Biotech Daily

Friday April 26, 2019

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market edged up 0.05 percent on Friday April 26, 2019, with the ASX200 up 3.5 points to 6,385.6 points. Nineteen of the Biotech Daily Top 40 stocks were up, 11 fell, seven traded unchanged and three were untraded. All three Big Caps were up.

Impedimed was the best, up 2.5 cents or 10.9 percent to 25.5 cents, with 4.8 million shares traded. LBT and Medical Developments climbed more than seven percent; Prescient was up 6.7 percent; Kazia improved 5.4 percent; Antisense and Nanosonics rose more than four percent; Benitec and Pro Medicus were up more than three percent; Clinuvel, Cyclopharm, Mesoblast, Neuren and Telix rose more than two percent; Avita, Cochlear, CSL, Proteomics, Resmed and Starpharma were up one percent or more; with Opthea and Paradigm up by less than one percent.

Alterity (Prana) led the falls, down 0.3 cents or 6.8 percent to 4.1 cents, with 87,287 shares traded. Imugene lost 5.6 percent; Compumedics, Orthocell and Universal Biosensors fell four percent or more; Immutep, Osprey and Uscom were down more than three percent; with Cynata and Volpara shedding more than two percent.

DR BOREHAM'S CRUCIBLE: SIENNA DIAGNOSTICS

By TIM BOREHAM

ASX Code: SDX

Share price: 6.0 cents

Shares on issue: 289,055,171

Market cap: $17.3 million

Chief executive officer: Matthew Hoskin

Board: Dr Geoffrey Cumming (chairman), Dr David Earp, Helen Fisher, Carl Stubbings

Financials (March quarter 2019): receipts of $100,000, cash burn of $583,000, cash balance $5.9 million, estimated current quarter cash outflows $1.3 million.

Major shareholders: Merchant Funds Management 9.19%, David Williams 7.65%, David Neate 7.24%, Traoj Pty Ltd (Trent Barry) 5.19%, Geron Corp (San Francisco biotech) 5.18%.

Shortly after listing in November 2017, the bladder cancer diagnostics house outlined a plan to acquire or in-licence complementary technologies that did not require the company to replicate its early research.

"All of the opportunities we are exploring have the ability to leverage Sienna's core competency, experience and market channels," said Sienna CEO Matthew Hoskin.

Lo and behold, the Melbourne-based Sienna last month came good with its first transaction: the purchase of the privately-owned Sevident Inc of the US for $US300,000 cash and $US1 million of scrip (plus potential revenue-based milestone payments of $US1.5 million).

In proof-of-concept stage, Sevident's molecular capture platform enables blood and urine samples to be 'cleaned' ahead of pathology lab testing, so that biomarkers can be more easily and quickly detected.

"It's about being able to capture targets from a 'noisy' sample every single time," Mr Hoskin says.

"It's an extremely important part [of testing] because if you put garbage in you normally get garbage out."

At first blush the Sevident purchase looks to be a good fit, given Sienna's reason for being is its commercial in-vitro test to detect the biomarker telomerase, which is present in most tissue-based cancers.

As former Sienna chief executive officer Dr Kerry Hegarty explained to Biotech Daily back in 2009, telomerase is the enzyme responsible for the maintenance of the ends of chromosomes, like the caps on the end of shoelaces to keep them from fraying.

Dr Hegarty said Australia's first woman Nobel laureate, Prof Elizabeth Blackburn and her colleagues proposed that a particular protein had the role of keeping chromosomes forever young, but “the flip-side of eternal youth … is uncontrolled growth and cancer” so telomerase is a biomarker for cancer. Prof Blackburn won the Nobel prize in 2009.

(A biomarker is a naturally occurring molecule that identifies the presence of a disease).

Specifically, Sienna’s anti-hTERT antibody detects the telomerase component - hTERT - in abnormal cells.

About Sienna

Sienna was founded by entrepreneur medico David Lance in 2006, who was savvy enough to realize there was no telomerase test on the market.

Part of the Bio21 incubator adjacent to the Royal Melbourne Hospital, Sienna kicked off with a small capital raising and subsequent raises of $3.5 million and $2.1 million (enough to fund a 300-patient study).

After three years of failed efforts by the company, the test was advanced by Dr Hegarty.

Sienna listed after raising $4.6 million, more with a whimper than a bang despite the backing of ex-Macquarie Group chief moneybags Allan Moss and rag-trader tycoon David Neate.

To date, Sienna has focused on testing for bladder cancer with urine samples.

The problem with current testing is that while 10 percent of urine cytology tests prove positive, a quarter of the tests can be indeterminate. And that’s where the Sienna test comes in handy.

Approved in the US, Europe and here for bladder cancer testing, Sienna’s test potentially could be expanded to test for other tumors including thyroid cancer.

Sienna and Sevident strive for synergies

Mr Hoskin said the Sevident technology could be licenced for other applications, such as infectious diseases. It could also be sold as a package with Sienna’s current and future tests.

Sevident’s molecular capture platform isolates and captures molecular and cellular biomarkers from clinical sample volumes “with high sensitivity and specificity”. Biomarker targets include exosomes, cells, proteins, nucleic acids and lipids.

Exosomes are particles that shed from cancer into the blood stream. Sevident's platform isolates the tell-tale exosomes from blood or plasma more quickly than the current methods and is "flexible, scalable and highly specific".

Sevident's technology was invented by Sevident chief scientist Dr Emily Stein who, happily, joins the Sienna camp. So too does Sevident CEO Dr Peter French, in an advisory capacity. (If the name sounds familiar, Dr French previously ran Fermiscan, Benitec and Bioxyne.)

Sienna's progress

Sienna has been as busy as a one-armed bricklayer of late, having secured distributor deals in China, Singapore and South Korea. In March, Sienna appointed Brazil's Inside Diagnosticos to exclusively distribute the test in the samba-loving nation - the world's ninth biggest economy.

Naturally, Sienna and its partners are striving for regulatory approval in these geographies.

"They are fairly complex markets to enter," Mr Hoskin says. "Korea, for example, requires an on-site audit of the manufacturing premises, which no other regulator does."

Currently, about 90 to 95 percent of Sienna's revenue is derived from laboratory customers in the US, via US distributor Statlab.

Sienna is heartened by the results of the world's biggest bladder cancer study, currently underway at the Maryland-based Johns Hopkins Hospital. The study of 500 urine specimens showed that the hTERT test increased the sensitivity to 52 percent, compared with 31 percent for urine cytology alone.

In other words, Sienna's in-vitro diagnostic (IVD) test was a useful clinical adjunct to urine cytology that might assist in identifying patients with an increased risk of bladder cancer.

Of 21 cases found negative by urine cytology alone, on follow-up four were detected with high-grade bladder cancer and one had low-grade bladder cancer. Furthermore, of 31 patients with an "atypical" urine cytology result and a positive hTERT result, 15 were found to have bladder cancer after undergoing a biopsy.

The data was published in the peer-reviewed journal Acta Cytologica, which is your columnist's favorite read after People magazine.

Meanwhile, the Royal Melbourne Hospital is hosting a proof-of-concept study to test the efficacy of Sienna's test for thyroid fine-needle aspirate samples.

With thyroid tumors, there's no way of determining whether they are malignant or benign in-vivo (in the body). The material has to be removed and 25 percent of the time it is benign. The trouble is that patients then must use hormone replacement treatments for the rest of their lives, which means they are relieved at being in the clear but a little peeved at the same time.

Finances and performance

The Sevident purchase was enabled by a $5 million rights issue and placement in July last year, backed by Melbourne biotech big cheese David Williams and the Perth-based Merchant Funds Management (now Sienna's largest shareholder).

The redoubtable Mr Williams chairs Medical Developments and Polynovo and is a corporate adviser to Bega Cheese.

Sienna shares have never achieved the 20 cent a share offer price, despite the IPO being well oversubscribed. They have meandered between a high of 15 cents shortly after listing, to a low of 4.9 cents in July 2018.

We're kind of guessing that revenues simply aren't material enough to get excited about. But Rome wasn't fabricated in a day, was it?

We also expect most of the pre-money investors availed of the listing to get out at a tidy profit.

Dr Boreham's diagnosis:

When your columnist last covered Sienna in August 2017, we reported that Sienna-Statlab needed to penetrate 15 percent of the US bladder cancer market to become profitable.

Their current reach is 3.0 percent, so there's still work to be done to convince pathology laboratories of the worth of the $US30-a-pop test (usually reimbursable).

Globally, around 3.5 million urine cytology tests are undertaken each year, around half of them in the US.

On the exosome (Sevident) side, Grand View Research cites a global market of $US2.28 billion by 2030.

Investor interest was whetted by the August 2018 acquisition of Exosome Diagnostics by Bio-techne, a deal involving $US250 million upfront plus $US325 million of performance milestones.

Meanwhile Sienna is scouring for more target assets, which could be owned by a smaller biotech, a research body or university.

"As long as pathology labs are the intended customer," Mr Hoskin says. "Sevident was the first deal, but it certainly won't be the last."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He's not sure about telomerase but wears RM Williams elastic-sided riding boots less as a fashion statement and more to avoid tying shoelaces.

TELIX PHARMACEUTICALS

Telix says data from a 49-patient, phase I/II trial of its TLX591 for metastatic-resistant prostate cancer shows a significant treatment benefit for patients.

Telix said that the research article, titled 'Phase I/II study of fractionated dose lutetium-177-labeled anti-prostate-specific membrane antigen monoclonal antibody J591 (177Lu-J591) for metastatic castration-resistant prostate cancer' was published in the journal Cancer on April 23, 2019.

An abstract is at: https://onlinelibrary.wiley.com/doi/abs/10.1002/cncr.32072.

The research article concluded that "fractionated administration of 177-Lu-J591 allowed higher cumulative radiation dosing".

"The frequency and depth of [prostate-specific antigen] decrease, overall survival and toxicity (dose limiting myelosuppression) increase with higher doses," the research article said.

The company said 49 patients received fractionated doses of Lu-J591 two weeks apart, ranging from 20 milli-Curie per square (mCi/M2) to 45 mCi/m2, which was well tolerated.

Telix said at the highest dose, toxicity was reversible and prostate-specific antigen (PSA) levels decreased the greatest amount, with median survival increased to 42.3 months and a significant anti-tumor effect delivered.

The company said 80 percent of patients had positive imaging of prostate-specific membrane antigen (PSMA), with those having less intense PSMA imaging tending to a poorer response "demonstrating the importance of PMSA imaging to select patients for therapy".

Telix said fractionated administration of Lu-J591 enabled higher cumulative radiation dosing with fewer side effects.

The company said the trial data supported development of its TLX591prostate therapy program.

Telix was up 2.5 cents or 2.8 percent to 91 cents.

NEUREN PHARMACEUTICALS

Neuren says it hopes to submit applications to the US Food and Drug Administration for orphan drug designation and a trial of NNZ-2591 for Phelan-McDermid syndrome.

Neuren said the applications for orphan designation this year and an investigational new drug application for a 2020 phase II trial were the first of potentially several for NNZ-2591.

Neuren chief financial officer Jon Pilcher told Biotech Daily that the company was considering a number of neuro-developmental disorders programs for NNZ-2591 which it had not yet disclosed.

In February, the company published data from pre-clinical mouse studies showing efficacy for Phelan-McDermid syndrome (BD: Feb 18, 2019).

Today, Neuren said it was conducting non-clinical studies that would allow the initial phase II trials in Phelan-McDermid syndrome to have a dosing duration of three months.

Neuren was up three cents or 2.7 percent to $1.145.

ANTISENSE THERAPEUTICS

Antisense says it will issue up to 45 million loan shares or options to directors at eight cents a share, subject to shareholder approval.

Antisense said the price was "a significant premium to the recent trading" and would allow the board and management "to participate in shareholder value growth above eight cents".

Antisense was up 0.2 cents or 4.55 percent to 4.6 cents with 2.6 million shares traded.

PRESCIENT THERAPEUTICS

Prescient says it its underwritten rights issue at five cents a share has raised $890,460 of the hoped-for $2.1 million, with Bell Potter Securities to place shortfall.

In March, Prescient said that it had commitments for $7.0 million in a placement and Bell Potter had underwritten the $2.1 million one-for-five non-renounceable rights issue to existing shareholders (BD: Mar 25, 2019).

Today, the company said it received applications for 17,809,202 shares raising $890,460, with Bell Potter to place the 24,568,363 shortfall shares for a further $1,228,418.

Prescient company said it would issue one attaching option for every two new shares, exercisable at 6.25 cents each by March 31, 2023.

Separately, Prescient said that today's extraordinary general meeting faced up to 13.9 percent opposition to the grant of 5,000,000 options to chief executive officer Steven Yatomi-Clarke, chair Steven Engle and directors Paul Hopper and Dr James Campbell (BD: Mar 27, 2019).

The company said it had 289,574,474 shares on issue, meaning that the votes against Mr Hopper's options amounted to 2.0 percent of the company, not sufficient to requisition extraordinary general meetings.

Prescient was up 0.3 cents or 6.7 percent to 4.8 cents with 1.3 million shares traded.

CANN GROUP

Cann says it has invested $NZ6 million ($A5.7 million) for a 20 percent stake in Auckland's Pure Cann NZ to cultivate and supply medical marijuana in New Zealand.

Cann said it would take 10 percent by August 30 and the balance on the earlier of ownership for new regulations coming into force in New Zealand or Pure Cann's board approving the construction of its commercial cultivation facility.

The company said it had an option to increase its holding to 30 percent.

Cann chief executive officer Peter Crock said "the strategic investment will allow the two companies to work collaboratively to capitalize on the growing domestic demand for medicinal cannabis in New Zealand and explore potential export opportunities as Pure Cann develops its own proposed cultivation and production facilities".

"Pure Cann is proposing to develop a range of organic medicinal cannabis products to serve patient needs in New Zealand and potential export markets," Mr Crock said.

Cann fell six cents or 2.5 percent to $2.36.

EYE CO PTY LTD

Eye Co says it has filed an international patent application for the use of a marijuana extract for the treatment and prevention of age-related macular degeneration (AMD).

Eye Co said that the patent, titled 'Low THC hemp extract and method of treatment or prevention of an eye disease', was filed in Australia last year and through Patent Cooperation Treaty this week and when granted the patent would provide coverage until April 2038.

The company said the application related to "the composition and treatment of age-related macular degeneration with hemp, hemp seed oil or a pharmaceutical active extract thereof".

Eye Co said the use of compositions comprising hemp seed oil as a carrier of pharmaceutical actives intended for intravitreal administration was also covered by the patent application.

Eye Co is a private company.

IMAGION BIOSYSTEMS

Imagion says its net operating cash burn for the three months to March 31, 2019 was $1,405,000 with cash at the end of the quarter of $2,903,000.
Imagion said that it had $157,000 in receipts from customers with an expected cash burn for the three months to June 30, 2019 of $1,844,000.
Imagion chief executive officer Robert Proulx told Biotech Daily the company was considering a possible capital raising at some time in the future.
Imagion fell 0.2 cents or 6.7 percent to 2.8 cents.

TPI (TASMANIAN POPPY INDUSTRIES) ENTERPRISES

TPI says its annual general meeting will vote on a change of name to Palla Pharma, a potential second strike board spill and the re-election of directors.
Last year, TPI earned a remuneration report first strike with the annual general meeting voting 9,423,732 votes (25.44%) against the report and 27,621,476 votes (74.56%) in favor (BD: Jun 1, 2018).
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed by more than 50 percent of votes the directors must stand for reelection at a subsequent meeting within 90 days.
If the spill vote fails, the trigger is reset to no opposition.
TPI said that shareholders would vote to change its name to Palla Pharma, grant security over its Coolaroo and Tasmanian properties, valued at $13,900,000, to lender Washington H Soul Pattinson, elect chair Simon Moore and director Sue MacLeman, and the remuneration report.
The meeting will be held at Arnold Bloch Leibler, Level 21, 333 Collins Street, Melbourne on May 30, 2019 at 3pm (AEST).
TPI was unchanged at $1.345.

PAINCHEK

Painchek has requested a trading halt for “an expected government announcement of a material funding of a proposed national trial of Painchek technology”.
Trading will resume on April 30, 2019 or on an earlier announcement.
Painchek was up 0.4 cents or 13.3 percent to 3.4 cents with 2.6 million shares traded.

POLYNOVO

Polynovo says it has appointed Kevin Whiteley as Polynovo North America LLC vice president to oversee US sales and marketing.
Polynovo said Mr Whiteley had more than 30 years’ experience in the medical imaging and diagnostics industry, most recently as Danaher Corporation’s head of marketing and business development.
The company said Mr Whiteley would receive 1,000,000 options vesting over four years and exercisable at 75 cents each by 2025.
Polynovo was unchanged at 95.5 cents with 1.5 million shares traded.