Biotech Daily

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Daily news on ASX-listed biotechnology companies

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*** CRESO CONVERTS 17.5m HALUCENEX PERFORMANCE SHARES**

*** STEMCELL EXTENDS 'JOINT VENTURE' SUSPENSION, AGAIN**

MARKET REPORT

The Australian stock market fell 0.42 percent on Friday December 10, 2021, with the ASX200 down 31.0 points to 7,353.5 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.

Telix was the best, up 47 cents or 6.3 percent to $7.97, with 862,627 shares traded, followed by Impedimed up 6.1 percent to 17.5 cents, with 3.7 million shares traded. Starpharma climbed 5.4 percent; Alterity, LBT and Opthea improved more than four percent; Oncosil and Paradigm were up more than three percent; Cyclopharm, Nova Eye and Pharmaxis rose more than two percent; with Imugene, Mesoblast and Universal Biosensors up by one percent or more.

Osprey led the falls, down four cents or 5.8 percent to 65 cents, with 100 shares traded. Cynata and Immutep fell four percent or more; Genetic Signatures lost 3.1 precent; Amplia, Antisense, CSL, Optiscan, Orthocell, Polynovo and Resmed shed more than two percent; Avita, Clinuvel, Cochlear, Nanosonics, Neuren, Next Science and Proteomics were down more than one percent; with Medical Developments and Pro Medicus down by less than one percent.

DR BOREHAM'S CRUCIBLE: VISIONEERING TECHNOLOGIES

By TIM BOREHAM

ASX code: VTI (Chess depositary interests)

Share price: 92.5 cents; **Shares on issue:** 23,635,500; **Market cap:** $21.9 million

Chief executive officer: Dr Stephen Snowdy*

Board: Dr David Mazzo (chair*), Dr Snowdy, Dr Dwight Akerman, Christine Van Heek, Jean Franchi, Zita Peach, Andrew Silverberg

* Dr Mazzo will temporarily run the company after Dr Snowdy's departure on January 9 2022

Financials (September quarter 2021): revenue $US1.97 million ($A2.75 million) (up 19%), operating cash outflows $US1.87 million, cash balance $US13.1 million (down 13%), quarters of available funding: 7 (the company has a fully-drawn $US2.87 million debt facility)

Identifiable major holders: Tiga Trading (Thorney Investments) 25.4%, Regal Funds Management 19.2%, Dr Paul Joseph Cozzi 6.7%

According to the consulting firm Korn Ferry, the average tenure of an Australian CEO is now 6.9 years - and falling.

So, announcing his resignation this week, Visioneering founder and CEO Dr Stephen Snowdy can be satisfied that he has beaten the average with his reign of eight years (and 13 years as a director).

What's more, the specialist vision outfit appears to be finding its groove, with forecast sales in calendar 2021 of $US7 million ($A9.85 million).

Often the optics of a CEO departure aren't good, such as this week's exit of Brett Cairns at fund manager Magellan Financial Group.

But there's a personal tinge to the aviation-loving Dr Snowdy's decision to remove the chocks and fly out.

"I am leaving to work in the oncology space," he says.

"As a cancer survivor, the husband of a cancer survivor and the father of children who run a not-for-profit organization, this is an area of great interest and passion."

Chair David Mazzo will run the show after Dr Snowdy leaves on January 9, pending a recruitment search.

Eyeing the problem

The Great Plague of 2020-’21 has done more than worsen the swelling problem of childhood obesity - it’s also hurting kids’ eyesight.

According to Dr Snowdy, the number of myopic (short-sighted) children has tripled since the pandemic begun because of the extra time they are in front of screens.

About one-third of the world’s kids are myopic, while in Asian nations the figure is more like 90 percent. The danger with too much screen time is not just squinting at the pixels all day, but not getting enough sunlight (which helps eye development).

Of course, there’s nothing new about myopia, but the difference now is that parents are demanding answers.

“It’s becoming much more common practice to actually do something about it, rather than just slapping on glasses.”

There’s growing corporate interest in the sector, which is said to be worth $US10 billion a year in China and more than $US2 billion in North America.

Visioneering’s core product is a disposable contact lens called Naturalvue, which is custom designed for both myopia and presbyopia - the inability to see things up close - in older people.

Presbyopia is actually a bigger market than myopia, but it’s more heavily competed.

“It may account for the majority of Naturalvue sales - we can’t be sure - but the company’s potential is really driven by myopia,” Dr Snowdy says.

Vision statement

The Atlanta, Georgia-based Visioneering sells disposable single-day contact lenses, as do much bigger players such as Alcon, Bausch + Lomb, Johnson & Johnson, Essilor and Cooper Vision.

But Visioneering contends the competitor offerings simply don’t do the job as well as its own lenses that have a special patented shape.

With a doctorate in nerve sciences, Dr Snowdy founded Visioneering in 2008. The company raised around $15 million ahead of listing on the ASX in 2017, when it gathered $25 million.

In 2013, Visioneering won US Food and Drug Administration (510k) clearance for its Naturalvue lenses.

Since then, the lenses have been approved in Europe, Australia, New Zealand, Hong Kong, Singapore and Canada.

Now, the company is preparing to sell its next-generation lenses in the US, where the it currently derives most of its sales.

The new lenses have the same optics, but are thinner with in-built lubricants to make them more comfortable. They are manufactured in Taiwan.

Eyeing the competitive landscape

Visioneering is a myopia minnow in a field of eyecare giants, albeit with an intense focus (sorry) on the condition.

In 2019, Visioneering signed a European distribution dela with Japanese contact lens maker Menicon to produce a private-label myopia brand, called Menicon Bloom Day.

The lenses were to be launched in Europe in March last year and after the pandemic delays, the event has just been revived.

Menicon Bloom Day shouldn’t be confused with Menicon Bloom Night which is a hard-lens ortho-keratology product.

Likened to orthodontics for the eyes, ortho-keratology is the use of specially designed and fitted contact lenses to temporarily reshape the cornea to improve vision.

In cahoots with Menicon, Johnson & Johnson has started an ortho-keratology based childhood myopia brand, Abiliti.

The other dominant contact lens maker, Cooper Vision, already has myopia soft contact lenses.

Arcelor, the world’s biggest eyecare company, has bought a small US outfit called Sight Glass Vision, which makes eye glasses to slow myopia progression in children.

Arcelor paid $US180 million for Sight Glass, which has no revenue and is in clinical trial stage.

“So, you have biggest eyecare and contacts companies jumping on board myopia, adding either eye glasses, ortho-keratology or soft disposable contacts to their portfolio,” Dr Snowdy says.

Dr Snowdy attributes the interest to the sheer size of the myopia market - an expected five billion people by 2050 - coupled with parents and paediatricians wanting to do more about the problem.

If left unchecked, myopia can cause conditions such as cataracts and glaucoma later in life. Worst still, the kids might even grow up to be myopic politicians.

Clinical approach

Dr Snowdy says the Sight Glass deal shows the importance of patient data, which is why Visioneering is launching a randomized trial in paediatric myopia.

Starting this quarter, the study will enroll 140 kids in Canada, the US and Hong Kong, with the first (one-year) data expected in mid-2023. The primary endpoint is slowing myopia progression - duh - while a secondary aim is to curtail the rate of ‘axial lengthening’ of the eyeballs. (Nearsightedness occurs because the eyeball is too far from front to back and growing too quickly.)

“We have to show that not only do we stop their vision from getting worse, but we also slow eyeball growth to a normal rate,” Dr Snowdy says.

The FDA has approved Naturalvue lenses for paediatric use, but for correcting near-sightedness rather than stopping its progression.

Doing more with less

With most US optometrists locked down at various stages, last year was difficult for Visioneering. The first (March) quarter of 2020 was pretty normal, but then sales halved in the June quarter to $US700,000.

The board responded by laying off half the staff, including two thirds of the sales force. Research ceased and the surviving employees agreed to forego cash salaries.

Activity rebounded in the September 2020 quarter, with $US1.6 million of revenue and a break-even cashflow position (excluding inventory purchases). The calendar 2020 revenue of $US5.1 million was flat on the previous year.

“As with a lot of companies, the pandemic taught us how to do a bit more with less,” Dr Snowdy said. “Picture me going to the board in normal times and telling them to take away two-thirds of the sales force, they would have thought I was crazy.”

A resident of Atlanta, Georgia, Dr Snowdy was in Australia on March 19, 2020, the day before Australia’s borders slammed shut. He rushed to the airport and made it out on the last Delta Airlines flight (yes, a prophetic name) full of fleeing pilots and ticketing agents.

Still, not quite like Saigon in ’75 or Kabul in ’21 and there are worse places to be stuck, cobber.

Finances and performance

With the calendar year fast drawing to its Gregorian conclusion, management sticks by guidance of $US7 million of revenue, up 40 percent.

In the September 2021 quarter, the company recorded cash outflows of $US1.87 million, in a period of relatively high cash use. The December quarter was expected to be similar, given the need to build up inventory of the new Naturalvue line ahead of launch.

The company also had $US13 million of cash, courtesy of a placement in March that raised $A22 million. A follow-on share purchase plan raised a further $A1.17 million.

The raising was backed by a number of new and existing institutions including Thorney Group, Regal Funds Management, Ellerston and Perennial.

Thorney (Tiga Trading) also holds a $US2.9 million convertible note which matures in July 2023.At the current share price, the ubiquitous Pratt family vehicle would emerge with a hefty chunk of the company.

In May this year, the company did the old trick of a share consolidation, on a one-for-100 basis. The gambit didn't work and the shares have lost more ground since. In adjusted terms, over the last 12 months the shares have traded between $3.40 (November 24 last year) and the current level of 85 cents.

Dr Boreham's diagnosis:

With a $20 million market capitalization, Visioneering is one of those intriguing stocks trading only slightly above cash backing.

In a recent research report, Bell Potter forecast calendar 2022 revenue of $US11.6 million, with a $US6.6 million operating loss.

"We are not going broke," Dr Snowdy says. "From an operational perspective we are doing what we should be doing, building a sustainable company with real product and 99 percent repurchase rates."

Your columnist is wary that Visioneering is in the presence of the aforementioned industry gorillas and their ability to out-spend Visioneering.

Dr Snowdy's stance is that there's plenty of room for all, with the big players' marketing dollars promoting the available products for the benefit of all competitors.

"We are not fighting over the customers yet. When the market's new, the tide lifts everyone at the same time."

Valuing the stock at $1.31, Bell Potter opines that the market "has not appreciated Visioneering's armamentarium of assets in the ocular space". Apart from having to look up 'armamentarium' we concur the share valuation looks unwarranted, with investors taking a myopic - but not entirely unjustified - approach to the company's prospects.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He agrees with the adage the market is never wrong, but merely short-sighted at times.

AMPLIA THERAPEUTICS

Amplia says its fully-underwritten, one-for-four rights offer at 18 cents a share has raised $6.97 million, taking the total raised to $12.37 million.
Last month, Amplia said it raised $5.4 million in a placement at 18 cents a share and expected to raise $7 million in the rights issue (BD: Nov 8, 2021).
Today, the company said the offer included one option for every three shares acquired, exercisable at 28 cents each by December 31, 2023.
Amplia said the shortfall of 19.9 million shares would be placed by the underwriter, Taylor Collison, implying that there were about 18.8 million shares applied for in the entitlement offer and over applications.
Amplia said the funds would be used for the first stage of a phase II clinical trial for AMP945, manufacturing and further pre-clinical studies and working capital.
Amplia fell half a cent or 2.9 percent to 17 cents.

TELIX PHARMACEUTICALS

Telix says its European marketing authorization application for Illuccix is in the final stage of regulatory assessment, with a final decision expected by March 23, 2022.
Telix said the evaluation of the Illuccix kit for the preparation of 68-gallium, prostate specific membrane antigen-11 injection (68Ga-PSMA-11), was led by the Danish Medicines Agency in its capacity as a reference member state.
The company said the Danish Medicines Agency confirmed that Telix had "fully responded to all information requests that have been issued … on behalf of the member states" and it would issue an approval decision notification within 90 days.
Telix said following a positive decision, national-stage approvals would begin within 30 to 60 days of the notification.
The company said Illucix was approved by the Australian Therapeutic Goods Administration, Brazil had granted "exceptional authorization", it had filed an application to the US Food and Drug Administration and was progressing an application in Canada.
Telix was up 47 cents or 6.3 percent to $7.97 with 862,627 shares traded.

RACE ONCOLOGY

Race says it has extended and expanded its pre-clinical cardio-protective research program for Zantrene with the New South Wales-based University of Newcastle.
On Wednesday, Race said Zantrene, formerly known as bisantrene, was able to protect heart muscle cells while improving the carfilzomib-mediated killing of cancer cells, in-vitro (BD: Dec 8, 2021).
Today, the company said the collaboration with the University's Prof Aaron Sverdlov and Prof Doan Ngo would "explore the cardio-protective attributes of Zantrene in-vitro when used in combination with an expanded panel of anti-cancer drugs known to damage the hearts of cancer patients, as well as to undertake animal studies".
Race said the pre-clinical program would "underpin a cardio-protective phase IIb clinical trial in cancer patients at high risk of anthracycline-induced heart damage … expected to begin treating patients in late 2022".
Race said the University of Newcastle program would cost $322,000 and would begin "immediately, with results to be reported over the coming 12 months".
Race fell three cents or 0.9 percent to $3.41.

ADALTA
Adalta has requested a trading halt pending an announcement in relation to a “proposed capital raising”.
Trading will resume on December 14, 2021, or on an earlier announcement.
Adalta last traded at 8.1 cents.

NEUREN PHARMACEUTICALS
The Auckland New Zealand-based Milford Asset Management says it has become a substantial shareholder Neuren with 6,733,814 shares or 5.2 percent.
Milford said it bought and sold shares between September 13 and December 9, 2021 with the single largest purchase 752,679 shares for about $2,430,000 or about $3.23 a share.
Milford provided two separate prices without explanation.
Neuren fell five cents or 1.3 percent to $3.85 with 1.4 million shares traded.

CARDIEX
C2 Ventures, Niall Cairns and Craig Cooper say they have increased their Cardiex holding from 177,242,010 (20.60) shares to 241,593,932 shares (21.98%).
C2 Ventures Pty Ltd, a related company to chair Niall Cairns and chief executive officer Craig Cooper said it exercised 2,420,455 listed options and 37,500,000 unlisted options at five cents each, amounting to $1,996,023, Mr Cooper converted 6,000,000 performance rights to shares, Carnethy Investments Pty Ltd acquired 6,000,000 shares off-market, and converted a note for 7,831,467 shares for $234,944 or three cents a share.
Cardiex fell 0.1 cents or 1.9 percent to 5.1 cents.

CRESO PHARMA
Creso said it has converted 17,551,077 performance shares issued to the vendors of the Windsor, Nova Scotia-based Halucenex Life Sciences into ordinary shares.
In July and August, Creso said it had acquired Halucenex and Canada had approved a controlled drugs and substances dealer’s licence for Halucenex (BD: Aug 16, 2021).
Last week, Creso said Health Canada upgraded Halucenex controlled drugs and substances dealer’s licence to include production and packaging (BD: Dec 2, 2021).
Today, Creso said the conversion of performance shares was based on Halucenex being granted an amended dealer’s licence by Health Canada and the shares would be subject to voluntary escrow restrictions until January 14, 2022.
Creso fell 0.3 cents or 3.45 percent to 8.4 cents with 5.8 million shares traded.

STEMCELL UNITED
Stemcell has requested a further extension to its voluntary suspension pending the release of announcement in relation to its proposed joint venture.
Since September, Stemcell has requested a trading halt, a voluntary suspension and a suspension extension for the announcement (BD: Sep 27, 29; Oct 29, Nov 30, 2021).
Today, the company said it expected the further extension to last until December 24, 2021 or the release of an earlier announcement.
Stemcell last traded at 1.4 cents