Biotech Daily

Friday May 10, 2019

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ANTISENSE UP 11%**
- ACTINOGEN; IMMUTEP DOWN 7%

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

*** GENETIC TECHNOLOGIES: 'NEW COLORECTAL, BREAST CANCER TESTS'**

*** ANALYTICA $2.7m 1-FOR-6 RIGHTS ISSUE**

*** SIMAVITA $3m CONVERTIBLE NOTES**

*** NEXT SCIENCE TO RELEASE 2.3m ASX ESCROW SHARES**

*** FIL BELOW 5% IN ACTINOGEN, TAKES LOSS**

MARKET REPORT

The Australian stock market was up 0.25 percent on Friday May 10, 2019, with the ASX200 up 15.6 points to 6,310.9 points.

Twelve of the Biotech Daily Top 40 stocks were up, 20 fell, six traded unchanged and two were untraded. All three Big Caps were up.

Antisense was the best, up 0.5 cents or 10.6 percent to 5.2 cents with 279,391 shares traded.

Genetic Signatures climbed 8.6 percent; Cyclopharm was up 5.65 percent; Impedimed and Patrys improved four percent or more; Prescient rose 2.4 percent; Cochlear, Dimerix, Ellex and Orthocell were up more than one percent; with CSL, Cynata, Opthea, Polynovo and Resmed up by less than one percent.

Actinogen and Immutep led the falls, both down 6.7 percent to 1.4 cents and 2.8 cents, respectively, with 34.2 million shares and 2.6 million shares traded, respectively.

Clinuvel lost 5.7 percent; Medical Developments fell 4.3 percent; Benitec, Osprey, Paradigm, Uscom and Volpara were down more than three percent; Alterity (Prana) and Oncosil shed more than two percent; Compumedics, LBT, Pro Medicus and Proteomics were down more than one percent; with Mesoblast, Nanosonics, Neuren, Starpharma and Telix down by less than one percent.

DR BOREHAM'S CRUCIBLE: RHYTHM BIOSCIENCES

By TIM BOREHAM

ASX code: RHY

Share price: 18 cents; **Shares on issue:** 100,750,000; **Market cap:** $18.1 million

Chief executive officer: Glenn Gilbert

Board: Shane Tanner (chairman), Dr Trevor Lockett (executive technical director), Lou Panaccio, David White

Financials (March quarter): revenue nil, cash burn $738,000, cash of $5,648,000, estimated current quarter outflows $1,375,000

Major shareholders: Michelle Wing (Ferndale and Northern Star) 10.23%, Loumea Investments 9.9%, Merchant Opportunities Fund 8.1%, Kitara Investments 2.6%, Commonwealth Scientific and Industrial Research Organisation (CSIRO) 2.5%.

On reaching the age of 50, Australians can expect a thoughtful gift in the mail from Canberra's health poo-reaucracy: an invitation to provide a stool sample to screen against bowel (colon and rectal) cancer.

Formally known as a faecal immunochemical test, or FIT, the diagnosis is an unwieldy seven-stage process of harpooning the stool in the toilet pan, gently swabbing it, inserting it in the sample vial provided, doing the paperwork (twice) and then sending it back to the laboratory within two days.

Popping the sample in a post box ahead of a stinking hot long weekend is not advisable. Oh, and the procedure has to be repeated for a second sample the next day.

For "personal or cultural" reasons, only a minority of this high-risk target group (that is, older people) avails of the free invitation. That's a pity, because there's a 90 percent chance of successful intervention if these cancers are detected early.

The test, however only detects blood in the stool rather than more definitive bowel cancer biomarkers.

But what if there were a better way?

Deploying know-how devised by the CSIRO, Rhythm is developing a non-invasive blood-based test called Colostat. If successful, the diagnostic could replace both the poo tests and - in many cases - follow-up colonoscopies.

"The CSIRO had the test for 15 years but in typical CSIRO fashion hadn't done anything with it," says Rhythm chairman Shane Tanner.

With ‘only’ four percent of colonoscopies proving positive, hospitals with limited endoscopic facilities need to be careful how they allocate their resources. Thus, the test could also be used a ‘triage’ method to prioritize patients with a positive stool test for a follow-up colonoscopy.

Rhythm’s Colostat is an easier and simpler test than the almost-related company, Clinical Genomics, which has the specialist and more complex Colvera blood test.

(Rhythm founder Dr Trevor Lockett was with CSIRO when it assisted Clinical Genomics founder Dr Larry LaPointe to develop Colvera.)

Dr Lockett says his test is better suited to screening.

The size of the prize

The Colostat test remains unapproved and in development. But if successfully commercialized, Rhythm will be tapping a capacious market. In Western countries, 118 million tests valued at $5.9 billion are done annually.

The US has a similar bowel cancer screening program to Australia, while 14 European Union countries also provide a universal test. Participation rates are 62.6 percent in the US, 46.9 percent in Australia and a niggardly 38.2 percent in Europe.

(Your columnist’s totally unproven theory about the superior US participation rate is if the country’s miserly health system throws you a freebie, you will avail of it).

Rhythm cites the targeted populace of 250 million 50 to 75-year-olds. But with an average of 52 percent not participating, the unscreened market (132 million tests) is worth another $6.6 billion.

A series of six small-sized patient studies carried out by the CSIRO since 2005 shows the precursor test to Colostat was accurate in 73 percent of total diagnoses, compared with 65 percent for FIT tests. At stage one (early) cancer, the comparison was 58 percent versus 53 percent.

A rare case, one could say, of the rhythm method being superior.

In the Rhythm for clinical trials

For the last year or so, the Rhythm story has been a somewhat soporific one of isolating the antibodies and proteins to develop the reagents to identify the relevant biomarkers.

With mission accomplished, the boffins have turned to scale-up manufacturing and “assay optimization”.

Rhythm hopes to include up to 10 biomarkers in the test, but the CSIRO has advised that four would give just as good a result.

“We are trying to come up with something that meets everybody’s needs,” says CEO Glenn Gilbert.

In April, the first patient was recruited for a 1,000-patient clinical trial, to be overseen by principal investigator Prof Rajvinder Singh of Adelaide’s Lyell McEwin Hospital.

The trial involves 1,000 volunteers taking the Colostat test, the poo test and undertaking a colonoscopy. Their reward for the ordeal? A fistful of dollars and the warm feeling that they are advancing medical science.

With the first results expected by the end of 2019, the trial will be used to support a marketing application to European authorities and the Australian regulator, the Therapeutic Goods Administration.

The hospital’s director of gastroenterology, Prof Rajvinder is a global expert on endoscopic imaging and treatment techniques for colorectal cancers.

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

“Surgical interventions for colorectal cancer are much more effective when the cancers are detected at an early stage when they can be removed during a colonoscopy procedure,” Prof Rajvinder says. “There is a real need for inexpensive, minimally invasive screening tests that will attract the public.”

Financials and performance

Rhythm listed on December 7, 2017, having raised $9 million at 20 cents apiece.

With cash of $5.64 million, management expects to have enough in the bank to get to European and TGA regulatory approval stage.

Given the company has been in the boring-but-important stage of reagent development, the shares are at the lower end of the 12-month price range of 13 cents (October 2018) and 34 cents (just after listing).

The Perth based Merchant Opportunities Fund has keenly supported the stock, having boosted its stake from 5.0 percent at listing to 8.1 percent.

The key to Colostat’s success is not necessarily enhanced accuracy, but cost and ease of use (eliminating the ‘faecal fear factor’).

While the obvious market is government, health insurers - including the biggest - Medibank Private and Bupa are keen. “A test at 70 percent efficacy would also be worth $500 million to a Roche or a Merck,” Mr Tanner says.

Mr Tanner says there are lots of blood tests, but they are costly.

“We are hoping to come in at $30 to $40 per test,” he says.

“We believe the poo tests costs about $150 each to administer. So, if we can come in a third of that it’s a big win.”

Dr Boreham’s diagnosis:

Globally, 850,000 people die of bowel cancer each year and it’s the third most prevalent cancer for the world, and the second most common in Western countries, where diets aren’t getting any better.

From a wide-eyed investor perspective, the question is what alternative new tests are in the pipeline - and in this regard Rhythm is not on its Pat Malone.

Rhythm acknowledges Novigenix’s Colox and the Sydney and New Jersey-based Clinical Genomics’ Colvera at the “high cost” molecular testing end (that is, the traditional tests). Clinical Genomics also has its Insure One faecal immunochemical test.

But in the ‘low cost’ protein-based end, the Belgian-based, New York Stock Exchange-listed Volition Rx is developing Nu Q, a blood test for bowel and lung cancers.

The test identifies nucleosomes, which are DNA segments overexpressed in the presence of cancer. Volition is rooting for regulatory approval around 2020, a similar time line to Rhythm.

But as well as being more expensive, the test requires three blood samples rather than one for Colostat.

Given the aim of Colostat is to introduce low cost simplicity as much as more accuracy, maybe there’s room for more than one.

Volition bears a market valuation of $US130 million ($A160 million) compared with Rhythm’s $18.1 million, which implies the latter is a value bet on successful commercialization.

In the meantime, expect a more commercial focus from the board now that most of the boffiney laboratory work has been done.

In November last year, 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 Biotherapeutics (now Seqirus).

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But you don’t need a Ph D to take the poo test – although it could be handy for the paperwork (twice).

GENETIC TECHNOLOGIES

Genetic Technologies says it is preparing to launch cancer risk assessment tests for colorectal cancer and breast cancer.

Genetic Technologies said the polygenic risk tests, Genetype for Colorectal Cancer and Genetype for Breast Cancer, would combine genetic markers called single nucleotide polymorphisms (SNPs) to assess risk in patients' genetic make-up.

The company said its tests were affordable and minimized clinical consultation times by using patient questionnaires.

Genetic Technologies executive chairman Dr Paul Kasian told Biotech Daily that pending agreements with the Phoenix, Arizona-based Translational Genomics Research Institute, it would launch the test in the US by the end of the year.

Dr Kasian said the tests did not require US Food and Drug Administration approval.

Dr Kasian said the company would then focus on China through its partners in the Government of the Hainan Free-Trade Zone and pending approval by the China Food and Drug Administration launch both tests in that country.

Dr Kasian said that, at this stage, the company was not intending to seek European or Australian approvals for the tests.

Dr Kasian said that the Genetype for Breast Cancer would address the 85 percent of women who had non-hereditary breast cancer, as well as the 10 percent of women that with hereditary breast cancer, that the existing BRCA tests did not pick-up.

In its media release, Genetic Technologies said the Genetype for Breast Cancer test was aimed at assessing risk other than BRCA1 and BRCA2 mutations, which significantly increased the risk for breast and other cancers, by assessing other genetic and clinical markers and the breast cancer test would cover 95 percent of women, with the remaining five percent already covered by BRCA1 and BRCA2 tests.

The company said it had improved on its legacy breast cancer test, Brevagenplus, by incorporating five-year and lifetime risk assessments.

Genetic Technologies said its first risk test for colorectal cancer would analyze DNA for more than 40 single nucleotide polymorphisms (SNPs) that had been clinically associated with colorectal cancer, providing a polygenic risk score.

The company said it would provide healthcare providers and patients with five-year, 10-year and life time risk assessments, based on multiple clinical and genetic risk factors.

Genetic Technologies said the test was validated for men and women over 30 years of age and for patients of Caucasian descent.

The company said it would work on additional ethnicities, as well as develop new tests for type 2 diabetes and cardiovascular disease by October 2019 and for prostate cancer and melanoma in 2020.

Genetic Technologies was up 0.4 cents or 57.1 percent to 1.1 cents with 231.7 million shares traded.

ANALYTICA

Analytica says it hopes to raise up-to $2,700,000 through a pro-rata, non-renounceable, one-for-six rights issue at 0.5 cents a share.

Analytica said the funds would be used to develop and commercialize its intra-vaginal Pericoach pelvic floor exercise system as well as the Autostart and Autoflush infusion systems, including prospective partner discussions and working capital.

The company said the record date would be May 15, the offer would open on May 20, and close on May 31, 2019.

Analytica fell 0.1 cents or 20.0 percent to 0.4 cents with 1.9 million shares traded.

SIMAVITA

Simavita says it has commitments to raise $3 million through convertible notes, subject to shareholder approval.

Simavita said it would receive the notes in three tranches, including $500,000 which had already been paid, more than $1.5 million on shareholder approval; and up to $1 million on completion of Conformité Européenne (CE) mark registration by November 1, 2019 and with written agreements to show market interest in Alertplus software platform for adult and infant incontinence.

The company said proposed conversion terms would be provided to shareholders in its notice of meeting for the special general meeting.

Simavita said professional and sophisticated investors would provide the funds and directors Michael Spooner and Gary Pace would each invest $50,000, subject to shareholder approval.

Simavita said its existing 2018 series one convertible note of $1 million would be held in abeyance until June 30, 2020, convertible at three cents per Chess depositary interest (CDI) (BD: Oct 4, 2018).

The company said its 2018 series two convertible note of $1 million would be terminated with no need for subscription of funds (BD: Mar 15, 2018).

Simavita said the funds would be used to commercialize Alertplus for the US nappy industry, for international sales and for working capital; and it would work with its auditors to lift its suspension from trading (BD: Sep 27, 2018).

Simavita last traded at 1.7 cents.

NEXT SCIENCE

Next Science says that 2,270,294 shares held in ASX escrow will be released on May 25, 2019.

A Next Science spokesperson told Biotech Daily that following the release of the shares, the company would have 104,884,253 quoted shares on the ASX, of which 39,823,525 were held in voluntary escrow; with a further 73,630,322 shares remaining in ASX escrow.

Next Science fell 13 cents or 5.9 percent to $2.07 with 809,459 shares traded.

ACTINOGEN MEDICAL

FIL Limited says it has ceased its substantial holding in Actinogen on Tuesday May 7, selling 15,000,000 shares at 1.4 cents a share, or $210,000.

The Hong Kong-based FIL said that on April 17 it bought 1,092,882 shares at 5.25 cents a share, or $57,376 and retained 54,554,674 shares or 4.87 percent.

On Tuesday, Actinogen said that its 186-patient, phase II trial of Xanamem for Alzheimer's disease "did not achieve statistical significance" and the company fell as much as 70.8 percent on the day (BD: May 7, 2019).

Earlier this year, FIL said it became a substantial shareholder in Actinogen, with 56,375,471 shares or 5.04 percent of the company and said that it had bought the shares between November 29, 2018 and March 11, 2019 at pricing ranging from 4.35 cents to 5.88 cents a share (BD: Mar 14, 2019).

Actinogen fell 0.1 cents or 6.7 percent to 1.4 cents with 34.2 million shares traded.