Biotech Daily

Friday May 21, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PATRYS UP 23%; GENETIC SIGNATURES DOWN 5%**

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MARKET REPORT

The Australian stock market was up 0.15 percent on Friday May 21, 2021, with the ASX200 up 10.7 points to 7,030.3 points.

Twenty-two of the Biotech Daily Top 40 stocks were up, nine fell and nine traded unchanged. All three Big Caps were up.

Patrys was the best on no news, up 0.5 cents or 22.7 percent to 2.7 cents, with 20.9 million shares traded.

Uscom climbed 12.5 percent; Immutep and Paradigm improved more than seven percent; Osprey rose 6.25 percent; Impedimed and Opthea were up more than four percent; Alterity, Avita, Optiscan and Resmed were up more than three percent; Actinogen, Amplia, CSL, Imugene, Nanosonics, Orthocell, Polynovo, Pro Medicus and Resonance rose two percent or more; LBT and Proteomics were up more than one percent; with Clinuvel, Cochlear and Next Science up by less than one percent.

Genetic Signatures led the falls, down six cents or 4.8 percent to $1.20, with 66,619 shares traded. Neuren and Telix lost more than three percent; Cynata and Kazia shed more than two percent; Dimerix, Nova Eye and Universal Biosensors were down more than one percent; with Starpharma down 0.6 percent.

DR BOREHAM'S CRUCIBLE: GENETIC SIGNATURES

By TIM BOREHAM

ASX code: GSS

Share price: $1.20

Shares on issue: 142,907,246

Market cap: $171.5 million

Chief executive officer: Dr John Melki

Board: Dr Nick Samaras (chair), Dr Melki, Dr Tony Radford, Michael Aicher (executive director), Dr Neil Gunn

Financials (March quarter 2021): revenue $4.3m (Up 136%), net cash outflows $3.43m, cash of $32m

Identifiable major holders: Christopher Abbott (Asia Union Investments) 26%, Perennial Value Management 14.9%, Fidelity Investments 7.7%, Regal Funds Management 5.97%

"Cometh the hour, cometh the man" goes the saying variously attributed to William Shakespeare or The Bible.

In the coronavirus context, what better company to cometh at humanity's troubled juncture than a molecular diagnostics testing house with approved products on market?

When your columnist last appraised Genetic Signatures in November 2019, Covid-19 was but a distant bat (or pangolin) squeak in Wuhan. As the ghastly extent of the virus became apparent, it didn't take Genetic Signatures too long to extend its testing capacity to Sars-Cov-2 (the bug that causes Covid-19).

But the Good Book***** also says: the Lord giveth and the Lord taketh away. Despite the company's undoubted progress, its stock price has retracted to close to pre-pandemic levels.

One concern held by investors is what the company's prospects look like when - not if - the pandemic recedes.

"We understand the pandemic won't be around forever - and that's a good thing," says Genetic Signatures CEO John Melki. "But testing isn't going to go away post vaccine."

Ultimately, Genetic Signatures wants to be known for its ability to use its core "3base" technology to detect a range of pathogens.

Assay, assay, what a great idea!

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 CSIRO.

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

Genetic Signatures sprung from CSIRO's laboratories in Sydney's North Ryde and Dr Melki joined the company in 2003, having researched DNA and microarray technologies.

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 retains a 26 percent stake.

Aussie success story aces the world (no, not Ash Barty)

Sold under the Easyscreen banner, Genetic Signatures' tests were developed (and made) in Australia and are sold in more than 30 countries.

The assays are based on the company's 3base technology, which can detect groups of organisms - up to 20 at a time - from the one patient.

More than two million patients have undergone at least one 3base test.

The tests replacing the old 'sample on a slide' laboratory methods, enabling rapid screening of pathogens so that antibiotics can be swiftly dispensed (turnaround times are reduced from days to less than five hours).

The Covid story

Following a regulatory submission in March 2020, a month later the company won consent to sell the tests in Europe and Australia - and wasted no time shipping them.

"We already had a pan-coronavirus test, including for 'flu and rhinovirus and we quickly modified the test to specifically pick up Covid," Dr Melki says.

"We worked incredibly hard to make sure we had stock in hand at a time of shipping disruptions and consumables shortages. We can proudly say we never let a customer down during the pandemic."

The tests also are able to detect that a patient not only does not have Covid-19, but does have a condition with the same symptoms. Dr Melki says pathology reports that 60 percent of suspected symptomatic Covid suspects had rhinovirus (that is, the common cold).

And the broader story...

A feature of 3base is its ability to detect the disease regardless of the incidence of mutants. With minimal effort, labs can get five to 10 extra results by putting different assays in their work flows.

Dr Melki says testing for other infectious diseases has been overlooked during the pandemic and clients are making a big effort to catch up, especially in the US and Europe.

The Covid kits join a suite of tests that cover 'flu and gastro enteric strains, flavivirus/alphavirus, antibiotic resistant bugs and sexually transmitted infections (STIs). The gastro bugs tackled include the infamous norovirus, the bane of cruise operators - but not so much when so many of their vessels lie idle off the Florida coast.

Genetic Signatures' clients are hospital and commercial laboratories.

"The kits contain everything the lab needs to perform the test," Dr Melki says.

While the tests themselves are "platform agnostic", the company also provides Easyscreen-specific instrumentation to labs with higher input.

What's in the pipeline?

The Covid test aside, the company has approved tests in Europe and Australia for enteric protozoan detection and antibiotic resistance. Earlier this year, the Europeans approved a test for STIs and other genital pathogens, while local Therapeutic Goods Administration consent is pending.

One tends to overlook the 'old' diseases, but the global market for STI molecular diagnosis is worth a cool $1.9 billion.

And they're not going away. According to an Australian Broadcasting Corp report this week, genomic sequencing has tracked syphilis outbreaks in Melbourne suburbs where the disease has not been prevalent.

Of course, the social distancing dictates of the Covid era - in theory - meant that STI rates should have declined, but we guess there's only so much Netflix you can watch.

Genetic Signatures's test, by the way, will detect not just the usual suspects of gonorrhoea and syphilis, but a broader suite of 12 organisms from the same sample.

Finances and performance

The Covid test resulted in a 350 percent revenue boost in the June 2020 quarter, followed by 585 percent and 744 percent increases in the September and December quarters respectively.

Genetic Signatures then posted revenue of $4.3 million in the March quarter of 2021, 136 percent higher than the March 2020 quarter. And now the downbeat bit: having chalked up a maiden $4.5 million profit in the half year to December 31, 2020, the March quarter showed cash outflows of $3.43 million.

In late 2019, Genetic beat the capital raising rush by raising a meaty $35 million in a placement and then $2.5 million in an oversubscribed share purchase plan, both at 98 cents a share.

With a current cash balance of $32 million, the company says it is well-placed to fund the intended new tests and chase US and European expansion.

International sales accounted for 24 percent of its turnover in the nine months to March 31, 2021, compared with nine percent in the 2019-'20 year.

The other way of viewing these numbers is that Australia, a relatively small market, still accounts for the lion's share of revenue.

"We were quite quick in getting regulatory approval [from the TGA] and that has underpinned the growth we have seen, not only for [Covid] but the entire respiratory portfolio such as 'flu or rhinovirus," Dr Melki says.

Conversely, the pandemic constrained US sales because of limited access to client sites, but kit sales are expected to "accelerate" in the current quarter. Indeed, in December last year, Genetic Signatures announced its first US customer for the Covid (Sars-Cov-2) test followed by the second client a mere three weeks later.

Genetic Signatures shares have traded as low as 25 cents (March 2018) and as high as $2.82 (July 27 last year).

Looking forward ...

A key focus is a US Food and Drug Administration (510k) submission for the enteric protozoan kit, which can detect gastro infections.

Found in the gut of humans and other mammals, enteric protozoa are diarrhoea-inducing parasitic infections including giardia and cryptosporidium. Like enteric bacteria and viruses, they can be found in water following direct or indirect contamination by faeces. They are hard to detect with traditional methods and can cause chronic illness.

"Our test will identify eight enteric parasites; others will do three to four of them but they might include non-parasite targets," Dr Melki says.

The Covid curse meant the company was stymied in launching trials at three US sites to satisfy the FDA's requirements, but the first one is now underway. The company plans to carry out 1,500 tests across the three sites.

Dr Melki says the expected US enteric protozoan approval will be a significant moment, with the company targeting a 10 to 15 percent share of the 5.5 million of these tests done in the US annually.

As you could imagine, the need for gastro testing subsided during the Covid lockdowns but has now returned to pre-pandemic levels.

Dr Melki also reveals the company is working on a custom, next generation instrument for 3base assays.

"The pandemic has shown us that labs want to have tests that are easy to use with minimal hands-on time," he says.

Dr Boreham's diagnosis:

Dr Melki says even before the pandemic, the company's strategy centred on overseas expansion in the knowledge that Europe and the US account for 75 percent of the relevant world market (compared with one to two percent here).

"The pandemic gave us access to new customers, which fast-forwarded our sales efforts," he says.

Dr Melki attributes Genetic Signatures' share price weakness partially to some larger institutions rebalancing their holdings after the stock's strong run.

"They will do what they do and we will focus on winning global sales for our molecular diagnostics tests."

Dr Melki notes a recent spate of consolidation in the global molecular diagnostics industry, with larger companies buying smaller rivals on revenue multiples averaging 19 times.

For instance, the Nasdaq-listed women's health group Hologic in April acquired the private French-Finnish molecular diagnostics outfit Mobidiag Oy, for just over $1 billion.

"We're frustrated [with the share price] because the company is really well-leveraged to reach our much larger customer base than 12 months ago," Dr Melki says.

"We really worked hard to increase customers base during pandemic. There's so much more to Genetic Signatures than Covid."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort.

**** As an ecumenical scribe, he accepts the Good Book can also mean the Torah, the Koran, the Tripitaka or a John Grisham legal potboiler***

Confession: the author owns Genetic Signatures shares.

MTP CONNECT

MTP Connect says that clinical trials contributed $1.4 billion to the Australian economy in 2019 and the sector employs more than 8,000 Australians.

The Federal Government MTP Connect said that the contribution to the economy was up 27.3 percent from $1.1 billion in 2015, the number of employees was up 15.9 percent in the four years since 2015 and the number of clinical trials increased 38.2 percent from about 1,360 in 2015 to about 1,880 in 2019.

The industry organization said that the data was detailed in a report on the size and scope of Australia's clinical trials sector and opportunities for future growth, titled 'Australia's Clinical Trials Sector: Advancing innovative healthcare and powering economic growth'.

MTP said that the report was developed in partnership with LEK Consulting and was available at: https://www.mtpconnect.org.au/Story?Action=View&Story_id=379.

The report said that the Covid-19 lockdown measures and social distancing restrictions in 2020 "posed significant challenges for clinical trials in Australia".

"Up to 90 percent of trials run by some companies were put on hold and patients were unwilling to participate in trials during the pandemic period," the report said.

"As a result, the number of clinical trials started in Australia contracted by 13 per-cent; from 1,880 to 1,640 in early 2020 … [but] Australia's effective pandemic response saw the sector rebound strongly from as early as May 2020, with a number of trials starting for Covid-19 vaccine candidates including Oxford-Astrazeneca, University of Queensland and Novavax," the report said.

MTP Connect managing-director Dr Dan Grant said that "Australia's clinical trials sector is large and vibrant, impacting lives and livelihoods, yet it is sometimes overlooked for the contribution it makes to our country".

"Clinical trials are an essential part of health and medical research and can lead to better health outcomes for patients," Dr Grant said.

"Not only that, but the sector sustains thousands of jobs and is a major contributor to economic growth, generating significant services export revenue," Dr Grant said.

Dr Grant said that Thursday May 20 was International Clinical Trials Day and paid tribute to "the work of Dr James Lind and his scurvy experiments with oranges and lemons onboard the HMS Salisbury in 1747".

Dr Grant said that Australia was "one of the few countries in the world with a sophisticated healthcare system where many Covid-19 related restrictions have been lifted or eased, which means we have the opportunity to attract even greater numbers of clinical trials to Australia".

"Over the next 10 years, we have identified four emerging opportunities to capture a greater share of global clinical trials and grow the sector more rapidly," Dr Grant said.

"These relate to building our capability in precision healthcare in trials and undertaking innovative clinical trial design, applying digital health innovations to enhance patient recruitment and achieve efficiencies, and an increased focus on patient awareness and engagement to increase recruitment," Dr Grant said.

"We must continue to optimize efficiency in ethics and governance processes towards a single ethical review and we must address the shortage of highly skilled and experienced clinical research associates and clinical trial coordinators," Dr Grant said.

"Improving the ease and scale of patient recruitment by increasing patient awareness and engagement and using patient-centric approaches like decentralized trials and digital health technologies will also be important to remain globally competitive," Dr Grant said.

"And we need to capture more detailed data and systemize reporting and tracking of our performance," he said.

AVECHO BIOTECHNOLOGY

Avecho says the Franklin Township, New Jersey-based Catalent Inc has completed the composition and design of its marijuana-derived cannabidiol soft-gel product.
Avecho said the prototype cannabidiol oil formulation was refined at Catalent's St Petersburg, Florida-based facility and the finalized composition would contain 75 mg of cannabinoid (CBD) per capsule.
Avecho chief executive officer Dr Paul Gavin said, "this is an important milestone on the critical path for the development of our pharmaceutical CBD product."
"It cannot be emphasized enough how important it is to get the chemistry, manufacturing and controls aspect of a formulation correct," Dr Gavin said. "Positive results from this process are as critical as successful clinical trials."
"We have been thorough and forward-thinking in our approach to manufacturing the soft-gel product, by ensuring we produce a [good manufacturing practice] finished product that is appropriate for scale up and registration with the [Australian Therapeutic Goods Administration]," Dr Gavin said.
The company said its phase I study was expected to begin by October 2021.
Avecho was up 0.2 cents or 13.3 percent to 1.7 cents with 19.2 million shares traded.

CRESO PHARMA

Creso says it has a one-year non-exclusive commercial agreement with Polvet Healthcare to market and distribute its Anibidiol animal health products in Poland.
Creso said Orzesze-based Polvet Healthcare Teodorowski Spółka Jawna would distribute its animal health products Anibidiol 2.5, Anibidiol 8, Anibidiol 500, Anibidiol dog treats, Anibidiol Equi and Anibidiol Swine for companion animals and livestock.
The company said Polvet had a "strong domestic consumer population" and distributed, sold, and commercialized animal health products through its online shop and directly to hospitals, clinics, and veterinarians.
Separately, Creso said it had developed Anibidiol Swine combining marijuana-based flour with oat meal for pig stress.
Creso was unchanged at 16 cents with nine million shares traded.

ANTERIS TECHNOLOGIES

Anteris has requested a trading halt "pending an announcement in relation to a proposed capital raising".
Trading will resume on May 25, 2021 or on an earlier announcement.
Anteris last traded down five cents or 0.6 percent to $8.00.

COCHLEAR

Veritas Asset Management says it has ceased it substantial shareholding in Cochlear reducing from 3,288,698 shares (5.002%) to 3,284,198 shares (4.995%).
The London-based Veritas said it sold 4,500 shares for $955,918 or $212.43 a share.
Cochlear was up 52 cents or 0.2 percent to $217.10 with 125,223 shares traded.