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Health Check: The endo-metriosis? Proteomics is on the case

By TIM BOREHAM

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- Having produced more positive diagnostics results, Proteomics plans to launch its Promarker Endo device locally this year
- Immutep posts more positive trial results, this time for soft tissue sarcoma
- Broker values EBR Systems share price at more than double current worth after capital raising

Proteomics International Laboratories (ASX:PIQ) has come up with more positive data to support its endometriosis diagnosis test Promarker Endo, presented – aptly – to the World Congress on Endometriosis, held in Sydney over the weekend.

Affecting one in nine women and girls, endometriosis is a common and painful disease that occurs when tissue similar to the lining of the uterus grows in other parts of the body.

The condition takes on average seven years to diagnose, owing to the need for an invasive laparoscopy followed by histopathology (a camera is inserted into the pelvis through a small cut in the abdominal wall).

The condition is often misdiagnosed.

Promarker Endo is a non-invasive alternative, providing a ‘traffic light’ risk score of low, moderate to high.

Derived from analysing 704 plasma samples, the latest results follow those of a 'breakthrough' study of 805 samples in December last year.

The latest results showed an 83-98% ability to detect the disease and a 95% ability to rule it out.

The company says the results shows that Promarker Endo "demonstrates high diagnostic accuracy across all stages of endometriosis using a single universal test."

The company plans to launch Promarker Endo locally, in the September quarter.

Immutep reports more promising cancer trial results

When it comes to its lead compound dubbed 'efti', immuno-oncology drug developer **Immutep (ASX:IMM)** can't be accused of depriving investors of news flow.

Immutep shares surged up to 11% after the company reported "remarkable" patient response rates in a German lung cancer trial.

Today, the company said a phase II soft tissue sarcoma trial hit its primary endpoint, when combining efti with radiotherapy and the standard of care checkpoint inhibitor, Keytruda.

A rare cancer, soft tissue sarcoma starts in the soft tissues of the body, including muscle, fat, nerves, blood vessels, and tendons.

The investigator-led trial exceeded the study's prespecified median of 35% tumour hyalinisation/fibrosis, versus 15% for historical data from radiotherapy alone in patients with resectable (operable) soft tissue sarcoma.

Tumour hyalinisation/fibrosis is an early surrogate endpoint at the time of surgical resection that has been associated with improved overall survival and recurrence-free survival.

Hyalinisation is a process where normal tissue degenerates into a translucent material called hyaline.

So, while hyalinsation/fibrosis seems like a 'bad' thing, the presence of it leads to a heightened anti-cancer response.

Enrolling 40 patients in January this year, the investigator-led trial was carried out at Warsaw's Maria Skłodowska-Curie National Research Institute of Oncology.

Immutep is also trialling efti, a so-called Lag-3 protein, for other solid tumours including non-small cell lung cancer, head and neck squamous cell carcinoma and metastatic breast cancer.

EBR shares find their groove

Fresh from **EBR Systems' (ASX:EBR)** $56 million capital raising last week, broker Canaccord values the company's stock at $2.50 per share, more than double their current worth.

By way of a placement, EBR's whip-'round was carried out to fund the US commercialisation of its Wise left-ventricle pacemaker, which the US Food & Drug Administration (FDA) approved in mid-April.

Now comes the equally hard part of convincing surgeons and obtaining reimbursement.

On the latter, Canaccord says EBR is on track to obtain full reimbursement by October 1, for both inpatients and outpatients.

The firm believes some surgeons and hospitals won't wait until then, with the first procedures likely in early August.

"Recent clinician discussions have suggested US hospitals are willing to absorb the cost of Wise pre reimbursement, for patients with a lack of alternative solutions."

In other words: "if you can't pay, don't worry – we will spot you".

While the initial implants are likely to amount to only a handful, they will show the "excitement about Wise among clinicians and patients".

Announced last Thursday, the placement was executed at $1 a share, a circa 18% discount on the frozen price of $1.215.

The stock initially was sold down to $1.06 but is now trading above the pre-placement price.

The shares were sold off sharply post FDA approval, partly reflecting expectations of a capital raise.

EBR has US$84 million in the bank, but Canaccord's valuation assumes the issuance of a further 105 million shares in a follow-on raising, in 2025-26 or 2026-27.

Medical devices 'safe haven'

Canaccord notes that medical device makers generally have proved a haven in the US market turmoil, outperforming both the healthcare index and the S&P 500 index.

US-listed device makers have gained 7.7% since the start of the year, compared with a 1.4% gain for the S&P 500 and a 3.3% decline for the proxy index, the Ishares US medical device ETF.

ASX device makers have enjoyed a purple patch, with the FDA approving **Orthocell's (ASX:OCC)** Remplir nerve regeneration device in early April.

In March the agency green-lit **Nanosonics' (ASX:NAN)** next-gen medical probe steriliser, Coris and **Artrya's (ASX:AYA)** AI-enabled coronary plaque detection tool.

Medical devices don't tend to offer the same upside as an approved drug, but they are far less risky proposition.

While-no one quite knows what's going on in the mind of Donald Trump, they are not in the firing line in the same way as overseas (notably European) drug makers.

Rhythm nails it with 'poo test' alternative

There's more on the diagnostics front, with **Rhythm Biosciences (ASX:RHY)** completing testing the second stage of testing of Colostat, its blood-based test for bowel cancer.

Using banked patient samples, the second-generation (beta) kit generated around 23,000 data points "to evaluate a variety of variables including inter and intraplate precision, interference and detection limits".

More than 96% of the total tests "comfortably met the performance targets for their operational use."

The remaining 4% will be "compensated for" in the final, manufactured product.

In short, the test meets the "performance required to meet or exceed the proposed clinical use as a triage test for patients symptomatic for bowel disease".

The next step involves Rhythm's partner Quansys producing pilot kits, followed by final testing with independent clinical samples.

"Following completion of the above, Rhythm will be able to make Colostat commercially available through Rhythm's commercial laboratory."

This would be by way of National Association of Testing Authorities verification, or through partner laboratories using their own accreditation.

Ultimately, the assay aims to replace the current 'poo test', which many users find cumbersome, abhorrent for cultural reasons or simply unattractive.