per share $2.73 up 22.4%, dividend per share $1.60 up 3%.

Identifiable major shareholders:** Baillie Gifford & Co 7.4%, Blackrock Group 7.2%, Vanguard Group 4.998%

* No relation (as far as we know)
** Hyperion Asset Management and Pinnacle Investment Management ceased to be substantial shareholders last September.

If anyone in the medical sector hasn't heard about the dangers of the coronavirus loud and clear by now, they should invest in one of Cochlear's implants.

The global hearing pioneer this week reported an essentially flat*** half year earnings in underlying terms, which looks like nothing to shout about at next Tuesday's International Cochlear Day events.

But we are not living in normal times. Cochlear shares hit a record high the day after the results, with the coronavirus-related downgrade all but forgotten. On February 11, Cochlear advised the market that the pervasive virus - now known as Covid-19 - would reduce expected full year earnings to $270-290 million, compared with the $290-300 million as guided at last year's annual general meeting.

Cochlear's problem is that hospitals in China, Hong Kong and Taiwan have postponed surgical procedures and at this stage the company doesn't know when they will resume. China is one of the top five markets for Cochlear. While the company does not break down the Middle Kingdom's contribution, broker EL&C Baillieu estimates that China accounted for 10 percent of the company's profits in the 2018-'19 year.

Hear! Hear!

One of Australia's most venerable exports, Cochlear first opened its doors in 1981, when it was part of the Nucleus Group. The company listed on the ASX in 1995.

The Cochlear name is a reference to the cochlea spiral tunnel of the inner ear that receives vibrations and sends them to the brain for interpretation and the adjacent cochlear canal or duct and cochlear nerve. The Cochlear implant is implanted in the cochlea. (Just thought you'd like to know that.)

Apart from turning a dollar for shareholders, Cochlear's mission is to make cochlear implants the standard for people with severe or profound hearing loss, mixed hearing loss or single-sided deafness (a.k.a. deaf in one ear).

As of June last year, the company had sold 550,000 implants.

Cochlear's core business is not just the implants, but the sound processors and other add-ons such as spare coils and cables, remote controls, repairs, shake-awake alarm clocks and travel insurance.

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

While not being overly acquisitive, Cochlear has picked up a few knick-knacks along the way.

In May 2017, Cochlear paid $US78 million ($A115 million) for Sycle LLC, the world's dominant supplier of audiology practice management software.

Via its innovation fund, in November 2018, the company announced a EUR13 million ($20 million) investment in the Copenhagen-based, Nasdaq-listed Nyxoah. The Danes are developing a best-in-class nerve stimulation therapy for obstructive sleep apnoea.

This month the company invested a further EUR8 million in Nyxoah. It's been a good punt so far, with the original stake revalued to EUR35.5 million, implying an after-tax profit of $25 million.

While finding a cure for snoring may seem far removed from Cochlear's core technology the therapy is based on an implant to modulate the hypoglossal nerve, which controls the functions of the tongue.

The interim result: nothing to shout about?

Cochlear's half year results had bits for the haters to hate and bits to enthuse its fans. Officially, earnings grew by 22 percent to $157.7 million, but that takes into account the unrealized Nyxoah gain.

Cochlear's core implant division increased volumes by a solid 13 percent to 18,894 units, despite some stiff comparative numbers in the previous first half. Notably, US implant volumes rose 10 percent as the company re-gained market share lost as a result of competitor activity.

We're referring here to Advanced Bionics (acquired by Sonova in 2010) and its hearing implant Hi-res Ultra 3D that is magnetic resonance imaging (MRI) compatible (wearers don't have to remove the batteries if they are undergoing such a scan).

At the time, the rival product affected Cochlear's sales in US and Germany, its two biggest implant markets.

Mr Howitt admits Cochlear has "definitely lost share" in the acoustics division, which houses the bone conduction implant business.

Bone conduction implants 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.

Acoustic sales declined an unexpected 10 percent, but there are mitigating circumstances. According to Mr Howitt, surgeons are also holding back patients ahead of the launch of Cochlea's Osia 2 product, the "next generation" of bone conduction implant.

Osia 2, which means 'osseo integrated steady state implant', was approved in the US last December and will be launched this year. European approval has been delayed. Osia 2 offers benefits such as simpler and easier surgery, a slim line design and a high frequency response for better reception.

Touted as the growth division, the services arm grew a weak five percent. Unfazed, Mr Howitt notes that it is a maturing business with sales oriented to upgrades to the Nucleus 7 sound processor. He adds the company is likely to benefit from improved reimbursement (and expanded indications) for its products, in geographies including Japan, Britain and Belgium.

What goes around, comes around

In 2011, Cochlear was forced to recall its Nucleus CI500 implants because of a moisture-related defect - at a cost of more than $100 million.

Now the ear trumpet is in the other auricle, so to speak, with rival Sonova Advanced Bionics announcing a "voluntary field corrective action" for some of its unused Hi-res Ultra and Hi-res Ultra 3D implants.

The news prompted broker Macquarie to upgrade Cochlear to an "outperform", which is broker speak for a buy. However rival analysts at Citi reckon that while the recall will benefit Cochlear, the benefit is hard to gauge at this stage.

Product tweaks

As with Resmed, Cochlear needs to keep ahead of the yapping competition with regularly updated devices and 'you beaut' iterations such as the Osia 2.

In 2018, the company launched Nucleus 7, which is compatible with both Android phones and Apple Iphones.

Cochlear spent $94 million on research and development during the six months to December 31, 2019 and has flagged a full-year spend of $184 million.

Management also has earmarked $180 million for capital expenditure, mainly to expand its Chinese manufacturing capacity and complete its new digs in Denver. This capital expenditure will abate to $100 million in the 2020-'21 year.

Finances and performance

The coronavirus curse aside, Cochlear is emerging from a 2018-'19 funk that saw implant volumes decline three percent to 34,083 units (having said that, sales and profits both rose seven percent).

At the midpoint of $280 million, the modified guided profit is still two to nine percent better than last year's $266 million. However, the market will be on high alert for further downgrades ahead of the August full-year results.

Investors didn't quite know how to react to this week's profit results, sending the shares down three percent on the day of the February 18 announcement. But the next day they bounced 11 percent to a record close of $251.55, as the late-breaking news from Advanced Bionics permeated the market.

Over the last 12 months Cochlear shares have shimmied between $165 (April last year) and this week's high. In October 2011 they plumbed a decade low of $53 after the Nucleus CI500 recall.

Lawyered up

The blackjack table known as the US legal system dealt Cochlear a dud card in November 2018, when the US District awarded $US268 million against the company in a long-running patent dispute. Cochlear has appealed the decision, launched by the Alfred E Mann Foundation and Advanced Bionics.

Cochlear put up $US335 million in an insurance bond to defer the judgment, but now the plaintiffs want $US123 million in prejudgment interest. The District Court will decide on this aspect sometime this year.

Cochlear says its lawyers reckon there's a good chance of success with the appeal, which would lead to a retrial. Mr Howitt says the judgment relates to expired products and does not affect Cochlear's current range.

The company is treating the amount as a contingent liability and has reversed a $21.3 million provision on the balance sheet, but a $19.6 million provision for legal and other costs remains. Still, if the current judgment stands it will make for a nasty profit hit, indeed.

Dr Boreham's diagnosis:

While Cochlear is a household name, its market penetration is surprisingly low.

Management believes 15 million people could benefit from a cochlear bone conduction implant, which implies it has penetrated only 3.6 percent of the market.

Globally, 460 million people suffer hearing loss, with one in three over 65 having impaired hearing to a disabling degree.

Cochlear has a 60 percent market share overall, with an especially dominant position in the children's market in developed countries.

The real growth lies in adults generally and kids in undeveloped geographies.

As investors enthuse about Cochlear's potential to find new markets, the analysts poring over the minutiae of the company's financials appear wary.

JP Morgan analyst David Low notes that while Cochlear remains the market leader, rivals have closed the gap in the last six to 12 months.

"At current (share price) levels we do not think the risk-reward profile is attractive," he opines.

As with fellow home-grown biotech heroes and Resmed, Cochlear trades on a generous earnings multiple, of around 50 times.

But despite the odd hiccough the company has never failed to justify this multiple with earnings growth.

We're sure that having survived product recalls, legal vicissitudes and often intense competitor activity, Cochlear can weather the coronavirus-induced China slowdown.

For investors who still can't stomach Cochlear's valuation, there's a small-cap listed ASX alternative in the hearing space.

Nuheara (code: NUH) has evolved from successfully developing an earbud-like gadget for music aficionados to a device for those with low-to-mild hearing loss.

In the December quarter Nuheara chalked up sales of $910,000 and posted a $202,000 surplus.

Nuheara's $32 million market cap pales against Cochlear's $10 billion, but watch out for the mouse that roars.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is all ears if someone can invent a device to combat selective hearing.

MAYNE PHARMA GROUP

Mayne says revenue for the six months to December 31, 2019 was down 17.2 percent to $227,152,000 with net profit after tax of $1,001,000 turned to a loss of $18,608,000.
Mayne said revenue included $183,868,000 from sales of its generic drugs, $42,644,000 from services, $508,000 in licence fees and $132,000 in royalties.
The company said that diluted loss per share was 1.2 cents, and net tangible asset backing per share fell 61.3 percent to 3.1 cents, with cash and cash equivalents of $98,529,000 at December 31, 2019 compared to $96,173,000 at December 31, 2018.
Mayne Pharma fell 2.5 cents or 6.25 percent to 37.5 cents with 14.4 million shares traded.

ELLEX MEDICAL LASERS

Ellex says receipts from customers for the six months to December 31, 2019 fell 5.5 percent to $41,909,000 with net loss after tax down 0.8 percent to $2,678,000.
Ellex said revenue from continuing operations was down 3.8 percent to $7,427,000.
The company said revenue was from sales of its Itrack laser for glaucoma and Retinal Rejuvenation Therapy (2RT) laser for intermediate age-related macular degeneration.
In December, Ellex said it had sold its laser and ultrasound business to the Lannion, France-based Lumibird Group SA for $100 million cash (BD: Jan 19, 2020).
Today, the company said diluted loss per share from continuing operations was down 26.4 percent to 2.04 cents, diluted loss per share was down 1.1 percent to 1.86 cents, net tangible assets per share fell 23.5 percent to 26 cents and it had cash and equivalents of $733,000 at December 31, 2019 compared to $19,682,000 at December 31, 2018.
Ellex said that a meeting to approve the Lumibird deal was proposed for late March 2020.
Ellex fell six cents or 7.5 percent to 74 cents.

MACH7 TECHNOLOGIES

Mach7 says revenue for the six months to December 31, 2019 was up 158.1 percent to $9,075,145 with net loss after tax of $4,437,797 turned to a profit of $674,799.
Mach7 said revenue included $4,989,630 in imaging software licence fees, $1,371,831 in service fees, $2,585,065 in maintenance fees and $128,619 in pay-per-use subscriptions.
The company said the revenue increase was due to new customer contracts, including the $5.7 million deal with Advocate Aurora Health (BD: Jul 9, 2019).
Mach7 said it diluted earnings per share was 0.4 cents, net tangible asset backing was up from 1.0 cent to 13.0 cents, with cash and cash equivalents of $23,283,406 at December 31, 2019 compared to $3,204,235 at December 31, 2018.
Mach7 was up 10.5 cents or 13.2 percent to 90 cents with 3.3 million shares traded.

IDT AUSTRALIA

IDT says revenue for the six months to December 31, 2019 was up 10.0 percent to $7,159,000 with net loss after tax down 50.5 percent to $1,183,000.
IDT said revenue was primarily from drug manufacturing and provision of pharmaceutical services as well as included $910,000 in previously capitalized milestones, following termination of its US generic temozolomide distribution agreement (BD: Jan 19, 2020).
The company said diluted loss per share fell 50.0 percent to 0.5 cents and it had cash and cash equivalents of $6,716,000 at December 31, 2019 compared to $9,056,000 at December 31, 2018.
IDT was up one cent or 7.1 percent to 15 cents.

ALLEGRA ORTHOPAEDICS

Allegra says revenue for the six months to December 31, 2019 was up 26.3 percent to $2,309,509 with net loss after tax up 70.0 percent to $817,314.
Allegra said revenue included $2,264,022 from sales of goods from its Waldemar Link GmbH range, its primary knee systems and clavicle fracture system, up 34.8 percent, and $45,487 in commissions revenue, down 69.5 percent.
The company said diluted earnings per share was up 70.8 percent to 0.82 cents, net tangible asset backing was down 18.4 percent to 4.47 cents, with cash and equivalents of $287,878 at December 31, 2019 compared to $1,180,731 at December 31, 2018.
Allegra was untraded at 11 cents.

IMMUTEP

Immutep says revenue for the six months to December 31, 2019 was $7,475,094 with net loss after tax down 31.4 percent to $5,950,345.
Immutep said revenue included a $7,366,493 milestone payment from Glaxosmithkline for dosing the first patient in a phase II trial of GSK2831781 for ulcerative colitis along with interest on deposits (BD: Sep 23, 2019).
The company said it had cash and cash equivalents of $20,516,150 at December 31, 2019 compared to $26,002,069 at December 31, 2018.
Immutep was up 1.5 cents or 3.75 percent to 41.5 cents with 4.4 million shares traded.

CYNATA THERAPEUTICS

Cynata says revenue for the six months to December 31, 2019 was $4,525,649 with net loss after tax down 14.5 percent to $2,548,661.
Cynata said revenue was primarily a single $US3 million ($A4,449,632) payment from Fujifilm Corporation for a graft versus host disease licence agreement and from interest income, down 41.2 percent to $76,017 (BD: Sep 26, 2019).
The company said it had cash and cash equivalents of $5,918,214 at December 31, 2019 compared to $10,639,848 at December 31, 2018.
Cynata fell one cent or 0.9 percent to $1.08.

RESAPP HEALTH

Resapp says it has commitments for $5 million through a placement to institutional and sophisticated investors at 20 cents a share.
The company said funds would be used to accelerate European commercialization of its respiratory diagnostics and for general working capital.
Resapp said Ashanti Capital and Morgans Corporate were joint lead managers.
Resapp fell half a cent or 2.1 percent to 23.5 cents with 2.3 million shares traded.

SIENNA CANCER DIAGNOSTICS

Sienna says it has raised $2,055,532 of $2,529,233 through a one-for-four, pro-rata, non-renounceable rights issue at 3.5 cents a share.
Last year, Sienna said it had raised $1,657,186 of a hoped for $1.7 million through a placement at 3.5 cents a share and hoped to raise a further $2.5 million through a rights issue (BD: Nov 29, Dec 6, 2019).
Sienna was untraded at 3.6 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it met the US Food and Drug Administration to discuss a phase III trial of injectable pentosan polysulphate sodium for osteoarthritis.
Paradigm said that it had “a positive and informative” pre-investigational new drug meeting with the FDA and discussed clinical, pre-clinical and manufacturing data.
The company said it planned to file the the investigational new drug application for the pentosan polysulphate sodium for osteoarthritis trial by the end of 2020.
Paradigm fell 10 cents or 2.7 percent to $3.57 with 2.5 million shares traded.

NOXOPHARM

Noxopharm says the US Food and Drug Administration has approved a phase Ib trial of Veyonda combined with doxorubicin for soft tissue sarcomas.
Noxopharm said the FDA approved the investigational new drug application (IND) application for a phase Ib study of Veyonda, or NOX66, in combination with doxorubicin for soft tissue sarcomas but did not mention the proposed number of patients nor the trial protocol.
The company said it would “explore available non-dilutive funding opportunities to enable the study to proceed”.
Noxopharm chief medical officer Dr Gisela Mautner said, “the IND approval, based on pre-clinical and clinical data presented to the FDA, is validation of the clinical potential of Veyonda”.
“In addition, Veyonda has met the very high standard set by the FDA for being a safe and well-tolerated drug,” Dr Mautner said.
Noxopharm climbed seven cents or 29.8 percent to 30.5 cents with 5.6 million shares traded.

TELIX PHARMACEUTICALS

Telix says Odile Jaume has resigned as head of European operations and been replaced by Ludo Wouters as interim head of European operations.
Telix said it had appointed Christian Davis as head of sales and marketing for Europe, the Middle East and Africa, effective from April 1, 2020.
The company said Mr Davis had more than 20 years’ experience in medical sales, previously led Sirtex Medical’s European sales and held senior and sales marketing roles at Terumo.
Telix said Ms Jaume would continue in an advisory capacity.
Telix was unchanged at $1.60.