Biotech Daily

Friday September 13, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: MEDADVISOR UP 14%; PARADIGM DOWN 6%**

*** DR BOREHAM'S CRUCIBLE: MEDICAL DEVELOPMENTS INTERNATIONAL**

*** VICTORIA $10m FOR LA TROBE UNI ARTIFICIAL INTELLIGENCE**

*** ONCOSIL: 30th PANCREATIC CANCER TREATMENT IN SPAIN**

*** KAZIA LICENCES PI3K FROM QIMR BERGHOFER**

*** NANOSONICS TELLS ASX: 'REVENUE IN LINE WITH GUIDANCE'**

*** ASX SUSPENDS BIOXYNE ON MARIJUANA GUMMIES MANUFACTURING**

*** PACIFIC EDGE: AMERICAN UROLOGICAL ASSOCIATION 'FEEDBACK'**

*** CLINUVEL SPILL RESOLUTION, 71% DIRECTORS' POOL HIKE AGM**

*** RICHARD GREEN, JTCA, JAYTACO DILUTED TO 15.5% OF LBT**

*** RYDER TAKES 7% OF LUMOS**

*** VISIONEERING: JEFF PRUET FINANCE HEAD; COO, CFO BRIAN LANE GOES**

MARKET REPORT

The Australian stock market was up 0.3 percent on Friday September 13, 2024, with the ASX200 up 24.2 points to 8,099.9 points. Seventeen of the Biotech Daily Top 40 companies were up, 12 fell, 10 traded unchanged and one was untraded.

Medadvisor was the best, up five cents or 14.3 percent to 40 cents, with 964,550 shares traded. Resonance climbed 8.3 percent; Emvision was up 5.9 percent; Amplia and Percheron improved more than four percent; Clinuvel climbed 3.1 percent; Aroa, Nova Eye and Pro Medicus rose two percent or more; Clarity, Medical Developments, Micro-X, Neuren, Polynovo and Starpharma were up more than one percent; with Cochlear, Opthea and Telix up by less than one percent.

Paradigm led the falls, down 1.5 cents or 5.9 percent to 24 cents, with 925,270 shares traded. 4D Medical, Dimerix, Genetic Signatures and SDI fell more than four percent; Orthocell lost 3.2 percent; Actinogen, Mesoblast and Nanosonics shed two percent or more; Avita, Immutep, Proteomics and Resmed were down more than one percent; with CSL down by 0.5 percent.

DR BOREHAM'S CRUCIBLE: MEDICAL DEVELOPMENTS INTERNATIONAL

By TIM BOREHAM

ASX Code: MVP

Share price: 44 cents; **Shares on issue:** 112,658,324; **Market cap:** $49.6 million

CEO: Brent MacGregor

Board: Gordon Naylor (chair), Dr Russell Basser, Mary Sontrop, Christine Emmanuel-Donnelly, Leon Hoare, Richard Betts

Financials (year to June 30 2024): revenue $33.15 million (up 2.5%), underlying net loss $8.2 million ($15.1 million loss previously), net reported loss $41 million ($5.6 million loss previously), cash of $9.7 million ($18.9 million in mid-August, after $10 million capital raising)

Major identifiable shareholders: David Williams 11.6%, Regal Funds 10% FIL Ltd (Fidelity) 4.5%

No company wants sub-optimal returns on their product - and pain management house Medical Developments is no exception.

For some years, management has believed that customers undervalued the worth of its flagship product, the first-line inhaled analgesic device Penthrox.

Colloquially known as the 'green whistle', Penthrox's methoxyflurane is administered to grimacing injured sportspeople as they limp from the field.

Of course, jacking up prices is notoriously difficult. But Medical Developments had a lucky break after Australia's Pharmaceutical Benefits Scheme (PBS) approved a 25 percent increase, effective from August 1 this year. There's nothing like a government body - the one that shells out reimbursement - ticking off on such a hefty increase.

CEO Brent MacGregor says the PBS approval will help the company to edge up pricing elsewhere, with improved returns in the UK and Ireland already apparent. "Where appropriate, we intend to adopt this increase in other parts of the market," he says.

A trifecta of better pricing, lower costs and sharper strategy helped the hitherto struggling company to report what management dubs a greatly improved result for the year to June 30, 2024 – but investors need to peer beyond the official $41 million loss (see below).

Mr MacGregor describes the results as encouraging "with strongly improved margins, earnings and cash flow".

But the company is not pain-free yet. Its long-planned US approval quest has been put on hold, as has a proposed trial in China and development of a self-administered extension product called Selfie.

The story to date

Medical Developments is all about re-inventing methoxyflurane - first used here in 1975.

Medical Developments holds worldwide rights to the 46-year-old painkiller and is its only manufacturer, with the Penthrox units used for inhaling the methoxyflurane made at two Melbourne facilities. Last year the company sold 764,000 Penthrox units, mainly in Australia (327,000) and Europe (282,000).

Methoxyflurane is also used as a veterinary drug, having been approved a decade ago in the US under the brand name Anafane.

The company also produces respiratory devices such as asthma spacers and masks and portable nebulizers, sold under the Breath-a-tech banner.

Medical Development was founded by prominent anesthetist Dr David Komesaroff, waaay back in 1972.

Penthrox was (and is) pitched as a rival product to nitrous oxide (laughing gas), morphine, Fentanyl (a powerful opioid) and ketamine (better known as a party drug and horse tranquillizer).

Steered by then chair and major shareholder David Williams, Medical Developments listed on the ASX in December 2003, after raising $8.7 million at 25 cents apiece.

Since then, Medical Developments has expanded into more than 40 countries - the US being a notable exception for Penthrox, see below - with more than seven million patients administered methoxyflurane safely and effectively.

In March 2022 CEO John Sharman resigned after a 10-year stint and shortly after bobbed up to head ASX-listed device maker Universal Biosensors.

Mr MacGregor assumed command in November 2020. Mr MacGregor was the head of commercial operations at Seqirus (CSL's old 'flu division) and formerly headed Novartis's influenza arm.

The founder of advisory firm Kidder Williams and chair of Polynovo and Inoviq, Mr Williams resigned from the board in April 2023 "to pursue other personal and business interests".

Financials and performance

In August, Medical Developments reported a net loss of $41 million, compared with a $5.6 million loss previously. The company also made an underlying loss of $8.2 million, an improvement on the previous $15.1 million deficit.

In truth, the key financial data was outlined in July, when the company embarked on a placement and rights issue that raised $10 million at $38 cents apiece (the retail leg raised $1.5 million, with a $1.6 million shortfall taken up by underwriters).

The bottom-line loss was attributable mainly to non-cash asset impairments, a one-off non-cash share payment expense relating to Mr MacGregor's remuneration and a de-recognition of tax losses.

Management focused on metrics such as the 2.7 percent revenue boost to $33.2 million, a five basis-point improvement in gross margins (to 74 percent) and a $10 million improvement in free cash flow (to a negative $14 million).

Pain management (Penthrox) revenue grew four percent to $21.3 million, with strong growth in Australia and Europe offset by lower revenues elsewhere (mainly as a result of higher prior-year inventory stocking in Canada, ahead of a re-launch).

The Nordic regions were especially strong, while French sales held up despite limited commercial activity there.

Driven by US sales, respiratory revenue improved 1.7 percent to $11.9 million, despite soft seasonal conditions in Australia, and European destocking.

Corporate costs fell by $5 million, with a further $3 million to $4 million reduction expected in the current financial year.

Mr MacGregor says the company targets positive operating cash flow by the end of 2025. He expects underlying earnings to "strongly improve" this year, driven by higher Penthrox prices and operating efficiencies.

Over the last year Medical Developments shares have traded between $1.02 (Jan 4) and 38 cents (May 23). The stock peaked at $10.50 in February 2020, just before the sharp-but-short share market meltdown as Covid crept across the land.

Australian EDs ease the pain

Mr MacGregor notes a 30 percent volume growth from emergency departments (EDs) - albeit from a small base - as more hospitals list Penthrox as suitable for use.

An additional 44 hospitals have added Penthrox to their treatment protocols, while the number of hospitals purchasing the device grew by 68, to 244. These include key Melbourne and Sydney emergency departments, with Penthrox listed for use across South Australian emergency departments.

But Mr MacGregor says emergency department take-up has been "slower than expected" and more time and effort will be needed.

"In short, ED physicians will need to learn more [about the product] to shift their behavior and influencing this will be a key effort for us."

To support take-up, the company has moved from a field-based sales approach to a stronger "medical engagement" in hospitals.

“We have concrete evidence that once use of Penthrox is established … it embeds a standard-of-care,” he says. “Our progress here will be leveraged to support our partner efforts in international markets, not just those we are in now but those we will seek to enter.”

Mr MacGregor also reports increased interest in obstetrics and gynaecology, which is not surprising given child birth involves an awful lot of screaming,

Swooping on the kids’ pain market

In 2019, the company launched a UK-based study called Magpie, which assessed the use of Penthrox for children and adolescents with acute trauma-related pain.

The 110-patient placebo-controlled study aimed to support the use of Penthrox for kids aged as young as six, compared with the current cut-off of 18 years.

The company warbled that the study met its aim of showing that the device was just as safe and efficacious for kids as adults; and submitted an approval application to European authorities on August 14 with an answer expected by August 2025.

Mr MacGregor says the Magpie results should increase the use of Penthrox by UK ambulance trusts, many of which are reluctant to adopt it while use is restricted to adults.

Publication of the results in a peer-reviewed journal is “close at hand”.

European tune-up

In Europe, the company’s biggest non-Australian market, the company has adopted a “capital light” operating model and scaled down promotional activity.

But management is happy with the performance of Gaelen, its UK and Irish distributor. In July, the company expanded the eight-year-old-arrangement. The company is in discussions with potential distributors in France and Switzerland.

Meanwhile, China is not Europe but we should mention that the company discontinued Penthrox trials in the Middle Kingdom in January 2023.

US misses ….

In April 2024, the company said its long quest for US regulatory approval for Penthrox had been “paused”, in favor of focusing on its operations elsewhere.

For years, the company has sought US approval, but has been burdened by history: methoxyflurane was used as an anaesthetic in the US, but not an especially good one and the agency withdrew approval for its use as a numbing agent. The company says the anaesthetic had 20 times the dose of the Penthrox’s device, with a different patient population.

This left Medical Developments the last man standing - Steven Bradbury-like - as the only methoxyflurane developer by the end of the 1980s.

In 2018, the FDA slapped a 'clinical hold' on the proposed trial program on undisclosed concerns, but lifted it in March 2022. The company's investigational new drug application – a precursor for carrying out a supportive trial - remains open and last October the company had a positive meeting with the regulator to hone the costs and timelines.

Mr MacGregor says there's still an "attractive investment opportunity" for Penthrox in the US.

The decision to halt development of Selfie was related to the US pause, because the US is considered the most appropriate market for the device (given the greater prospect of reimbursement for Selfie's higher cost of goods relative to Penthrox).

… and hits

While US Penthrox approval is on ice, the stars-and-stripes nation has proved highly receptive to its respiratory products, with revenues there increasing 37 percent last year.

These sales also have increased at a three-year compound annual growth of 30 percent.

Mr MacGregor says there's still a lot of upside in the US, given the spacers are still not stocked by the two largest chemists, Walgreens and CVS.

The company also is targeting hospital networks and group purchasing organizations.

Dr Boreham's diagnosis:

One would have thought that given the raging opioid usage problem in the US, the company would have a good case for gaining Penthrox approval there. But as we know, the FDA can move in mysterious ways.

In the meantime, Mr MacGregor expects the overall "positive momentum to continue in the current year".

Five years ago, we pondered whether Medical Developments - ASX code MVP - could become the ASX-listed biotech sector's GOAT. (That was an incredibly witty reference to the sporting terms Most Valuable Player and Greatest of All Time.)

The financial results show that Medical Developments' tune-up is starting to show reward. While GOAT status remains elusive, the company is playing well enough not to be benched, although investors sitting on steep losses may demand the company to lift its game further.

Disclosure: Dr Boreham is not a qualified medical practitioner, does not possess a doctorate of any sort and never troubles the scorers in backyard footy.

VICTORIA GOVERNMENT, LA TROBE UNIVERSITY

The Victoria Government says it has invested $10 million to help La Trobe University build its Australian Centre for Artificial Intelligence in Medical Innovation, or Acami.
The Government said Centre researchers would use artificial intelligence to advance medical research capabilities and collaborate with other institutions.
A media release from the Victoria Treasurer and Minister for Industrial Relations and Economic Growth Tim Pallas said the Centre would be the first in Australia to use Nvidia's supercomputer DGXH200 to conduct research and development.
The Government said the centre would study a biosensor that enabled cancer-cell detection as well as an artificial intelligence-driven color map that tracked the spread of breast cancer to predict how cells would respond to treatment.
La Trobe vice-chancellor Prof Theo Farrell said Acami would be within the university's Research and Innovation Precinct "a core component of the University City of the Future".

ONCOSIL MEDICAL

Oncosil says it completed the 30th pancreatic cancer treatment using its brachytherapy device, on September 11, 2024 at Madrid's Hospital HM Sanchinarro.
Oncosil said 12 sites in Spain were currently using the Oncosil device, while another four sites had completed training and were ready to begin treatment.
Oncosil chief executive officer Nigel Lange said "reaching 30 treatments in Spain is a remarkable accomplishment and a testament to the growing recognition of Oncosil as an innovative treatment for pancreatic cancer".
"Spain has become one of our key markets in Europe, and we are proud to see such strong engagement from leading hospitals and clinics across the country," Mr Lange said.
Oncosil was up 0.05 cents or four percent to 1.3 cents with 18.5 million shares traded.

KAZIA THERAPEUTICS QUEENSLAND INSTITUTE FOR MEDICAL RESEARCH

Kazia says it has licenced PI3K inhibitor-related intellectual property from Brisbane's Queensland Institute of Medical Research Berghofer (QIMR).
In 2022, Kazia said it had a pre-clinical collaboration with the Queensland Institute of Medical Research to explore the use of paxalisib in solid tumors (BD: Dec 15, 2022).
At the time, Kazia said paxalisib was a PI3K inhibitor, and PI3K inhibitors had shown anti-cancer effects, with five therapies approved by the US Food and Drug Administration.
Today, Kazia said that it acquired the licence for an "upfront licence fee" and development milestones related to phase I, II and III trials and first product approval.
The company said the royalty-bearing, licence was to "certain intellectual property for the development of any drugs or product candidates within the PI3K inhibitor class in combination with immunotherapy or PARP (poly ADP-ribose polymerase) inhibitors".
Kazia said its collaboration with QIMR had led to patents that included the use of paxalisib as an "immune modulator" for treating breast cancer, and that QIMR's research team had shown in pre-clinical studies that paxalisib with Keytruda resulted in "highly consistent and statistically significant signals of efficacy including overall tumor volume, metastases, and inflammatory markers", and potentially reinvigorated immune cells within tumors.
Kazia chief executive officer Dr John Friend said the company was "very pleased" to have the potential intellectual property rights for PI3K inhibitors, which was a step to exploring cancer treatments beyond the brain, including solid tumors such as breast cancer.
On the Nasdaq, Kazia fell 1.86 US cents or 5.09 percent to 34.65 US cents (51.5 Australian cents) with 21.6 million shares traded.

NANOSONICS

Nanosonics has told the ASX it believes its results for the year to June 30, 2024 were within the range of its published guidance, of $164 million to $171 million.
In August, Nanosonics said revenue for the year to June 30, 2024 was up 2.4 percent to $170,012,000 (BD: Aug 27, 2024).
The ASX said the company's share price increased 24.1 percent on August 27, 2024 immediately prior to the release of its results, from $2.70 to an intraday high of $3.35.
Nanosonics fell seven cents or two percent to $3.47 with 977,680 shares traded.

BIOXYNE

The ASX says it has suspended Bioxyne for failing to provide specific information related to its 'two-year manufacture and supply agreement' of marijuana gummies.
The ASX said that Bioxyne was suspended under Listing Rule 17.3.1.
The ASX said that on September 12, 2024, it required Bioxyne "to provide specified information for release to the market in relation to 'a 2-year manufacture and supply agreement' as announced in [Bioxyne's] announcement 'BXN Manufactures First Pharmaceutical Cannabis Gummies' on August 21, 2024".
The ASX said that Bioxyne had "failed to comply with that requirement … [and would be] suspended from quotation immediately under Listing Rule 17.3.1, until such time as ASX is satisfied with [Bioxyne's] compliance with the Listing Rules and that it is otherwise appropriate for [its] securities to be reinstated to quotation".
In August, Bioxyne said subsidiary Breathe Life Sciences had an agreement with an unnamed "alternative medicine clinic" to supply up-to $28 million worth of marijuana gummies (BD: Aug 21, 2024).
Bioxyne was unchanged at 1.3 cents with 4.3 million shares traded.

PACIFIC EDGE

Pacific Edge says it will consult the American Urological Association, while the Centers for Medicare and Medicaid Services (CMS) might extend local coverage determination.
Last year, Pacific Edge said its Medicare administrative contractor Novitas had warned its Cxbladder tests would cease to be covered by Medicare because it did not consider the tests "medically reasonable and necessary"; and later, said Novitas had delayed implementing the changes with submissions on the draft local coverage determination (LCD) for non-coverage to take up-to a year (BD: Jul 6, 28; Sep 11, 2023).
Today, the company said the CMS indicated it had agreed to extend deliberations on the draft local coverage determination to ensure Novitas had "time to respond to a large volume of detailed comments" and because the determination raised "unique issues", with Novitas confirming it had been granted an extension to finalize the draft.
Pacific Edge said it would review the American Urological Association micro-haematuria guideline, which was potentially significant as guidelines played a "substantial role in medical reimbursement policy" and had a "significant influence" on urologists.
The company said chief medical officer Dr Tamer Aboushwareb was contributing to the association's consultation on the micro-haematuria guideline, under confidentiality.
Pacific Edge said that despite the deliberations it continued to receive reimbursement and it did not expect matters to be resolved before of its annual meeting on September 24, 2024, contrary to its expectations in July, but it remained possible that the CMS could make a pricing decision for its Cxbladder detect test before the meeting.
Pacific Edge was untraded at 8.1 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says shareholders will vote on a conditional spill resolution and to increase its non-executive director remuneration 71.2 percent to $1,200,000 at its annual meeting.
In 2023, Clinuvel said its annual general meeting voted up to 39.74 percent against the adoption of its remuneration report and 41.42 percent against its performance rights plan, with the votes against the remuneration report amounting to 16.3 percent of the shares on issue, sufficient to requisition extraordinary general meetings (BD: Oct 31, 2023).
Today, the company said the spill resolution would only be put if it received a 'second strike' on its remuneration report with 25 percent or more of votes cast against the report.
Clinuvel said a spill resolution required it to hold a shareholder meeting within 90 days, with non-executive directors Prof Jeffrey Rosenfeld, Dr Karen Agersborg and Susan Smith to automatically cease to hold office pending their re-election by shareholders.
Clinuvel said the increase of its non-executive director remuneration pool would allow it to "attract, appoint and retain additional [non-executive directors] of the highest international calibre to join the board" as well as provide "further flexibility, if required, to allow room to increase annual [non-executive directors]".
The company said its shareholders would vote to elect non-executive directors Matthew Pringle, Mr Guy van Dievoet, Dr Pearl Grimes, Ms Smith and Dr Agersborg, as well as adopt its remuneration report.
The meeting will be held at Tower 2, Level 5, 727 Collins Street, Melbourne on October 16, 2024 at 10am (AEDT).
Clinuvel was up 47 cents or 3.1 percent to $15.59 with 160,477 shares traded.

LBT INNOVATIONS

Adelaide's Jaytayco director Richard Green says his 266,117,750 share-holding in LBT has been diluted from 17.12% percent to 15.45 percent.
Mr Green said that with Jatayco Nominees and JTCA Finance Pty Ltd, between July 10, 2024 and September 11, 2024 he was "diluted through the successive issue of shares".
In the substantial shareholder notice, Jaytayco director Richard Green said that JTCA had a relevant interest in the securities by having voting power of above 20 percent in LBT director Dan Hill's Viking BCM Pty Ltd.
Mr Green said he had a relevant interest in the securities by having control over JTCA and Jatayco and Jatayco had a relevant interest in the securities by having control over JTCA and voting power above 20 percent in JTCA.
Mr Green said he had a relevant interest in the securities by having control over Jatayco and by having voting power of above 20 percent in Jatayco.
In July, Mr Green said that JTCA and Jatayco bought and sold shares between January 12 and June 27, 2024 selling 41,700,000 shares for $1,199, 645 or 2.88 cents and exercising options over 70,888,396 shares for $354,442 or 0.5 cents a share.
LBT was unchanged at 1.3 cents.

LUMOS DIAGNOSTICS

Sydney's Ryder Capital says it has increased its substantial shareholding in Lumos from 25,601,613 shares (5.32%) to 40,376,502 shares (7.17%).
Ryder said that it bought and sold shares between November 13, 2023 and September 9, 2024, buying 14,724,889 shares for $559,546 or 3.8 cents a share on September 9, 2024 in the institutional entitlement offer (BD: Sep 4, 6, 2024).
Lumos fell 0.2 cents or 5.6 percent to 3.4 cents with 3.35 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says it has appointed Jeff Pruett as head of finance, from September 19, 2024, with chief operating officer and chief financial officer Brian Lane to resign.

Visioneering Technologies said Mr Pruett had more than 40 years of experience in finance, including at KPMG and as chief financial officer and treasurer of Techpro Power Group, and had held a similar role at Industrial Inspection and Analysis,

The company said Mr Pruett held a Bachelor of Business Administration from Atlanta's Georgia State University.

Visioneering said Mr Lane would depart after a transition period on November 15, 2024.

Visioneering fell half a cent or 4.35 percent to 11 cents.