

Biotech Daily

Friday November 29, 2019

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.26 percent on Friday November 29, 2019, with the ASX200 down 18.0 points to 6,846.0 points.

Six of the Biotech Daily Top 40 stocks were up, 17 fell, 12 traded unchanged and five were untraded. All three Big Caps were up.

Actinogen was the best, up 0.2 cents or 4.65 percent to 4.5 cents with 8.6 million shares traded. Kazia climbed 3.25 percent; Immutep and Pharmaxis improved two percent or more; Compumedics was up 1.3 percent; with Cochlear, CSL, Resmed and Starpharma up by less than one percent.

Yesterday's 13.2 percent best, Resonance, led the falls, down 2.5 cents or 11.6 percent to 19 cents with 6.3 million shares traded. Opthea lost 6.2 percent; Orthocell fell 5.8 percent; Polynovo retreated 4.3 percent; Impedimed, Nanosonics, Paradigm, Patrys and Telix shed more than two percent; Clinuvel, Cynata, Prescient and Volpara were down more than one percent; with Medical Developments, Mesoblast, Next Science 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: 6.7 cents; Market cap: \$26.7 million; Shares on issue: 399,135,152

Chief executive officer: Dr Stephen Snowdy

Board: Fred Schwarzer (chairman), Dr Snowdy, Christine Van Heek, Jean Franchi, Zita

Peach, Tom Dooley

Financials (September quarter 2019): revenue \$2.2 million (2018: \$1.6 million, up 38%), loss of \$4.5 million, cash balance \$7.2 million, expected current quarter cash outflows \$7.14 million.

Identifiable major holders: Charter Life Sciences 20.3%, Regal Funds Management 15.47%, Tiga Trading (Thorney Investments) 10.64%, Paul Cozzi 8.1%, Memphis Biomed Ventures 6%, Kinetic Investment Partners 5.29%, Renaissance Smaller Companies 5.17%

Ever since the advent of TV, worried parents have cautioned their kids that too much time in front of John Logie Baird's infernal device will make them go blind - a warning routinely shrugged off by the juvenile couch potatoes.

It seems that mother was right after all, but not because of any direct causal effect between screen gazing and retinal degeneration.

As Visioneering chief Dr Stephen Snowdy explains, too much screen use is making children myopic (short sighted) because they are not going outdoors and are being deprived of bright sunlight.

And - no - eating carrots doesn't help.

In Asia 80 to 90 percent of kids are near sighted - double the incidence of three decades ago - with the condition declared an epidemic in China and Singapore.

"It's become such an issue that Chinese elementary schools are putting in sky lights to try to get more light on these kids," Dr Snowdy says.

"As the eyes in a child are developing, exposure to bright light is extremely important. But in Asian nations that time outside is a thing of the past."

Even in sunny Australia, childhood myopia rates have doubled over the last three decades, from six percent to 12 percent.

"The near sightedness is not the problem," Dr Snowdy says. "It's just that as it gets worse, they are at greater risk of going blind."

Vision statement

The Atlanta, Georgia-based Visioneering sells disposable single-day contact lenses, which is no different to what the bigger global contacts makers do.

But what distinguishes Visioneering from its peers is its laser-like focus (excuse the pun) on two opposite conditions: childhood myopia and adult presbyopia.

Derived from 'presby' (Greek for old) and 'opia' (vision), presbyopia is the loss of ability to see things up close. "This happens in 98 percent of people over 45, it affects everybody," Dr Snowdy says.

Typically, he says, patients have worn contact lenses to see distance, but at 45 they lose ability to see up close.

These are two separate problems that need to be addressed, but current contacts and spectacles do not do that well.

"Patients will have a prescription for a multifocal contact lens and at the bottom of the prescription it says 'for use with reading glasses'," Dr Snowdy says of the US system.

"That's just stupid."

In the US, eight million US adults are already wearing contacts for distance use, which at an average \$US400 (\$590) per year implies a \$US3.2 billion annual market.

Kids' myopia is worth another \$US2 billion.

Eyes on the prize

With a doctorate in nerve sciences and a venture capitalist, 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. A further \$13 million has been raised since.

The company won US Food and Drug Administration (510k) clearance for its Naturalvue lenses in 2013. Since then the lenses have been approved in Europe, Australia, New Zealand, Hong Kong and - this month - Singapore.

Regulators in Canada - which has a big Asian population - are expected to approve the lenses "any day now".

In the September quarter, the company inked a deal with Menicon, Japan's biggest contact lens maker, to provide its myopia lenses for Menicon on a white-label basis.

Menicon is launching in Europe under a new brand called Bloom and has placed an initial \$US500,000 order with Visioneering.

This month rival lens maker Cooper Vision won FDA approval for its child multifocals to halt myopia - the first specific US consent for that indication.

Unusually, we were informed of this development via a Visioneering disclosure to the ASX. A free kick to the opposition perhaps, but according to Visioneering, the approval helps clarify its own regulatory path to win consent for the indication of halting - rather than just treating - childhood myopia.

Science-y stuff

What causes short and long sightedness?

Dr Snowdy is glad you asked.

Within the peepers, lenses collect light bouncing off the objects you are looking at and converge these rays to the back of the eye. Two lenses shape this light - the cornea at the front of the eye and just behind it the "crystalline" lens.

The crystalline lens is connected to muscles and will change shape according to how close the object is.

The nearer an object is to your face, the higher the angles the light rays enter your eye. The crystalline lens detects how far it needs to bend the light rays to converge on the retina. If the convergence is not spot on, the image is blurred.

As people age the muscles on the crystalline lens weaken and they can't bend the light enough, so near objects are blurred.

Reading glasses have 'plus' power, which increases the bend in the light to move convergence point forward to the retina.

Conversely, kids become myopic because from front to back their eyeballs have grown too long. As a result, the convergence point overshoots the retina. So called 'minus power' lenses address the problem by 'unbending' the light.

The Box Brownie effect

The problem is that current lenses don't correct distance and near vision at the same time.

To address this, Visioneering's was inspired by the "aperture effect" - a photographic principle for more than a century.

At his investor prezzos, Dr Snowdy's well known parlor game is to have the participants peer at printed material through a hole on a black card.

At very near distance, the otherwise blurred wording becomes clear, because the eye is blocking out light rays that enter at very steep angles.

"We call it induced aperture and it's a principle we use in our lens," Dr Snowdy says.

In other words, unfocused light rays are blocked while the focused ones pass through the aperture.

Sizing up the rivals

Visioneering doesn't exactly have the field to itself, given there are five big contact lens companies competing globally: Alcon, Bausch + Lomb, Johnson & Johnson, Essilor and the aforementioned Cooper Vision.

They all sell around \$US1 billion of contacts annually, "but no-one can do our particular shape of optics because it's our patent" Dr Snowdy says.

With paediatric myopia, an old anti-nerve agent drug called atropine has been used to treat the condition, with some efficacy.

There's a big problem though: locally, the Therapeutic Goods Administration banned the product after one compounding chemist erroneously mixed the solution at 1.0 percent strength rather than the intended 0.01 percent: 100 times the intended volume.

Oops!

According to the Australian Journal of Pharmacy, using full-strength atropine can result in "extreme discomfort" and an aversion to bright light.

"It was very bad juju for the kids who took it," Dr Snowdy says.

Another method called orthokeratology involves the kid wearing a hard lens at night, which reshapes the eyeball.

This works in 60 percent of cases," but by mid-afternoon they can't see anything again."

Ok, so it doesn't work that well after all.

Financials and performance

Visioneering's revenue grew from \$US200,000 (\$A295,500) in 2016 to \$US1 million in 2017 and then tripled to \$US3.3 million in calendar 2018.

September quarter revenues grew 39 percent to \$US1.5 million, year-on-year. While this sounds jolly enough, growth was off the pace relative to market expectations.

In mid-October, management warned that calendar 2019 revenue would come in at \$US5.7million to \$US5.9 million, which will still be 73 to 79 percent higher but 10 percent short of previous guidance.

The company burnt \$US3.06 million of cash in the September quarter, compared with \$US2.83 million in the June quarter. The company expects \$US4.83 million of outflows in the current quarter.

These numbers prompted the ASX to query whether the company has the funds to last the distance, given its September cash balance of \$US4.83 million.

The company replied that it was "actively seeking funding through a number of channels and believes it will be successful in securing additional capital in the (December) quarter."

Mid-year the company raised circa \$11 million: \$5.8 million from a rights issue and a \$4.3 million placement and convertible notes issue to Thorney Investments.

Dr Snowdy says the company's cash burn is expected to moderate in 2021, but he adds: "We have a long way to go to break even. We will have to raise more money and that is another reason why the share price languishes."

Visioneering shares have traded between 55 cents in early 2018 and 4.2 cents in early June this year.

Dr Boreham's diagnosis:

Visioneering clearly is most excited about myopia and is encouraged - rather than threatened - by the big contact lens companies talking about the problem.

"This year has been a watershed year for myopia," Dr Snowdy says.

He notes that Alcon, which demerged from Novartis and listed on the Swiss and New York bourses in April - has specified myopia as a key growth pillar.

We're not quite sure what the US approval for Cooper Vision really means.

Five companies have formed the Global Myopia Awareness Coalition, with Visioneering as the founding member.

Two years ago, Dr Snowdy says, the company could have "all gone to goose eggs" but now has a clear development path.

The way we view it, Visioneering's practical challenge is to forge meaningful sales from a modest resource base.

If momentum continues, the company is likely to be acquired by one of the aforementioned contacts rivals, or one of the private equity players interested in the sector.

We shall see.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He does possess about 12 sets of glasses but often can't find any because he's not wearing his glasses.

FEDERAL GOVERNMENT

The Federal Government says it will provide \$100 million for a program to increase clinical trial participation in rural, regional and remote areas.

A media release from Federal Health Minister Greg Hunt said the Rural, Regional and Remote Clinical Trial Enabling Infrastructure Program would remove barriers to clinical trial participation, including distance, cultural difference, geographical isolation and workforce capacity.

The Government said the program would improve facilities, equipment, services and systems, reduce the burden, costs and risks for patients and their families and would increase research capacity.

The media release said almost of third of people living in rural, remote and regional areas had worse health outcomes and shorter life expectancies.

For more information, go to: https://www.grants.gov.au/ or https://business.gov.au/.

SIENNA CANCER DIAGNOSTICS

Sienna says it hopes to raise up to \$4.2 million through a \$1.7 million placement and \$2.5 million one-for-four, pro-rata, non-renounceable rights issue at 3.5 cents a share. Sienna said the rights issue would include a top-up facility to allow shareholders to apply for additional shares not taken up by other shareholders.

The company said the record date for the rights issue would be December 4, it would open on December 6 and would close on December 17, 2019.

Sienna said the funds would be used to commercialize Sien-Net, fund co-development expenditure for a pancreatic cancer diagnostic test with Minomic International and an exosome-based therapeutic for critical limb ischemia with Viva Zome, to evaluate acquisition or licencing opportunities and provide additional working capital.

The company said Merchant Corporate Advisory would be lead manager and book runner to the placement and earn a six percent of funds received in the placement.

Sienna said that neither the placement nor the rights issue was under-written.

Sienna fell 0.2 cents or 6.45 percent to 2.9 cents.

ACRUX

Acrux says its annual general meeting faced up to 22 percent opposition to director Norman Gray and director Dr Simon Green resigned on the day of the meeting. Acrux said 12,456,224 votes (22.0%) were opposed to the appointment of Mr Gray, with 44,212,657 votes (78.0%) in favor.

The company said that the resolution to re-elect Dr Green "was withdrawn at the start of the annual general meeting and before voting took place" but did not disclose the number of proxy votes cast on Dr Green's re-election.

"Due to personal commitments Dr Green withdrew his nomination," Acrux said.

The company said that all resolutions faced opposition, including 9,033,763 votes (16.2%) against the grant of 2,733,330 rights to directors Dr Timothy Oldham, Dr Green, Dr Geoff Brooke and chairman Ross Dobinson, followed by 8,398,788 votes (14.6%) opposing the 10 percent placement capacity, 6,752,005 votes (12.1%) against the remuneration report and 4,336,931 votes (7.6%) opposing the re-election of Dr Brooke.

According to Acrux's most recent Appendix 3B announcement, the company had 166,732,711 shares on issue, meaning the votes against Mr Gray amounted to 7.5 percent of the company, sufficient to requisition extraordinary general meetings. Acrux fell half a cent or 2.4 percent to 20 cents.

RESONANCE HEALTH

Resonance says that despite apparent opposition, the issue of 3,000,000 options to each of four directors was passed at its annual general meeting.

In October, Resonance said it proposed to issue chairman Dr Martin Blake and directors Dr Travis Baroni, Mitchell Wells and Simon Panton 3,000,000 options each, exercisable in equal tranches at 15 cents, 17.5 cents and 20 cents, vesting when the company share price reached the exercise price, and expiring on November 28, 2022 (BD: Oct 28, 2019). After the market closed, yesterday, Resonance posted its meeting results which said that more than 43 million proxy votes opposed the resolutions with 26 million in favor.

The notice said that polls of votes for the four resolutions then showed more than 77.3 million votes in favor and up to 8,618,475 votes against.

A Resonance executive told Biotech Daily that a shareholder changed their mind after the close of proxy votes and that had been rectified by the poll.

All other resolutions passed easily.

According to the company's most recent Appendix 3B new issue announcement it had 427,133,933 shares on offer meaning the final vote against the director options amounted to 2.0 percent, not sufficient to requisition extraordinary general meetings.

Resonance fell 2.5 cents or 11.6 percent to 19 cents with 6.3 million shares traded.

MACH7 TECHNOLOGIES

Mach7 has requested a trading halt "pending an announcement to be made by the company to the market in connection with a proposed capital raising".

Trading will resume on December 3, 2019 or on an earlier announcement. Mach7 last traded at 69.5 cents.

DIMERIX

Dimerix has requested a trading halt "pending an announcement of a capital raising". Trading will resume on December 3, 2019 or on an earlier announcement. Dimerix last traded at 13 cents.

G MEDICAL INNOVATIONS HOLDINGS

G Medical has requested a voluntary suspension to follow the trading halt pending the release of an announcement regarding a proposed capital raising (BD: Nov 27, 2019). G medical said it expected the suspension to last until December 3, 2019 or on the release of an earlier announcement.

G Medical last traded at 10 cents.

PRESCIENT THERAPEUTICS

Australian Ethical Investment says it has reduced its substantial shareholding in Prescient from 44,141,543 shares (11.20%) to 37,321,543 shares (9.47%).

The Sydney-based Australian Ethical said that on November 27, 2019 it sold 6,820,000 shares for \$875,755.35 or 12.8 cents a share.

Prescient fell 0.1 cents or 1.1 percent to 8.7 cents with 33.3 million shares traded.

IMAGION BIOSYSTEMS

William Taylor Nominees says it has been diluted below the five percent substantial shareholder level in Imagion.

The Sydney-based William Taylor Nominees said it held 21,700,000 shares which Biotech Daily calculates to by 4.3 percent of the company.

Last week, Imagion said it raised \$3.6 million in a one-for-one rights issue at two cents a share (BD: Nov 22, 2019).

Imagion was unchanged at 1.8 cents with 4.4 million shares traded.