Biotech Daily

Friday May 3, 2019

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: ONCOSIL UP 17.5%; IMPEDIMED DOWN 16%**

*** DR BOREHAM'S CRUCIBLE: CYNATA THERAPEUTICS**

*** RESMED Q3 REVENUE UP 12% TO $947m, PROFIT DOWN 4% TO $151m**

*** ACTINOGEN REQUESTS XANADU ALZHEIMER'S RESULTS HALT**

*** IMPEDIMED: 'STUDY BACKS BIS FOR LYMPHOEDEMA'**

*** RESPIRI, MEDACHIEVERS J-V FOR WHEEZO INDIA**

*** GENETIC TECHNOLOGIES NASDAQ MARKET CAP WARNING**

*** AIRXPANDERS EXTENDS 'DEBT AGREEMENT' SUSPENSION**

MARKET REPORT

The Australian stock market slipped 0.04 percent on Friday May 3, 2019, with the ASX200 down 2.6 points to 6,335.8 points. Eighteen of the Biotech Daily Top 40 stocks were up, 13 fell, five traded unchanged and four were untraded.

Oncosil was the best for the second day in a row on no news, recovering a further 1.1 cents or 17.5 percent to 7.4 cents, with 9.5 million shares traded.

Resmed climbed 9.9 percent; LBT was up 5.0 percent; Antisense and Patrys improved more than four percent; Clinuvel and Uscom were up more than three percent; Cyclopharm, Mesoblast, Neuren, Optiscan, Telix and Universal Biosensors rose two percent or more; Avita, Cynata, Medical Developments and Starpharma were up more than one percent; with Ellex and Opthea up by less than one percent.

Yesterday's 12.5 percent best, Impedimed, led the falls, down five cents or 15.9 percent to 26.5 cents with 6.2 million shares traded.

Proteomics lost 8.2 percent; Osprey shed 7.1 percent; Kazia, Orthocell and Prescient fell more than four percent; Immutep and Pharmaxis were down more than three percent; Alterity (Prana) shed 2.4 percent; Compumedics was down 1.8 percent; with Cochlear, CSL, Paradigm, Polynovo and Volpara down by less than one percent.

DR BOREHAM'S CRUCIBLE: CYNATA THERAPEUTICS

By TIM BOREHAM

ASX code: CYP

Share price: $1.175; **Shares on issue:** 101,835,053; **Market cap:** $119.7 million

Chief executive officer: Dr Ross Macdonald

Board: Dr Paul Wotton (chairman), Dr Ross Macdonald, Dr Stewart Washer, Dr John Chiplin, Peter Webse

Financials (March quarter): revenue nil, cash outflows $2,223,000, cash balance $9,275,000*****, estimated current quarter cash outflows $2,132,000.

***** The company raised $938,000 from the exercise of in-the-money options during the quarter

Identifiable major holders: Fidelity International 9.87%, Fujifilm 7.94%, Dr Ross Macdonald 2.46%, Dr Mal Washer family account 2.47%, John King Nominees 2.42%, Prof Igor Slukvin 2.33%.

A keen student of Japanese business practices, Cynata chief Dr Ross Macdonald notes that you can make a cup of tea in three minutes - or else turn it into an aesthetic ceremony lasting half a day.

Dr Macdonald is certainly hoping that Cynata's Japanese partner Fujifilm is taking the 'tea ceremony' approach to a crucial deal simply because it can. After all, the Japanese have access to any type of seafood but some still chance their lives eating the deadly fugu fish.

Why? Because they can.

(Fujifilm is a 'legacy' name. The company is now involved in everything from cosmetics and photocopiers to nuclear medicine.)

"That's just the way they do it," he says of the delay. "Why care about weeks when you are talking about a decades-long relationship?"

The deal - or non-deal at this stage - is Fujifilm's failure to meet a deadline to take up the global rights for Cynata's stem-cell based treatment for graft-versus-host disease (GvHD).

Fujifilm was due to exercise its rights by the end of March of this year, but then deferred its decision to September 19.

Dr Macdonald remains confident that Fujifilm will sign: "If they had found gremlins in the [intellectual property] they easily could have walked away."

But for Cynata investors, the uncertainty has been as toxic as the poison left by a careless - and soon to be jobless - fugu chef: the stock plunged 35 percent on news of the delay.

The GvHD remedy, CYP-001, would be the first treatment that Cynata brings to market using its Cymerus stem cell manufacturing platform. An immunological disease, GvHD afflicts bone-marrow recipients and is usually fatal in the case of candidates resistant to steroid treatment.

In the meantime, Cynata is preparing for phase II trials for GvHD, osteoarthritis and critical limb ischemia (a severe arterial blockage that prevents blood flow to the extremities).

Cynata's therapy is also a potential treatment for heart attacks, acute respiratory disorder syndrome, asthma, glioblastoma, diabetic wounds and cytokine release syndrome (a life-threatening diseases from cancer immunotherapy).

Cynata, by the way, back-door listed in October 2013 using the shell of Eco Quest, which sold green-friendly disposable nappies before getting into the poo.

The stem cell dilemma

Cynata claims to be the only stem cell play in the world that can produce mesenchymal stem cells (MSCs) on a commercial scale without requiring multiple donors.

MSCs are adult stem cells which can be isolated from human and animal sources and can produce more than one kind of specialist cell. Currently these precursor cells are derived from embryos, which presents some ethical challenges and rely on a painful process called bone marrow aspiration.

... and Cynata's answer

Cynata hopes it has the solution with its patented Cymerus manufacturing process. The technology is based on induced pluripotent stem cells (iPSCs), from which MSCs are derived. The 'pluripotent' bit means the iPSCs have the ability to develop into any type of adult cell. They can be derived from anywhere in the body - typically skin and blood - and grown in limitless quantities in the lab.

IPSCs derived from the work of Prof Slukvin, from the University of Wisconsin-Madison as well as Japanese research. UWM is a global leader in stem cell research, while Japanese researcher Prof Shinya Yamanaka won a Nobel Prize in 2012 for his work in the area.

The MSC sector is certainly active, with 650 trials currently taking place including for cardio-vascular, lung disease (such as asthma) and strokes.

A snapshot of the Fujifilm deal

The Fujifilm deal is - or was - worth $US3 million in an upfront payment, as well as milestones of up to $US60 million and ongoing double-digit royalties. Fujifilm would also have assumed responsibility for winning approvals and all commercialization costs.

In its March quarterly report, Cynata says: “It remains our view that the actions of Fujifilm indicate an intention to exercise the licence option for GvHD.”

Dr Macdonald says Fujifilm still believes a new drug would be worth $US300 million in annual sales, which would deliver at least $US30 million in annual royalties to Cynata.

In an investor prezzo in January, Fujifilm devoted three pages to the potential of Cynata’s stem cells - and followed up with an advertisement In Nature magazine that extolled the virtues of Cynata’s regenerative medicine.

Fujifilm may also have been preoccupied with its $US900 million acquisition of Biogen’s Danish manufacturing site, thus delaying the Cynata deal.

The other factor is that if wasn’t still as keen as wasabi, Fujifilm simply could have said ‘sayonara’ if it was not interested.

CYP-001 for GvHD is AOK

The other reason for optimism about the deal going ahead is that the clinical results to date for CYP-001 have been highly promising.

A 15-patient phase I trial showed that by day-100, 13 of them had shown improvement in the severity of GvHD symptoms. Eight of the 15 showed a complete response rate: in other words, all GvHD signs and symptoms had disappeared.

The trial is significant because it is the first time any patient has been treated with an iPSC-derived mesenchymal stem cells product of any description, the patients’ own cells or otherwise.

“A successful outcome will support the application of CYP-001 in many medical and commercially significant targets where therapeutic MSCs have shown promising results,” Dr Macdonald says.

In both groups, the patients hadn’t responded to traditional cortico-steroid treatment and were most unwell.

Other partnering deals?

Meanwhile, Dr Macdonald says the company is in active discussions with other parties about other disease targets.

While these ailments are not specified they could include asthma, Crohn’s disease, critical limb ischemia and coronary heart disease.

In December last year, the National Health and Medical Research Council said it would fund a 448-patient, phase II trial for osteoarthritis, one of the biggest MSC trials undertaken. Cynata itself plans to fund a 90-patient critical limb ischemia trial, due to start this year.

Finances and performance

With cash of $9.3 million Cynata still looks adequately funded, presuming other partners will fund the future clinical work. The kitty was bolstered by a $5.2 million placement in May last year which introduced Fidelity International to the register (at $1.27 a share).

Dr Macdonald estimates the osteoarthritis trial would have cost the company $25 million if it were to have been funded it off its own bat. But the NHMRC is likely to do it more cheaply because of 'in-kind' services provided by hospitals.

Broker Shaw and Partners forecasts revenue of $15 million and a $4 million net profit in the 2019-'20 year, increasing to a material $42 million of turnover and $23m profit in 2020-'21.

The firm also values Cynata stock at $2.50 a share. This of course assumes the Fujifilm deal clicks into place and the GvHD treatment is approved.

Over the last 12 months Cynata shares have traded between $1.79 (mid-March this year) and 97 cents (mid-December 2018).

Dr Boreham's diagnosis:

When your columnist last covered Cynata in February last year he referred to the then $73 million market cap Cynata as the poor man's version of the $600 million market cap Mesoblast.

The valuation differential is now more like $680 million, so we'll maintain that stance.

While Cynata lacks the desired broad institutional backing, its investors include self-storage mogul John King and the family account of Dr Mal Washer, a former Federal Health Minister and old man of Cynata director Stewart and medical cannabis queen Elaine Darby.

Dr Macdonald admits the Fujifilm issue has left Cynata between a rock and a hard place.

"A bit like Brexit, it was always going to be a less than perfect outcome," he says.

"We could have flexed our muscles and extinguished the rights. I believe we could have found someone else. Once you have clinical data showing the product works it becomes a completely different asset."

Come September 19, we'll know whether the Japanese were simply taking their time or whether they have spat Cynata out like a mouthful of ill-prepared fugu fish.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has never been fond of fugu fish but is happy to settle for sushi from Safeway.

RESMED

Resmed says revenue for the three months to March 31, 2019 was up 11.9 percent to $US662,228,000 ($A946,721,149) with net profit after tax down 4.3 percent to $US105,416,000 ($A150,702,714).
Resmed said revenue for the nine months to March 31, 2019 was up 10.8 percent to $US1,901,608,000 ($A2,718,538,797) with net profit after tax up 63.2 percent to $US335,791,000 ($A480,046,814).
Resmed said a dividend of 3.7 US cents for the at the record date of May 9 would be paid on June 13, 2019.
Resmed chief executive officer Mick Farrell said the company "had another strong quarter with top-line revenue growth across all categories of our business, including a solid contribution from recently acquired [software as a service] companies and growth in international device sales".
"Our expanding mask portfolio continues to drive share growth across all geographies, and we have a solid product pipeline to support future growth, including the recent launch of the Airfit P30i," Mr Farrell said.
"We delivered operating leverage this quarter, even as we execute on our long-term strategy to provide innovative products, software, and solutions to improve outcomes, create efficiencies, and reduce overall healthcare system costs," Mr Farrell said. "We are on a trajectory to improve 250 million lives in out-of-hospital healthcare in 2025."
Resmed was up $1.46 or 9.9 percent to $16.26 with 3.4 million shares traded.

ACTINOGEN

Actinogen has requested a trading halt "pending an announcement regarding the disclosure of results from the phase II Xanadu Alzheimer's disease trial".
Actinogen previously said the trial was a 186-patient, double-blind, placebo-controlled safety, tolerability and efficacy study (BD: Sep 7,2017).
Trading will resume May 7, 2019 or on an earlier announcement.
Actinogen last traded at 4.8 cents.

IMPEDIMED

Impedimed says a 508-patient trial shows its bioimpedance spectroscopy test for post cancer lymphoedema is superior to the standard tape measure assessment.
Impedimed that patients were followed for a minimum of 12 months post-surgery and split into the bioimpedance spectroscopy (BIS) group and tape measure (TM) group.
The company said 109 of 508 patients triggered a pre-threshold intervention, 68 from the TM group and 41 from the BIS group.
Impedimed said BIS had a 15 percent trigger rate compared to the TM group's 28.5 percent and took 9.5 months to trigger compared to the TM group's 2.8 months.
The company said 12 triggering patients required complex decongestive physiotherapy, 10 from the TM group and two from the BIS group.
Impedimed said this was a 67 percent relative reduction and 9.8 percent absolute reduction in patients requiring CDP but was not statistically significant.
The company said the data was presented at the American Society of Breast Surgeons meeting and a media release by the researchers, titled 'Innovative lymphedema surveillance program and early intervention significantly help prevent progression' is at https://www.breastsurgeons.org/meeting/2019/press_releases/lymphedema.
Impedimed fell five cents or 15.9 percent to 26.5 cents with 6.2 million shares traded.

RESPIRI

Respiri says it has a joint venture agreement with the New Delhi-based Medachievers Private to sell Wheezo for asthma and chronic obstructive pulmonary disease in India.
Respiri said it would pay Medachievers a fixed monthly retainer to sell Wheezo to a network of 200 “tier one” and “tier two” hospitals by October and November 2019.
The company said it would then target Medachievers’ network of “tier two” and “tier three” hospitals in rural India.
Respiri said it was working with Medachievers founder and managing director Dr Harsha Vardhan and was supported by Australian-India business trade expert Michael Koss.
The company said that “initial feedback suggests Wheezo will be sold as a product across patient demographics at similar pricing to other markets, due to the value it is able to deliver”.
Respiri said that Conformité Européenne (CE) mark and Australian Therapeutic Goods Administration approvals, Australian based clinical studies and its Australian and UK key opinion leader advisory boards “all provide an excellent platform for Wheezo to be branded in India as a trusted premium quality product”.
The company previously said that its Airsonea At-Home had a class IIa Conformité Européenne (CE) mark approval (BD: Apr 12, 2017).
Respiri was unchanged at 9.9 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says the Nasdaq has informed it that it was below the minimum market capitalization of $US2,500,000 ($A3,572,750) at December 31, 2018.
Genetic Technologies said it would have 45 days to submit a plan to comply with the capital deficiency notice, and if accepted the Nasdaq could grant it an extension of up to 180 days to comply, from April 29, 2019.
Genetic Technologies said that the deficiency notice did not immediately affect its Nasdaq listing and the letter only applied to the Nasdaq and not the shares trading on the Australian Securities Exchange.
Genetic Technologies was unchanged at 0.6 cents with 4.4 million shares traded.

AIRXPANDERS

Airxpanders has requested an extension for its voluntary suspension “until it can finalize its negotiations and provide the market with an accurate update on its future plans”.
Last month, Airxpanders requested a voluntary suspension following its March 29, 2019 “debt agreement” trading halt (BD: Mar 29, Apr 2, 2019).
The company said it expected suspension to last until May 20, 2019.
Airxpanders last traded at 3.5 cents.