



Biotech Daily

Friday November 24, 2017

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market slipped 0.06 percent on Friday November 24, 2017, with the ASX200 down 3.6 points to 5,982.6 points. Twelve of the Biotech Daily Top 40 stocks were up, 21 fell, six traded unchanged and one was untraded.

Oncosil was the best, up 2.5 cents or 19.2 percent to 15.5 cents with 8.6 million shares traded.

ITL climbed 9.3 percent; Cyclopharm improved 4.2 percent; Acrux and Opthea were up more than three percent; Benitec and Nanosonics rose more than two percent; Ellex, Orthocell and Sirtex were up more than one percent; with Cochlear, CSL, Impedimed and Mesoblast up by less than one percent.

Actinogen led the falls, down half a cent or 9.4 percent to 4.8 cents, with 320,174 shares traded.

Cellmid and Factor Therapeutics lost five percent or more; both Prana and Prima fell 4.2 percent; Avita, Bionomics and Pharmaxis were down more than three percent; Compumedics, Pro Medicus and Volpara shed more than two percent; Clinuvel, LBT, Medical Developments, Osprey, Polynovo, Resmed and Universal Biosensors were down more than one percent; with Airxpanders, Neuren, Reva and Starpharma down by less than one percent.

DR BOREHAM'S CRUCIBLE: PSIVIDA CORP

By TIM BOREHAM

ASX code: PVA; **Nasdaq code:** PSDV

Share price: \$1.80

Market cap: \$81.4 million

Shares on issue: 39,336,416 (Nasdaq), 5,863,896 (CDIs); total: 45.2 million.

Chief executive officer: Nancy Lurker

Board: Dr David Mazzo (Chairman), Nancy Lurker, Michael Rogers, Douglas Godshall, Dr James Barry, Dr Jay Duker, Kristine Peterson

Financials (September quarter): revenue of \$US385,000 (up 39%), expenses \$US6.4 million (down 15%), loss \$US5.98 million (\$US7.17 million previously), expected current quarter outflows (\$US5.5-6 million), cash on hand \$US11.8 million. Subsequent to the quarter the company raised a further \$US6 million.

Major Shareholders: Perceptive Advisers LLC (5.06%), Renaissance Technologies (6.2%), directors (3.51%).

When it comes to the prospects for the back-of-the-eye disease specialist Psivida, it's a classic case of good news and bad news.

Okay – do you want the bad news first?

Psivida has enough cash to last until July 2018, which is rather tight but does not quite cast existential doubt on the Watertown, Massachusetts-based play.

Not surprisingly, management is pondering “multiple alternatives” including equity and debt financings, corporate collaborations, other partnerships and transactions.

The good news? Psivida and its partner Alimera Life Sciences already have a drug (or technically drug delivery system) on market and its clinical trials for extension products are promising.

Psivida is responsible for three of four sustained-release ophthalmic products approved by the US Food and Drug Administration.

Despite Psivida’s strong prospects in tackling hard-to-treat ophthalmic diseases, Psivida shares are trading near record lows, having peaked at \$6.65 in January 2016.

Or as one fund manager puts it, there's a "disconnect between what appears to be a very strong execution relative to how the share price is doing".

Eyeing prospects

The key achievement for Psivida to date has been a partnership with big pharma Alimera Life, which it inked more than a decade ago.

This was in relation to Iluvien, Psivida's treatment for the difficult-to-treat eye disorder diabetic macular oedema (DME).

The deceptive thing about one's peepers is that while they look fragile, they have robust barriers to prevent the incursion of foreign bodies - including helpful drugs.

Psivida's intellectual property is based on polymer layers that control the rate and duration of the release of the drug in question. The delivery object itself is tiny - about three millimetres long - but delivers a minute and controlled daily dose.

Through Alimera, Iluvien has been sold in the US since 2015 and is also sold in the UK, Germany, Italy, Spain and Portugal.

Psivida also licensed Bausch & Lomb to sell Retisert (and a variant called Vitraser) to treat posterior segment uveitis, a non-infectious inflammatory disease that is the third leading cause of blindness in developed countries.

Retisert, which required a surgical procedure, is no longer sold.

Clinical success

Psivida's current clinical work centres on its next-generation product called Durasert, which is licensed to Alimera except in the US.

Durasert aims to treat posterior segment uveitis with an insert that slowly releases a corticosteroid over three years.

The company is on track to file a new drug application to the US Food and Drug Administration in December or early January.

"It's an orphan disease and a relatively modest market (in the US)," chief executive officer Nancy Lurker says.

"We anticipate a market of 80,000 to 120,000 [patients]. However because we don't expect to spend a lot on commercialization it should be a nicely profitable product relatively soon," Ms Lurker says.

Two phase III Durasert trials are taking place.

The first includes 129 patients across 16 US centres and 17 elsewhere.

Of these guinea pigs, 87 were treated with Durasert and 42 with a sham agent. On interim data, the trial reached its primary endpoint of preventing recurrence of the disease after six months.

Of the treated group, only 18.4 percent saw recurrence of the disease while 78.6 percent of the sham group did. After 12 months, it was 27.6 percent versus 85.7 percent.

The second trial, involving 153 patients across 15 centres in India, saw similar results: 21.8 percent versus 53.8 percent.

With Durasert, the patient requires only one injection into the eye, rather than repeat monthly visits.

Ms Lurker says that patients with posterior segment uveitis have limited treatment options.

"The current standard of care is frequent injections of steroids or an implant that lasts only two to three months with a list price of \$US1,400 per device or a three-year equivalent price of nearly \$US17,000," she says.

"Use of systemic steroids and immuno-suppressants are associated with the potential for significant side effects. Steroid eye drops have limited efficacy, given their limited ability to reach the posterior segment of the eye," Ms Lurker says.

Other prospects

Psivida has also identified candidates for wet and dry age-related macular oedema, glaucoma, osteoarthritis pain and other diseases.

In the US alone there were 600,000 procedures for severe knee osteoarthritis last year with the number expected to grow.

In October, Psivida announced a partnership with ophthalmology company Nicox to develop sustained-release formulations of glaucoma drugs.

Initially, Nicox is funding \$US750,000 of research, with additional payments of \$US200,000 for ongoing development.

Forging a better deal

The Alimera tie up initially delivered in spades, with Psivida pocketing a \$US25 million milestone payment in October 2014.

Otherwise, it hasn't exactly resulted in a river of cash, with Psivida chalking up \$US970,000 of royalty income last year.

In July this year, the deal was amended so that rather than being entitled to a share of Alimera's relevant profits, Psivida is entitled to a royalty stream. This cut starts at two percent and rises to six percent by January 2019 and then eight percent after annual sales hit \$US75 million.

Ms Lurker says the revised arrangement is a much better deal for Psivida, with greater transparency and more predictable revenue.

"We are more aligned with Alimera which is what you should be with partners."

Dr Boreham's diagnosis:

Psivida admits the market for back of the eye diseases is "highly competitive", with competition from big pharma as well as hospitals, government entities and not-for-profit organisations.

For example Genentech markets Lucentis for diabetic macular oedema, while Roche's cancer drug Avastin often is used off-market for diabetic retinopathy.

"Most of our competitors and potential competitors are larger, better established and more experienced and have substantially more resources than we or our partners have," Ms Lurker says.

Oh!

Still, Psivida isn't going to die wondering with an expected \$US14.9 million research and development spend in the current year, compared with \$US14.4 million in 2015-'16 and \$10.6 million in 2014-'15.

Ms Lurker, who took over from long-serving chief executive officer Paul Ashton in September last year, has an extensive history in pharmaceutical commercialization.

"I saw companies that failed massively when they went to market and everything in between," she says.

Psivida lost \$US18.48 million on revenue of \$US7.54 million in the 2016-'17 year and has accrued losses of \$US310 million.

We reckon it's time for Psivida to emulate the success of their home state heroes, the Boston Red Sox and step up to the plate.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. The thought of even one injection to the eye gives him the complete heebie-jeebies, but if the alternative is going blind he'll take a stab at it.

THE BIO-MELBOURNE NETWORK

The Bio-Melbourne Network has called for the Victoria Government to invest in a physical Medical Technologies and Pharmaceuticals Innovation Hub in Melbourne.

Bio-Melbourne Network chief executive officer Dr Krystal Evans said that she wanted to see a physical space that included a number of biotechnology and pharmaceutical companies, emerging incubators and accelerators, as well as venture capital and finance firms “that could be an entry point to Melbourne for off-shore companies and visitors”.

Dr Evans said that the submission to Victoria Government was intended for the May 2018 Budget and a forerunner to the State election to be held in November 2018.

The Network said the Medical Technologies and Pharmaceuticals Innovation Hub would provide a central physical anchor point for Melbourne’s health innovation ecosystem.

The Bio-Melbourne Network said the Hub would provide commercial office space for start-ups and high growth potential small and middle-sized enterprises, as well as a “landing pad” for international businesses looking to engage with the sector.

The industry organization said that the Hub would “facilitate engagement with a dedicated cohort of advisors with knowledge and networks across the gamut of pharmaceutical and medical technologies, to facilitate connections between technology developers and the appropriate service providers or experts in the field”.

“Victoria’s medical technologies and pharmaceuticals sector is vibrant and growing and contributing significantly to the State’s economic development,” Dr Evans said.

“The sector needs a place to accelerate its growth [and] a Medical Technologies and Pharmaceuticals Innovation Hub … is important for innovation,” Dr Evans said.

“It’s more than an address, the innovation hub would be a space for engagement, events, meetings, co-working and knowledge sharing,” Dr Evans said.

The Bio-Melbourne Network said that its pre-budget submission included recommendations to create jobs by implementing a payroll tax deferral system for the sector, develop metrics to map the sector’s success and identify gaps and undertake a scoping study for a Victoria biotechnology innovation manufacturing facility.

“Bio-Melbourne Network members contribute significantly to economic development in Victoria and by implementing the recommendations in Bio-Melbourne Network’s pre-budget submission, the State Government of Victoria can substantially increase the sector’s contribution with only a small investment,” Dr Evans said.

ITL HEALTH GROUP

ITL says it has launched its Transfer Cap Set for blood culture testing.

ITL said the product was developed by its Biomedical division and was designed “to transfer positive blood culture samples from a bacterial collection bottle to a vacuum tube safely and efficiently”.

The company said the Transfer Cap Set was designed for use in hospital laboratories that automate smearing samples from positive bacterial detection bottles.

ITL said the Transfer Cap Set was designed in partnership with clients to meet their needs and the launch was “in line with [its] strategic plan to launch multiple products over the next six to 12 months”.

ITL Biomedical general-manager Craig Wilson said that “the Transfer Cap Set has received considerable interest from the market during pre-launch consultation with potential customers”.

“It expands our bacterial detection ancillary range to suit the larger automated laboratories”, Mr Wilson said.

ITL was up four cents or 9.3 percent to 47 cents.

MEDIGARD

Medigard says it has binding commitments to raise a further \$150,000 through a private placement of 8,571,428 shares at 1.75 cents a share.

Last month, Medigard said it had commitments to raise \$150,000 through a placement to a sophisticated investor and two directors at the same price (BD: Nov 1, 2017).

Medigard said the new placement involved the issue of 8,571,428 shares with directors Dr Ian Dixon and Dr Chris Bishop and company secretary Patricia Boero would be issued 1,428,571 shares each, pending shareholder approval, with 4,285,714 shares to be placed with two unrelated investors.

Medigard said that on receipt of the funds it would have raises a total of \$300,000 in recent months

Medigard fell 0.3 cents or 10 percent to 2.7 cents.

MEMPHASYS

Memphasys says it has been offered a \$400,000 grant from the New South Wales Medical Devices Fund to develop its Felix sperm separation device.

Memphasys said that Felix automated the separation of the best sperm from a semen sample, with application in human and animal in-vitro fertilization.

The company said the Fund was administered by the New South Wales Department of Health and Medical Research and the funds we expected in the next three weeks.

Memphasys said that the grant was required to be used to meet development milestones by June 30, 2018 including developing the product requirements specification for the next generation clinical-grade Felix device which would contain disposable cartridges; having the Felix device be assessed by in-vitro fertilization clinics, prior to market launch; and signing an engineering contract for the design and build of the devices.

The company said that unspent funds must be refunded.

Memphasys was untraded at 0.2 cents.

ONCOSIL MEDICAL

Oncosil says that 3,000,000 loan shares for chief executive officer Daniel Kenny will be released from voluntary escrow on December 8, 2017.

Oncosil said the 13 cents would vest on the third anniversary of Mr Kenny's employment with the company.

Oncosil climbed 2.5 cents or 19.2 percent to 15.5 cents with 8.6 million shares traded.

GENETIC SIGNATURES

The Sydney-based Asia Union Investments says it has decreased its holding in Genetic Signatures from 41,370,962 shares (39.57%) to 38,274,590 shares (36.83%).

The Asia Union substantial shareholder notice said that on November 21, 2017, Genetic Signatures, Asia Union and Christopher Abbott bought 1,314,045 shares, but failed to disclose the price paid for the shares as required by the Corporations Act 2001.

Genetic Signatures chief executive officer Dr John Melki told Biotech Daily that the reduction in number and percentage of shares related to the release from escrow of shares as well as the issue of shares under the employee share plan.

Dr Melki said that the 38,274,590 shares were held by Asia Union, Mr Abbott and related companies and Mr Abbott's personal holding had increased.

Genetic Signatures was unchanged at 29 cents.

GI DYNAMICS

GI Dynamics says that non-executive directors Anne Keating and Graham Bradley have resigned.

GI Dynamics said that Ms Keating and Mr Bradley joined the board in June 2011.

In June, GI Dynamics said that 13-year non-executive director Mike Carusi had resigned due to “other numerous commitments” (BD: Jun 2, 2017).

Following the resignation of Ms Keating and Mr Bradley the GI Dynamics board will decrease from six to four directors.

In May, the company’s annual general meeting voted up to 80 percent against the grant to six directors of options over 78,000 US shares, equivalent to 3,900,000 Chess depository instruments (CDIs) which were “in the money” at the time (BD: May 23, 2017).

GI Dynamics was up 0.2 cents or 7.1 percent to three cents.