Biotech Daily

Friday August 23, 2024

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: CURVEBEAM UP 8%; PRESCIENT DOWN 4%**

*** DR BOREHAM'S CRUCIBLE: PRO MEDICUS**

*** TELIX H1 REVENUE UP 65% TO $364m; LOSS TO $42m PROFIT**

*** MAYNE PHARMA REVENUE UP 112% TO $388m; PROFIT TO $174m LOSS**

*** POLYNOVO REVENUE UP 58% TO $105m; LOSS TO $5m PROFIT**

*** ANTERIS H1 REVENUE DOWN 9% TO $2.5m; LOSS UP 76% TO $53m**

*** PROTEOMICS REVENUE DOWN 4% TO $1m; LOSS UP 4% TO $6.5m**

*** FISHER & PAYKEL GUIDANCE: $1.8b REVENUE, $316m PROFIT**

*** FEDERAL $323k FOR FLOREY IRON DISORDER BLOOD TEST**

*** PROTEOMICS: 'PROMARKER D GOOD FOR TYPE 1 DIABETES'**

*** AMPLIA AGM 15% OPPOSE PLACEMENT FACILITY**

*** BIOXYNE PLEADS 'SCHULZ, MARIJUANA GUMMIES' TO 143% ASX QUERY**

MARKET REPORT
The Australian stock market slipped 0.04 percent on Friday August 23, 2024, with the ASX200 down 3.1 points to 8,023.9 points. Eighteen of the Biotech Daily Top 40 companies were up, 12 fell and 10 traded unchanged. All three Big Caps were up.

Curvebeam was the best, up 1.5 cents or 8.1 percent to 20 cents, with 31,335 shares traded. Resonance rose 7.4 percent; Atomo was up 4.8 percent; Aroa, Compumedics, Medical Developments and Proteomics climbed more than three percent; Neuren, Nova Eye and Paradigm rose two percent or more; Alcidion, Clinuvel, Dimerix and Medadvisor were up more than one percent; with Cochlear, CSL, Cyclopharm, Opthea, Polynovo, Pro Medicus and Resmed up by less than one percent.

Yesterday's 13.95 percent best, Prescient, led the falls, down 0.2 cents or 4.1 percent to 4.7 cents, with 1.55 million shares traded. 4D Medical, Amplia, Micro-X, Syntara and Telix lost three percent or more; Clarity, Cynata and Orthocell shed more than two percent; Avita and Nanosonics were down more than one percent; with Mesoblast down by 0.5 percent.

DR BOREHAM'S CRUCIBLE: PRO MEDICUS

By TIM BOREHAM

ASX code: PME

Share price: $151.49; **Shares on issue:** 104,424,882; **Market cap:** $15.82 billion

Chief executive officer and co-founder: Dr Sam Hupert

Board: Peter Kempen (chair), Dr Hupert, Anthony Hall (co-founder and executive director), Anthony Glenning, Dr Leigh Farrell, Deena Shiff, Alice Williams

Financials (year to June 30, 2024): revenue $161.5 million (up 29%), net profit $82.8 million (up 36.5%), earnings per share 79.1 cents (up 36%), cash and investments $155.5 million (up 28%)

Identifiable major shareholders: Dr Sam Hupert 24.07%, Anthony Hall 24.11%

The home-grown, giant-killing radiology software outfit is proving that its technologies are suitable for more than just the 'sandstone' academic hospital institutions from which it first gained its foothold in the US market.

All up, in the year to June 30, 2024 the company won nine new contracts with a total contract value of $245 million. This includes the biggest to date, the Dallas, Texas based integrated delivery network (IDN) Baylor, Scott and White Health.

A recent omnibus of five contract wins was notable not just for the value - a collective combined minimum of $45 million - but for the varied nature of the clients.

These included paediatric hospitals in Ohio and Florida, private radiology chains and Florida's Moffitt Cancer Centre.

The jobs are characterized by software-as-a-service (annuity) revenue based on minimum transaction levels.

Despite chatter that the company is priced to perfection, Pro Medicus shares soared 13 percent in the two trading days after the August 14 disclosure of a 36 percent full-year profit surge, to $82.79 million.

CEO and co-founder Dr Sam Hupert describes a "record year in all metrics, not just revenue and profit but also in terms of new sales and completed implementations".

He says the company's products are proving to be suitable for "virtually all segments of the market" from smaller groups to some of the largest IDNs and academic medical centres.

"It has been the most successful year in the company's history on all fronts," he chimes.

Coming from the clouds

Pro Medicus provides diagnostic imaging, practice management and image archiving software to hospitals and radiology practices.

Rather like cloud-based, book-keeping pioneer Xero, Pro Medicus claims to be the only genuine internet-based provider, in a profession that still likes its pencils and clipboards.

The company was founded by Melbourne general practitioner Dr Hupert and his technologist friend Anthony Hall in 1983. Back then clouds came in three key varieties: cirrus, cumulus and stratus.

The company's key products are Visage RIS (as in radiology information system) and the cornerstone Visage 7 (enabling users to consolidate information requiring multiple views into a customized single platform).

The image storage tool Visage Open Archive was introduced in 2017, with Visage Workflow Management emerging in 2020.

Not the America's Cup, but better

At the height of the global financial crisis, Pro Medicus acquired the California-based Visage Imaging for a knock-down $5 million. It was the company's 'Alan Bond' moment (a reference to Kerry Packer buying back his Nine Network from the failed Perth mogul for a knock-down sum).

The purchase price was quickly validated, because Pro Medicus shed Visage Imaging's unwanted research arm shortly after for $15 million.

Dr Hupert says the company was in the right place at the right time. (But you make your own luck, don't you?)

Size counts

A key driver for the company is the need for more data capacity for imaging procedures.

For example, 300 megabytes used to be adequate for a mammography, but today, a high-definition version needs eight to 10 gigabytes per study. The same goes for a full-body positron emission tomography (PET) scan, while a high-definition, multi-slice computed tomography (CT) scan might require more than 10,000 images.

Traditionally, a scan produces a file which is compressed and sent to a highly- configured work station, where the image is enhanced and manipulated.

"The trouble is that the files are getting too big and it takes too long to open them and do the manipulation locally," Dr Hupert says. "Our model allows the files to go to a single back-end server. All of the sophisticated enhancements are done in real time and the pixels are streamed to the radiologist or clinician.

“The two huge advantages are that it is instant - one second or less - and the radiologist’s work station doesn’t have to be highly configured. When you have hundreds or thousands of these screens, it is a huge cost saving.”

Finances and performance

Last week’s full-year numbers show the company is on a roll, with revenue increasing 29.3 percent to $161.5 million.

It wasn’t profitless growth either, with earnings up 36 percent in both net profit (to $82.8 million) and diluted earnings per share terms (79.1 cents per share).

“We have contained our cost base so margins have grown further from last year as our footprint increases,” Dr Hupert says.

The company cites forward revenue of $608 million over five years.

“Most contracts are delivered as software-as-a-service, with minimum amounts,” Dr Hupert says.

Investors were rewarded with a 22 cents a share final dividend, up 33 percent, although suffice to say they are unlikely to be in the stock just for the paltry yield.

Of the revenue, 85 percent derived from the US. North American turnover rose 34 percent, while Australian revenue gained a more sedate 5.9 percent. European revenue declined seven percent, if only because of a chunky German sale in the previous period.

The company has cash (and financial investments) of $155 million and no debt.

Over the last 12 months Pro Medicus shares have ranged between $70.80 (mid-August last year) and the August 16, 2024 peak of $150.67.

Five years ago, the shares were worth $26 and ten years ago they could be bought for less than a dollar (these days, a dollar won’t even buy a dim sim).

Last November, Dr Hupert and Mr Hall both sold one million shares - approximately four percent of their personal holdings - at $88 apiece in response to an approach from an individual fund.

At the time they said they did not intend to sell any more shares “in the foreseeable future”. In March this year the stock was elevated to the ASX100 index.

Coming up

Dr Hupert cites an increasing flow of requests for proposals, overwhelmingly for cloud-based upgrades often mandated by health regulators.

“We believe we are one of the few companies - if not the only one - that can provide a true cloud-based implementation of scale,” he says.

The company has a long-standing interest in expanding into the ‘ologies’, with a cardiology extension product in development.

Dr Hupert says Pro Medicus is close to a cardiology “version 1.0”, but there are nuances involved over and above the quality of the actual imaging (such as reporting requirements).

Following US Food and Drug Administration approval, Pro Medicus last year commercialized an algorithm to measure breast density, the problem being that ‘dense’ breasts are harder to scan than ‘fatty’ breasts because both the tumor and the background come out as white on the image.

“We are confident it is highly accurate and will be the more consistent result than humans reading the same mammogram,” Dr Hupert says.

A.I. is coming

Dr Hupert says healthcare is perfectly suited to artificial intelligence (A.I.) and thus has been one of the first sectors to embrace the brave new world.

Not that radiologists need to be too afraid (see below).

“Interestingly, 80 percent of FDA-approved healthcare algorithms are in diagnostic imaging,” Dr Hupert says.

To date, the artificial intelligence has been embedded in imaging equipment. “If someone moves during a [scan], AI may be able to improve the image or warn the technologists they may need to take another exam.”

Artificial intelligence can prioritize which images should be viewed first in emergency settings and an act as a “second set of eyes” in breast cancer and lung screening.

However, Dr Hupert believes automated diagnosis is some way off - and even artificial intelligence itself agrees.

According to Chat GPT: “A.I. has the potential to significantly enhance radiology by improving efficiency and accuracy, but it is unlikely to fully replace radiologists in the foreseeable future.”

Meanwhile Dr Hupert says the acute global shortage of real-life radiologists - partly caused by high burnout - isn’t getting any better.

“Tele-radiology groups used to fighting for clients are now freezing new work and some groups are even giving back contracts they can’t service adequately,” he says.

The shortage will take years to ameliorate, because it takes three to five years to train a radiologist.

Sizing the rivals

Depending on the sector, Pro Medicus competes with the likes of GE Health, Siemens and Philips and the erstwhile camera film makers Agfa, Fujifilm and Carestream.

It also bumps into smaller ASX-listed peer Mach7 in the US market, although they tend to run their own race.

Pro Medicus claims to be winning share because it is nimbler than its more lumbering peers and can offer a full suite of products.

“We are confident we are number one in the three areas that count: speed, functionality and scalability,” Dr Hupert says.

He doesn’t mention ‘cheapness’: Pro Medicus tends to have most expensive products but with the best claimed return on investment and clinical accuracy.

“We allow radiologists to do what they otherwise couldn’t do, or if they could it would take too long to do.”

Dr Boreham’s diagnosis:

Despite its seemingly endless roll call of new and expanded clients, Pro Medicus lays claim to only seven percent of the US market of 650 million annual exams.

The company believes it can access 85 percent of this market “from a commercial perspective”. Goldman Sachs expects a market share of 13 percent by 2030 as more hospitals creak and groan into the modern era.

Investors might wonder whether Pro Medicus is ignoring the rest of the world, but the truth is that the US offers the best reimbursement relative to, say, the European market.

As the company grows its client book, the rules of mathematics dictate that such heady growth rates will be harder to maintain.

“Clearly, maintaining growth rates of 30 percent-plus year-on-year gets harder as our base gets bigger,” Dr Hupert says. “But we believe we can maintain our trajectory with strong, profitable growth. Our clients are growing well above the industry average and if they grow, we grow.”

On broker estimates the company trades on an earnings multiple of around 130 times. While they love the company to bits, the prevailing view is the stock is priced to perfection.

The trouble is, you columnist opined the same things seven years ago - when the stock traded at $5.00.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Or a decent crystal ball, for that matter.

TELIX PHARMACEUTICALS

Telix says it had record revenue for the six months to June 30, 2024, up 64.8 percent to $363,964,000, with last year's $10,018,000 net loss turned to a $41,553,000 profit.
Telix said the majority of revenue was from sales of its Illuccix imaging agent for prostate cancer in the US "in its second full year of commercial sales".
Telix managing-director Dr Christian Behrenbruch said Telix continued to increase revenue from Illuccix, gross profit margin and "manage costs effectively while investing for future growth".
"Building on our commercial success with Illuccix, we are focused on expanding the near-term opportunity in precision medicine diagnostics with three new products planned for launch in 2025, subject to regulatory approval," Dr Behrenbruch said.
"We also continue to build-out our internal manufacturing capability, which we believe is a competitive advantage for our radio-pharmaceutical supply chain and ability to deliver patient doses globally," Dr Behrenbruch said.
"We believe the radio-pharmaceutical sector is at an inflection point and Telix has the proven commercial ability, clinical experience and balance sheet strength to advance our leading-edge [diagnostic and therapeutic] pipeline," Dr Behrenbruch said.
"With a proven revenue stream and a clear path to future business growth, Telix is positioned at the vanguard of this fast-growing field," Dr Behrenbruch said.
Telix said diluted loss per share for the year to June 30, 2023 of 4.51 cents was turned to diluted earnings per share of 8.75 cents, and it had negative net tangible assets per share of 9.7 cents, compared to positive net tangible assets per share of 3.6 cents.
Last year, Telix said net tangible assets per share was 0.72 cents for the six months to June 30, and 3.59 cents for the year to December 31, 2023 (BD: Aug 24, Feb 23, 2024).
Today, the company said it had cash and cash equivalents of $118,837,000 at June 30, 2024, compared to $131,729,000 at June 30, 2023.
Telix fell 60 cents or three percent to $19.18 with 3.3 million shares traded.

MAYNE PHARMA GROUP

Mayne Pharma says revenue for the year to June 30, 2024 was up 111.6 percent to $388,399,000, with last year's $117,157,000 net profit turned to a $174,233,000 loss.
Mayne said revenue from its dermatology business was up 206.8 percent to $174.9 million, with women's health products up 130.7 percent to $142.8 million and international sales of its branded and generic pharmaceuticals up 9.3 percent to $70.7 million.
The company said its loss included $33,246,000 from its class action settlement with the US Department of Justice, as well as "earn-out and deferred consideration liabilities reassessments" payments of $82,671,000 and increased expenditure in research and development, marketing and administrative costs.
Earlier this year, Mayne Pharma said it would pay $38 million to settle a class action brought by Phi Finney McDonald, and that the proceedings related to "alleged misleading or deceptive conduct and breaches of continuous disclosure obligations in respect of alleged anti-competitive conduct in the US": (BD: Jul 4, 2024).
The company said diluted earnings per share for the year to June 30, 2023 of $1.41 was turned to a diluted loss per share of $2.19 in the year to June 30, 2024.
Last year, Mayne said its diluted earnings per share was $1.48 (BD: Aug 31, 2023).
Mayne said net tangible assets per ordinary share of 21 cents in the prior period was turned to a negative net tangible asset per share of $1.45, and it had cash and equivalents of $110,068,000 at June 30, 2024, compared to $92,616,000 at June 30, 2023.
Mayne was up 44 cents or 11.2 percent to $4.38 with 616,970 shares traded.

POLYNOVO

Polynovo says revenue for the year to June 30, 2024 was up 58.4 percent to $104,727,000, with last year's $4,924,000 loss after tax turned to a $5,261,000 profit.
Polynovo said revenue was from sales of its Novosorb biodegradable wound treatment, with US sales up 54.2 percent to $79.8 million, Australia and New Zealand sales up 37.55 percent to $6.6 million, and sales in "other countries" up 92.9 percent to $16.8 million.
The company said that employee expenses rose 50.7 percent to $59.4 million, corporate and administrative expenses were up 39.5 percent to $24.3 million and research and development expenses increased 47.1 percent to $10.9 million.
Polynovo chair David Williams said that the "continued growth achieved in 2023-'24 reflects a wider geographic footprint, more sales staff, and a growing acceptance of Novosorb … by surgeons wanting the next generation dermal regeneration solution".
"Polynovo is now the category leader in burn procedures in several markets around the world and has a track record of leveraging this reputation in other arenas, including trauma and limb salvage," Mr Williams said.
"In 2024-'25 we expect to see strong revenue growth in direct markets particularly the US, UK [and Ireland], [Australia and New Zealand], India, and Hong Kong," Mr Williams said.
"We are confident that our key distributor markets, Germany, and Canada, will continue their strong growth," Mr Williams said.
Mr Williams said the company had submitted further applications to the US Food and Drug Administration for 510(k) clearances that were expected by June 30, 2025 and would expand its Novosorb product portfolio.
The company said that reimbursements for research and development from the US Biomedical Advanced Research and Development Authority (BARDA) were up 176.4 percent to $10,159,000.
Polynovo said last year's diluted loss per share of 0.72 cents was turned to a diluted earnings per share of 0.75 cents.
The company said net tangible assets per share was up 11.7 percent from 9.4 cents in the prior corresponding period to 10.5 cents.
Polynovo said it had cash and cash equivalents of $45,907,000 at June 30, 2024 compared to $46,847,000 at June 30, 2023.
Polynovo was up two cents or 0.8 percent to $2.61 with 1.2 million shares traded.

ANTERIS TECHNOLOGIES

Anteris says revenue for the six months to June 30, 2024 was down 8.6 percent to $2,529,716, with net loss after tax up 76.1 percent to $53,290,894.
Anteris said revenue from customer contracts, primarily the sale of its heart valve "tissue products" fell 9.5 percent to $2,126,203, with the remainder coming from interest income.
The company said the increased loss was "primarily due to significant [research and development] expansion including recruitment of additional personnel in preparation for the US [Food and Drug Administration] pivotal study and upscaling in-house manufacturing".
Anteris said research and development expenditure was up 141.7 percent to $23,411,777, primarily related to its trial of the Duravr transcatheter heart valve system for acute aortic stenosis, atrial flutter and ablation procedures.
Anteris said its diluted loss per share rose 36.8 percent to $2.75, net tangible assets per share fell 85.2 percent from $1.28 to 19.0 cents, and it had cash and cash equivalents of $10,844,340 at June 30, 2024 compared to $20,255,505 at June 30, 2023.
Anteris fell 25 cents or 1.6 percent to $15.25.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says revenue for the year to June 30, 2024 was down 4.2 percent to $1,409,641, with net loss after tax up 4.0 percent to $6,481,813.

Proteomics said revenue came from its analytic services and licencing income which was up 22.15 percent to $892,143.

The company said its loss reflected “normal operational costs and non-cash items”.

Proteomics said basic loss per share fell 4.3 percent to 5.07 cents, net tangible assets per share was even at seven cents and it had cash and cash equivalents of $6,640,244 at June 30, 2024 compared to $6,027,315 at June 30, 2023.

Proteomics was up three cents or 3.6 percent to 86.5 cents.

FISHER & PAYKEL HEALTHCARE CORPORATION

Fisher & Paykel says it expects full year revenue of $NZ1.9 billion ($A1.74 billion) and $NZ2.0 billion, with net profit after tax $NZ320 million and $NZ370 million.

Fisher & Paykel said that it had updated its previous forecast for the year to March 31, 2025, with revenue expectations unchanged but net profit after tax guidance up from between $NZ310 million and $NZ360 million to $NZ320 million and $NZ370 million.

In May, the company said revenue for the year to March 31, 2024 was $NZ1,742,800,000, with a profit of $NZ132,600,000 (BD: May 29, 2024).

Fisher & Paykel said the change in profit guidance was based on a change in US to NZ exchange rates from $NZ1.00 worth 0.59 US cents to 0.62 US cents.

The company said it had not revised revenue forecasts “due to the additional and variable impact of northern hemisphere seasonal hospitalization rates, which historically occur towards the end of our second half”.

Fisher & Paykel was up $3.49 or 11.9 percent to $32.83 with 1.1 million shares traded.

THE FLOREY INSTITUTE, FEDERAL GOVERNMENT

The Florey Institute says it has $322,990 from the Federal Government’s Australia’s Economic Accelerator program to develop quantum sensor-based iron deficiency tests.

The Florey Institute said standard iron tests measured how much ferritin, a primary iron storage protein, was contained in a blood sample but was an indirect test of iron storage often misled by other underlying health conditions, such as inflammation.

The Institute said research led by Prof Gawain McColl was developing a ferritin bound iron technology, called Febi, that used “diamond-based quantum sensors to measure the magnetic fields produced by iron atoms contained in ferritin”.

The Florey said iron deficiency could “cause fatigue, poor concentration, a weakened immune system, poor sports performance, pregnancy complications and … anaemia”.

The Institute said the project was a collaboration with the University of Melbourne and the Commonwealth Scientific and Industrial Research Organisation.

The Florey said one in five Australian women, and one in 20 men, were iron deficient, but many were unaware “due to inaccurate and outdated blood tests”.

Prof McColl said inaccurate iron testing had “the potential to cause major health consequences, for women in particular."

“Febi gives an extremely accurate readout of iron levels within ferritin,” Prof McColl said.

“The problem with current testing is that common health conditions such as diabetes or obesity elevate people’s ferritin but not their iron,” Prof McColl said. “Because blood tests detect all ferritin, regardless of whether it is iron-laden or iron-empty, they fail to diagnose many iron-deficient people because they have underlying health conditions.”

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says its Promarker D blood test showed 90 percent specificity and 78 percent sensitivity in a phase II trial of 92 type one diabetes patients.
Proteomics said the 2019 study found the Promarker D test, which was originally developed and validated for predicting renal decline in type 2 diabetes, was "at least as good a prognostic test for renal decline in type one as type two diabetes".
Proteomics said Promarker D had a 47 percent positive predictive value, a 97 percent negative predictive value, and 97 percent for predicting renal decline in type 1 diabetes.
The company said the results, titled 'Application of a Validated Prognostic Protein Biomarker Test for Renal Decline in Type Two Diabetes to Type One Diabetes: The Fremantle Diabetes Study Phase II', would be presented today at the Australasian Diabetes Conference in Perth, Australia, held from August 21 to 23, 2024.
Proteomics said managing-director Dr Richard Lipscombe said "this significant advancement highlights the versatility and robustness of the Promarkerd test".
"We are excited about the potential impact this could have on managing kidney health in both type one and type two diabetes patients," Dr Lipscombe said.

AMPLIA THERAPEUTICS

Amplia says its annual general meeting passed all resolutions but with up to 14.59 percent against the special resolution to approve the 10 percent placement facility.
Amplia said the resolution to approve its placement facility was opposed by 18,637,150 votes (14.59%), with 109,101,550 votes (85.41%) in favor.
The company said resolutions to adopt the remuneration report, issue shares to managing-director Dr Chris Burns, ratify the issue of 3,500,000 options and elect directors Dr Robert Peach and Jane Bell were all passed overwhelmingly.
According to its most recent filing, Amplia had 274,211,991 shares on offer, meaning that the votes against the placement facility amounted to 6.8 percent of the company, sufficient to requisition extraordinary general meetings.
Amplia fell half a cent or 3.85 percent to 12.5 cents with 1.4 million shares traded.

BIOXYNE

Bioxyne has told the ASX that it is not aware of any information it has not announced which, if known, could explain the recent trading in its securities.
The ASX said Bioxyne's share price rose 142.9 percent from a low of 0.7 cents to a high of 1.7 cents, today, and noted the "significant increase" in the volume of shares traded.
Bioxyne said it released an announcement on Wednesday August 21, 2024 marked price sensitive, titled 'Bioxyne Successfully Delivers Australia's First Pharmaceutical Cannabis Gummies Manufactured Under GMP Licence'.
After the announcement, Bioxyne's share price climbed as high as 40 percent to 0.7 cents on August 21, and closed at 0.7 cents yesterday, August 22.
Today, Bioxyne climbed as much as 142.9 percent to 1.7 cents, before closing up half a cent or 71.4 percent at 1.2 cents with 41.9 million shares traded.