Biotech Daily

Friday September 13, 2019

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PROTEOMICS UP 22%; AMPLIA DOWN 8%**

*** DR BOREHAM'S CRUCIBLE: IMAGION BIOSYSTEMS**

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*** VIBURNUM TAKES 19% OF UNIVERSAL BIOSENSORS**

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MARKET REPORT

The Australian stock market was up 0.21 percent on Friday September 13, 2019, with the ASX200 up 14.3 points to 6,669.2 points.

Eleven of the Biotech Daily Top 40 stocks were up, 18 fell, 10 traded unchanged and one was untraded.

Proteomics was the best, up 6.5 cents or 21.7 percent to 36.5 cents, with 739,550 shares traded.

Alterity, Mesoblast and Prescient climbed more than seven percent; Starpharma was up 5.4 percent; LBT and Opthea improved more than four percent; Telix was up 3.85 percent; Cochlear and Next Science rose more than two percent; Neuren was up one percent; with Compumedics up 0.8 percent.

Amplia (Innate) led the falls, down 0.7 cents or 8.05 percent to eight cents, with 50,000 shares traded.

Cynata lost 7.8 percent; Actinogen and Oncosil retreated more than six percent; Pro Medicus fell 5.7 percent; Nanosonics and Resonance were down three percent or more; Clinuvel, Osprey, Pharmaxis, Polynovo and Universal Biosensors shed more than two percent; Cyclopharm, Orthocell and Paradigm were down more than one percent; with Avita, CSL, Ellex, Genetic Signatures and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: IMAGION BIOSYSTEMS

By TIM BOREHAM

ASX code: IBX

Market cap: $12.3 million

Share price: 3.8 cents

Shares on issue: 323,705,324

Chairman and CEO: Bob Proulx

Board*: Bob Proulx, Michael Harsh, Jovanka Naumoska, Bronwyn Le Grice, Mark Van Asten, David Ludvigson

***** Dr John Hazle resigned in late June

Financials (half year to June 30 2019): revenue $300,674 (up 19.5%), loss of $1.0 million (previously $4.4 million deficit), cash of $1.14 million (down 73%).

Major holders: Manhattan Scientific 19.8%, Kemper Shaw 9.82%, Drake Special Situations 7.74%, William Taylor 6.7%, The Board of Regents of the University of Texas System 3.26%, Anthony Faillace 3.21%.

Imagion executive chairman Bob Proulx says the junior diagnostics outfit's remit is simple enough: to change dramatically the way cancer - and potentially other diseases - is diagnosed.

It's not as if there's a shortage of ways to image the body: magnetic resonance imaging (MRI), computed tomography (CT), x-rays, ultrasounds and positron emission tomography (PET) are all widely used.

The key difference with Imagion's Magsense device is that with the exception of magnetic resonance imaging, all of these rely on radiation.

Magsense is based on biologically harmless nanoparticles that eventually are extracted from the body in - ahem - the normal manner. And standard MRIs are both time-consuming and claustrophobic.

Magsense also promises improved functionality, such as the ability to distinguish between a malignant tumor and a benign growth.

The nanoparticles are also being spruiked as a contrast (imaging) agent to detect breast cancer.

Mr Proulx says Magsense offers “many times improvement” over the current standard of care.

“This is potentially going to change dramatically the way we diagnose cancer,” he says.

But let’s not put the cart before the horse: the Magsense project is in pre-clinical stage, but this might soon change.

In July the company won ‘breakthrough device’ status with the US Food and Drug Administration, to test for HER-2 breast cancer.

To qualify for this accolade, a device needs to “provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions”.

About Imagion

The Magsense technology was owned by the Los Alamos, New Mexico diagnostics house Senior Scientific.

Senior Scientific initially focused on mapping magnetic fields in the brain but then pursued a more sensitive technology to detect tumors after founder Edward R Flynn’s wife developed breast cancer.

In 2011 Senior Scientific was acquired by Manhattan Scientifics. In 2016, Senior Scientific was spun out and merged into an Australian-incorporated entity, Imagion Biosystems.

To settle the purchase, Manhattan received 62.4 million Imagion shares, which then accounted for 30 percent of the company.

Imagion listed on the ASX on June 21 2017, raising $12 million at 20 cents apiece in the process.

While Imagion is headquartered in Melbourne, most of its activities take place in San Diego, California.

Imaging re-imagined

Magsense’s key selling point is that it can detect specific diseased cells without biopsy, via the injection of nanoparticles labeled with cell-specific targeting antibodies.

The technology is known as super-paramagnetic relaxometry and in Mary Poppins lexicon could well be supercalifragilisticexpialidocious.

The nanoparticles are subject to a low magnetic pulse, with their location detected by an ultra-sensitive super-conducting quantum interference device (Squid to friends).

The nanoparticles attached to the cancer cells lose their magnetism more slowly than the unattached ones.

“They act like a magnetic beacon. All other imaging uses radiation or in the case of MRIs, water molecules to identify water build up in the tumor,” Mr Proulx says.

“Unlike positron emission tomography (PET) scans or x-rays, Magsense does not expose the patient to ionizing radiation or radioactive tracers and uses magnetic fields orders of magnitudes less than that used in MRIs.”

Geeing up a human trial

Having won breakthrough device designation, the company has lodged a pre-submission with the FDA’s Center for Devices and Radiological Health, in view of filing for an investigational device exemption.

That, in effect, is permission to run a human device trial. The company has also requested a “sprint” discussion, which is not a recap of Usain Bolt’s finest moments but a request to hurry things along.

Mr Proulx anticipates a small study of 10 to 20 patients with HER-2 metastatic breast cancer, whose primary tumor has spread to lymph nodes.

The trial will focus on the tolerability of the tracer agents and whether they get to the cancerous cells with an “appropriate” signal.

When scheduled for surgery, patients are injected with Magsense, along with the standard particles to drain the lymph nodes. “We are just piggy-backing on standard procedure,” Mr Proulx says.

“We are not asking patients to incur anything outside of the normal standard of care.”

This work will look for safety and a signal if a tumor is present. But without about 75 percent of samples proving benign, the lack of a signal is also important.

“It’s not the pivotal study that ultimately will get us clearance, but it’s the first assessment that the clinically intended use of them is likely to be borne out,” Mr Proulx says.

Why HER-2?

Mr Proulx says company is targeting the human epidermal growth factor receptor 2 (HER-2) for two main reasons.

Firstly, HER-2 is one of the more aggressive types and commonly spreads to the lymph nodes. “We thought we could have a bigger impact pursuing HER-2 rather than all invasive breast cancers.”

Secondly, a large number of antibodies already target HER-2. The most common drug, Herceptin, is off-patent and there are a large number of biosimilars available.

“We have a choice of antibodies to use. We don’t have to bring new antibodies to the FDA,” Mr Proulx says.

Better or cheaper?

Imagion envisages a “printer and cartridge” revenue model, which involves selling the capital equipment (the measuring stations on which the patients repose) and the consumables (the nanoparticles).

But does Magsense need to be better or cheaper than the standard-of-care, or perhaps both?

“If we are more sensitive than the current imaging modalities, the competitive position will be straightforward,” Mr Proulx says.

“We don’t think we will get away with being less sensitive, but if we are as sensitive as a biopsy procedure the commercial path is quite clear.”

Given that 50 to 70 percent of lymph node tests are negative, Magsense may save an awful lot of these appendages being removed unnecessarily.

The company has deployed Melbourne product developer Planet Innovation to design the scanning units, which are expected to sell for around $500,000. But not surprisingly, management first wants to prove the nanoparticles work in humanoids.

“The goal for us is to keep the cost of the instrument down as it’s a new capital expenditure purchase [for the customers],” Mr Proulx says.

Finances and performance

With $1.1 million in the bank at June 30 and a $2 million Federal Research and Development Tax Incentive in July, Imagion has enough cash to get to the start of the human trial - but not the end of it.

“We expect in the next two months we will undertake a capital raising,” Mr Proulx says, adding it’s likely to be by way of a placement and rights offer.

He believes the 10 to 20 patient trial will cost $500,000 to $1 million: “It’s not extraordinarily expensive.”

Imagion raised $12 million at its 2017 IPO at 20 cents apiece, following up with a $4.25 million rights issue last October.

Along the way, the company derives some modest but useful revenue - $200,000 to $300,000 a year - by renting out its intellectual property for other research.

In Israel, a company is experimenting with the Magsense particles (which heat up in the body) as a hypothermia treatment.

Imagion shares have sashayed between 17 cents in late June 2017 and 1.6 cents in late June 2019.

Mr Proulx says the weak share price has been more the result of buyers being unable to obtain stock because of poor liquidity, rather than an avalanche of sellers off-loading shares. “The lack of liquidity has really hurt,” he says.

Low turnover aside, the board is otherwise happy for the company to remain domiciled on the ASX.

“The ASX is a good exchange for us,” he says. “It’s highly secure and has good governance rules, unlike some other exchanges where it can be a bit loosey-goosey.”

Dr Boreham’s diagnosis:

Mr Proulx reckons the nearest ASX comparator to Imagion is Telix Pharmaceuticals, which is in phase II and phase III phase for its molecular targeted radiation therapy.

Telix’s circa $345 million market cap dwarfs Imagion’s circa $13 million.

“Our view is we are pretty undervalued given the opportunity we present,” he says.

“We should not be valued at $13 million a few months out from a human study.”

Mr Proulx also hopes Magsense can be deployed for early detection of ovarian and lung cancers, where survival chances are grim.

The San Diego-based Mr Proulx admits he hasn’t done as good a job as he should in communicating with the company’s Australian shareholders over the last 18 months.

Then again, there hasn’t been that much to talk about either.

But things will change if - and when - Imagion leaves the mice modelling stuff behind and tests Magsense on human guinea pigs.

“Now we are getting close [to human trials] we should keep the news flow going.”

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Like his dance moves, his writing style can be a bit loosey-goosey at times.

POLYNOVO

Polynovo says the US Food and Drug Administration has given guidance on the endpoints for its Novosorb biodegradable temporizing matrix pivotal, full-thickness burn trial.
Polynovo said the FDA confirmed that it saw “the potential of Novosorb” biodegradable temporizing matrix (BTM) for the proposed burn population and advised it to submit its trial application through the breakthrough technology pathway.
Polynovo said it would revise the protocol design and planned to submit its application in December 2019, with patient recruitment scheduled by June 30, 2020.
The company said the Biomedical Advanced Research and Development Authority (BARDA) supported the process.
Polynovo said it would announce the updated protocol and budget for the trial by April 2020.
Polynovo said that it would make an FDA premarket approval (PMA) application for Novosorb BTM on successful completion of the trial.
Polynovo fell six cents or 2.8 percent to $2.10 with 4.6 million shares traded.

PROTEOMICS

Proteomics says it has launched its Promarkerd predictive diagnostic test for diabetic kidney disease in Spain in a two-year exclusive licence agreement with Patia Europe.
Yesterday, Proteomics said its clinical diagnostics partner, the Dublin-based Atturos, would manufacture a mass spectrometry version of its Promarkerd test for European laboratory use (BD: Sep 12, 2019).
Today, the company said Patia would commercialize Promarkerd and Proteomics would receive a royalty on each test sold through the Patia Europe licence agreement.
Proteomics was up 6.5 cents or 21.7 percent to 36.5 cents.

INVITROCUE

Invitrocue says directors Prof Hanry Yu, Ee Ting Ng and Kit Wei Lui have called a meeting to remove recently appointed director Geoffrey Thomas (BD: Sep 10, 2019).
Last week, Invitrocue filed two board spill motions, one from Prof Yu, Mr Lui and Ms Ng to remove chief executive officer Dr Steven (Boon Sing) Fang as a director and one from Dr Fang and directors Gary Pace and Andreas Lindner to remove Prof Yu and Mr Lui as directors (BD: Sep 9, 2019).
On Wednesday, Invitrocue said a meeting had been called to remove Dr Steven Fang by Prof Yu, Mr Lui and Ms Ng (BD: Sep 11, 2019).
Invitrocue was in a suspension and last traded at six cents.

OPTHEA

Kifin Limited says it has increased its substantial shareholding in Opthea from 13,360,137 shares (5.36%) to 16,275,227 shares (6.52%).
The Tortola, British Virgin Islands-based Kifin said that on September 7, 2019 it bought 2,915,090 shares for $9,415,267 or $3.23 a share.
Opthea was up 14 cents or 4.2 percent to $3.45.

UNIVERSAL BIOSENSORS

Viburnum Funds says it has increased its substantial shareholding in Universal Biosensors from 31,525,653 shares (17.91%) to 33,710,445 shares (19.01%).
The Nedlands, Western Australia-based Viburnum said that between May 3 and 9, 2018 it bought 394,109 Chess depositary interests (CDIs) for $91,582 or 23.2 cents a share and between September 11 and 12, 2019 it bought 1,790,683 CDIs for $340,262 or 19.0 cents a share.
Universal Biosensors fell half a cent or 2.6 percent to 19 cents.

PHYLOGICA (TRADING AS PYC THERAPEUTICS)

Phylogica says it has appointed Dr Fred Chen to its scientific advisory board and as a founding member of its ophthalmology clinical advisory board.
Phylogica said Dr Chen was currently a consultant vitreo-retinal surgeon at the Royal Perth Hospital and the Lions Eye Institute.
The company said Dr Chen qualified as an ophthalmic surgeon at the Royal Australian and New Zealand College of Ophthalmologists, held a Doctor of Philosophy from University College London and completed a surgical and medical retina fellowship at London's Moorfield Eye Hospital.
Phylogica said that Dr Chen had been the principal or associate investigator in 20 clinical trials and had published more than 130 journal articles.
Phylogica fell 0.1 cents or 2.1 percent to 4.7 cents.