Biotech Daily

Friday February 23, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ITL UP 6%; NANOSONICS DOWN 12%**

*** DR BOREHAM'S CRUCIBLE: CYCLOPHARM**

*** KAZIA (NOVOGEN) GDC-0084 ORPHAN STATUS FOR GLIOBLASTOMA**

*** MAYNE H1 REVENUE DOWN 17.5% TO $243m, PROFIT TO $173m LOSS**

*** PROBIOTEC H1 REVENUE UP 18% TO $33m, PROFIT UP 68% TO 1.4m**

*** NANOSONICS H1 REVENUE DOWN 17% TO $30m, PROFIT DOWN 90%**

*** IMMUTEP (PRIMA) POSTS $2.6m H1 REVENUE, LOSS UP 6.5% TO $4.3m**

*** OBJ H1 REVENUE UP 12% TO $1.6m, LOSS DOWN 83% TO $410k**

*** NUHEARA IQBUDS AVAILABLE AT 66 ACUITIS EUROPEAN SHOPS**

*** CANN ANALYTICS DEAL WITH UNDER THE TREE**

*** RESONANCE BDO ALISON LAWS PROMOTED TO CEO ON $165k**

MARKET REPORT

The Australian stock market was up 0.82 percent on Friday February 23, 2018 with the ASX200 up 48.9 points to 5,999.8 points. Fifteen of the Biotech Daily Top 40 stocks were up, 10 fell, 13 traded unchanged and two were untraded. All three Big Caps were up.

Yesterday's 17.1 percent worst, ITL, was today's best, up two cents or 6.35 percent to 33.5 cents with 58,081 shares traded.

Optiscan and Pharmaxis were up more than three percent; Actinogen, Admedus and Bionomics rose more than two percent; Avita, CSL, Medical Developments, Orthocell, Osprey and Psivida were up more than one percent; with Airxpanders, Clinuvel, Neuren, Resmed and Viralytics up by less than one percent.

Nanosonics led the falls, down 36 cents or 12.1 percent to $2.62 with 6.5 million shares traded.

LBT lost 8.1 percent; Reva fell 4.3 percent; Prana was down 3.3 percent; Factor Therapeutics and Impedimed shed more than two percent; Telix was down 1.9 percent; with Sirtex, Starpharma and Volpara down by less than one percent.

DR BOREHAM'S CRUCIBLE: CYCLOPHARM

By TIM BOREHAM

ASX code: CYC

Share price: 95 cents

Shares on issue: 68,636,501

Market cap: $65.2 million

Chief executive officer: James McBrayer

Board: David Heaney (chairman), James McBrayer, Vanda Gould and Tom McDonald

Financials (June first half): revenue $6.06 million, net loss $1.43 million, underlying earnings before interest taxation depreciation and amortization $861,000, dividend 0.5 cents, cash $10.62 million.

Identifiable holders: ASX listing: CVC Ltd (Alexander Beard) 13.8%, Australian Ethical 7%; Nasdaq: Anglo Australian 19.3%, Barings Acceptance 16.75%, Chemical Trustees 11.72%.

A quirk of Cyclopharm's lung imaging technology is that it's been around for 30 years and is sold in 55 countries, with 1,500 units purchased by hospital nuclear medicine departments.

While Cyclopharm's core product Technegas is the diagnostic of choice to detect pulmonary embolism in these countries, it's not yet approved or sold in the US: the biggest nuclear medicine market and the land of the spluttering masses.

Cyclopharm is striving to right this glaring omission with an approval submission to the US Food and Drug Administration, a process that requires a $US7 million trial.

"Half the nuclear medicine departments are in the US and we are already servicing the other half," says chief executive officer James McBrayer.

He is buoyed by Cyclopharm's success in Canada, where Technegas now accounts for most of the market and has displaced traditional imaging, based on the isotope xenon-133.

In September, Cyclopharm bought its distributor in the Benelux countries, IC Medical for EUR200,000 ($A314, 000) plus another EUR200,000 in performance payments.

It is hoped this purchase will expand the use of Technegas to new indications by providing access to respiratory physicians and also expand commercialization of a new product, Ultralute.

Potted history

Cyclopharm was founded in 1986, with the technology developed by Australian National University's Dr Bill Burch.

A component of nuclear medicine, the Technegas process involves the patient breathing radioactive particles that, when ensconced in the lung, are read by traditional imaging equipment.

At the core of the process is a generator: the isotope technetium-99 in liquid form is heated in a carbon crucible to 2,700 degrees Celsius, to form a gas-like particle that is then inhaled by the patient.

The nano-particles have a six-hour radioactive life, after which they are eventually dispersed through normal lung excretion processes.

The process is more reliable than the standard of care, based on the isotope xenon-133.

"Its hallmark is simplicity," says Cyclopharm chief James McBrayer. "It only takes few breaths to get a read-out on lung ventilation."

Technegas also has the advantage of producing three-dimensional (3D) images.

While inhaling a lungful of radioactive isotopes sounds as unhealthy as chugging on a full-strength Marlboro, Mr McBrayer notes there has never been an "attributable adverse event" with patients.

Since 1987, more than 3.8 million patients have been diagnosed using Technegas, including 200,000 in 2016.

Technegas has also chalked up $83 million in sales over this period.

While the company derives 60 percent of its revenues from Europe, Canada is the biggest country market and the best harbinger of what's in store in the US.

Currently, the US lung diagnostic market is shared by xenon-133 and another Technetium-99 based agent called DTPA, which is an abbreviation of a very long name.

Okay: it's diethylenetriaminepentacetate (as in: diethylene-triamine-pent-acetate).

DTPA is actually meant for renal imaging but is used off-label for pulmonary embolisms. Based on a wet aerosol, DTPA can cause blotchy imaging that hides underlying issues.

Annually, four million Americans are diagnosed for pulmonary embolisms, but Mr McBrayer estimates an addressable sub-market of 600,000.

In the US, computed tomography pulmonary angiography (CTPA) is the main way to diagnose pulmonary embolisms.

But nuclear medicine is used for in-patients who are contra-indicated: in other words, the procedure could harm them in other ways.

For instance, they may have renal impairment or be pregnant, in which case the radiation is unhelpful indeed.

This sub-market may be a mere drop in the ocean of respiratory misery, but it's still a diagnostic market worth $US90 million a year.

Clinical trial: enrolling now

To support its US Food and Drug Administration application, in September the company started enrolling the first of 240 patients across 15 sites, initially at the Washington University in St Louis, Missouri.

At last count, 31 were enrolled with results expected by October 2018.

The trial compares Technegas against xenon-133.

Being a non-inferiority trial, all the trial needs to do is to prove Technegas works as well as the standard-of-care.

Unusually, the FDA will allow a preliminary read of 40 patients to support a mini submission by April. This will give a useful official steer on trial design.

Happily, Cyclopharm has stored some nuts away already, having raised $7 million in June last year to fund the trial. Intriguingly, the rights offer was underwritten by major holder Australian Ethical, which eschews nuclear bombs, but doesn't mind nuclear medicine.

Cyclopharm's other priority is to expand Technegas for use in bigger markets of asthma detection, chronic obstructive pulmonary disease (COPD) and patient management. COPD alone is 30 times the size of the pulmonary embolism market.

"We are now seeing a resurgence in new applications as the respiratory medicine world expands its thinking on patient care," Mr McBrayer says.

Why not sooner?

An obvious question is that if Technegas is so superior, why is it yet to be approved in the US?

“It’s been a combination of things,” Mr McBrayer says.

“We are a unique product and the FDA didn’t know whether to classify us as a drug or a device.”

In the end the agency decided Technegas was both.

Another issue was that the FDA would have preferred a technetium-99 based trial to be compared with another technetium-99 based product.

But with DTPA used off-label for pulmonary embolism, there was no formal clinical data to enable this.

But given Technegas has special protocol assessment status with the FDA, the company and regulator are singing from the same hymnal, hopefully with melodious results.

You beaut, Ultralute

Cyclopharm is also about to launch a second product called Ultralute, to expand the useful life of generators that produce the nuclear materials in hospitals by about 50 percent.

Without sounding like a nuclear physicist – or Homer Simpson – molybdenum-99 decays into technetium-99, the isotope used in 80 percent of all medical diagnostic procedures.

There was a global supply issue with molybdenum-99 in 2009, because most of North America was supplied by an ageing Canadian reactor the Canuck government still wants to close.

Currently, supply is okay, but it can’t be relied on.

Hence the need for more reactors to produce moly generators to get as much bang for their buck as possible.

Oddly enough, Cyclopharm is not in a position to build a nuclear reactor, but it can make the existing supply chain more efficient. That is where Ultralute comes in handy.

So much so that the International Atomic Energy Association is working with the company to see if the technology can be made available to developing countries.

Cyclopharm expects to launch Ultralute commercially early this year.

Printer-and-cartridge model

Cyclopharm adheres to what Mr McBrayer dubs “the printer-and-cartridge model”:

Eighty percent of revenue is derived not from the generators themselves, but consumables and service.

Cyclopharm has a track record of profitability, with the half-year deficit of $1.43 million attributed to $1.58 million of FDA trial expenses.

In other words, ignore this one-off cost and the company made a slender profit.

Unusually, Cyclopharm also has a dividend paying record, dispensing half a cent for the interim dividend for the six months to June 30, 2017.

The company reports its full year to December 31, 2017 numbers next week.

Cyclopharm also has no debt and more than $10 million of cash.

Excluding a large Chinese order in 2016 that creates a skewed comparison, the board expects “modest growth in underlying Technegas volumes” for the 2017 year.

Dr Boreham’s diagnosis:

Cyclopharm investor prezzos are usually accompanied by testimonials from enthralled practitioners, usually Canadian ones ruing the misfortune of their cross-border colleagues who cannot yet access the device.

No doubt the makers of xenon-133 and rival angiogram products will claim that Technegas is not the bee’s knees for whatever reasons.

But this faux practitioner is convinced, if only because Cyclopharm has a solid revenue track record.

Cyclopharm shares have meandered between 70 cents and $1 over the last year.

The current circa $65 million market cap does not seem extravagant and should see a decent spurt when the FDA says yes.

Of course, expect the opposite if the agency issues a surprise rejection.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He once won a spelling bee because he was not asked to spell diethylenetriaminepentacetate.

KAZIA THERAPEUTICS (FORMERLY NOVOGEN)

Kazia says the US Food and Drug Administration has granted orphan drug designation to GDC-0084 for the brain cancer glioblastoma multiforme.
Kazia said the designation could provide up to seven years of exclusivity, extending the effective commercial life, along with grant funding, protocol assistance and financial benefits, such as a waiver of application fees and tax credits.
The company said the compound was licenced from Genentech in October 2016 and was due to begin a US phase II clinical trial in glioblastoma in late March or early April 2018.
Kazia said that more than 130,000 patients were diagnosed with glioblastoma multiforme worldwide each year, with a median survival of 12 months to 15 months.
The company said its phase II study was expected to provide an initial read-out in 2019.
Kazia was up 2.5 cents or 3.8 percent to 68.5 cents.

MAYNE PHARMA GROUP (FORMERLY HALCYGEN)

Mayne Pharma says revenue for the six months to December 31, 2017 fell 17.5 percent to $243,256,000 taking last year's profit to a net loss after tax of $173,136,000.
Mayne chief executive officer Scott Richards said the results reflected a "challenging generic environment and a disappointing specialty brands result".
Mr Richards said his company had a "number of strong performing business segments, products and pipeline opportunities … [with the pipeline] expected to drive growth in future periods driven by key launches including generic Nuva Ring and our patented formulation of Suba-itraconazole as an anti-fungal in the United States".
In 2015, Mayne said it would invest $US2.5 million in Hedgepath Pharmaceuticals to accelerate development of Suba-itraconazole for cancer (BD: May 18, 2015).
In 2008, the then Halcygen filed an application with the US Food and Drug Administration for pivotal pharmacokinetic studies of Suba-itraconazole (BD: May 14, 2008).
Mayne said last year's diluted earnings per share of 5.15 cents turned to a diluted loss per share of 11.9 cents for the six months to December 31, 2017, with net tangible assets per share up 52.9 percent to 7.8 cents and the company had cash and cash equivalents of $55,957,000 at December 31, 2017 compared to $80,820,000 at December 31, 2016.
Mayne was up 7.5 cents or 10.7 percent to 77.5 cents with 38.3 million shares traded.

PROBIOTEC

Probiotec says its revenue for the six months to December 31, 2017 climbed 17.7 percent to $32,624,000 taking net profit after tax up 68.2 percent to $1,394,000.
Probiotec said it would pay a fully-franked dividend of 0.75 cents a share for holders at the record date of March 21 on April 20, 2018.
The company said that during the half year it "incurred $300,000 in non-recurring costs relating to the acquisition of [Sydney-based] South Pack Laboratories".
Probiotec said that despite the acquisition cost, net profit after tax showed "significant improvement over the prior corresponding period".
The company said its net tangible assets per share was down 36.6 percent to 30.1 cents at December 31, 2017, with diluted earnings per share up 124.1 from 0.79 cents to 1.77 cents, but diluted earnings per share from continuing activities was up 42.7 percent to 2.24 cents.
The company said it held cash and cash equivalents of $943,609 at December 31, 2017 compared to $141,203 at December 31, 2016.
Probiotec was up three cents or 3.1 percent to 99 cents.

NANOSONICS

Nanosonics says that revenue for the six months to December 31, 2017, fell 16.9 percent to $30,009,000, reducing net profit after tax by 90.0 percent to $2,188,000.
Nanosonics said that it installed 1,700 Trophon EPR ultrasound probe cleaning systems, but revenue fell by four percent for the six months to December 31, 2017.
The company said that two distribution agreements for the Middle East were signed and sales had begun in Kuwait and Lebanon, with discussions underway for expansion into Israel, the United Arab Emirates and Saudi Arabia, and it had hired a regional business development manager for the European and Middle Eastern regions.
Nanosonics said that diluted earnings per share fell 90.0 percent to 0.73 cents for the six months to December 31, 2017, with net tangible assets per share down 4.5 percent to 25.90 cents.
The company said it had cash and cash equivalents of $66,507,000 at December 31, 2017, compared to $56,873,000 at December 31, 2016.
Nanosonics fell 36 cents or 12.1 percent to $2.62 with 6.5 million shares traded.

IMMUTEP (FORMERLY PRIMA BIOMED)

Immutep says revenue for the six months to December 31, 2017 was $2,580,410, with the net loss after tax increased 6.5 percent to $4,324,912.
Immutep said it received two payments each worth $US1 million ($A1.3 million) from Novartis for IMP701 and EOC Pharma for a China trial approval, as well as a $1.3 million cash rebate from the French Government for research and development activities.
The company said that diluted loss per share fell 5.3 percent to 0.18 cents for the six months to December 31, 2017, with net tangible assets per share down 38.6 percent to 0.35 cents.
Immutep said it had cash and cash equivalents of $13,701,707 at December 31, 2017, compared to $16,570,000 at December 31, 2016.
Immutep was unchanged at 2.2 cents with 2.45 million shares traded.

OBJ

OBJ says that revenue for the six months to December 31, 2017, was up 11.8 percent to $1,609,933 with net loss after tax down 83.3 percent to $410,179.
OBJ said that the revenue was primarily licencing fees from Procter & Gamble.
The company said that diluted loss per share was reduced 85.7 percent from 0.14 cents in the previous year to 0.02 cents for the six months to December 31, 2017, with net tangible assets per share down 25.0 percent to 0.3 cents.
The company said it had cash and cash equivalents of $4,776,854 at December 31, 2017, compared to $5,560,028 at December 31, 2016.
OBJ was up 0.1 cents or 2.8 percent to 3.7 cents with 2.15 million shares traded.

NUHEARA

Nuheara says it has furthered its partnership with European optical and hearing retailer Acuitis, which will sell its Iqbuds wireless earbuds at all 66 of its shops.
Nuheara said the deal would include a six-week sales campaign targeted at younger customers, to begin March 1, 2018 to coincide with Hearing Awareness Week.
The company said the Iqbud launch price would be EUR250 ($A393).
Nuheara was up half a cent or 8.1 percent to 6.7 cents with 8.4 million shares traded.

CANN GROUP

Cann says it has a memorandum of understanding with Melbourne's Under The Tree Biopharmaceuticals Pty Ltd for cannabis research.
Cann said that Under The Tree would establish a laboratory within its licenced Northern facility in Melbourne.
The company said that Under The Tree would set-up and develop analytical techniques with a view to providing analytical services to the medicinal cannabis industry in Australia.
Cann said that Under The Tree would establish the service through Australian Cannabis Laboratories, its joint venture with ACS Laboratories (Australia).
The company said that the joint venture would conduct research into improving analysis of cannabis botanical raw material, intermediates and finished medicinal cannabis products, development of medicinal cannabis manufacturing techniques for various delivery formulations and development and implementation of enterprise software to control manufacturing operations and supply chain tracking and traceability.
Cann chief executive officer Peter Crock said agreement with Under The Tree aimed to provide access to independent analytic services in quality control testing for its products.
"Working alongside [Under The Tree] will provide us with expertise in cannabis science research that will help us to stay at the forefront of the local industry," Mr Crock said.
Under The Tree research and regulatory affairs director Abdul Rehman Mohammad said working in-house at Cann's facility was "an important opportunity as it continues research into understanding the role and potential benefits of specific minor cannabinoids in certain strains of cannabis".
Under The Tree chief executive officer Sergio Pagliazzi said that "cannabis will become a major addition to future medicines, as it has many therapeutic applications, and an alignment with Cann will help us fast track commercialisation of revolutionary medicines derived from the plant".
Cann was up six cents or 2.1 percent to $2.96.

RESONANCE HEALTH

Resonance says business development officer Alison Laws has been promoted to chief executive officer, effective from today and starting on $165,000.
Resonance said that Ms Laws had "significant commercial experience and has worked in a variety of roles in small and large businesses".
The company said that Ms Laws was "instrumental in the work undertaken during the company's restructuring efforts in order to meet organizational needs and commercial objectives and has had significant impact on the company since joining in 2016".
Resonance was up 0.1 cents or 4.2 percent to 2.5 cents.