



Biotech Daily

Friday October 27, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: CELLMID UP 16%; FACTOR THERA DOWN 9%**
- * **DR BOREHAM'S CRUCIBLE: PRIMA BIOMED**
- * **POLYNOVO SHARE PLAN RAISES \$16m, TAKES TOTAL TO \$23m**
- * **LUINA WINS \$405k QUEENSLAND GRANT**
- * **CANN FEDERAL MARIJUANA IMPORT-EXPORT LICENCE**
- * **RESMED Q3 REVENUE UP 12.5% TO \$686m, PROFIT UP 13.2% TO \$113m**
- * **LBT SELLS MICROSTREAK TO CHINA'S AUTOBIO FOR \$2m**
- * **MEDICAL DEVELOPMENTS 26% OPPOSE DIRECTORS FEES HIKE**
- * **STARPHARMA AGM FOR 1m MORE CEO 'PERFORMANCE RIGHTS'**
- * **ANTISENSE VOTES ON POTENTIAL 2nd STRIKE BOARD SPILL**
- * **ANALYTICA AGM FOR 20m EURO, US LICENCE DIRECTOR OPTIONS**
- * **ELLEX AGM FOR 150% DIRECTORS FEES POOL HIKE TO \$500k**
- * **JCP TAKES 5% OF OSPREY**
- * **CLARIFICATION: OVENTUS**
- * **REGAL FUNDS REDUCES TO 8.6% OF ONCOSIL**

MARKET REPORT

The Australian stock market fell 0.22 percent on Friday October 27, 2017 with the ASX200 down 13.1 points to 5,903.2 points. Thirteen of the Biotech Daily Top 40 stocks were up, 19 fell, six traded unchanged and two were untraded.

Cellmid was the best, up 0.3 cents or 15.8 percent to 2.2 cents with 4.2 million shares traded. Impedimed climbed 9.1 percent; Prima was up 7.1 percent; Resmed improved 4.9 percent; Acrux, LBT and Orthocell were up more than three percent; Opthea, Medical Developments and Viralytics rose more than two percent; Admedus, Clinuvel and Psivida were up more than one percent; with Pro Medicus up 0.3 percent.

Factor Therapeutics led the falls, down 0.5 cents or 9.4 percent to 4.8 cents with 162,430 shares traded. Actinogen lost 8.8 percent; Benitec fell 7.5 percent; Living Cell shed six percent; Universal Biosensors was down 5.4 percent; Dimerix lost 4.8 percent; Oncosil and Sirtex were down more than three percent; ITL, Mesoblast, Osprey and Polynovo shed more than two percent or more; with Airxpanders, Avita, Cyclopharm, Pharmaxis and Volpara down more than one percent.

DR BOREHAM'S CRUCIBLE: PRIMA BIOMED

By TIM BOREHAM

ASX code: PRR

Nasdaq code: PBMD

Share price: 3.0 cents

Shares on issue: 2,362,662,532

Market capitalisation: \$70.9 million

Chief executive officer: Marc Voigt

Board: Lucy Turnbull, Albert Wong, Marc Voigt, Dr Russell Howard, Pete Meyers, Grant Chamberlain

Financials (September quarter): receipts \$1.3 million, operating cash outflow \$726,000, cash balance \$16.95 million (previously \$12.3 million), estimated current quarter outflow \$4.3 million

Identifiable shareholders: Thomas Tscherepko (1.1 percent), Marc Voigt 1.03 percent, Frederic Triebel 0.88 percent, Lucy Turnbull 0.86 percent.

(There are no substantial shareholders, but the annual report says that Mr HSBC Custody Nominees owns 37.1%, of which the Miami Beach Wayne Holman and Ridgeback Capital are believed to own about 5%.)

Mr Harbourside Mansion may be accused of a lack of empathy when it comes to the common folk but there's no lack of this quality on the Lucy Turnbull-chaired Prima Biomed board.

"Regarding our recent share price performance, your board and management team are acutely aware of this and share in the frustrations of shareholders given the recent flow of positive company news," she said in the annual report.

Lucy's \$150,000 a year Prima role survived a probity review before hubbie Malcolm deposed Tony Abbott as PM, but she had to scuttle her directorship of ferry operator Sealink and bid auf wiedersehen to the board of the German-Australian Chamber of Industry and Commerce.

Lucy owns a decent wad of Prima shares herself and happily for the stretched Turnbull family budget Prima shares in early October rallied from near lows of 2.2 cents to as high as 4.0 cents (briefly and on no real news).

Still, it's cold comfort for Prima holders who have seen the company consistently defy expectations ever since morphing out of Prima Resources in the early noughties.

The shares peaked at 42 cents in 2011, following some very interesting day-trader activity in the Global Financial Crisis that pumped the company from half a cent in January 2009 to 1.6 cents by April 13 and the big jump to 11 cents by April 20, 2009.

Changing course

Having originally focused on the CVac ovarian cancer vaccine, Prima Biomed these days is all about the sexy but still largely unproven field of cancer immunotherapy.

A year ago, Prima sold CVac to a New York based former online advertising company called Sydys, in a deal worth up to \$400 million in milestones and royalties. This was after Prima's phase II ovarian cancer trial flopped in September 2014.

The \$400 million sounds superb, but there's a catch: the deal didn't involve cash but a 10 percent stake in the impecunious Sydys, which had about \$US800 in the bank. That's correct – not \$US800 million or even \$US800,000, but just an old-fashioned \$US800, almost enough for a one-way flight to New York in peasant class.

At last report Sydys, which is listed on the US over-the-counter market, was seeking to raise funds for further clinical trials. However recent ovarian cancer trial setbacks elsewhere are thought to have made the task a tad difficult.

In a cleansing prospectus in relation to a proposed issue of warrants, Prima says: "As Sydys possessed no significant cash reserves at the time of the transaction and generally lacks product diversity, there are significant risks associated with this transaction."

Chief executive officer Marc Voigt says: "We wish them well. But if nothing comes of it at least there's no downside for us."

New aim, new name

Prima's new immunotherapy stuff was acquired via the takeover of the French biotech Immutep in 2014 for up to \$US28 million. Given Prima is now all about the acquired portfolio, the company proposes changing its name to Immutep at its November 17 AGM.

Makes sense

The technology revolves around a protein called lymphocyte activation gene-3 (LAG-3), a so-called checkpoint inhibitor. LAG-3 was discovered in 1990 by Immutep's scientific founder Prof Frederic Triebel, now Prima's chief scientific officer.

Without getting too sciencey, LAG-3 is of great interest as an agent that regulates T-cell immune responses.

Immune checkpoint inhibitors account for about 70 percent of the market for cancer immunotherapies.

Prima's lead candidate, IMP321, is a soluble form of LAG-3. It is hoped that by being directly injected into the tumor it will activate the antigens present in the cells to boost immune response.

Prima has early stage clinical programs underway for metastatic melanoma and breast cancer.

Management reports recruitment is progressing well, with Prof Triebel due to present melanoma data to the World Immunological Congress in Basel on October 31.

The company also has coveted poster presenter status at the Society for Immunology of Cancer pow-wow, to be held in Maryland on November 10.

Prima is recruiting in Europe for a phase IIb, 226-patient, metastatic breast cancer trial called AIPAC, which combines IMP321 with chemotherapy drug paclitaxel (sold as Taxol).

Recruitment is also underway on a combination drug phase-one skin cancer trial called TACTI-mel, as in Two ACTIVE Immunotherapeutics in MELAnoma (gettit?)

The trial combines IMP321 with Keytruda, a.k.a. The Drug That Saved Businessman Ron Walker.

"Based on our current assumptions, the 22-patient trial should be fully enrolled by the end of the first half of calendar 2018," Prima says.

First data on progression-free survival is expected "as early as the first half of calendar 2019".

Take your partners

In buying Immutep, Prima inherited some big-ticket big pharma support for its programs.

Under licence from Prima, Novartis (formerly Co-Stim Pharmaceuticals) has the developments rights for IMP701, an antagonist (blocking) antibody targeting the LAG-3 molecule on T-cells.

Named LAG525 by Novartis the program has generated modest royalties for Prima (the company received a second payment of \$US1 million in August). The program is subject to phase I/II studies at 13 different locations.

Prima says that according to "certain publicly available records" Novartis increased the number of patient enrolments from 240 to 416 in the 2016 financial year.

Prima is also in bed with Glaxosmithkline, which has the global rights to an antibody called IMP731.

Glaxo's investigational product (derived from IMP731) "aims to kill the few activated LAG-3 T-cells that are autoreactive in autoimmune diseases, leading to long-term disease control without generalised immune suppression".

In effect, it's all about suppressing overactive immune systems, rather than stimulating them.

Glaxo is in phase III trials with a "potential" regulatory filing between 2021 and 2025.

This collaboration produced a single-digit (sub \$10 million) milestone payment in January 2015, with the promise of £64 million in potential milestones and royalties.

"This has the chance of becoming a real game-changer in the way auto-immune diseases are treated," Mr Voigt says.

Mr Voigt adds that he was heartened that this program was not part of a recent review at Glaxo that saw the axing of 13 clinical and 20 preclinical programs.

In China, Prima's partner Eddingpharm and its affiliate EOC Pharma are working on Chinese regulatory and clinical pathways.

Prima says: "as the legitimacy of LAG-3 as a therapeutic agent ... continues to garner industry acknowledgment, so does our engagement with potential partners which is becoming more intense".

Dr Boreham's diagnosis:

Prima is in a sound financial position, courtesy of a \$6.5 million placement to specialist US investors in June (Prima has been Nasdaq-listed since 2012 but this was the first US raising).

These punters were also issued warrants which, if fully exercised before the January 2023 expiry, would raise \$US4.9 million.

Prima lost \$9.3m in 2016-'17, but with a \$17 million cash balance there are enough bikkies in the tin to see out calendar 2018.

Prima and its buddies have more clinical irons in the fire than a gold rush era blacksmith, but with such a surfeit of activities there's the risk of being unfocused.

Sceptics have questioned why Immutep's owners were willing to sell for such a modest sum if the clinical prospects were so bright.

If only one clinical program succeeds, Lucy and her fellow holders may finally strike gold dust. But as with a polly on the hustings, there's no such thing as a core promise in biotechland.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has never been dubbed Mr Harbourside Mansion but is happy to become one.

POLYNOVO

Polynovo says its share purchase plan has raised \$16.0 million at 27 cents a share taking the total raised, with last month's placement to \$23.0 million (BD: Sep 25, 2017)

Polynovo said the funds would be used to expand sales and support in the US and other markets, accelerate the research and development program for breast and hernia applications, as well as a possible licence for the drug elution pellet and working capital. Polynovo fell one cent or 2.9 percent to 33 cents with 3.5 million shares traded.

LUINA BIO

The Brisbane-based Luina Bio says it has received a \$405,000 Made in Queensland grant from the Queensland Government.

Luina was formerly known as Pharmasynth, which was spun-out from Progen, now TBG Diagnostics, in 2016 and manufactures recombinant proteins, vaccines and synthetic molecules for human and veterinary uses (BD: May 4, 2016).

Today, Luina said the Made in Queensland program was part of the State Government's \$200 million Jobs and Regional Growth Package providing \$20 million in grant funding "to support Queensland small and medium enterprises ... to become more internationally competitive, adopt innovative process and technologies and to support job creation".

The company said that the grant was "match funding" and it would contribute \$405,000 towards the costs of the new equipment, development and benchmarking activities.

Luina chief executive officer Les Tillack said the grant would help acquire and install specialized manufacturing equipment along with additional auxiliary equipment to support and enable extra advanced manufacturing and enable five members of the management team attend a leadership development program.

Luina executive chairman Chris Burrell said the grant would help "undertake an international competitive market analysis assessment of the global biopharmaceutical industry in recombinant protein expression, microbiome anaerobe fermentation, sterile fill and finish and [non-clinical good manufacturing practice] development ... [and support the creation of 15 new advanced manufacturing jobs at our facility in Darra, Queensland".

Luina is a private company.

CANN GROUP

Cann says the Federal Office of Drug Control has granted it a licence to import and/or export cannabis genetics and medicinal cannabis products.

Cann said the licence meant it could apply for a permit to export raw cannabis material and cannabis oil for analytical testing and it intended to use the Vancouver, British Columbia Anandia Laboratories analytical services to complement Australian capabilities, subject to an export permit and reciprocal Canadian import approvals.

The company said the licence allowed it to apply for a permit to import cannabis genetics and medicinal cannabis products and it was working with Vancouver's Aurora Cannabis and Anandia to identify suitable genetics and medicinal cannabis products.

Cann said it intended to submit the permit application "as a matter of priority".

Cann chief executive officer Peter Crock said the import and export licence was "an important milestone in the company's goal of building a genetic database of locally and internationally sourced cannabis strains for cultivation under its medicinal cannabis licence, while facilitating the development of a plant breeding program under its cannabis research licence".

Cann was up seven cents or 4.5 percent to \$1.64 with 634,768 shares traded.

RESMED

Resmed says that revenue for the three months to September 30, 2017 was up 12.5 percent to \$US523,659,000 (\$A685,779,000) with net profit after tax up 13.2 percent to \$US86,125,000 (\$A112,791,000).

The company said research and development expenditure for the quarter was up 8.6 percent to \$US37,415,000 or 7.1 percent of revenue.

Resmed climbed 50 cents or 4.9 percent to \$10.65 with 5.5 million shares traded.

LBT INNOVATIONS

LBT says the Zhengzhou, China-based Autobio Diagnostic Co will invest \$2 million in its shares for its Microstreak intellectual property.

LBT said that Autobio would investigate the potential path to re-commercialize the technology following its return from the Lyon, France-based Biomérieux, which marketed Microstreak as its Previ Isola (BD: Aug 23, 2007; Aug 27, 2015).

Today, the company said that Microstreak was its “foundation technology invented in 2004 and was successfully commercialized over subsequent years” with 450 to 500 Previ Isola instruments sold in 30 countries.

LBT chief executive officer Brent Barnes said “we have been collaborating with Autobio for some time which has helped both LBT and Autobio better understand the market opportunity for Microstreak in China”.

Mr Barnes said the sale to Autobio could “facilitate further collaboration between research and technology innovation provided by LBT and typically lower cost engineering and manufacturing expertise found in China by Autobio”.

LBT said that Autobio would become one of its top 20 shareholders.

The company said that Autobio would receive \$2,000,000 new shares under the existing placement capacity at 31 cents a share and with one free attaching option for every two shares subscribed, exercisable at 44 cents each within 12 months of issue.

LBT said that the funds would be used for its core business of commercializing the automated plate assessment system (APAS) through joint venture company Clever Culture Systems AG.

LBT was up one cent or 3.3 percent to 31.5 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments annual general meeting voted significant dissent against the 33 percent increase in the directors’ fees pool and changes to the constitution.

Medical Developments said that 3,015,909 votes (25.8%) opposed the 33 percent increase in directors remuneration from \$300,000 to \$400,000, with 8,356,048 votes (71.6%) in favor and 300,801 (2.6%) at the proxy’s discretion.

The company said that 4,948,012 votes (19.5%) opposed the amendments to the constitution which required a 75 percent majority, with 7,221,320 votes (28.5%) in favor and 13,192,199 votes (52.0%) at the proxy’s discretion.

The remuneration report was passed easily but the re-election of director Allan McCallum faced 10.9 percent opposition while director Max Johnston faced 0.05 percent opposition.

The company’s most recent Appendix 3B new issue announcement said it had 59,097,220 shares on issue, meaning that the votes against the constitution change amounted to 8.4 percent of the company, sufficient to requisition extraordinary general meetings.

Medical Developments was up 13 cents or 2.25 percent to \$5.92 with 219,211 shares traded.

STARPHARMA

Starpharma will vote to grant chief executive officer Dr Jackie Fairley 1,120,000 free 'performance rights' valued at \$1,523,200 at today's closing price of \$1.36 a share. Last year, Starpharma investors approved the issue of 1,100,000 free performance rights to Dr Fairley, with 176,199,813 votes (90.11%) in favor and 19,329,682 votes (9.89%) against (BD: Nov 30, 2016).

Starpharma's then most recent Appendix 3B new issue announcement said the company had 368,436,766 shares on issue, meaning the votes against Dr Fairley's rights amounted to 5.2 percent of the company, sufficient to requisition extraordinary general meetings. Today, the company said that shareholders would also vote on the remuneration report, the re-election of directors Robert Thomas and Richard Hazleton, the employee performance rights plan and the alteration of the takeover provisions of the constitution. The meeting will be held at the offices of Norton Rose Fulbright, Level 15, RACV Tower, 485 Burke Street, Melbourne on November 29, 2017 at 3pm (AEDT). Starpharma fell one cent or 0.7 percent to \$1.36.

ANTISENSE THERAPEUTICS

The Antisense annual general meeting will vote on the remuneration report and a potential second strike board spill.

Last year, the Antisense annual general meeting gave the remuneration report a 'first strike' with 17,651,304 votes or 27.3 percent opposed (BD: Nov 10, 2016).

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and at the later meeting and if passed by more than 50 percent of votes the directors must stand for reelection at a subsequent meeting within 90 days.

If the spill vote fails, the trigger is reset to no opposition.

Antisense said that the meeting would vote on the re-election of direct Dr Graham Mitchell and the approval of the 10 percent placement capacity.

The meeting will be held at the Boardroom, Level 7, 333 Collins Street, Melbourne on November 29, 2017 at 1pm (AEDT).

Antisense was untraded at 3.2 cents.

ANALYTICA

Analytica will vote to grant directors Dr Peter Corr and Ross Mangelsdorf 10,000,000 options each pending European and US licences for the Pericoach system.

Analytica said options would be exercisable at 1.3 cents each, 308 percent of the closing price of 0.4 cents on October 16, 2017 and within five years.

The company said that half of each of the directors' options would vest over three years and become exercisable on the Pericoach intra-vaginal pelvic floor strengthening system being licenced in the US or a change in control of the company with the balance exercisable on a European licence or change in control of the company.

Analytica said that shareholders would vote to adopt the remuneration report, re-elect director Dr Corr and approve the enhanced placement capacity.

The meeting will be held at the Oxley Room, Level 1, Christie Conference Centre, 320 Adelaide Street, Brisbane, on November 30, 2017 at 10am (AEST).

Analytica was unchanged at 0.4 cents.

[ELLEX MEDICAL LASERS](#)

Ellex says its annual general meeting will vote to increase the aggregate directors' fees by 150 percent from \$200,000 to \$500,000.

Ellex currently has five directors.

The company said that shareholders would vote to re-elect director Meera Verma, adopt the remuneration report, approve the prior issue of placement shares and approve the 10 percent placement capacity.

The meeting will be held at Ellex, 3 to 4 Second Avenue, Mawson Lakes, Adelaide on November 28, 2017 at 2pm (ACDT).

Ellex was unchanged at \$1.145.

[OSPREY MEDICAL](#)

JCP Investment Partners says it has become a substantial shareholder in Osprey with 17,401,322 shares or 5.13 percent.

The Melbourne-based JCP said that between June 24 and October 24, 2017 it bought, sold and "transferred" shares with the largest single purchase 2,279,648 shares for \$911,859 or 40 cents a share.

JCP said the shares were held by National Nominees, HSBC Custody Nominees, BNP Paribas Nominees, JP Morgan Nominees and UBS Nominees.

Osprey fell one cent or 2.6 percent to 37 cents.

[OVENTUS MEDICAL](#)

Last night's edition reported an Oventus 10-patient trial showed its O2Vent T reduced "sleep events" by 30 percent compared to competitor obstructive sleep apnoea products. The 30 percent figure was described in the "key points" and in the text of the document. Today, Oventus executive director Dr Chris Hart told Biotech Daily that "comparing the O2Vent T with the vent open to the vent closed, simulating simple non-vented mouth-guard type devices, the O2Vent demonstrated an average 72 percent reduction in sleep events in the 10-patient trial."

No sub-editors were hurt in making this clarification.

Oventus fell one cent or 2.3 percent to 43 cents.

[ONCOSIL](#)

Regal Funds Management says it has reduced its substantial shareholding in Oncosil from 47,707,780 shares (9.79%) to 41,853,223 shares (8.59%).

The Sydney-based Regal Funds substantial shareholder notice said that between May 15 and October 24, 2017 it sold 5,854,557 shares at prices ranging from nine to 16 cents.

Oncosil fell half a cent or 3.85 percent to 12.5 cents.