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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.