Biotech Daily

Friday December 2, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MICRO-X UP 7%; PATRYS DOWN 8%**

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*** ADHERIUM RECEIVES $1.3m FEDERAL R&D TAX INCENTIVE**

*** PERENNIAL REDUCES, DILUTED TO 11.7% OF MICROBA**

*** PIE FUNDS REDUCES TO 5% OF PROBIOTEC**

*** MILFORD BELOW 5% OF NEUREN**

*** THORNEY, TIGA TAKE 38.2% OF VISIONEERING**

*** ADHERIUM LOSES DIRECTOR JAMES WARD-LILLEY**

*** VAXXAS APPOINTS DOUG CUBBIN CFO**

MARKET REPORT

The Australian stock market fell 0.72 percent on Friday December 2, 2022, with the ASX200 down 52.9 points to 7,301.5 points. Nine of the Biotech Daily Top 40 stocks were up, 16 fell, 13 traded unchanged and two were untraded. All three Big Caps were up.

Micro-X was the best, up one cent or 7.4 percent to 14.5 cents, with 920,839 shares traded. Compumedics climbed seven percent; Cyclopharm improved 5.8 percent; both Oncosil and Pro Medicus rose 2.1 percent; Clinuvel, Cochlear, CSL, Pharmaxis, Resmed and Volpara were up more than one percent; with Nanosonics up by 0.4 percent.

Patrys led the falls, down 0.2 cents or 7.7 percent to 2.4 cents, with 19.1 million shares traded. Alcidion lost 5.9 percent; Emvision fell 4.1 percent; Neuren, Paradigm and Prescient were down more than three percent; Cynata, Imugene, Polynovo and Universal Biosensors shed two percent or more; Antisense, Avita, Genetic Signatures and Resonance were down more than one percent; with Proteomics and Starpharma down by less than one percent.

DR BOREHAM'S CRUCIBLE: FISHER & PAYKEL HEALTHCARE

By TIM BOREHAM

ASX, NZX code: FPH

Share price: $22.84

Market cap: $13.2 billion

Shares on issue: 577,689,557

Chief executive officer: Lewis Gradon

Board: Scott St John (chair), Mr Gradon, Michael Daniell, Pip Greenwood, Dr Lisa McIntyre, Neville Mitchell, Donal O'Dwyer, Dr Cather Simpson, Geraldine McBride

Financials (first half to September 30, 2022): revenue $NZ690.6 million (down 23%), net profit $NZ95.9 million (down 57%), net debt $NZ42.6 million (previously net cash of $221.6 million), interim dividend per share NZ17.5 cents (up 2.9 percent).

Identifiable major shareholders: Mitsubishi UFJ Financial Group 6.1%, Blackrock Inc 6.6%

***** $A1.00 = $NZ1.07

Now for a shot at the $1 million prize - or 300,000 bags of Pineapple Lumps (and that's a clue).

The question is: what sleep apnoea company is listed on the ASX and has thousands of employees and is valued at billions of dollars?

If you answered Resmed you wouldn't be wrong, but the answer we were looking for is the Auckland, New Zealand based Fisher & Paykel Healthcare, which keeps a low profile - at least on this side of the ditch - relative to its $12 billion market capitalization.

Not to be confused with the Fisher & Paykel whitegoods operation, Fisher & Paykel Healthcare manufactures products for respiratory and acute care, including continuous positive airways pressure (CPAP) pumps and masks to treat obstructive sleep apnoea.

Its products are sold in 120 countries and have been used by 20 million patients.

Most of the company's revenues derive from devices and consumables used in hospitals for both invasive and non-invasive ventilation, nasal high flow therapy and surgery. Fisher & Paykel competes with Resmed on CPAP devices and ventilators.

The company is the global leader in respiratory humidification devices.

On a bum note, Fisher & Paykel Health is among a cohort of ‘Covid comedown’ companies that saw bumper revenues during the plague, having sold 10 years’ worth of hardware in only two years.

At Tuesday’s half-year results, CEO Lewis Gradon referred to a “normalization of sorts” but added that conditions remained challenging because of excess inventories, absenteeism and ongoing supply chain issues.

“Customer stock levels of hospital consumables continued to reflect purchases of considerable amounts during our prior half [year], in preparation for an Omicron [Covid variant] wave hospitalization that proved less than severe as anticipated,” he says.

Whatever the case, investors looked beyond the subdued interim numbers, pushing the stock up 12 percent on the day.

From refrigerators to respirators

Fisher & Paykel was founded in 1934 by New Zealand businessman, philanthropist and racing enthusiast Woolf Fisher, as an importer of refrigerators, washing machines and radios. The co-founder was Maurice - you guessed it - Paykel.

Four years later it signed a compact with Kelvinator and in the 1950s and moved to manufacturing its own whitegoods.

The company became involved with healthcare in the late 1960s, to tap its electronic expertise. The first device was a respiratory humidifier for hospital intensive care.

Fisher & Paykel Industries Limited listed on the New Zealand and ASX bourse in November 2001 and later became Fisher & Paykel Healthcare. The company also listed on the Nasdaq, but like many antipodean companies it discontinued it for cost reason (in February 2003).

Lewis Gradon has run the company since 2016, having been senior vice-president (products and technology) since 2001. He took over the top job from the retiring Michael Daniell, who remains a director.

Remind me what the company does

Fisher & Paykel Healthcare products fall into two broad categories: respiratory and acute care and obstructive sleep apnoea (OSA).

The former category includes single-use reusable chambers and breathing circuits and accessories. These are designed to humidify and deliver the gases that a patient receives during mechanical ventilation, non-invasive ventilation, oxygen therapy and keyhole laparoscopic surgery.

The OSA side consists of continuous positive airway pressure (CPAP) products. As with Resmed, these prevent the airways from closing during sleep, which should obviate the snoring.

The company also makes neo-natal infant warmers to maintain the bub's normal body temperature, as well as infant resuscitators.

The company's products include Bubble CPAP generators (with an auto leveling feature), Flexitrunk nasal CPAP interfaces and Neopuff infant resuscitators to deliver "controlled consistent and precise pressures independent of operator experience".

Wigglewings are not attached to the Big Red Car, but are gadgets to stabilize or reposition naso-gastric tubes to infants.

In New Zealand, the company recently launched Airvo 3, which builds on the "market leading" Airvo 2, enabling targeted oxygen delivery, with an integrated battery to enable therapy while a patient moves through a hospital.

The company started selling its Evora Full OSA mask in the US in April this year, having won regulatory clearance. Promoted as being more comfortable, the mask has already been launched in NZ, Australia Europe and Canada.

The company also recently launched Optiflow Switch and Optiflow Trace, which help to administer anaesthetics.

In 2021-'22, North America accounted for 39 percent of the company's $NZ1.68 billion ($A1.55 billion) of sales, with Europe and the Asia Pacific accounting for 28 percent and 26 respectively.

The company's' sales are two-thirds skewed to hospital care, as opposed to homecare (mainly OSA masks and generators).

Most of the products are made at the company's 51,000 square metre (167,300 square feet) facility in Auckland's East Tamaki. In August, the company paid $NZ275 million for a 105-hectare site in Karaka, 20 kilometres away.

The NZ capacity is supplemented by three facilities in Tijuana, Mexico. The company has leased manufacturing space in Guangzhou, China, where it has operated a sales team for many years.

Finances and performance

At a headline level Fisher & Paykel reported a 23 percent revenue downturn in the six months to September 2022, to $NZ690.6 million.

It was a tale of two divisions, with the hospital arm (humidification and respiratory, acute and surgical care) recording a 35 percent revenue decline to $NZ438.7 million. But revenues from Homecare - the OSA side - climbed 10 percent to $NZ250 million.

Mr Gradon notes the strong initial performance of Evora Full since it was launched in the US in April.

He says while hospital revenues seemed to take a nasty tumble, they were 24 percent higher than in the first half of 2020-'21 year: pre-pandemic, that is. The overall revenue was also $20 million higher than guided at the company's strategy jamboree in August this year.

Higher freight costs were a key factor in the company's earnings falling 57 percent, to $NZ96 million. Management reports freight rates softened in the September quarter and have continued to do so into the second half.

The company's gross margin slipped to 59.8 percent from 63.1 per cent and is now well shy of management's targeted 65 percent.

The profit deterioration resulted from reduced product volumes coupled with fixed overheads costs, but management expected a 200-basis point (two percentage point) improvement in the current half.

Management has declined to offer any guidance for the full year to March 2023, citing ongoing uncertainties about Covid 19, the extent of the northern hemisphere winter influenza and the rate of hospitalizations for respiratory syncytial virus (RSV).

However, second half revenues are expected to exceed the first half run rate.

Chief finance officer Lyndal York is unfazed about the apparent deterioration in the company's balance sheet: net debt of $NZ42.6 million compared with $221 million of net cash a year ago. The higher gearing in part reflects the purchase of the Karaka property.

She notes the company has $NZ312 million of "available liquidity", including $NZ70 of cash and undrawn debt. Nonetheless, the company has reactivated its dividend reinvestment plan, by which investors receive shares rather than cash dividends.

Meanwhile, the company spent $NZ84 million on research and development - 11 percent of revenue - and expects this proportion to rise to 15 percent this year.

Over the last 12 months, Fisher & Paykel Healthcare shares have traded between $32.30 (November last year) and $16.11 (early October this year). The stock hit an all-time high of $34.20 in August 2020 and in 2002 traded at a low of $1.50.

Bouquets and brickbats

Platypus Asset Management Prasad Patkar recently praised Fisher & Paykel Healthcare for not raising prices for its respiratory products during the pandemic.

"They felt that it was not the right thing to do and absorbed the elevated costs into their own gross profit margin," Mr Patkar told the Australian Financial Review. "It's a great example of a company managing its business for the long term."

Meanwhile, broker Wilsons opines that the stock is trading on an "elevated'' multiple of 38 times expected current year earnings, and is "unlikely to outperform until the market's expectations have been reset appropriately".

In case you were wondering, Resmed (the firm's preferred stock of the two) trades on a more modest earnings multiple of 24 times, while fellow device giant Cochlear is on an earnings multiple of 26 times.

Dr Boreham's diagnosis:

Mr Gradon proclaims: "Our confidence in the future is unchanged, evidenced by the significant level of investment in new product development, our global sales force and our infrastructure."

Way to go, bro!

Soaring rhetoric aside, Fisher & Paykel Healthcare's five-year table shows the company's revenue increasing 70 percent to between 2018 and 2022, with net profit and earnings per share doubling. The company also has a consistent record of paying dividends.

With an emphasis on long term planning, management targets revenue to double every five to six years.

But where will this growth come from?

Ms York describes the market for existing products as a $NZ25 billion opportunity, with high barriers to entry.

Priority growth areas are home respiratory and surgical technology, including nasal high-flow anaesthesia products.

But changing clinical practice is a "slow process that never stops" she told a recent investment forum.

"After harnessing clinical evidence, the clinicians then have to be persuaded to buy the equipment and use it routinely on patients."

Evidently a member of the glass-half-full camp, Ms York says the pandemic continues to deliver benefits even as it fades into history (although the locked down and restless the Chinese populace might argue with that premise).

"Covid has accelerated our placement of hardware and given us a wonderful opportunity to advance our long-term plans," she says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His idea of long-term planning is to sort out what he's having for dinner by mid afternoon

FEDERAL GOVERNMENT

The Federal Government says it has introduced legislation to establish the $15 billion National Reconstruction Fund to “support, diversify and transform” Australian industry.
A media release from Prime Minister Anthony Albanese, Minister for Finance Katy Gallagher and Minister for Industry and Science Ed Husic said the fund would invest in “seven priority areas … renewables and low emission technologies; medical science; transport; value-add in agriculture, forestry and fisheries; value-add in resources; defence capability; and enabling capabilities”.
The Federal Government said the Fund would be governed by an independent board to make investment decisions, including through loans, equity and guarantees.
The media release said there would be public consultation to further define the scope of the priority areas and how the fund would make investment decisions, with more information available at: https://consult.industry.gov.au/national-reconstruction-fund.
The Government said that responses were required by February 3, 2023.
Mr Husic told the National Press Club on Tuesday that the National Reconstruction Fund would support the medical science industry and its manufacturing capabilities, including areas such as synthetic biology.
“It is one mechanism through which we will realize our ambition to better connect science and industry, to ensure Australian-made discoveries can be commercialized and scaled in our nation,” Mr Husic said.
“I don’t want scientists, researchers and innovators thinking their nation turned their back on them, and that the only way to realize their dreams is to head offshore,” Mr Husic said.
“We want more Australian companies to think globally and build locally,” Mr Husic told the National Press Club.
In the media release Mr Husic said the Government was “taking a collaborative approach and consulting across industry, the finance sector, unions and the community on the implementation of the [Fund]”.
Ms Gallagher said the pandemic made it clear that Australia “must be a country that supports local businesses and industries to make more things here”.
“This is a great opportunity to support Australian innovation and industry after years of uncertainty and lack of a plan,” Ms Gallagher said.
“The National Reconstruction Fund is about building a better future for all Australians, right here on Australian shores,” Ms Gallagher said

VECTUS BIOSYSTEMS

Vectus says that it raised $3,653,070 in its $3.5 million placement at 80 cents a share and has a retail share plan for a further $1 million under the same terms.
Last week, Vectus said it had “firm commitments” to raise $3.5 million in a placement at 80 cents a share and hoped to raise a further $1 million in a non-renounceable retail share plan, with a record date of November 22, 2022 (BD: Nov 23, 2022).
Today, the company said that eligible shareholders could apply for up to $30,000 worth of new shares, with the plan capped at $1 million, or 1,250,000 shares, allocated on a first-come, first served basis.
Vectus said the plan opened on December 1 and would close on December 19, 2022.
The company said proceeds would be used to accelerate its phase Ib clinical trial for VB0004, for the prevention and reversal of fibrosis in the heart and kidneys, as well as development of other compounds and working capital.
Vectus fell two cents or two percent to 96 cents.

BLUECHIIP

Bluechiip says it has received a $787,810 grant from the Federal Government's Supply Chain Resilience Initiative program for its chip 'enabled consumables'.
Bluechiip said the grant application titled, 'Automated Semiconductor Micro-Electro-Mechanical-Systems (MEMS) Device Singulation and Packaging,' covered the preparation of computer chips from the company's silicon wafers onto antennas, which are then "manufactured into Bluechiip enabled consumables".
The company said the project involved "setting up a highly specialized micro-electronics fabrication processing line" using semiconductor fabrication equipment, which would cost $1.85 million over two years.
Bluechiip said the project would "reduce reliance on foreign supply-chain manufacturers; improve control over production scalability and reduce overall time to market; reduce costs through savings in shipping and subsequent production scaling; and build local skills in advanced micro-electronic fabrication".
Bluechiip managing-director Andrew McLellan said the grant vindicated "the cutting-edge research" his company had undertaken in "the tracking space" and would help establish a production line that separated and packaged the MEMS devices.
"Bluechiip will receive improved margins on some of its more complex products... we will become more agile and flexible, with improved in-house capability including for our project with Fujifilm Irvine Scientific in the global [in-vitro fertilization] market," Mr McLellan said.
"In addition, it will enable further expansion of our applications, and expand our opportunities, especially in our target life science market," Mr McLellan said.
Bluechiip was unchanged at three cents.

CRONOS AUSTRALIA

Cronos says it has terminated its intellectual property licence deed with its wholly-owned subsidiary Cronos Australia Operations Pty Ltd, and Cronos Group Inc.
Cronos said that Cronos Group Inc granted it and affiliated rights to use "various aspects of intellectual property owned by [Cronos Group Inc] and its affiliates including, but not limited to, know-how and trademarks including the 'Cronos' name".
The company said that following shareholder approval to change its name to Vitura Health Limited, the intellectual property licence was "less relevant to the group".
Cronos said that it would cease all uses of the intellectual property within 180 days.
Cronos fell two cents or three percent to 68 cents.

FIREBRICK PHARMA

Firebrick says it, the Australian Therapeutic Goods Administration and the Administrative Appeals Tribunal have agreed to a Nasodine appeal decision timetable.
In March, Firebrick said it would appeal against the TGA decision not to approve its Betadine-based anti-viral Nasodine nasal spray based on the data (BD: Mar 1, 2022).
In July, the company said the TGA confirmed its decision not to approve Nasodine nasal spray for sale in Australia (BD: Jul 7, 2022).
At that time, Firebrick said the TGA remained unconvinced about Nasodine's efficacy, based on the first phase III trial not meeting its primary endpoint, but said it intended to apply to the Administrative Appeals Tribunal for "an earlier approval of Nasodine".
Today, Firebrick said that on or about May 30, 2023 a conciliation conference with the TGA would take place, conducted by a Tribunal-appointed conciliator.
Firebrick fell 2.5 cents or 9.6 percent to 23.5 cents.

NOXOPHARM

Noxopharm says 1,200mg of Veyonda, in combination with nivolumab (Opvido) is safe and well tolerated and will progress to the 1,800mg dosing cohort.
Last year, Noxopharm said it had dosed the first of 30 patients in a phase I study of Veyonda and nivolumab for a range of tumor types (BD: Oct 26, 2021).
Noxopharm was up half cent or 3.1 percent to 16.5 cents.

PHARMAUST

Pharmaust says it has completed dosing of the first cohort of six patients in its phase I/II trial of monepantel for motor neurone disease, or amyotrophic lateral sclerosis.
Pharmaust said that monepantel had been well tolerated by patients in the first cohort, and that further data would be reviewed after 28 days of treatment.
The company said dosing at the next level of monepantel was expected to begin in 2023.
In October, Pharmaust said it has dosed the first of 12 patients in its open-label, four-week dose-escalating, phase I/II trial to assess the safety and tolerability of monepantel in patients living with motor neurone disease, also known as Lou Gehrig's disease, and with concurrent animal studies, would determine whether monepantel should proceed to larger phase II studies (BD: Oct 3, 2022).
In 2020, the company said the charity Fight MND had granted its $881,085 for a phase I trial of monepantel for motor neuron disease (BD: Sep 21, 2020).
Pharmaust was up 0.6 cents or 9.4 percent to seven cents.

ADHERIUM

Adherium says it has received $1,287,000 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Adherium said the rebate related to research and development expenditure for the year to June 30, 2022.
Adherium was untraded at half a cent.

MICROBA LIFE SCIENCES

Perennial Value Management says it has reduced and been diluted in Microba from 40,898,790 shares (14.91%) to 40,232,627 shares (11.73%).
The Sydney-based Perennial said between October 27 and December 1, 2022 it bought and sold shares, with the single largest sale on November 7 of 1,680,202 shares for $301,596.26 or 17.95 cents a share.
On Tuesday, Microba said Sydney's Sonic Healthcare would pay $17.8 million for a 19.99 percent holding, at 26 cents a share with a further five percent worth $7.5 million, subject to approval (BD: Nov 29, 2022).
Microba fell three cents or 9.1 percent to 30 cents.

PROBIOTEC

New Zealand's Pie Funds Management says it has reduced its substantial holding in Probiotec from 5,000,874 shares (6.150%) to 4,130,203 shares (5.079%).
The Auckland-based Pie Funds said that from December 1, 2021 to November 29, 2022 it sold 870,671 shares at prices ranging from $2.13 to $2.35 a share.
Probiotec fell two cents or 0.9 percent to $2.23.

NEUREN PHARMACEUTICALS

Milford Asset Management says it has ceased its substantial holding in Neuren after selling 321,225 shares for $2,571,228 or an average of $8.00 a share.
Last week, the Auckland, New Zealand-based Milford said it held 6,771,157 Neuren shares or 5.174 percent (BD: Nov 23, 2022).
Neuren fell 28 cents or 3.6 percent to $7.43 with 705,542 shares traded.

VISIONEERING TECHNOLOGIES

Thorney and Tiga say they have increased their substantial holding in Visioneering from 11,607,173 shares (37.05%) to 11,958,626 shares (38.17%).
The Melbourne-based Thorney and Tiga, or Thorney Investment Group Australia, said that between November 18 and December 1, 2022, they bought shares, with the largest purchase on November 29 of 150,000 shares, for $44,940 or 29.76 cents a share.
Visioneering was up five cents or 16.7 percent to 35 cents.

ADHERIUM

Adherium says director James Ward-Lilley resigned from the board, effective November 30, 2022.
Adherium said he had resigned due to his “full-time executive commitments as chief commercial officer at the Aerogen Group”.

VAXXAS PTY LTD

Vaxxas says it has appointed former Telix chief financial officer Doug Cubbin as its chief financial officer, effective from December 1, 2022.
Vaxxas said that Mr Cubbin had more than 30 years of experience in finance, mergers and acquisitions and business development, most recently working at Telix and previously as Australia Nuclear Science and Technology Organisation chief financial and operating and chair of its nuclear medicine division, as well as with DHL Oceania and South Pacific chief financial officer.
According to his Linkedin page, Mr Cubbin held a Bachelor of Business Administration from the Bathurst, New South Wales-based Charles Sturt University.
Vaxxas is a private company.