Biotech Daily

Friday August 17, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: POLYNOVO UP 8%; ITL DOWN 10.5%**

*** DR BOREHAM'S CRUCIBLE: ANATARA LIFESCIENCES**

*** PHARMAXIS REVENUE UP 182% to $51m, LOSS TO $18m PROFIT**

*** MEDICAL DEV REVENUE DOWN 5% to $18m, PROFIT DOWN 87% TO $243k**

*** BIONOMICS REVENUE DOWN 56% to $12.5m, LOSS UP 258% TO $25m**

*** ACRUX REVENUE DOWN 86% TO $3.4m, LOSS UP 5,736% TO $14.1m**

*** VISIONEERING H1 REVENUE UP 289% to $1.6m, LOSS $10m**

*** JCP REDUCES TO 6.2% OF NANOSONICS**

*** TIM ROBERTSON, FARJOY TAKE 10.5% OF MEDLAB**

*** ROBERT LEDERER, RTL GROUP TAKE 8% OF ANATARA**

MARKET REPORT
The Australian stock market was up 0.17 percent on Friday August 17, 2018 with the ASX200 up 10.9 points to 6,339.2 points. Seventeen of the Biotech Daily Top 40 stocks were up, 12 fell, 10 traded unchanged and one was untraded. All three Big Caps fell.

Yesterday's 9.1 percent worst, Polynovo, was today's best, up four cents or eight percent to 54 cents with 1.2 million shares traded.

Cynata and Telix climbed more than six percent; Prescient improved 5.7 percent; Compumedics and Uscom were up more than three percent; Immutep, Pro Medicus and Universal Biosensors rose two percent or more; Avita, Clinuvel, Cyclopharm, Nanosonics, Orthocell, Pharmaxis and Volpara were up one percent or more; with Medical Developments up 0.25 percent.

ITL led the falls, down two cents or 10.5 percent to 17 cents with 70,000 shares traded.

Bionomics lost 8.4 percent; Factor fell 5.2 percent; LBT was down 4.35 percent; Dimerix and Mesoblast were down more than three percent; Benitec shed 2.6 percent; Genetic Signatures, Impedimed, Neuren, Resmed and Starpharma were down more than one percent; with Cochlear, CSL and Sirtex down by less than one percent.

[DR BOREHAM'S CRUCIBLE: ANATARA LIFESCIENCES]

By TIM BOREHAM

ASX code: ANR

Share price: 64.5 cents; **Shares on issue:** 49,413,236; **Market cap:** $31.2 million

Interim chief executive officer: Dr Tracie Ramsdale

Board: Dr Jay Hetzel (interim chairman), Iain Ross, Dr Tracie Ramsdale, Paul Grujic

Financials (June quarter): revenue nil, net cash outflows $1.1 million, cash balance $7.65 million, estimated September quarter cash burn $1.3 million

Identifiable holders: Parma Corp (former chairman, Dr Mel Bridges) 11.95%, Myeng Pty Ltd (chief scientific officer, Dr Tracey Mynott) 8.9%, RTL Group (Lederer family) 8.1%, Iain Ross 2.6%, Jacoby Management Services 1.9%, David Charles Venables 1.6%.

If there's ever a case of the devil being in the detail, it's the animal and human health outfit's fall from investor grace after releasing an investor presentation on May 15 about its newly-inked animal health distribution deal with global giant Zoetis.

Anatara shares lost almost 40 percent over the next two trading days, because the disclosed financial terms simply were not as tasty as investors expected.

Oddly enough, Anatara shares increased 12 percent the day before, when the company announced the deal - but without the confidential details.

If only management could have maintained its cone of silence! As it happened, the board felt it needed to tell all because investors evidently thought the terms of the deal were much grander than what they actually were.

At least the company managed to forge a deal, unlike so many other biotechs.

Anatara's interim CEO Dr Tracie Ramsdale said the company was pleased with the Zoetis deal because it was expanded to include multiple livestock, rather than just pigs.

"Zoetis is the largest global animal health company and we could not have hoped to have found a better partner," she said, adding the terms were within the typical range for a global animal health deal.

Rough end of the pineapple

Anatara's reason for being revolves around the blunt end of the pineapple - and no Queenslander jokes please! The stems of the tropical fruit produce bromelain, a substance long-known to promote gut health and prevent diarrhoea.

(In a previous life former executive chairman Dr Bridges, chief scientific officer Dr Tracey Mynott and director Dr Tracie Ramsdale attempted to commercialize the bromelain-based ICV0019 for cancer, with Incitive listing on the ASX in 2006, but gave up in 2009 swapping it for a heart monitoring system before de-listing in 2010.)

Anatara's activities to date have focused on commercializing Detach, a natural alternative to treat scour (diarrhoea). Given scour is caused by multiple organisms such as bacteria, viruses and parasites, it's difficult to treat.

The current standard treatment of antibiotics is problematic, because porkers are becoming increasingly resistant to antibiotics. In any event, health authorities are mandating the removal of antibiotics from the food chain.

Detach doesn't target the pathogens, but the underlying cause of the diarrhoea.

The Zoetis deal frees up management to focus on developing an over-the-counter dietary supplement to treat humanoid disorders such as irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD), ulcerative colitis and Crohn's disease.

Once again, any human product is expected to be partnered-out.

Pigs love it

With a taste akin to citric acid - or so we're told - Detach's active enzyme blocks the receptor sites in the gut to which the parasites attach (thus causing diarrhoea).

Detach was on the market here in the 1991, when it was owned by Ciba-Geigy. However, Ciba-Geigy was taken over by Novartis, which preferred to focus on human health.

The product achieved a 40 percent market share, despite there being no imperative at the time to remove antibiotics from the food chain.

One of the inventors of the original Detach and now Anatara's chief scientific officer, Dr Tracey Mynott dusted off the files and worked on a reformulation.

While not the discoverers of bromelain - its magical powers had been known for some time - Dr Mynott and her PhD supervisor Dr David Chandler were responsible for the discovery that it could prevent the attachment of pathogenic bacteria to receptors in the gut.

Anatara listed in October 2014 after raising $7 million at 50 cents apiece.

Field trials at European piggeries confirmed that Detach was efficacious with an average 40 percent reduction in scour, a 22 percent weight gain and a 55 percent reduction in antibiotics use.

In 2017, the US Food and Drug Administration confirmed bromelain's 'generally regarded as safe' status. However, Detach is yet to be re-approved by the Australian Pesticides and Medical Veterinary Authority, which is reviewing Anatara's application.

Anatara’s listed fortunes were driven by executive chairman Dr Mel Bridges, who retired in May after 40 years’ involvement in the biotech sector.

Two-legged health

The company describes inflammatory bowel disease (IBD) and irritable bowel syndrome (IBS) as two areas of huge unmet need.

IBD affects about five million people globally, while IBS afflict about 11 percent of the population. The maladies result in symptoms such as cramping, bloating, appetite loss and - of course - diarrhoea.

Roughly half of IBS sufferers turn to dietary supplements or complementary healthcare.

Known for now as the GAstrointestinal Repositioning Product, or GaRP, Anatara’s remedy aims to restore normal microbial functions, treat inflammation and repair mucosal damage. In turn, this should stop the trots.

As novelist John Irving might have said, the word according to GaRP is that Anatara is positioning the product as a “dietary supplement”, which means it can be sold over the counter with fewer regulatory barriers, barring any car crashes.

At this stage there’s no definitive data to show that bromelain works in humans. But Anatara is seeking to rectify this with proof of concept studies and dose optimization studies using our biological near neighbor: pigs.

The company aims for a partnering deal by 2020 and is already having deep and meaningful discussions with the usual suspects.

Four-legged health

At the big picture level, Anatara and the Pfizer spin-off Zoetis are on to something big if Detach can become the standard-of-care in animal husbandry.

Research house Marketsandmarkets estimates the animal antibiotic/antimicrobial market will be worth $US4.7 billion by 2021, with production animals accounting for 70 percent of this (in turn, pigs account for 25 percent of this portion).

Anatara can develop Detach for other animal types and indications.

The Asian market is of particular interest: China is the world’s biggest producer, with its biggest housing 1.1 million porkers.

The current standard-of-care there is zinc oxide, a soil pollutant banned in Europe. China is also as keen as anyone to take antibiotics out of the food chain.

Finances and performance

Anatara raised $7 million in the October 2014 listing and then a further $9 million in 2015. With around $8.7 million in the bank, the company says it has enough of the folding stuff to last until that human health deal in 2020.

The level of royalties accruing to Anatara over the life of the drug is one of those great unknowns. Broker Wilsons estimates a peak annual market of $US40 million to $US50 million, implying annual royalties (at best) of perhaps $1.5 million.

Under the terms of the Zoetis deal, Anatara pockets $US2.5 million of up-front payments, $US2 million of which the company has already received.

Anatara is then entitled to $US6.3 million of payments based on undisclosed commercial milestones and a royalty of three to four percent.

Anatara shares soared from 50 cents at listing to a December 2016 peak of $1.78 a share, for a market capitalization nudging $90 million. In hindsight, the shares 'ran' far too hard.

But the stock has a true porcine believer in the Lederer family, the owner of Primo Smallgoods that accounts for seven percent of the register. Dr Bridges remains the biggest holder on just under 12 percent.

Dr Boreham's diagnosis:

The global over-the-counter (O-T-C) gastro-intestinal and digestive health market is estimated at $25 billion, growing to $36 billion by 2021.

But as anyone perusing the so-called 'wellness' shelves at Chemist Warehouse could attest, a slew of probiotics/prebiotics products target gut health by rebalancing bacteria levels.

"We also aim to do that but also to reduce inflammation and repair the mucosal damage done to the gut as well," Dr Ramsdale says. "As far as we are aware no other product does that."

If Anatara's putative tall handsome partner can demonstrate just that, it could have an O-T-C blockbuster on its hands.

Less clear is how much of the riches trickle down to Anatara.

The salutary warning to investors is not to get too carried away by the overall size of the market if the actual partnering deal only delivers a small size of the pie.

Unlike the underlying affliction, it won't all come in a rush.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he is hot to trot on this one.

PHARMAXIS

Pharmaxis says that revenue for the year to June 30, 2018 rose 182.4 percent to $50,833,000, with last year's $18,346,000 net loss turned to a $6,428,000 profit after tax.
Pharmaxis said that revenue included milestone payments of $26.9 million and $15.2 million from Boehringer Ingelheim, $6.1 million in sales of Bronchitol and Aridol, clinical trial reimbursement of $1.4 million and interest of $600,000.
The company said that total Bronchitol sales rose 46.6 percent from $2,785,000 million in the previous corresponding period to $4,084,000 million for the 12 months to June 30, 2018, while sales of Aridol remained at $2.0 million after increased sales in Europe and Australia were offset by a decrease in Asia.
Pharmaxis said that Western Europe sales rose 61.1 percent from $1,128,000 in the year to June 30, 2017 to $2,900,000 for the year to June 30, 2018.
The company said that net tangible assets per share rose 200 percent to 3.0 cents, with diluted earnings per share of 2.0 cents, compared to last year's diluted loss per share of 5.8 cents.
Pharmaxis said it had cash and cash equivalents of $31,073,000 at June 30, 2018 compared to $21,504,000 at June 30, 2017.
Pharmaxis was up half a cent or 1.6 percent to 32.5 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that revenue for the year to June 30, 2018 was down 5.2 percent to $17,929,000, with net profit after tax down 86.6 percent to $243,000.
Medical Developments said that its Penthrox inhaled methoxyflurane analgesic had been approved across most of Europe, with sales underway, but revenue from sales of its respiratory devices, primarily asthma spacers, fell two percent.
The company said it would pay a fully-franked final dividend of two cents for holders at the record date of August 31 to be paid on October 5, 2018, with a dividend reinvestment plan again being offered with a five percent discount to the 10-day volume weighted average price leading up to the record date, following the fully-franked interim dividend of two cents a share paid during the year.
Medical Developments said that net tangible asset backing per share was negative 17.9 cents compared to negative 4.0 cents for the previous corresponding period.
The company said that diluted earnings per share was down 87.1 percent to 0.4 cents and it had cash and cash equivalents of $794,000 at June 30 2018, compared to $1,691,000 at June 30, 2017.
Medical Developments was up one cent or 0.25 percent to $3.99.

BIONOMICS

Bionomics says revenue for the year to June 30, 2018, fell 55.9 percent to $12,456,446 with net loss after tax up 258.2 percent to $24,583,423.
Bionomics said that the revenue consisted of payments from Merck Sharp and Dohme, revenue from subsidiaries Neurofit and Prestwick, rental income, interest, the Federal Research and Development Tax Incentive and other incentives.
The company said that net tangible asset backing per share fell 71.2 percent to 1.99 cents, with diluted loss per share up 500 percent to 5.0 cents.
Bionomics said it had in cash and cash equivalents of $24,930,461at June 30, 2018, compared to $42,873,656 at June 30, 2017.
Bionomics fell four cents or 8.4 percent to 43.5 cents.

ACRUX

Acrux says that revenue for the year to June 30, 2018 fell 85.7 percent to $3,432,000 with last year’s net loss of $243,000 up 5736.2 percent to $14,182,000.
Acrux said that net sales of its Axiron testosterone replacement for the year amounted to $US15.4 million compared to the previous year’s $US143.0 million, following the company’s withdrawal of the product’s new drug application from US Food and Drug Administration and the termination of its licencing agreement (BD: Sep 6, 2017).
The company said it had withdrawn Axiron from its licensing agreement following court proceedings in the US that ruled that Axiron’s formulation and axilla application US patents were invalidated, and that it and its distributor Eli Lilly were defendants in product liability lawsuits in the US alleging cardiovascular and related injuries (BD: Nov 23, 2017).
Acrux said the lawsuits would not have a material impact on its operating expenditure.
The company said that net tangible asset backing per share was down 18.2 percent to 18 cents and last year’s diluted loss per share of 0.15 cents was up to a 8.52 cents diluted loss per share.
Acrux said it had the company had $28,470,000 in cash and cash equivalents at June 30, 2018, compared to $33,974,000 at June 30, 2017.
Acrux was unchanged at 21.5 cents.

VISIONEERING TECHNOLOGIES

Visioneering says that revenue for the half year to June 30, 2018 rose 288.9 percent to $US1,162,314 ($A1,598,763), with net loss after tax down $1,116 to $9,972,926.
Visioneering said revenue was from sales of its Naturalvue multi-focal contact lenses, which it began selling in the US following pilot launches in 2015 and 2016.
The company said that net tangible assets per share fell 61.5 percent to 5.0 US cents, with diluted loss per share down 44.4 percent to 5.0 US cents, compared to 9.0 cents last year.
Visioneering said it had cash and cash equivalents of $7,099,000 at June 30, 2018 compared to $23,395,000 at June 30, 2017.
Visioneering was untraded at 18 cents.

NANOSONICS

JCP Investment Partners says it has reduced its substantial shareholding in Nanosonics from 21,622,248 shares (7.22%) to 18,446,857 shares (6.16%).
The Melbourne-based JCP said that between August 3 and 15, 2018 it sold shares, with the single largest sale 1,200,000 shares for $4,011,525, or $3.34 a share.
JCP said its shares were held by National Nominees, HSBC Custody Nominees, BNP Paribas Nominees, JP Morgan Nominees and UBS Nominees.
Nanosonics was up five cents or 1.45 percent to $3.51 with 1.2 million shares traded.

MEDLAB CLINICAL

The Sydney-based Farjoy Pty Ltd says it has increased its substantial shareholder in Medlab from 15,000,000 shares (9.33%) to 21,855,556 shares (10.51%).
The substantial shareholder notice, signed by managing-director Timothy Robertson, of Weston Woodley Robertson, said that Farjoy bought and sold shares between August 16, 2016 and August 16, 2018 at prices ranging from 30 cents to 90 cents.
Medlab fell half a cent or 1.15 percent to 43 cents.

ANATARA LIFESCIENCES
The Sydney-based Robert Anthony Lederer says he has increased his substantial shareholding in Anatara from 3,477,000 shares (7.04%) to 3,977,000 shares (8.05%).
Mr Lederer said the shares were held by RTL Group Investments Pty Ltd and his superannuation fund, with 500,000 shares acquired on-market between November 14, 2017 and May 15, 2018.
Mr Lederer yet again failed to state the price paid for the shares, as required under the Corporations Act 2001 (BD: Nov 14, 2017; May 16, 2018).
Anatara was up five cents or 8.4 percent to 64.5 cents.