Biotech Daily

Friday December 17, 2021

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: OPTHEA UP 6%; AMPLIA DOWN 9%**

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*** RADIOPHARM COMPLETES PHASE I BREAST CANCER IMAGING**

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*** ALCIDION DIRECTOR MALCOLM PRADHAN DILUTED TO 10.55%**

*** EX-CHAIR RAY BLIGHT DILUTED TO 8% IN ALCIDION**

*** USCOM CHAIR PROF ROBERT PHILLIPS TAKES 21.3%**

*** IMAGION CHAIR ROBERT PROULX 25% PAY RISE TO $446k A YEAR**

*** 4D APPOINTS EVONNE COLLIER DIRECTOR**

*** INVEX APPOINTS PROF MICHAEL WALL 'EVOLVE' TRIAL CHAIR**

MARKET REPORT

The Australian stock market was up 0.11 percent on Friday December 17, 2021, with the ASX200 up 8.3 points to 7,304.0 points. Fourteen of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and one was untraded. All three Big Caps fell.

Opthea was the best, up seven cents or 5.7 percent to $1.295, with 443,867 shares traded. Nanosonics climbed 5.2 percent; Telix was up 4.9 percent; Cynata, Genetic Signatures and Impedimed were up more than three percent; Optiscan and Prescient rose more than two percent; Kazia, LBT, Next Science, Starpharma and Volpara were up more than one percent; with Avita up by 0.6 percent.

Amplia led the falls, down 1.5 cents or 8.8 percent to 15.5 cents, with 1.2 million shares traded. Resonance retreated 8.8 percent; Mesoblast lost 7.1 percent; Nova Eye was down 5.9 percent; Polynovo and Universal Biosensors fell more than four percent; Cyclopharm, Imugene and Neuren were down more than three percent; Antisense, Clinuvel, Cochlear, Immutep, Paradigm and Resmed shed more than two percent; Medical Developments, Orthocell, Osprey and Pro Medicus were down one percent or more; with CSL down by 0.3 percent.

DR BOREHAM'S CRUCIBLE: IMAGION BIOSYSTEMS

By TIM BOREHAM

ASX code: IBX

Share price: 7.5 cents

Market cap: $84.1 million

Shares on issue: 1,121,018,534 (including the recent exercise of 96,706,395 options).

Chief executive officer: Bob Proulx

Board: Bob Proulx (executive chair), Michael Harsh, David Ludvigson, Jovanka Naumoska, Mark Van Asten, Dianne Angus

Financials (September quarter 2021): receipts $34,000, cash outflows $2.18 milion, cash balance $11.99 million, quarters of available funding 5.5

Identifiable major holders: Manhattan Scientific (4.68%), The Board of Regents of the University of Texas System 0.9%, Anthony Faillace 0.9%

The 'Covid-induced trial, interrupted syndrome' is no more apparent than within the walls of Imagion's San Diego headquarters, where the company is spearheading a new form of diagnostic imaging based on pin-pointed magnetic targeting.

Firstly, the company's patient recruitment for its Australian-based breast cancer study was slowed by the availability of suitable candidates, given many screening clinics had closed or lockdowns reduced appointments to a trickle.

To be eligible for Imagion's Magsense imaging, the patients needed to express the HER-2 biomarker and not to have been treated yet.

Unlike Covid, there is a cure for trial disruptions and happily Imagion's early-stage, safety-oriented trial is now making headway.

"We have four sites up and running and they are all fully available and recruiting," reports Imagion chief Bob Proulx.

If Imagion achieves its ultimate goal, clinicians will have access to a screening method more effective than the current regimen of positron emission tomography (PET) scans followed by a painful - and often unnecessary - biopsy.

"This has never been done before. No one has ever developed a magnetic nanoparticle with a targeting body on it," Mr Proulx said.

Imagion that

Imagion's Magsense technology was owned by the Los Alamos, New Mexico based diagnostics house Senior Scientific, which 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.

Senior Scientific was acquired by Manhattan Scientifics but the relevant activities ended up within the newly-formed Imagion, which listed on the ASX on June 21, 2017 after raising $12 million. While Imagion is headquartered in Melbourne, most of its activities take place in San Diego, California.

Squid Games (non-lethal version)

The established cancer imaging techniques, magnetic resonance imaging (MRI), computed tomography (CT), X-Rays, ultrasounds and PET, are all widely used.

Magsense involves injecting nanoparticles labelled with cell-specific targeting antibodies, contained within an iron oxide solution.

The technology is known as super-paramagnetic relaxometry, which sounds like something offered out of a Nimbin shopfront along with tie-dye caftans and chakra alignment devices. The nanoparticles are subject to a low magnetic pulse, with their location detected by an ultra-sensitive super-conducting quantum interference device. Yep, that's a SQUID.

The nanoparticles attached to the cancer cells lose their magnetism more slowly than the unattached ones, acting as a magnetic beacon. While MRIs use water molecules to detect tumors, PET scans use ionizing radiation or radioactive tracers.

(En)roll up …

Recruiting across two sites in Melbourne, one in Sydney and one in Brisbane, Imagion's trial won human research ethics committee approvals in October 2020.

The first site was lined up in February last year, but the pandemic meant the first patient was not enrolled until May this year. Mr Proulx said the company's initial goal was 12 to 15 patients by the end of 2021.

"We are clearly not in a position to achieve that, but I think we will have made substantial progress," he says.

The key endpoints are safety and tolerability, which is not likely to pose too many problems given iron oxide has been used as an imaging adjunct for three decades.

The active component - the antibody - is a form of the commonly used cancer drug Herceptin, but about one per cent of the strength used in therapy.

But does it work?

Preclinical work in animal and in-vitro models showed that the antibody targeting particle was “highly specific” for human epidermal growth factor receptor-2 (HER-2) expressing tumor cells.

In one study, mice were induced with both HER-2 and non-HER-2 expressing tumors and only the former lit up like a Christmas tree (or Channukah candle)

Mr Proulx says the company is looking for a “finger in the wind” as to whether Magsense is effective. If so, the company will then progress to a pivotal global study - perhaps 500 patients - pitched at registration.

He adds the trial is being run in Australia because the regulatory process has been “really well worked out”.

While any US trial will require Food and Drug Administration consent, the local Therapeutic Goods Authority is willing to defer to the ethics approval process. Oh, and there’s also Australia’s research and development tax offset, which was not the key driving factor but the “icing on the cake”.

In July 2019, the company won ‘breakthrough device’ status with the FDA to test for HER-2 breast cancer. To qualify, a device needs to “provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions”.

The path to commercialization

Let’s not forget that Magsense is only a prototype instrument, so there’s a long way to go. After gaining approval for HER-2 breast cancer, the company plans to expand Magsense’s use to other hard-to-detect cancers such as prostate and ovarian.

“The reality is if the device can only do HER-2 it will only be used every couple of days, which is not attractive economically for the clinics,” Mr Proulx says.

Revenue will be the way of the fabled printer and cartridge model, by which the hardware (the measuring stations on which the patients’ repose) is virtually given away. The company gleans annuity income from the consumables (the injectable imaging agent with the nanoparticles attached).

“We are looking at being slightly less expensive than a biopsy, but more expensive than a current imaging agent such as gallium,” Mr Proulx says.

The market, he says, is screaming for a non-invasive way to detect these cancers earlier.

“In the case of ovarian cancer, an ultrasound can’t detect a mass in and around the fallopian tubes until it gets to about ten billion cells - that’s a two-to-three centimetre lump.”

He’s confident Magsense can detect as few as ten million cells: “still orders of magnitude better than the current standard of care”.

Scintillating tie ups

This year, Imagion signed a deal with San Diego's Global Cancer Technology, to develop its nano-crystals to treat breast cancer. Imagion will be paid for its research and development input and earn part ownership of the product, called a nano-scintillator.

Imagion has also signed a compact with the ASX-listed Patrys. This one involves combining Patrys's compound deoxymab with Imagion's particles to treat brain cancer.

Making America nuclear free

Annually in the US, one million men with potential prostate issues, undergo a painful biopsy which involves a 12-pronged needle being inserted up the rectum, Mr Proulx says.

Intriguingly, Australia is ahead of the US in the use of PET imaging, because of concerns in the US about radioisotopes that require local production (with a nearby cyclotron).

Er - hasn't the US embraced nuclear power, nuclear submarines and nuclear weapons? True - but no-one likes a nuclear reactor in their own backyard.

Another reason for the high rate of biopsies is that the reimbursement system makes PET PSMA (prostate) tests more expensive.

"Physicians say: 'I will do a biopsy and I will find out what I'm looking for'," Mr Proulx says. "There's also the scenario of competing factions in the US: pathologists and guys doing biopsies saying if you are doing a PET [prostate test] you are taking revenue from me."

Peer review

Strictly speaking, Imagion has no competition because no-one else is working on an alternative to PET tracers as a targeted MRI agent.

"There's a lot of academic research, but no one has turned it into a product," Mr Proulx says.

But there's plenty of activity with cancer imaging generally among ASX-listed proponents.

Paul Hopper's Radiopharm listed on November 25 this year, having raised $40 million. The company is developing diagnostic and therapeutic radiopharmaceuticals for cancer.

Telix listed in November 2017, having raised $50 million to develop diagnostics and treatments based on molecularly targeted radiation.

Clarity listed in August this year, raising $92 million to develop its program based on two copper radio-isotopes.

Volpara, which uses algorithms to detect breast cancer more effectively. The company has also developed automated tools to improve the efficiency of screening clinics.

Finances and performance

With $12 million in the bank, Imagion is funded for the next five quarters, but will need to raise more funds for any further trials.

The company has just bolstered its coffers with $4.8 million from the exercise of options, which had a November 26 expiry and converted at five cents each.

Imagion's shareholder mix changed significantly when the shares bolted from around eight cents in November 2020 to 20 cents in January 2021.

In other words, some parties took profits. Over time the biggest holder, Manhattan Scientific, has been diluted below five percent, but that's more because it did not participate in past raisings.

The company has no substantial shareholders (with five percent or more) and an unusual retail-heavy base of 10,000 holders.

Imagion shares peaked at 22 cents on February 17 this year, but on September 22 traded at a 12-month low of six cents.

In April 2020, the shares plunged to a record low of one cent.

Dr Boreham's diagnosis:

When we last looked at Imagion in the carefree pre-pandemic times of October 2019, Mr Proulx said the company's core remit was to change dramatically the way cancer - and potentially other diseases - are diagnosed.

We guess nothing has changed. But progress has been slower than expected - not that there's anything unusual about that in the life sciences milieu.

With the company's trial interruptions now in the past, investor attention should focus on the progress of the patient enrolment, followed by any hints about the envisaged pivotal trial.

Meanwhile, Imagion has no plans to abandon the ASX in search of a Nasdaq listing and the somewhat mythical ability of the process to bolster a company's value overnight.

"The ASX has served us well. We have 10,000 investors who are enthusiastic about what we are doing," Mr Proulx says.

Arise cobber Bob! We declare you an honorary Australian.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is however a qualified Australian, proficient in lassoing koalas and bareback kangaroo riding.

PALLA PHARMA (FORMERLY TASMANIAN POPPY INDUSTRIES)

Palla says it has entered voluntary administration with Craig Shepard and Bryan Webster of Korda Mentha appointed voluntary administrators.

Palla said the recent review of its strategy and operations "highlighted, amongst other things, the further impact the Covid Omicron variant is having on elective surgery volumes, particularly in the UK, and therefore on forecast sales".

The company said that, while it was currently solvent it was "likely to become insolvent at some future time and, hence, that administrators should be appointed".

Palla said that the administrators had assumed control of the company and would work with the board during the administration period to "maximize the outcome for all stakeholders of the company".

Palla said the administrators had requested that trading in its shares on the ASX remain suspended during the administration period.

In November the company said it had sold its Coolaroo site north of Melbourne for $33.1 million and would lease it back.

In September, Palla said that revenue for the six months to June 30, 2021, was down 42.7 percent to $7,060,872 with net loss after tax up 267.2 percent to $33,105,663, and it had cash and equivalents of $897,312 at June 30, 2021 (BD: Sep 1, 2021).

In May, Palla said that having "settled all outstanding legal issues" with its largest ingredient customer (poppy-derived products), the Bolton, England-based M&A Pharmachem, it had begun a long-term production partnership (BD: May 4, 2021).

In December 2020, the company said that founder and chief executive officer Jarrod Ritchie has resigned from the company (BD: Jan 17, 2021).

The then Tasmanian Poppy Industries listed on the ASX in 2015, with the annual report from that year saying that Mr Ritchie had 20 years' experience in the poppy industry and had been a director of the company since February 2004.

Palla last traded at 29.5 cents.

RADIOPHARM THERANOSTICS

Radiopharm says it has completed a phase I imaging trial of RAD201 for human epidermal growth factor receptor 2 positive (HER2+) breast cancer in China and the UK.

Radiopharm said the study was investigating the safety, dosimetry and efficacy of RAD201 and imaged 40 patients at Shanghai General Hospital under the direction of Dr Jinhua Zhao and was conducted at Nanomab in London and Hong Kong.

The company said the procedure involved injecting the subject with RAD201, allowing time for the single domain antibody to localize at the HER2+ cancer and clear from non-target organs, then imaging the subject two hours post-injection using a single photon emission computed tomography (Spect) camera.

Radiopharm said the procedure "yielded uniformly excellent, easy to interpret images … [which showed] outstanding target-to-background, making quantification straightforward and RAD201 Spect imaging a potentially fast and non-invasive way of gaining insight to HER2 overexpression in breast cancer primary and metastatic lesions".

Radiopharm said that "no concerning safety signal was observed, with only a minor grade 1 adverse event reported as unrelated to RAD201.

The company said it planned to accelerate development of RAD201 and begin a phase I therapy study for RAD202 under an investigational new drug application recognized by the US Food and Drug Administration by July 2022.

Radiopharm was up 2.5 cents or 6.9 percent to 38.5 cents with 2.8 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says it has completed the second cohort in its chlorotoxin chimeric antigen receptor T-cells phase i dose escalation study at the Los Angeles' City of Hope.
Last month, Chimeric said the trial of chlorotoxin chimeric antigen receptor T-cells (CLTX-Car-T-cells) for glioblastoma showed "disease control" in three of four patients at the lowest dose (BD: Nov 15, 22, 2021).
The company said the results gave it "confidence as higher dose levels and dual routes of administration commence".
Today, the company said the second dose cohort had both intra-ventricular and intra-tumoral administration compared to the first cohort which had intra-tumoral only.
Chimeric said the third and fourth cohort would administer intra-ventricular and intra-tumoral CLTX-Car-T-cells at higher doses.
Chimeric was up three cents or 12.0 percent to 28 cents with one million shares traded.

INCANNEX

Incannex says that "comments" from the US Securities and Exchange Commission have delayed its initial public offering in the US.
Incannex said that its September annual general meeting voted 99.98 percent in favor of the issue of 180,000,000 shares for the initial public offer, but the approval was valid for three months, expiring today.
The company said it had "taken several months to address comments raised by the SEC".
Incannex said that with its investment bank Roth Capital Partners, it "believes that it is [sic] has adequately addressed such comments" and was in a position to conduct the initial public offering in January 2022.
Incannex said it would list American depositary shares on the Nasdaq under the code IXHL
Incannex fell three cents or six percent to 47 cents with three million shares traded.

ALCIDION GROUP

Alcidion executive director Malcolm Pradhan says his 134,582,403 share-holding in the company has been diluted from 13.58 percent to 10.55 percent.
Last week, Alcidion said its placement and institutional rights offer raised $43.4 million, with $11.6 million expected in the retail offer (BD: Dec 17, 2021).
Alcidion was up half a cent or two percent to 26 cents with 1.8 million shares traded.

ALCIDION GROUP

Former Alcidion chair Ray Blight says his 101,871,831 share-holding has been diluted from 10.15 percent to 7.99 percent.
Mr Blight said the dilution followed a capital raising (see above).

USCOM

Uscom executive chair Prof Robert Phillips says he has increased his shareholding from 32,202,535 shares (20.66%) to 41,863,296 shares (21.308%).
On Wednesday, Uscom said its rights issue at 11 cents raised $4,359,073 with Prof Phillips subscribing for his full entitlements of $1,062,684 in shares (BD: Dec 15, 2021).
Uscom was untraded at 11 cents.

IMAGION BIOSYSTEMS

Imagion says it has increased executive chair Robert Proulx's base salary by 25 percent to $US320,000 ($A446,180) per annum.
Imagion said Mr Proulx had not sought a salary increase since the initial public offering in 2017 and the company said it would backdate the increase to July 1, 2021.
According to Imagion's annual report for the year to December 31, 2020, previously Mr Proulx was on a base salary of $US240,000 a year.
Imagion was up 0.3 cents or 4.2 percent to 7.5 cents with six million shares traded.

4D MEDICAL

4D says it has appointed Evonne Collier as an independent non-executive director, effective immediately.
4D said Ms Collier had experience in sales and marketing in medical and financial technologies and was previously a director at 1300Smiles and Vault Intelligence.
The company said that Ms Collier was currently a director of Sage Automation, Curae Health, Sniip and Motorama Group.
According to her Linkedin page, Ms Collier held a Bachelor of Arts from the University of Queensland had a Master of Business from Queensland University of Technology.
4D fell half a cent or 0.4 percent to $1.29.

INVEX THERAPEUTICS

Invex says it has appointed Prof Michael Wall as the trial steering group chair for its 240-patient, phase III 'Evolve' trial of Presendin for idiopathic intracranial hypertension.
Invex said Prof Wall was a professor of ophthalmology and neurology at the University of Iowa College of Medicine and director of the Iowa Visual Field Reading Centre.
Invex fell 3.5 cents or five percent to 66.5 cents.