Biotech Daily

Friday September 16, 2022

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 1.4 percent on Friday September 16, 2022, with the ASX200 down 95.9 points to 6,747.0 points. Ten of the Biotech Daily Top 40 were up, 20 fell, six traded unchanged and four were untraded.

Actinogen was the best, up 0.4 cents or 5.1 percent to 8.2 cents, with 666,782 shares traded. Impedimed and Neuren improved more than four percent; Pharmaxis was up 3.7 percent; Orthocell rose 2.6 percent; Antisense was up 1.1 percent; with Clinuvel, Cochlear, Mesoblast, Opthea and Proteomics up by less than one percent.

Kazia led the falls, down two cents or 8.5 percent to 21.5 cents, with 61,785 shares traded, followed by Patrys down eight percent to 2.3 cents, with 1.9 million shares traded.

Volpara lost 6.8 percent; Prescient was down 5.4 percent; Amplia fell 4.55 percent; Alcidion, Atomo, Avita, Dimerix, Genetic Signatures, Micro-X and Paradigm were down more than three percent; Cynata, Medical Developments, Nanosonics, Oncosil, Resmed and Universal Biosensors shed two percent or more; Pro Medicus was down 1.3 percent; with CSL, Emvision and Telix down by less than one percent.

DR BOREHAM'S CRUCIBLE: INOVIQ

By TIM BOREHAM

ASX code: IIQ

Share price: 67 cents

Market cap: $61.7 million

Shares on issue: 92,018,702

Chief executive officer: Dr Leearne Hinch

Board: Dr Geoffrey Cumming (chair), Robert (Max) Johnston, Philip Powell, Prof Allan Cripps

Financials (year to June 30, 2022): product revenue $276,745 (down 41%), loss of $6.26 million (previously an $11.1 million deficit), cash of $15.4 million (up 206%).

June quarter 2022: receipts of $163,000, cash burn $1.68 million, cash balance $15.4 million, quarters of available funding nine.

Identifiable major shareholders: Merchant Funds Management 12.63%, Moggs Creek Super (David Williams) 5.3%, Dr Irmgard Irminger-Finger 4.4%.

Inoviq? Ino-who?

Most investors would struggle to recognize one of the newest names in the ASX biotech family which, we're reliably informed, means "intelligent innovation".

Given the company's three-pronged program covering cancer diagnostics and involving lots of dense acronyms, investors could also be forgiven for understanding where these innovative smarts are being directed.

For those who haven't been paying attention, Inoviq is the new moniker for Bard1, which subsumed fellow ASX-listed Sienna Diagnostics at the onset of the pandemic in mid-2020.

While the two companies are pretty much an omelet these days, the active programs are weighted to the old Sienna.

Inoviq chief Dr Leearne Hinch admits the company can seem complicated, given its various technology strands and multi-product pipeline.

"People have a better understanding of therapeutics; there's less understanding of what diagnostics, do although Covid has significantly changed that," she says.

Inoviq's ultimate aim is simple enough: to commercialize better diagnostics for some of the most common cancers.

"The current cancer diagnostics are far from reliable," Dr Hinch says.

"The key unmet need is to detect cancer earlier and more accurately. We have a host of opportunities, from screening to diagnosis to treatment selection and patient monitoring."

How the omelet was cooked

Sienna listed in mid-2017, backed by deep-pocketed names including former Macquarie Bank chief Allan Moss and rag trader tycoon David Neate.

Sienna developed an approved adjunct diagnostic product for bladder cancer called hTERT (anti-hTERT, strictly speaking).

Launched in 2016 initially as a laboratory reagent, it remains Inoviq's legacy, revenue-generating product.

In 2019, Sienna acquired an exosome technology asset called Exo-net.

In April 2020, the company licenced a cancer-busting protein - clumsily monikered Sub-B2M - from the University of Adelaide and Griffith University.

Bard1 emerged from the shell of Eurogold in 2016, with its work focused on lung cancer and an auto-antibody platform based on the Bard1 protein.

In mid-2020, Bard1 acquired Sienna in a scrip deal valuing the whole shebang at around $76 million.

Apart from cancer diagnostics, the other common feature was that Merchant Opportunities Fund owned a large slab of both of them.

In December last year, Bard1 renamed itself Inoviq.

Dr Hinch joined Bard1 as CEO in November 2016.

A trained veterinarian, Dr Hinch previously headed the ASX-listed Immuron and held executive roles at the listed OBJ Ltd, Hollista Colltech and the now-defunct Healthlinx (also cancer diagnostics) and Chemeq.

Dr Hinch, by the way, joins vets-turned human biotech execs Dr Jackey Fairley and Dr Paul MacLeman.

"I have seen this company through a lot of change from one that had a single technology - Bard1's auto-antibody platform - to acquiring Sienna for its Exo-net asset," Dr Hinch says.

Exosome or go home

Exosomes are a hot area of research, with the ASX-listed Exopharm specializing in the field.

While Exopharm is all about therapeutics, Inoviq focuses on diagnostics and claims to be a leader in the race to commercialize a product.

Exosomes are small extra cellular vesicles, or as Dr Hinch puts it: “Little balls released from all cells in the body, including healthy and diseased ones.”

Inside the exosomes are different sorts of molecules, such as DNA fragments, ribonucleic acid (RNA), proteins and lipids.

Inoviq’s Exo-net is a matrix of antibodies that ‘capture’ the exosomes for analysis.

In the case of an ovarian cancer, the company compares exosomes from cancer cells with normal ones.

“Inside the cancer exosomes, we found a number of informative biomarkers such as micro-RNAs and proteins,” Dr Hinch says.

“That combination of biomarkers goes into an algorithm, which enables the earlier and more accurate detection of ovarian cancer.”

Tapping the burgeoning research market

Inoviq has targeted Exo-net as a research tool for interested parties such as academia and drug companies developing exosome-based therapies.

“Because it doesn’t have to be approved for use in research, this provides a faster market opportunity to get it in the hands of key scientists,” Dr Hinch says.

Dr Hinch cites a potential $US661 million ($A944 million) market for global exosome research, up from $US440 million in 2021.

In July 2022, the company appointed US mob Precurso Life Sciences, which already offers exosome research products, as a contract sales agent.

“This is a nascent industry that is growing rapidly because of the amount of research being done in this sector in both diagnostics and therapeutics,” Dr Hinch says.

Currently there is only one approved exosome-based diagnostic, for prostate cancer.

Inoviq aims build a pipeline of exosome-based diagnostics, firstly for cancer but also for neurogenerative diseases (such as Alzheimer’s and Parkinson’s) or metabolic ailments such cardiovascular disease, obesity and diabetes.

The company has an exosome-based ovarian cancer diagnosis in development with the University of Queensland, in view of a mass screening test.

Dr Hinch adds that Exo-net can be customized by using different antibodies to capture exosomes from the brain, lung or ovaries.

Sub optimal time for a Neu name, Eliza?

Dr Hinch concurs that Sub-B2M is an “awful name” that’s ripe for changing - and no doubt will be.

Totally unconnected to submarines - nuclear powered, French-built or otherwise -Sub-B2M is an engineered protein that detects a pan-cancer biomarker called Neu5Gc.

Neu5Gc is a sugar found on any cancer cell, but not any healthy human cell (or any mammalian one for that matter).

“Somehow cancer has found a way to produce this Neu5Gc; hence it is a pan-cancer biomarker,” Dr Hinch says.

Earlier studies showed that Sub-B2M could detect more than 95 percent of breast cancers across all stages (stages one to four), with no false positives.

This work was done in 2018 and 2019. Since then, the company has focused on transferring the tech to a simple format called Eliza, as in enzyme linked immunosorbent assay.

Sorry - these names are not getting any better.

“It’s a simple assay that is cost effective and used in pathology labs around the world,” Dr Hinch says.

“We are seeking to improve on existing cancer monitoring tests.”

One such test has already been approved by the US Food and Drug Administration for monitoring ovarian cancer, focused on detecting the protein on cancer cells called CA125.

Ditto a second test for the breast cancer protein biomarker CA15.3.

Anyone for a sandwich?

The aforementioned tests aren’t especially effective, because these biomarkers can be elevated for reasons other than cancer.

So Inoviq proposes a “sandwich assay” approach by which its test detects both the proteins and Neu5Gc, which narrows their occurrence to cancer cells.

“The sugar was very much known as a cancer biomarker, but no one knew how to bind the sugar with high sensitivity and specificity,” Dr Hinch says.

At least that’s until the University of Adelaide and Griffith University nutted out how to bind the antibodies and the sugar “with great affinity”.

As with Exo-net, Inoviq plans to sell the diagnostic as a laboratory-based test. This would be followed by a clinical trial to support an FDA application under the 510(k) predicate device pathway.

The test could be used either to improve the existing tests, or as a routine blood- based assay along with the standard tests for glucose, liver enzyme and cholesterol levels.

In late July, Inoviq showed that Sub-B2M was effective in detecting melanomas and distinguishing the malignant growth from benign ones.

This was based on 144 samples.

Fewer biopsies? Bladder believe it

Inoviq’s anti hTERT is an immune-cyto-chemistry test used as an adjunct to urine cytology. The test detects the hTERT human telomerase, which is elevated in cancer cells.

The problem with current methods is that 25 percent of the cells are indeterminate, which means it’s not clear whether it’s cancer or not.

To reduce the number of patients referred for an unnecessary cystoscopy and biopsy, the samples are stained with hTERT.

As with a Band-Aid, hTERT has no particular disease claim and has also been approved in Europe, South Korea and Australia.

In an ideal world of daisies and fluffy kittens, every relevant sample would be double tested with the hTERT kit. But as Americans would attest, healthcare boils down to money and preferably someone else’s.

Finances and performance

Inoviq recorded $160,000 sales in the June quarter of 2022, all from the hTERT product. Sales for the 2021-’22 year came in at a Covid-affected $276,745 million, which compares with peak annual revenues of $500,000 per annum.

At the end of June, the company had a tad over $15 million of cash, with the coffers bolstered by an $18.4 million placement and share purchase plan in mid-2021.

“Based on our current cash burn, we have enough cash to cover the next two years,” Dr Hinch says.

“But that will depend on our development programs. We expect our spending to increase over the next couple of years as we move our programs forward and into clinical validation.”

Inoviq shares are down 50 percent compared with a year ago, but up a hefty 45 percent since June 30, 2022.

Since the 2020 merger, Inoviq has traded as low as 41 cents (June 24 this year) and as high as $3.99 (March 2021) following the February announcements of “100 percent” success for sensitivity and specificity for ovarian cancer and 95 percent and 100 percent, respectively, for breast cancer.

Dr Boreham’s diagnosis:

Ideally, Inoviq will emerge with commercialized breast and ovarian cancer monitoring tests (Sub-B2M) and ovarian cancer screening for asymptomatic folk (Exo-net).

We’ve barely mentioned the old Bard1’s legacy, early-stage lung cancer program, but neither has the company.

A screening product is harder to get to market, partly because a higher patient sample is required to prove efficacy. So, if anything, investor hopes centre on the more advanced Sub-B2M program, with numerous studies across both cancers underway.

Sometimes the seemingly small things count in biotech research and fortunately the company has access to a bio-bank of ovarian cancer samples and matched controls, held by University College London.

“This is really important because accessing ovarian cancer samples is very difficult,” Dr Hinch says.

There’s certainly much going on by way of intelligent innovation at Inoviq, but we suspect the dense nature of the company’s material has contributed to the company’s share price decline.

“We are in a tough market now,” Dr Hinch says.

“We have been hit hard but we are focused on moving our key programs forward and expect value to return to the share price.”

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Rather than the company’s material being dense, it could well be just him.

ADHERIUM

Adherium says it has “commitments” for $13.5 million in a placement at 0.5 cents a share and share purchase plan at the same price, subject to shareholder approval.
Adherium last traded at 0.8 cents and Biotech Daily calculates the placement price to be a 37.5 percent discount to the closing price on September 14, 2022.
The company said that one unlisted option exercisable at one cent each by March 31, 2024, would be issued for every two shares acquired.
Adherium said the placement included “cornerstone investments” from the London, Ontario-based Trudell Medical, Melbourne’s Bioscience Managers Translation Fund 1, and another unnamed “significant institutional investor.
Adherium said the placement would be in three tranches and it would call an extraordinary general meeting, expected in late October, to approve the second tranche, the issue of options, the third tranche to Trudell, which would take the company to more than 20 percent of Adherium, and the share plan.
The company said that chair Lou Panaccio would subscribe for 20,000,000 shares, and 10,000,000 options in the second tranche of the placement.
Adherium said the funds would be used for product development, business and marketing development, research and development, general administration and working capital.
The company said that Sydney’s MST Financial was the sole lead manager for the placement.
Adherium fell 0.1 cents or 12.5 percent to 0.7 cents with 1.6 million shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says the US Food and Drug Administration has granted rare paediatric disease designation to DUNP19 for osteo-sarcoma.
Earlier this month, Radiopharm said the FDA had granted orphan drug designation to DUNP19 for osteo-sarcoma (BD: Sep 9, 2022).
Today, Radiopharm said rare paediatric disease designation allowed companies to receive a priority review voucher from the FDA when marketing authorization was granted, which could be used to expedite approval, or transferred or sold to other companies, with recent voucher prices selling for $US105 million ($A156.4 million) to $US110 million.
Radiopharm managing-director Riccardo Canevari said the designation was “again excellent recognition of the work to date by Dr David Ulmert and his team and the potential for DUNP19 to make a significant difference to young patients in need”.
Radiopharm was up 1.5 cents or 9.1 percent to 18 cents.

RESAPP HEALTH

Resapp says it will be removed from the ASX following its acquisition by Pfizer Australia for about $179 million.
Earlier this month, Resapp said shareholders approved the Pfizer offer and the New South Wales Supreme Court approved the scheme of arrangement (BD: Sep 8; Sep 14, 2022).
Last month, Pfizer raised its original 11.5 cents a share offer, valuing Resapp at about $100 million, to 20.8 cents a share valuing it at about $179 million (BD: Aug 3, 2022).
Resapp said it had requested a suspension from the ASX from the close of business on September 15, 2022, and that it would continue until the implementation of the scheme of arrangement, expected on September 26, 2022, and then would be removed from the official list of the ASX.
Resapp last traded at 20.5 cents.

LIVING CELL TECHNOLOGIES

Living Cell says the Sydney-based Opticellai Pty Ltd has completed the first stage of the planned use of artificial intelligence in NTCell's manufacture.

In May, Living Cell said it would pay Opticellai $360,000 to use artificial intelligence for NTCell pig brain cell selection and optimization (BD: May 23, 2022).

In March, the company said the University of Technology Sydney would optimize its NTCell encapsulated pig choroid brain cells for a clinical trial in Parkinson's disease in 2024 (BD: Mar 30, 2022)

Today, the company said the first stage comprised the finalization of the necessary hardware, software and testing specifications, as well as creating the final design of its NTCell.

Living Cell said Opticellai would progress to the second stage of assembling the necessary software and providing a prototype to it for trials, with research expected to ultimately result in the development of two prototype machines, and trained artificial intelligence for NTCell optimization and section requirements.

Living Cell executive chair Prof Bernie Tuch said the company welcomed "the completion of stage one of the [artificial intelligence] research with Opticellai".

"This is ground-breaking research with enormous potential, not only for Living Cell but for Parkinson's disease and medical research globally," Prof Tuch said.

Living Cell was unchanged at 1.3 cents.

MEDLAB CLINICAL

Medlab says it has ethics and clinical trial registration approval for two observational studies of its marijuana therapies, Nanabis and Nanocbd.

Medlab said that the trials were designed to assess adverse event information, dosing versus outcomes, ongoing cognitive capacity, as well as side effects and treatment success over a long timeframe.

The company said that Nanabis was its marijuana-based drug for cancer bone pain, as an alternative to opioid use, and that Nanocelle its delivery platform, delivering medicine in particle form by spraying the buccal, or cheek.

Medlab said that its current observation study had about 1,200 patients and showed "positive tolerability" in relation to use with cancer therapies, co-prescribed tolerance and efficacy, pain reduction, quality of life improvements and overall medication reductions.

Medlab said the Nanabis study was titled, 'Observational Study of the Safety, Tolerability and Efficacy of Tetrahydrocannabinol-Cannabidiol Oro-buccal Sprays, MC-1019 and MC-1022', expected to enrol 1,000 participants, with the primary endpoint of "incidence, type and severity of adverse events", with secondary measures assessing the efficacy for improving quality of life, patterns of Nanabis use, and change in use of other medications.

The company said the Nanocbd study was titled 'Observational Study of the Safety, Tolerability and Efficacy of Cannabidiol (CBD) Oro-buccal Sprays for Treating Pain and/or Stress', would be a 2,000-participant trial with the endpoints as the Nanabis study.

Medlab research director Dr Jeremy Henson said the studies would "provide a wealth of data for supporting registration and also facilitate valuable engagement with prescribers, consumers and key opinion leaders".

Medlab chief executive officer Dr Sean Hall said "both studies are designed to closely reflect data points typical to a phase IV study, with stronger focus on eliciting adverse event information, dosing versus outcome and ongoing cognitive assessment, and expansion of our longitudinal data".

Medlab fell 20 cents or 1.6 percent to $12.10.

AUSBIOTECH

Ausbiotech says Ausbiotech and Ausbioinvest 2022 conferences will be held in Perth, Western Australia from October 26 to 28, 2022.
Ausbiotech said Ausbioinvest was Australia's largest life sciences investment conference", with up-to 30 public and private company presentations, as well as speakers who would discuss "insights to support informed investment decisions in a complex scientific field".
The organization said the program was at: https://www.ausbiotechinvestment.com.au/.
Ausbiotech said qualified investors could apply for complimentary registration at: https://ausbiotech.eventsair.com/ausbiotech-2022/investor-application/Site/Register.
The industry organization said that the three-day conference program had more than 110 speakers over 40 sessions, and would address issues "essential to growing commercial opportunities for the life sciences sector".
Ausbiotech said that keynote addresses would include Telstra Health's Elizabeth Koff, Prof Fiona Wood, Texas Medical Centre's Bill McKeon, the University of Colorado's Prof Marvin Caruthers and DLA Piper's Dr Lisa Haile.
The organization said that delegates would benefit from "from exchanging ideas, building their networks, and finding new partnerships that will drive their own business success and the ongoing development of the biotech sector in Australia" and that registration was open at: https://www.ausbiotechnc.org/register2022.
Ausbiotech managing-director Lorraine Chiroiu said "our ability to attract high-quality industry experts to Ausbiotech 2022 speaks volumes for the Australian biotech sector which is providing significant economic and social value for our country, including a surge in the creation of high-value, knowledge-based jobs".

COCHLEAR

Cochlear's annual general meeting will vote to issue $2,458,125 in long-term incentive performance rights to chief executive officer Dig Howitt, pending performance hurdles.
Cochlear said the meeting would also vote to increase the maximum remuneration for non-executive directors by $500,000 or 16.7 percent to $3,500,000 a year, as well as re-elect Yasmin Allen, Michael del Prado and Karen Penrose as directors.
The company said that Mr Howitt would receive a combination of 50 percent options and 50 percent performance rights, with the long-term incentive for 2022-'23 worth up to $2,458,125, or 125 percent of Mr Howitt's annual salary, with the 19,087 options valued at $64.39 each and the 6,041 performance rights valued at $203.44 each, vesting after the full year results were announced in 2026.
Cochlear was up $1.51 or 0.7 percent to $214.23 with 267,088 shares traded.

POLYNOVO

Polynovo has requested a trading halt in relation to "finalizing an announcement on the clearance by the [US Food and Drug Administration] of a major new product".
Trading will resume on September 20, 2022 or on an earlier announcement.
Polynovo last traded at $1.355.