Biotech Daily

Friday October 23, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PROTEOMICS UP 8%; PATRYS DOWN 11%**

*** DR BOREHAM'S CRUCIBLE: RHYTHM BIOSCIENCES**

*** KAZIA $2.8m RETAIL RIGHTS APPLICATIONS, RAISE $8.8m; TOTAL $25.2m**

*** PROTEOMICS 'HEAVILY OVER-SUBSCRIBED' PLACEMENT RAISES $6m**

*** BIOSCEPTRE, CMRI WORK ON CAR-T FOR MULTIPLE CANCERS**

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*** PATRYS PLEADS SCHULTZ TO ASX 26% PRICE QUERY**

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*** PRO MEDICUS 100% DIRECTOR FEE POOL HIKE AGM**

*** ALTHEA: 5.5m M-D JOSHUA FEGAN PERFORMANCE RIGHTS AGM**

*** BAKER BROTHERS INCREASES, DILUTED TO 10% OF OPTHEA**

*** ARIX REDUCES TO 9% OF PHARMAXIS**

*** POKIES BRUCE MATHIESON REDUCES TO 10% OF RESPIRI**

MARKET REPORT

The Australian stock market fell 0.11 percent on Friday October 23, 2020, with the ASX200 down 6.8 points to 6,167.0 points. Nine of the Biotech Daily Top 40 stocks were up, 24 fell, six traded unchanged and one was untraded.

Proteomics was the best, up 4.5 cents or 8.2 percent to 59.5 cents, with 300,063 shares traded. Immutep improved four percent; Compumedics and Polynovo rose more than two percent; Neuren, Nova and Resmed were up more than one percent; with Avita, Cochlear, Cyclopharm and Cynata up by less than one percent.

Yesterday's 17.4 percent best, Patrys, led the falls, down 0.3 cents or 11.1 percent to 2.4 cents, with 19.1 million shares traded. Osprey lost 7.7 percent; Pharmaxis fell 6.4 percent; LBT and Telix fell four percent or more; Amplia, Genetic Signatures and Prescient were down more than three percent; Alterity, Medical Developments and Uscom shed more than two percent; Dimerix, Impedimed, Imugene, Kazia, Nanosonics, Next Science, Opthea, Orthocell, Pro Medicus, and Volpara were down one percent or more; with Clinuvel, CSL, Mesoblast and Paradigm down by less than one percent.

DR BOREHAM'S CRUCIBLE: RHYTHM BIOSCIENCES

By TIM BOREHAM

ASX code: RHY

Share price: 21 cents; **Shares on issue:** 201,495,811; **Market cap:** $42.3 million

Chief executive officer: Glenn Gilbert

Board: Otto Buttula (chair), Dr Trevor Lockett, Lou Panaccio, David White, Eduardo Vom

Financials (year to June 30 2020): revenue nil, cash burn $4.02 million, cash of $1.79 million - ahead of $6 million capital raising post balance date

Major shareholders: Otto Buttula 13.6%, Michelle Wing (Ferndale and Northern Star) 9.49%, Loumea Investment 5.93%.

A few 'Karens' aside, Australians are largely willing to take the basic steps to avoid the coronavirus - but they are remarkably dismissive about the risks of developing the country's second most prevalent cancer.

Citizens of advancing age would be familiar with the National Bowel Screening Program, which sends out the free Faecal Immunochemical Test - FIT, or the 'poo test' - to 50 to 74-year olds.

Only about 40 percent of recipients bother to execute and return the test, which is yucky to carry out and downright fiddly, while the sample is captured. Some recipients decline for cultural or personal reasons - and fair enough.

But get this! Of the minority who do send the sample back courtesy of Australia Post, only 68 percent bother to visit their GP for a referral for a colonoscopy (the gold standard detection method).

Not FIT for purpose?

Faecal aversion aside, a key limitation of the FIT test is it only detects blood in the stool, rather than more definitive bowel cancer biomarkers. Rhythm is working on a blood-based test as a cheaper, more reliable and more palatable alternative to the FIT test.

According to Rhythm chief Glenn Gilbert, 90 percent of bowel cancers are treatable if detected early enough. "It's a 'good' cancer to get if you catch it early because it's an easier fix, versus the alternatives," he says.

Rhythm's Colostat test could be done during a routine doctor check-up for a patient of any age, from the same blood sample used for standard assays such as cholesterol or blood sugar tests. (While the 50 to 74-year olds are most vulnerable, bowel cancer is also the most common cancer for 25 to 29-year olds).

“Some say ‘she’ll be right, I could just have haemorrhoids or an irritable bowel, so I won’t get checked’,” Mr Gilbert says. “But if I’m your doctor and I’m talking to you anyway about cutting down on cheese because you have returned a high cholesterol test, I can say to you ‘you might not be dying, but why not get a colonoscopy just in case?’.”

Colostat could also be used as a triage tool, to prioritize patients with a positive stool test for a follow-up colonoscopy (bearing in mind limited hospital resources).

Moving to the Rhythm

Colostat is based on intellectual property developed by the venerable Commonwealth Scientific and Industrial Research Organisation (CSIRO), which seems to be behind 99 percent of the nation’s technical innovations.

The CSIRO toyed around with the know-how for 13 years before hiving off the tech to Rhythm, which listed on the ASX on December 7, 2017 after raising $9 million at 20 cents apiece. In November 2018, CEO and 35-year CSIRO veteran Dr Trevor Lockett was “transitioned” to the role of technical director in favor of Mr Gilbert, then the company’s chief operating officer.

Mr Gilbert has a sales and marketing background, having worked in senior roles at Medical Developments and CSL Biotherapies (now Seqirus).

In a further management shuffle, financial services entrepreneur Otto Buttula became chair in November 2019, replacing Shane Tanner.

Mr Buttula then ran a corporate review which saw the company increase staff, especially in the research and development department. The revamp also saw another shareholder, Eduardo Vom join the board (in June this year).

Mr Vom co-founded the local technology development and commercialization outfit Planet Innovation, which is almost as well known as the CSIRO in biotech circles.

The boring but important bit

While Rhythm still has a way to go, the company is on the cusp of being able to send the test specifications to a third-party contract manufacturer.

For the last few years, Rhythm has been doing the boring but important stuff of identifying the biomarkers and antibodies at the core of the test. The company has technically validated the final two of five biomarkers that underpin the core intellectual property. This is a key milestone in terms of keeping ahead of putative rivals.

The company initially strived for 10 biomarkers, but Mr Gilbert says management decided it was “inefficient” to strive for such precision when four or five would suffice.

Rhythm has also own won key patent and trade mark approvals and reaffirmed a quality certification called ISO 13485 (nothing to do with ‘iso’ quarantine).

“The development program has come along in leaps and bounds,” Mr Gilbert says. “I’m trying to be calm but we are really excited about how things are progressing.”

Trial, interrupted

Using commercially sourced individual biomarker tests on limited patient samples, the company has shown a superior performance, relative to the FIT samples.

Overall, the earlier studies showed that Colostat had a sensitivity of 73 percent and specificity of 95 percent. Sensitivity is the ability to correctly identify patients with a disease, while specificity is the ability to identify those without the disease.

The FIT tests averaged a 63 percent sensitivity at a 92 percent specificity.

“We would be wanting to better the accuracy of the FIT tests, and we are confident we will achieve that,” Mr Gilbert says.

The company is now in the midst of a full-blown clinical trial, which aims to enrol around 1,000 patients but has been interrupted by the pandemic which caused non-urgent colonoscopies to cease.

The trial will test Colostat’s efficacy relative to a colonoscopy in detecting colorectal cancers and advanced adenomas (benign tumors). The study will also involve “related comparisons” to the FIT tests.

Based at Adelaide’s Lyell McEwen Hospital, the trial was expanded to three Melbourne sites (Monash Health, Royal Melbourne Hospital and The Alfred).

But to avoid the lockdown delays in the Covid capital, the company has signed up two additional sites: Newcastle’s John Hunter Hospital and the University of Wollongong’s Illawarra Health and Medical Research Institute.

The trial involves participants taking the poo test and the Colostat blood test and then undergoing a colonoscopy as planned. The patient samples are augmented with blinded samples from patients known to have bowel cancer.

The Victorian poo tests are being collected and the Colostat samples are being safely stored in the freezer.

The route to approval

Mr Gilbert says that “before the world ended” with the pandemic, Rhythm eyed an approval application to the Therapeutic Goods Administration by late 2021.

Now it can’t be definitive on the timeline, which hinged on positive trial results. That said, the company is keen to rev-up recruitment.

Another option is to seek European (CE mark) approval, independently of the trial outcome. “This won’t necessarily mean sales, because you need the clinical adoption, but it will help with further collaborations and partnerships,” Mr Gilbert says.

In the meantime, management is confident the trial will validate the positive vibes from the initial testing.

“We will effectively know the result before we ask the question, based on the cancerous and healthy blood sample testing,” Mr Gilbert says.

As they say I politics: never launch an inquiry unless you know the outcome.

Staying one step ahead of rivals

Rhythm is by no means the only developer of a blood-based cancer test, but Mr Gilbert contends that there is no low-cost blood test for bowel cancer anywhere.

Currently, most non-poo tests are molecular or genetic based - and they’re not cheap. Nor are they designed for the mass screening market, such as Rhythm’s.

Clinical Genomics (formerly of Sydney and now of New Jersey) has a blood test called Colvera for bowel cancer recurrence, which accounts for 20 to 30 per cent of all cases. Intriguingly, CSIRO helped founder Dr Larry LaPointe to develop that test.

The Belgian based, US-listed Volition Rx is developing Nu Q, a blood test for bowel and lung cancers. But as well as being a more complex molecular test, it is also dearer.

Finances and performance

Rhythm’s revenue proposition is based on both undercutting the cost of the existing tests and reducing the incidence of bowel cancer hospitalizations through more effective screening to the global mass market.

The company estimates a FIT test could cost the National Bowel Screening Program $130 to $150 each, while bowel cancer can cost the health system $60,000 to $100,000 per patient.

The Colostat test is expected to be reimbursed for approximately $30 to $50 each. This is similar to the prostate specific antigen (PSA) test, despite having four more biomarkers.

With first revenue not expected until sometime in late 2022 or early 2023, Rhythm has replenished its coffers with a $6 million raising, via a $2.4 million placement and $3.6 million three-for five rights issue.

Mr Buttula kindly chipped in $1.5 million of the placement which, as with the rights issue, was struck at six cents a share.

The company also banked a $1.1 million research and development tax incentive.

So far this calendar year Rhythm shares have plumbed a record low of four cents (March 27) and a high of 31 cents (October 6) - not far off the zenith of 36.5 cents on the December 27, 2017 listing date.

Mr Gilbert says he was getting plenty of “unofficial advice” - a.k.a. abuse - from shareholders when shares wallowed.

“Now they are all ringing and saying they want more shares,” he says.

Indeed - winners are grinners.

Dr Boreham’s diagnosis:

It doesn’t take a Nobel Prize winner in medicine to appreciate the benefit of an easy and widely available blood-based test for bowel cancer.

The company estimates the colorectal cancer screening sector is worth potentially $38 billion, across key target geographies of US, Europe, China, Japan and Australia.

Of the 769 million 50 to 74 year olds in these countries, circa 530 million (69 percent) remain unscreened.

Mr Gilbert says Rhythm’s mass market test is on-trend, in that blood-based tests are now standard for detecting cervical cancer (an evolution from the ‘scrape’ test) and prostate cancer.

If approved and commercialized, Colostat should appeal to governments by increasing screening coverage at a lower cost.

And if the incidence of bowel cancer is reduced, private health insurers might be willing to adopt Colostat and fully fund colonoscopies (as is the case in the US).

According to Mr Gilbert, some investors believe the company has been “over enthusiastic” about the timeline to commercial development.

That’s a common problem. But as with one’s favorite sports team, we would rather an excess of zeal and ambition than a dearth of one.

“Whether it’s this year, next year or the year after, this is a massive opportunity for a small Australian company to take over the world,” Mr Gilbert says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. What he lacks in formal qualifications he makes up for in over enthusiasm, but will settle for domination of Goat Island* rather than the world.

[***** Editor’s note: it’s in Sydney Harbour – google it]

KAZIA THERAPEUTICS

Kazia says its fully underwritten, one-for-three, non-renounceable retail rights offer at 80 cents a share has raised $8.8 million, taking the total raised to $25.2 million.
Earlier this month, Kazia said it had raised $16.4 million in the institutional portion of its rights offer to fund its trial of paxalisib, or GDC-0084, for glioblastoma GBM Agile trial and for working capital (BD: Oct 2, 2020).
Today, the company said $2.8 million worth of shares in the retail rights offer were subscribed by shareholders, with the remaining $6 million worth of shares to be placed with the underwriter Bell Potter Securities.
Kazia fell 1.5 cents or 1.8 percent to 80 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says its “heavily oversubscribed” placement at 48 cents a share has received firm commitments to raise $6 million.
Proteomics said the share price was a 14.9 percent discount to the 20-day volume weighted average price.
The company said it would be able to place the over-subscribed shares under its 15 percent additional placement capacity.
Proteomics said the funds would be used for the manufacture and up-scaling of its Promarkerd predictive test for kidney disease, marketing, regulatory approval, development and commercialization of its Promarkerd pipeline, and working capital.
The company said that it would issue 1,100,000 options, exercisable at 75 cents each within two years, to lead manager Euroz Hartleys Securities and corporate advisor Candour Advisory.
Proteomics was up 4.5 cents or 8.2 percent to 59.5 cents.

BIOSCEPTRE (AUSTRALIA) PTY LTD
CHILDREN’S MEDICAL RESEARCH INSTITUTE

Biosceptre says it will establish a Car-T cell immunotherapy research program with the University of Sydney and Children’s Medical Research Institute at Westmead.
A subsidiary of the Cambridge, UK-based Biosceptre said it was developing chimeric antigen receptor-T-cells (Car-T) anti-cancer therapies, including targeted therapeutics and immune-oncology products that targeted most types of cancers, “with the goal of developing novel treatments for a wide range of malignancies”.
The company said that paediatric oncologist and Car-T innovator Dr Patrick Schlegel would lead the research team.
Biosceptre said that Dr Schlegel “pioneered the use of the Car-T with a novel targeting system that has the potential to treat a broad spectrum of cancers” and would further develop this technology in Australia and he would be appointed to Children’s Medical Research Institute Cancer Centre for Children in The Children’s Hospital at Westmead and as a professor of the University of Sydney.
The company said that its laboratory would be based at the Institute at Westmead.
Biosceptre chief executive officer Gavin Currie said that “the cluster of leading cancer research programs and facilities were a major attraction for us”.
“When coupled with a state-of-the-art children’s hospital and the country’s largest paediatric hospital network, there’s terrific potential for further innovation in research and collaboration,” Mr Currie said.
Biosceptre is a private company.

IMMUTEP

Immutep says it has an agreement with the Czech Republic's University Hospital Pilsen for an up-to 110 patient phase II trial of IMP321 for Covid-19.

Immutep said the investigator-initiated, placebo controlled, randomized, double-blinded trial would investigate whether early administration of IMP321, or eftilagimod alpha, could prevent disease progression in hospitalized adult Covid-19 patients by boosting the patient's immune response and controlling the viral load.

The company said that IMP321 was an antigen-presenting, cell-activator which could help control the viral load in hospitalized patients by boosting CD8 effector T-cells.

Immutep said the trial patients would receive sub-cutaneous injections of 10mg of IMP321 on days one, three and seven following hospitalization, in addition to standard care.

The company said the primary endpoint was the patient's clinical status at day-15.

Immutep chief scientific officer Dr Frederic Triebel said that "the most effective anti-viral therapy for Covid-19 is likely an effective CD8 T-cell that has been empowered by activated dendritic cells and given a licence to kill by these antigen presenting cells".

"This effector CD8 killer T-cell is then able to detect and eliminate epithelial cells which serve as reservoirs where the virus can replicate," Dr Triebel said.

Immutep said it would provide IMP321 to the University at no cost, and the University would fund the trial, led by the University's Prof Martin Matejovic.

Prof Matejovic said that the IMP321 safety profile to date "and its proven efficacy as an [antigen-presenting cell] activator gives us the confidence to initiate a phase II study for our patients as soon as they are hospitalized and before their condition deteriorates".

Immutep said it had necessary approvals from the Czech Republic's State Institute for Drug Control and would begin the recruitment of patients immediately.

The company said recruitment would start with an open-label, safety run-in of six patients, followed by cohort of 26 randomized patients, with successive cohorts being recruited following data monitoring committee recommendations.

Immutep said it expected interim results "to be reported from early 2021".

Immutep was up one cent or four percent to 26 cents with 2.9 million shares traded.

PAINCHEK

Painchek says it had partnered with Perth's Nulsen Group for a six-month trial of its Painchek pain assessment application for patients with complex disabilities.

Painchek said trial would recruit participants from the National Disability Insurance Scheme (NDIS) at five shared residential homes to use the Painchek smartphone application and evaluate the software's ability to improve the detection of pain in individuals with complex disabilities, particularly when a change of behavior was detected or an individual was visibly distressed.

The company said Painchek would be used by nurses, allied health professionals, management and support workers across the five Nulsen Group homes.

Painchek said Nulsen would pay a standard licencing fee for use of the Painchek application, but it did not expect the revenue to be material.

Nulsen chief executive officer Gordon Trewern said that "those with disabilities who are unable to express their pain are the most vulnerable in our society for the mis-identification or non-identification of pain".

"Painchek allows us to trial a new way that could help the disability support sector to further improve their services, and outcomes for these most vulnerable people," Mr Trewern said.

Painchek was unchanged at 9.7 cents with two million shares traded.

PYC THERAPEUTICS (FORMERLY PHYLOGICA)

PYC says the US Food and Drug Administration has requested further data in response to the company's orphan drug designation request for VP-001 for retinitis pigmentosa.
PYC said the FDA requested data from the use of VP-001 in an animal model of retinitis pigmentosa, or retinal dystrophy due to pre-mRNA processing factor-31 (PRPF31) gene mutations, or in human patients with the disease, and the company said it would consider whether there was an appropriate animal model to provide the data, or whether to defer the provision of further data until the first in-human efficacy read-outs were available.
PYC was unchanged at 17.5 cents with 3.7 million shares traded.

PATRYS

Patrys has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the share price rose 26.1 percent from 2.3 cents on October 21 to a high of 2.9 cents on October 22, 2020 and noted a "significant increase" in the trading volume.
Patrys fell 0.3 cents or 11.1 percent to 2.4 cents with 19.1 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 58.8 percent from 1.7 cents on October 15 to 2.7 cents on October 22, and noted a "significant increase" in the trading volume.
Neurotech said it was "pleased with its recent progress" including studies of its marijuana strains, and the appointment of Brian Leedman as chair (BD: Sep 23, Oct 19, 2020).
Neurotech was unchanged at 2.6 cents with 10.8 million shares traded.

PRO MEDICUS

Pro Medicus says its annual general meeting will vote to increase its director remuneration pool by 100 percent from $500,000 to $1,000,000 a year.
Pro Medicus said shareholders would vote to adopt the remuneration report and elect directors Deena Shiff, Anthony Hall and Dr Leigh Farrell, and the virtual meeting will be held on November 25, 2020 at 10am (AEDT) at: https://agmlive.link/agm/PME20.
Pro Medicus fell 49 cents or 1.4 percent to $33.63 with 315,666 shares traded.

ALTHEA GROUP HOLDINGS

Althea says investors will vote to issue managing-director Joshua Fegan with up to 5,490,625 long-term incentive performance rights, exercisable at no cost.
Althea said it proposed to issue Mr Fegan with up to 390,625 free performance rights, based on the absolute total shareholder return and 5,100,000 free performance rights based on achieving company revenue of $30,000,000 in any 12-month period between December 1, 2020 and November 30, 2022, expiring at the discretion of the board.
The company said shareholders would vote to adopt the remuneration report, approve the 10 percent placement capacity and re-elect director Penelope Dobson
The virtual meeting will be held on November 26, 2020 at 4pm (AEDT) at: https://us02web.zoom.us/meeting/register/tZwpfuytqz8rG9cxqdiViTnrbpSqN6lDA7UI.
Althea was up one cent or 2.1 percent to 48 cents.

OPTHEA

Baker Brothers Advisors LP says its substantial holding in Opthea has increased but been diluted from 26,526,759 shares (10.60%) to 34,020,359 shares (9.86%).
The New York-based Baker Brothers said that on October 20, 2020 it acquired 7,493,600 shares for $US1.6875 ($A2.3693) a share.
Opthea fell four cents or 1.7 percent to $2.34 with 790,858 shares traded.

PHARMAXIS

Arix Bioscience Holdings says it has reduced its substantial shareholding in Pharmaxis from 39,421,131 shares (9.9%) to 35,205,833 shares (8.9%).
Earlier this week, the London-based Arix said it had reduced its holding in Pharmaxis from 43,693,000 shares (11.1%) to 39,421,131 shares (9.9%) (BD: Oct 19, 2020).
Today, Arix said that between October 19 and 22, 2020 it sold 4,215,298 shares for $389,061 or an average of 9.2 cents a share.
Pharmaxis fell 0.6 cents or 6.4 percent to 8.8 cents with 2.5 million shares traded.

RESPIRI

Investment Holdings and gambling machine operator Bruce Mathieson say they have reduced in Respiri from 72,008,027 shares (11.05%) to 65,541,554 shares (10.05%).
The substantial shareholder notice signed by the Melbourne-based Investment Holdings director and former Respiri chairman Ross Blair-Holt said between October 20 and 22, 2020, Investment Holdings sold 6,466,473 shares for $1,328,390 or 20.5 cents a share.
Respiri fell 1.5 cents or 7.1 percent to 19.5 cents with 1.6 million shares traded.