Biotech Daily

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Daily news on ASX-listed biotechnology companies

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- NOVA EYE, STARPHARMA DOWN 10%

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*** CRONOS LOSES CMO, DIRECTOR, 24% HOLDER DR BENJAMIN JANSEN**

MARKET REPORT

The Australian stock market fell 1.87 percent on Friday September 23, 2022, with the ASX200 down 125.5 points to 6,574.7 points. Four of the Biotech Daily Top 40 companies were up, 28 fell, six traded unchanged and two were untraded. All three Big Caps fell.

Emvision was the best, up 5.5 cents or 3.77 percent to $1.515, with 38,402 shares traded, followed by Dimerix up 3.7 percent to 14 cents with 803,309 shares traded. Antisense and Paradigm were up more than one percent.

Nova Eye led the falls, down 2.5 cents or 10 percent to 22.5 cents, with 30,300 shares traded, followed by Starpharma down 9.9 percent to 63.5 cents with 249,771 shares traded.

Oncosil lost 7.7 percent; Imugene was down five percent; Clinuvel, Kazia, Nanosonics, Polynovo and Volpara fell four percent or more; Actinogen, Alcidion, Cochlear, Impedimed, Pro Medicus, Resonance and Telix were down three percent or more; Avita, Cyclopharm, Mesoblast, Orthocell, Pharmaxis, Proteomics and Resmed shed more than two percent; Atomo, Compumedics, CSL, Genetic Signatures, Immutep, Neuren and Next Science were down one percent or more; with Opthea down by 0.4 percent.

DR BOREHAM'S CRUCIBLE: VECTUS BIOSYSTEMS

By TIM BOREHAM

ASX code: VBS

Share price: 66 cents

Market cap: $24.4 million

Shares on issue: 37,033,100

Financials (year to June 30 2022): revenue $1.3 million (up 27%), loss of $3.99 million (previously a $3.86 million loss), cash of $1.28 million (down 77%), debt of $5.889 million (consists of $5.44 million of convertible notes and $442,291 of director loans)

June quarter 2022: receipts nil, cash outflows $1.4 million, quarters of available funding: 0.9 (the company received a $936,000 Federal R&D Tax Incentive in July 2022)

Chief executive: Dr Karen Duggan (co-founder)

Board: Dr Ronald Shnier (chair), Maurie Stang (deputy chair, co-founder), Dr Duggan, Peter Bush, Dr Susan Pond.

Identifiable major shareholders: Ajjika Tech (Dr Duggan) 10%, Energy Trading Systems (Maurie Stang) 8%, Bernard Stang 8%, Kefford Holdings 7.2%, Truebell Capital 4.2%.

As with almost every other drug developer on the planet, Vectus co-founder Maurie Stang believes his fibrotic diseases outfit is of interest to potential, deep-pocketed partners.

The difference is that given his life science pedigree, his comments hold more weight. "There's a lot of management by press release in this market and that's not us," he says.

Given that, investors will be intrigued to know that a "very well-known biotech" is paying close interest to Vectus, while the company has already knocked back "a few barbarians at the gate" with undercooked proposals.

"All the premature attempts to get hold of the crown jewels have been rebuffed," he says.

The former (now deputy) chair of Nanosonics, Mr Stang steered the sterilization device giant from a minnow to a $1.1 billion market cap company.

He also founded Henry Schein, the country's biggest dental supplies provider, as well as Regional Healthcare Dialysis and, in the US, x-ray innovator Lumitron.

Vectus dwells in fibrosis, which is linked to heart, kidney and liver failure, respiratory failure (pulmonary fibrosis) and Covid (long or otherwise).

Mr Stang says it's a case of focusing on the science, while also understanding the business case for an eventual drug.

The key attraction is that while current treatments such as so-called Ace inhibitors might slow down fibrosis, they won't reverse the condition.

It's hoped that Vectus's lead drug, VB-0004, will do just that.

Giving patients the VIP treatment

Accounting for 40 percent of all deaths, fibrosis is the thickening and scarring of connective tissue.

VB-0004 is a native vasoactive peptide, or VIP. It's based on a mimetic platform, which is about creating compounds to resemble the active components of a naturally-occurring peptide.

More broadly, Vectus has a library of 1,000 compounds, derived from the platform underpinning VB-0004.

And seeing you asked, the key candidates are VB4-A32 (liver fibrosis, including alcoholic and non-alcoholic steato-hepatitis), VB4-A79 (pulmonary fibrosis, including idiopathic pulmonary fibrosis, asbestosis and black lung disease) and VB4-A5 (tubular cell death consequent to cytotoxic therapy).

"VIP is in all our bodies," Mr Stang says. "The only time you don't see them is when you're ready for a heart or kidney transplant.

"While VIPs are a well-known marker of disease, no-one before saw them as a regulator of disease."

Vectus's compounds work by stimulating a natural repair process in the body: activating receptors that prompt macrophages to take out scar tissue and regenerate functional tissue.

Mr Stang is highly encouraged by the results of in-vivo (animal) and human cell line testing.

"We see rigid aortas that are not functioning and they go back to being soft and normalizing blood pressure," he says.

In the case of kidneys, it's hoped that one of the compounds can protect them from the toxic effects of chemotherapy.

"A significant number of patients won't go on to dialysis if they are on our drug."

Deviating into drug development

Vectus was founded in 2005 by Mr Stang and hypertension expert Dr Karen Duggan.

Mr Stang said he vowed to stick with devices, rather than drug development. As it happened, an eminent professor told him to have a gander at the underlying technology, which was owned by the New South Wales health system and the University of New South Wales.

Before he knew it, he had co-founded the company with Dr Duggan. “It was a sub-optimal situation because everyone wanted [the technology], but no one would write a cheque to do it properly,” he says.

Vectus listed on the ASX in February 22, 2016, having raised $5.1 million at $1.55 apiece, for a total market valuation of $22 million.

An expert in imaging fibrosis, chairman Ron Schneir is the medical director of I-Med.

Among several other roles, Dr Duggan is the immediate past chair of the National Blood Pressure and Disease Advisory Committee.

Fellow director Susan Pond was the head of Ausbiotech.

The company is based at the CSIRO’s old facility in North Ryde, Sydney, having engaged the agency for its drug synthesis ability.

Vectus also has a diagnostic platform called Accugen, which consists of reagents and software. In essence, Accugen provides a new way of standardizing a PCR (quantitative polymerase chain reaction) test, as used widely by molecular biology labs.

Readers keen to know more on that one can take Greens leader Adam Bandt’s advice and “Google it, mate”.

Nice and safe

Vectus is now moving to first-in-human, phase Ib trials of VB-0004 on patients with mild to moderate hypertension with low cardio-vascular risk.

“We are pretty confident we will see some efficacy,” Mr Stang says.

This follows single and ascending dose safety trials on healthy volunteers, which showed no adverse effects on strengths of up to 100 milligrams.

The last of the three cohorts in the multiple ascending dose study was completed this month, with no significant adverse events recorded. Mr Stang says the evidence to date suggests VB-0004 will be amenable to once daily dosing “a desirable feature” for treating the aforementioned diseases.

Financials and performance

With $1.2 million in the bank, Vectus could do with a trip to the proverbial ATM.

The directors said that with the company posting a 2021-'22 million loss of $3.99 million and with a net asset deficiency of $3.53 million, there was a risk the company could not continue as a going concern. The last time Vectus went to the market was in December 2020, raising $7 million in a placement at 90 cents per share.

"The directors remain confident that this can be repeated as required to support the group's continuing activities and the group has budgeted a further capital raising of $4 million in October 2022 and a further raising in 2023 if required."

Or failing that, the company will reduce its spending.

Mr Stang adds the company is looking at "one or more [possible pharmaceutical company] deals within a very acceptable time horizon". Of course, the longer the cash runway a company has, the more negotiating power it has at the partnering table.

Vectus shares peaked at $2 in mid-October 2021 and hit a low of 29 cents in early February 2019.

500 million Chinese livers can't be wrong

As well as being in discussion with some "well known" pharma companies, Vectus has appointed an advisory group in China, in view of having the liver-specific agent VB-A32 licenced there.

The attraction of the Middle Kingdom is that a whopping 40 percent of the populace has been exposed to hepatitis.

While VB-A32 shares the same DNA as VB-0004, its mechanism of action differs because it's not desirable to reduce blood pressure in the liver. Mr Stang reckons a Chinese drug alone could be worth $1 billion-plus in annual revenue.

Peering at the peers

Astute bio-watchers will note the similarities between Vectus and the ASX-listed Pharmaxis, which specializes in conditions including myelofibrosis, stromal (fibrotic) cancers such as pancreatic and liver cancer, NASH, pulmonary fibrosis, chronic kidney disease, liver fibrosis and fibrotic scarring from burns and other trauma.

In other words: the fibrotic A to Z.

Another listed peer is Dimerix, which is in phase III trials for proving up a drug for the kidney disease focal segmental glomerulosclerosis (FSGS).

Yet another is Adalta as it pursues its I-body candidate AD-214 drug for idiopathic pulmonary fibrosis and - possibly - wet age-related macular degeneration. Adalta is valued at a mere $15 million while Dimerix and Pharmaxis are worth around $45 million.

Then there's the intriguing tale of Fibrotech Therapeutics, which attracted the backing of Uniseed and the Medical Research Commercialisation Fund (Brandon Capital) for its repurposed drug candidate for diabetic kidney disease.

Fibrotech was acquired by British drug maker Shire in 2014 for a cool $US500 million ($A735 million). Two years later, Shire itself was acquired by Baxalta, which dropped a number of programs including Fibrotech's

Baxalta handed back the rights to Brandon Capital and the program lives on within Certa Therapeutics, which in 2018 raised $25 million.

Dr Boreham's diagnosis:

Mr Stang says he had more than enough on his plate, but became involved in Vectus because of the potential for high social - and commercial - impact.

"We are totally committed to our shareholders but we are not doing this for a quick financial return," he says.

"We believe that doing something extraordinarily will get a better return for shareholders and ourselves."

Vectrus has been travelling under the radar, but to mix metaphors the company is now coming out of its shell: "we are the unsung hero on the ASX".

Mr Stang says that at recent investor meetings, participants would start out with crossed arms but by the end of the company's prezzo they were "taking notes like school children" (or biotech writers).

Mr Stang says every transaction the company has pondered has been "well in excess" of its market cap.

"The risk/reward for shareholders is pretty good," he says. "I'm personally of the view this will be one of Australia's most important drug discovery companies."

He leaves one last message for the doubters: "I had the same problem when Nanosonics when it was 18 cents a share and no-one thought we would become the lead company in automating infection prevention."

Over to you, Maurie …

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he's diligently taking notes.

NANOSONICS

Nanosonics says its Coris endoscope cleaner has US Food and Drug Administration Safer Technologies Program acceptance, with non-US approval expected by the end of 2023.

Nanosonics has published updates on its first new technology since the Trophon EPR ultrasound probe cleaner, but not in a standalone announcement.

Biotech Daily apologizes for missing the news in the updates and financial reports.

A Nanosonics executive told Biotech Daily that the Coris was being developed for the complex cleaning of endoscope probes.

The executive said the Coris would be roughly the same size as the Trophon EPR, previously described as about the size of a microwave oven on its side, but the technology did not use nebulized hydrogen peroxide, like the Trophon.

In its 2022 full year report, Nanosonics said Coris had FDA de-novo status and had been accepted into the FDA Safer Technologies Program (Step), recognizing the cleaning system had “the potential to improve the risk-benefit profile of endoscopic procedures”.

The company said that through the Step program the FDA provided sponsors of devices with additional review resources, facilitating more interactive and timely communication through the submission review process.

Nanosonics company described Coris as “our next instrument reprocessing product platform” and said that it had invested $22.3 million in research and development including for the Coris “endoscope reprocessing platform”.

The company said Coris would address the challenges of manual cleaning of endoscope channels through an automated technology “that revolutionizes the cleaning process, thereby reducing the risk of ineffective endoscope reprocessing and resulting patient infection”.

Nanosonics said that reusable flexible endoscopes had advanced technology supporting complex, minimally-invasive procedures and navigating challenging anatomical situations but “have been associated with infections and reprocessing failures across all endoscope types”.

The company said that with multiple interconnected channels ranging in size, with some “so narrow or geometrically complex that they are physically impossible to brush” endoscopes took 55 to 200 steps including channel brushing and flushing.

The company quoted studies which found persistent contamination in 92 percent of endoscopes despite manual cleaning with “extensive biofilm accumulated in the majority of new air and water channels … despite routine cleaning” with biofilm resisting and protecting underlying organisms from high level disinfection or sterilization.

Nanosonics said Coris delivered “automated cleaning to large and small channels, including those that cannot be manually brushed … [and was] designed to navigate complex internal geometries across a wide range of endoscope models.

The company said Coris was designed to remove the “toughest build-up biofilm models” with superiority over manual cleaning in the channels that cannot be brushed.

Nanosonics said it had employed a team of scientists expert in biofilms and artificial soils, built a dedicated bioscience project laboratory and had a comprehensive test program.

The company said there were more than 60 million endoscopy procedures each year with the cost of cleaning a single gastro-intestinal endoscope ranging from $16.60 to $55.80.

Nanosonics chief executive officer Michael Kavanagh said that Coris was “being designed as a global solution ultimately to be used across all channelled flexible endoscope types”.

“The Coris technology continues to advance with the company targeting progressive market introductions aligned with regulatory approvals, with the first introduction targeted for calendar 2023 and likely to be in Australia and/or Europe,” Mr Kavanagh said.

Nanosonics fell 15 cents or 4.2 percent to $3.42 with 931,350 shares traded.

PACIFIC EDGE

Pacific Edge says it has an agreement with New Zealand's Te Whatu Ora Southern for use of its non-invasive Cxbladder genomic biomarker tests for bladder cancer.
According to its website, the Dunedin-based Te Whatu Ora Southern was "responsible for planning, funding and providing all publicly funded health care services for the Southern district", including Dunedin, Wakari, Invercargill and Queenstown.
Pacific Edge said that the contract remained "unsigned" and that the business case was with Te Whatu Ora management team before it would "enter an approvals cycle".
Pacific Edge was up one cent or 2.4 percent to 42 cents with 12 (twelve) shares traded.

PRESCIENT THERAPEUTICS

Prescient says that Cellpryme-A with immunotherapy is effective on tumors, making the product ready for clinical trials and licencing to cell therapy programs, in mice.
Prescient said that Cellpryme-A was an adjuvant or neo-adjuvant therapy that could be administered to cancer patients as an intravenous infusion either prior to, or shortly after, cellular immunotherapy.
The company said that Cellpryme-A attempted to "counteract the hostile cold tumor micro-environment that is known to dampen the tumor killing ability of [chimeric antigen receptor]-T-Cells and similar types of cellular therapy… [by] reducing the numbers of suppressive regulatory T-cells (Tregs) that infiltrate into the tumor".
Prescient said that data presented at the CAR-TCR meeting in Boston showed that Cellpryme-A reduced the numbers of problematic Tregs in solid tumors by 66 percent ($p < 0.05$), and significantly increased Car-T-cell penetration into tumors, CD4+ Cat-T-cells by three-fold ($p = 0.01$) and CD8+ Car-T-cells by four-fold ($p < 0.0001$).
The company said that the addition of Cellpryme-A to Cellpryme-M pre-treated Car-T-cells showed "impressive and demonstrable synergies in the aggressive MC38 [mouse] colon cancer model" ($p < 0.05$, n=7 per group), and that only one animal that received the combination treatment had a detectable tumor by day-15.
In June, Prescient said it had developed Cellpryme-M in collaboration with Melbourne's Peter McCallum Cancer Centre (BD: Jun 8, 2022).
Prescient said that Cellpryme-A increased survival of animals across different treatment groups ($p < 0.05$), and that it "doubled the numbers of CD8+ cytotoxic Car-T-cells in the spleen… known to be a site of Car-T-cell accumulation".
Prescient said Cellpryme-A had been developed in collaboration with the Peter MacCallum Cancer Centre, was ready for clinical testing and could be licenced to external parties for incorporated in their cell therapy programs.
Prescient managing-director Steven Yatomi-Clarke said that Cellpryme-A was "a distinct but complementary addition to Cellpryme-M, to expand our stable of cell therapy enhancements".
"Together with Prescient's next-generation Car platform, Omnicar, Prescient has placed itself enviably at the forefront of cellular immunotherapy by creating technologies that overcome the challenges facing the field," Mr Yatomi-Clarke said.
"These challenges - which include targeting an array of antigens; post infusion control; cell exhaustion and a suppressive tumor micro-environment - simply must be overcome in order to bring this promising new class of therapies to more patients, and to conquer different malignancies," Mr Yatomi-Clarke said.
"Prescient will be seeking to licence Cellpryme-A, with or without Cellpryme-M, to external parties for incorporation into their own cell therapy programs," Mr Yatomi-Clarke said.
Prescient was unchanged at 18.5 cents with 2.7 million shares traded.

IMPEDIMED

Impedimed says shareholders will vote to issue interim chief executive officer David Anderson's 60 percent of his annual salary of $US360,000 ($A543,583), in shares.
Impedimed said that Mr Anderson had elected to participate in the executive share plan for up to 60 percent of his gross yearly salary, and where applicable, up to 60 percent of any upfront and deferred cash awarded to him as a short-term incentive.
The company said that if Mr Anderson remained interim chief executive officer for 2022-'23, then based on its current share price and exchange rate, it would issue him about 2,800,000 shares for the financial year, or about 680,673 shares each quarter.
Impedimed said that its annual general meeting would vote on the remuneration report, to elect directors Dr Robert Graham and Janet West, the additional 10 percent placement capacity, the executive share plan.
The company said the meeting will be held at Johnson Winter & Slattery, Level 25, 20 Bond Street, Sydney, on October 26, 2022 at 9am (AEDT).
Impedimed fell 0.2 cents or three percent to 6.5 cents.

IMMUTEP

Immutep says it has received a EUR1,804,341 ($A2,693,046) research and development tax incentive from the French Government.
Immutep said the incentive under the French Crédit d'Impôt Recherche scheme was for expenditure primarily incurred by conducting research and development activities in Europe through its subsidiary Immutep SAS for the year to December 31, 2021.
The company said the funds would be used to "support the ongoing and planned global clinical development of eftilagimod alpha and the preclinical development of IMP761".
Immutep fell half a cent or 1.9 percent to 26 cents with 2.6 million shares traded.

MEMPHASYS

Chair Alison Coutts says she has increased her substantial holding in Memphasys but been diluted from 79,625,139 shares (10.85%) to 89,592,819 shares (8.70%).
Ms Coutts said that on September 21, 2022 she was issued 3,967,680 shares for $79,354 or two cents a share in the recent rights issue.
Last month, Memphasys said it had commitments to raise $1.6 million in a placement at two cents a share, and had an underwritten one-for-nine rights offer at the same price to raise a further $1.76 million (BD: Aug 17, 2022).
Memphasys fell 0.1 cents or five percent to 1.9 cents with 1.3 million shares traded.

EPSILON HEALTHCARE (FORMERLY THE HYDROPONICS COMPANY)

Epsilon says director Patrick Baiyu Xu has resigned, sold his six percent holding and Alan Beasley has been re-appointed as a director, effective September 22, 2022.
Epsilon said executive chair Steven Xu had returned to the role of non-executive chair.
Separately, the Sydney-based Mr Xu said that on September 22, he sold his 17,647,059 shares (5.9%) for $750,000 or 4.25 cents a share.
The company said Mr Xu's resignation was "immediately prior to his conduct of an off-market transfer… [at] a premium of over 84 percent to the last traded price".
In 2021, Epsilon said 64.31 percent of votes at its annual general meeting voted founder and then Hydroponics former chair Alan Beasley off the board (BD: Jul 29, 2021).
Epsilon was up 0.2 cents or 8.7 percent to 2.5 cents with 2.05 million shares traded.

CRONOS AUSTRALIA

Cronos says chief medical officer and director Dr Benjamin D N Jansen “ceased his position” effective from September 22, 2022.

Cronos said Dr Jansen was a founding director of Cannabis Doctors Australia, which it acquired in 2021 (BD Sep 14, Dec 16, 2021).

In December 2021, Dr Jansen said he had become substantial in Cronos with 129,890,570 shares or 23.68 percent,

Today, Cronos said that it previously believed that Dr Jansen would be able to continue as a director it had legal advice that “under the company’s constitution, the office of a director is vacated if the director is appointed as a director occupying a full-time, or substantially full-time, executive position in the company or a related body corporate and thereafter ceases to be an employee of the company or its related bodies corporate”.

Dr Jansen’s Appendix 3Z final director’s notice said that he held directly 333,333 shares, as well as 130,223,903 shares held indirectly, through Elizabeth Sarah Jansen as trustee for Stanford Investment Trust.

According to its most recent filing, Cronos had 554,370,703 shares on issue, and Biotech Daily calculates Dr Jansen holds 23.55 percent of Cronos.

Earlier this week, Cronos said it had received a section 249D notice calling for the removal of two directors, chief executive officer Rodney Cocks and chief commercial officer Guy Headley, from Matua Hasyo Charlie Jansen as trustee for the Whanau Family Trust who controlled more than five percent of the company (BD: Sep 20, 2022).

Cronos was up three cents or five percent to 63 cents.