Biotech Daily

Friday June 7, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ACTINOGEN UP 17%;**
- MEDICAL DEVELOPMENTS DOWN 8%

*** DR BOREHAM'S CRUCIBLE: GENETIC SIGNATURES**

*** LTR: 'SPONTAN FASTER THAN VARDENAFIL TABLET'**

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*** INOVIQ REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** OPTHEA REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** HONSUE CHO TRANSFERS XIAOYI WU INVION SHARES, HOLDS 18%**

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*** MTP CONNECT 'AUSTRALIAN CLINICAL TRIALS GENERATE $1.6b'**

MARKET REPORT

The Australian stock market was up 0.49 percent on Friday June 7, 2024, with the ASX200 up 38.2 points to 7,860.0 points. Eighteen of the Biotech Daily Top 40 were up, 10 were down, 11 traded unchanged and one was untraded.

Actinogen was the best, up 0.5 cents or 17.2 percent to 3.4 cents, with 7.25 million shares traded. 4D Medical climbed 16.1 percent; Syntara was up 13.6 percent; Dimerix improved 6.5 percent; Curvebeam was up five percent; Atomo, Emvision and Universal Biosensors were up more than three percent; Cyclopharm, Mesoblast and Pro Medicus rose two percent or more; Avita, Immutep and Imugene improved more than one percent; with Clarity, Clinuvel, Cochlear, Neuren, Polynovo and Resmed up by less than one percent.

Medical Developments led the falls, down 3.5 cents or 7.95 percent to 40.5 cents, with 236,018 shares traded. Compumedics and Nova Eye lost more than six percent; Alcidion was down three percent; Nanosonics, Prescient and Telix shed more than two percent; Impedimed and Percheron were down more than one percent; with CSL and SDI down by less than one percent.

DR BOREHAM'S CRUCIBLE: GENETIC SIGNATURES

By TIM BOREHAM

ASX code: GSS

Share price: 75 cents

Shares on issue: 266,571,206

Market cap: $199.9 million

Chief executive officer: Dr Neil Gunn (acting, permanent CEO Allison Rossiter starts in September 2024

Board: Dr Nick Samaras (chair), Dr Gunn, Dr Tony Radford, Michael Aicher, Caroline Waldron, Stephane Chatonsky

(Half year to December 31, 2023): revenue $3.6 million (down 65%), loss of $10.5 million ($6.48 million deficit previously)

Identifiable major holders: Christopher Abbott (Asia Union Investments) 23.5%, Perennial Value Management 12.4%, Fidelity Investments 9.7% (pre-capital raising).

Biotech investors need the patience of Job, but things are starting to happen for on a number of fronts.

This week, breast cancer diagnostics house Bcal Diagnostics launched a $10 million capital raise to support local and US market approval, while cancer drug developer Inoviq announced a breast cancer therapy breakthrough that sent the shares soaring.

After a four-year wait, parasitic diseases detector Genetic Signatures won US Food and Drug Administration (FDA) approval for its Easyscreen proprietary molecular test, which can detect eight tummy bugs (enteric protozoan pathogens) in the one assay.

The company also won approval for an associated automated workflow kit.

To support the rollout, Genetic Signatures has launched a $30 million capital raising through a placement and rights issue.

Genetic Signatures' acting CEO Dr Neil Gunn dubs the approval, the first in the US for the company, as a "momentous occasion" as it opens an addressable market of $500 million a year-plus.

"This is a great moment and one to savor - it doesn't come along that often," he says.

The reason for the excitement is that the eight detectable nasties compare with three or four for the current US tests on market - so in simple terms it is at least twice as good.

The eight tests also cover 90 percent of US gastro infections that afflict the US citizenry.

Dr Gunn adds that Genetic Signatures' 3base technology (see below) offers simpler workflows than the current polymerase chain reaction (PCR) DNA tests, which require a stool sample to be sent to a lab and analyzed under a microscope.

Genetic Signatures claims a reliability of 90 percent-plus, compared with around 55 percent for the standard assays.

Testing times

Genetic Signatures' smarts are based on its 3base platform, which enables syndromic (multiple) tests. These assays can detect up to 20 organisms at a time from the one patient, thus shortening the wait time from days to about five hours.

The tests replace the old 'sample on a slide' laboratory methods, enabling rapid screening of pathogens so that the right antibiotics can be swiftly administered.

Technically speaking, 3base converts the 4base microbial genome to three, with no additional steps required by the operator.

Genetic Signatures' current flagship test, Easyscreen, is approved and sold in dozens of countries but mainly in Australia, with more than five million patients tested to date.

Found in the gut of humans and other mammals, enteric protozoa are diarrhoea-inducing parasitic infections including giardia and cryptosporidium. They are hard to detect with traditional methods and can cause chronic illness.

Across the board Genetic Signatures' kits can detect more than 150 diseases across five broad categories: enteric (intestinal), respiratory, antimicrobial resistance, fungal and sexually transmitted infections.

The tests can detect norovirus (the bane of cruise ships), salmonella, giardia and - lest we forget - Sars-Cov-2.

In late May this year, the company canned development of a respiratory (Covid) product for the US, citing lower testing rates and the emergence of more rival products.

Genetic Signatures' signature moves

Genetic Signatures was founded in 2001 by prominent fund manager Christopher Abbott and the late Dr Geoffrey Grigg, former head of microbiology at the esteemed Commonwealth Scientific and Industrial Research Organisation (CSIRO).

The company's original focus was on commercializing technology using a sodium bisulphite conversion method which, it was discovered, could be used to develop molecular assays for infectious pathogens.

Genetic Signatures sprung from CSIRO's laboratories in Sydney's North Ryde.

The company listed on the ASX in March 2015, raising $7.5 million at 40 cents apiece. The co-founder of boutique investment house Maple Brown Abbott, Christopher Abbott, retained a 23 percent stake in the company ahead of the raising.

On April 30, this year, the company announced that CEO Dr John Melki would leave the building, having steered Genetic Signatures for 21 years.

His replacement, Allison Rossiter, will clock on in September.

Dubbed by Dr Gunn as a "highly experienced commercially focused CEO who has sold into North America multiple times" Ms Rossiter had headed the Australian arm of Roche Diagnostics since 2019.

Dr Gunn will resume his non-executive director duties.

Sizing up the US opportunity …

In the US, an estimated 65 million parasitic infections occur each year, with 15 percent (9.7 million) resulting in a doctor's visit.

Typically, the doctor will say the cause of the infection is not clear and prescribe antibiotics.

"We estimate 5.5 million of these patients go forward for further testing," Dr Gunn says.

"Our initial target is this space and we believe we can approach a 40 percent market share over the next five years - 2.2 million tests - because we have the broadest coverage of any molecular test."

The company has been sprung like a steel trap in anticipation of the approval, with product ready and distribution channels primed.

Reimbursement-wise, Easyscreen is subject to an existing 'current procedural terminology (CPT) code, to the tune of around $US260 per test.

This means that the client labs will buy the material from Genetic Signatures and be reimbursed over and above what's on offer for current testing (microscopy tests attract reimbursement in the low teens).

The company cites an indicative selling price of $US60 test, which accrues fully to the company as it runs an in-house sales channel and thus does not have to share the spoils with other parties.

The figure is derived from a 'bottom up' assessment of what are likely to be willing to pay, combined with a 'top down' appraisal based on reimbursement levels.

… segment by segment

The company says the US market falls into four segments: the large commercial labs, the large hospital networks, specialty labs and independent hospitals.

While the mega lab chains such as Quest and Sonic will “drive the needle” on sales growth’; eventually, Genetic Signatures initially will focus on nine ‘customer experience’ sites: laboratories that have been working with the company but have not been able to buy the hitherto unapproved tests.

Seven of these labs are definitely on board, so the next step is for the company to negotiate volume-related contracts with them.

“We hope to convert these initial labs within 60 to 90 days of launch,” Dr Gunn says, adding that a number of large hospital chains have also expressed interest.

Genetic Signatures is also eyeing the market for unapproved ‘lab developed’ tests, which involve the lab buying the separate components such as enzymes, buffers and probes and developing their own tests to run on a PCR instrument.

Laboratory developed tests are intended to be designed, manufactured, and used within a single laboratory that meets stipulated quality requirements.

“These have been known for years and have a very important place where there is no other test available,” Dr Gunn says. “However, the FDA has been pushing for additional enforcement and this year declared that lab-developed tests should transition to FDA-cleared tests if one is available.”

In effect it will be just as easy for the labs to adopt an approved test - such as Easyscreen - rather than develop their own.

Currently, the company makes its tests at its Sydney North Ryde facility, which boasts high capacity “as was evidenced during the pandemic”. The company also has its own US warehouse and distribution capacity and is likely to open ‘fill and finish’ manufacturing facilities there.

Finances and performance

The capital raising is by way of a $6 million placement and a $24 million non-renounceable, accelerated rights issue, on the basis of one share for every 5.82 held.

The price is 75 cents, a shade (2.7%) above the 73 cents closing price before the shares went into trading halt on May 31.

The fully underwritten raising will take Genetic Signatures’ cash kitty to $50.3 million – more than enough to fund the US rollout. Dr Gunn expects the company to become cash-flow positive “in a couple of years”.

Investors will be relieved to know the company has no plans for a further raising, having also pulled in $15.9 million in January this year by way of a rights issue at 37 cents a pop.

Genetic Signatures' March (third) quarter revenue of $1.7 million was 15 percent below the previous corresponding quarter, owing to reduced respiratory kit sales, here. Of the total turnover, 84 percent derived from Australia.

This week, Dr Gunn said local respiratory sales are going well in a "difficult" season - difficult for the patients, that is, because respiratory infections are running at elevated levels. In its record year to June 2022, the company posted revenue of $35 million.

Genetic Signatures shares were up as much as 10 cents or 13.3 percent to 85 cents after the trading halt was lifted on June 6.

Prior to that, the shares had traded in a 12-month range of 41 cents (January 2 this year) to 76 cents (May 22 this year). The shares peaked at $2.59 in July 2020, when the company's Covid tests were walking off the shelves.

Dr Boreham's diagnosis:

Dr Gunn dubs the company's US push as "ambitious and bold" because management decided on a never-before-attempted approval strategy based on the eight most clinically significant targets.

"They went with a very difficult study plan and achieved it, which was brave and bold and strategically very smart."

With the company on the verge of boosting its revenue fourfold and achieving profitability, the gamble certainly paid off.

While investor attention will focus on the rollout in the Land of the Free and Diseased, Dr Gunn says the company's ambitions don't stop there.

"I suspect with the FDA clearance, certain jurisdictions in Europe, the Middle East and Africa will pay [us] a lot of attention," he says. "Beyond that, we are not stopping. We are investing in research and development and leveraging the 3base technology to bring on new detection kits."

In particular, the company plans to reactivate a 'next-generation' instrument, which was on hold to preserve cash.

The 'sample-to-result' gizmo is capable of running 400 samples per shift, even with mixed specimen types.

"We have a unique opportunity in a market that uses older technology," he says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He likes to think of himself as brave and bold and strategically very smart but others might not agree.

LTR PHARMA

LTR says a trial of its Spontan nasal spray for erectile dysfunction met its primary and secondary endpoints, including bioavailability compared to vardenafil.

Last year, LTR said it would conduct an 18-patient, randomized study of 5mg Spontan vardenafil nasal spray compared to a vardenafil 10mg tablet for erectile dysfunction (BD: Mar 29, 2023).

Today, the company said half the patients initially used its Spontan vardenafil nasal spray, while the other half took a vardenafil tablet, with the cohorts swapping dosage method after three-days.

LTR said initial data showed Spontan nasal spray reached the same maximum concentration level as oral administration, despite being administered at a lower dose, and achieved this in an average of 12 minutes compared to 56 minutes with the oral dose, and also showed “better consistency in response”.

The company said the safety profile of doses of Spontan spray and vardenafil tablets were “comparable” but that the oral delivery resulted in one participant withdrawing due to “treatment adverse events” with no serious adverse events observed in either cohort.

LTR said that vardenafil (Levitra), sildenafil (Viagra) and tadalafil (Cialis) were all PDE5 inhibitors and the trial showed that Spontan had “better safety profile … compared to oral PDE5 dosing”.

LTR chair Lee Rodne said the initial results from the “pivotal clinical study are encouraging”.

“Spontan has the potential to make a significant impact on the global PDE5 inhibitor market, providing men with a more convenient and effective solution for erectile dysfunction,” Mr Rodne said.

“This study further underscores the rapid onset of action of Spontan and represents a significant advancement over existing gold-standard oral therapies, which can take over an hour to take effect,” Mr Rodne said.

LTR said it would conduct a complete statistical analysis over the “coming month” to compare the difference between maximum concentration and time to maximum concentration, and said it would release these results in a “future company announcement”.

LTR was up 16.5 cents or 25.8 percent to 80.5 cents with 6.1 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says its products and clinical trials are “unaffected by a recent shortage of actinium-225” (Ac-225) that had delayed recruitment in other research trials.

Clarity chair Dr Alan Taylor said “there are still a number of challenges to be overcome to bring clinical and commercial stage [actinium-225] production online, as well as other alpha radio-pharmaceuticals such as lead-212 (Pb-212), while these isotopes continue to be relatively unproven in clinical trials”.

“Clarity and all our current clinical development programs utilise [copper-67], which is produced domestically in the US on relatively low-cost electron accelerators, by our partners, including Northstar Medical Radioisotopes LLC,” Dr Taylor said.

“Clarity continues to source high purity and high specific activity Cu-67 for our three therapeutic programs with no interruptions and with capacity to support future pivotal trials and commercial launch,” Dr Taylor said.

Clarity said all its Cu-67 suppliers were based in the US, and that it did not source any Cu-67 from Russia.

Clarity was up one cent or 0.2 percent to $5.19 with 1.4 million shares traded.

ARTRYA

Artrya says it has lodged a second “Q-submission” to the US Food and Drug Administration for 510(k) clearance its Salix coronary anatomy system.

In 2023, Artrya said it had lodged a “Q-submission” to the US Food and Drug Administration (FDA) for its Salix coronary anatomy system for coronary plaque identification, a “key enabling step” in the US regulatory process (BD: May 3, 2023).

The FDA website did not explain what the ‘Q’ represented but said a ‘Q-Submission’ or ‘Q-Sub’ referred to the “system used to track the collection of interactions” and were opportunities for submitters to share information with the FDA and receive input beyond the submission of an application.

Today, the company said a ‘Q-sub’ was a “formal written request from a company for feedback from the FDA to help guide product development and/or application preparation” and that it expected a meeting “within four to six weeks”.

Artrya said the first Q-Sub meeting with the FDA in June 2023, determined the 510(k) pathway, which was “a premarket submission made to the FDA to demonstrate the device to be marketed is as safe and effective, that is, substantially equivalent to an existing FDA approved software as a medical device”.

The company said it had requested the second meeting to “validate and confirm” the approach it had taken since its first meeting, and it was a “key final step in completing the FDA application process”.

Artrya chief executive officer Mathew Regan said “we have over the past 11 months diligently worked through the detailed program of activity determined with the FDA during our first Q-Sub meeting in June last year”.

"I have requested this second Q-Sub meeting to validate and confirm our approach,” Mr Regan said. “We will move into the submission process following the meeting with full confidence and increased certainty that we are on track for FDA approval expected during the second half of this year.”

Artrya was up half a cent or two percent to 25.5 cents.

PYC THERAPEUTICS

PYC says its RNA stem cell treatment restores the deficient Shank3 protein in neurons causing Phelan-McDermid Syndrome, increasing expression 1.4 times, in-vitro.

PYC said Phelan-McDermid Syndrome was caused by a loss of one functional copy of the Shank-3, or SH3 and multiple ankyrin repeat domains-3, protein.

The company said it induced Shank-3 protein expression in pluripotent stem cells derived from a single Phelan-McDermid Syndrome patient’s cortical glutamatergic neurons using its RNA drug candidate, claiming a “one-way analysis of variance $p < 0.05$” which Biotech Daily understands would be equivalent to the more usual two-way analysis of $p < 0.10$.

PYC said it induced Shank-3 protein expression in stem cells from two unaffected individuals, also increasing Shank-3 protein expression 1.4 times ($p < 0.0001$) “using one-way analysis of variance” and would progress towards studies required for human trials, which it expected to begin in 2025.

PYC chief executive officer Dr Rohan Hockings said the company had been able “to generate the data with two different chemistries of RNA therapy, one of which has already demonstrated clinical benefit in patients with disorders occurring in neurons”.

“This gives us clear line of sight into first in human studies where we believe an RNA therapy offers the greatest potential benefit to [Phelan-McDermid Syndrome] patients and their families,” Dr Hockings said.

PYC was up one cent or 10 percent to 11 cents with 6.8 million shares traded.

RESONANCE HEALTH
Resonance says it has received $819,706 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Resonance said the rebate related to research and development expenditure for the year to June 30, 2023.
Resonance was unchanged at 6.2 cents.

BLUECHIIP
Bluechiip has requested a trading halt pending an announcement “in connection with a capital raising program”.
Trading will resume on June 12, 2024 or on an earlier announcement.
Bluechiip last traded at 0.55 cents.

INOVIQ
Inoviq has requested a trading halt pending an announcement “in relation to a proposed capital raising”.
Trading will resume on June 12, 2024 or on an earlier announcement.
Inoviq last traded at 56.5 cents.

OPTHEA
Opthea has requested a trading halt pending an announcement “in relation to a proposed capital raising”.
Trading will resume on June 12, 2024 or on an earlier announcement.
Opthea last traded at 48.5 cents.

INVION
Michael Honsue Cho says the group has reduced its holding from 1,467,459,930 shares (22.89%) to 1,146,031,359 shares (17.84%).
The Melbourne-based Mr Cho said the 321,428,571 shares were transferred off-market for no consideration.
Invion said that the change related to the transfer of shares from RMW Cho Health Technology to Xiaoyi Wu, in whose behalf it was holding the shares.
“This change in ownership of the shares does not affect and is unrelated to the holdings of Invion shares of Michael Cho, the Chairman of RMW Cho Group, the licensor of the Photosoft technology,” Invion said
Invion was untraded at 0.45 cents.

IMPEDIMED
Impedimed says it has appointed Fiona Bones as a non-executive director, effective from June 7, 2024.
Impedimed said Ms Bones was the head of finance and international controller at Google, and had worked for Google for more than 20 years.
According to her Linkedin page, Ms Bones held a Bachelor of Arts from the Donegal, Republic of Ireland’s Atlantic Technological University.
Impedimed fell 0.1 cents or 1.4 percent to seven cents with 1.75 million shares traded.

MTP CONNECT

MTP Connect says its report shows clinical trials generated $1.6 billion for the Australian economy in 2022, up more than four percent compared to the previous year.

MTP Connect chief executive officer Stuart Dignam said clinical trials were “a critical step in the [research and development] pipeline for new treatments … [and] these new figures show clinical trials are more valuable for the economy than ever before.”

“While the figures show value has increased, there are signs of stagnation in other key metrics,” Mr Dignam said.

“Areas we’ve identified for ongoing attention include improving efficiency in trial start up, enhancing data transparency, increasing patient awareness to support recruitment and expanding the workforce to support clinical trials growth,” Mr Dignam said.

“Recent commitments to expansion of the National One Stop Shop initiative, with its ability to provide streamlined, cross-state ethics and governance approvals, are welcome,” Mr Dignam said.