



Biotech Daily

Tuesday May 10, 2016

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: ANTISENSE UP 12.5%, ACTINOGEN DOWN 8%**
- * **MESOBLAST Q3 REVENUE DOWN 2%, CELGENE OPTION EXPIRY**
- * **AVIRAGEN Q1 BIOTA ROYALTIES REVENUE DOWN 10% TO \$7m**
- * **UP TO 15% OF UNILIFE VOTES OPPOSE 10-TO-1 CONSOLIDATION**
- * **QBID TO DISTRIBUTE IMMURON TRAVELAN, PROTECTYN IN CHINA**
- * **GI DYNAMICS CUTS COSTS, STAFF BY FURTHER 30%**
- * **UBS AG BUYS, SELLS, BORROWS, RETURNS 7% OF IMPEDIMED**
- * **GI DYNAMICS APPOINTS BRIAN CALLAHAN CHIEF COMPLIANCE OFFICER**
- * **ADHERIUM APPOINTS MARK LICCIARDO JOINT COMPANY SECRETARY**

MARKET REPORT

The Australian stock market was up 0.42 percent on Tuesday May 10, 2016 with the ASX200 up 22.1 points to 5,342.8 points. Ten of the Biotech Daily Top 40 stocks were up, 18 fell, 10 traded unchanged and two were untraded.

Antisense was the best, up 0.5 cents or 12.5 percent to 4.5 cents with 232,309 shares traded.

Medical Developments and Nanosonics climbed more than four percent; Cochlear, Prima and Resmed rose more than two percent; Compumedics, Impedimed, Sirtex, Universal Biosensors and Viralytics were up more than one percent; with Pro Medicus up 0.2 percent.

Actinogen led the falls, down 0.8 cents or 8.2 percent to nine cents with 5.95 million shares traded.

Living Cell fell 7.3 percent; Bionomics and Opthea fell more than five percent; Cellmid and Orthocell shed more than four percent; Anteo, Atcor, Ellex, Mesoblast, Oncosil and Pharmaxis were down more than three percent; Starpharma lost 2.3 percent; Admedus and Neuren were down more than one percent; with Acrux, CSL, Polynovo and Reva down by less than one percent.

MESOBLAST

Mesoblast says that revenue for the three months to March 31, 2016 fell 2.4 percent to \$US4,142,000 (\$A5,650,770), due to lower deposit interest returns.

Mesoblast communications director Julie Meldrum told Biotech Daily that bank interest fell from \$US491,000 in the three months to March 31, 2015 to \$US292,000 in the three months to March 31, 2016.

Ms Meldrum said that commercialization revenue was up 2.6 percent to \$US3,850,000 of which \$US99,000 was for the first sales of Temcell for graft versus host disease in Japan in the period from the February 24 launch to March 31, 2016.

Biotech Daily understands that in a teleconference the expiry of the Celgene option was raised and that discussions between Mesoblast and Celgene were continuing.

Last year, Mesoblast said the New Jersey-based Celgene would acquire 4.5 percent of the company, or 15.3 million shares for \$58.5 million, and had taken an option on its mesenchymal stem cells for graft versus host disease, oncologic diseases, inflammatory bowel diseases and organ transplant rejection (BD: Apr 13, 2015).

In October, Mesoblast said the Celgene option had been extended a further six months, expiring in mid April 2016 (BD: Oct 16, 2015).

Mesoblast said its cash burn for the three months to March 31, was \$22,034,000 and it had cash and cash equivalents of \$US99,929,000 at March 31, 2016.

The company said that for the six months to March 31, 2016 it had reduced its cash burn by 25 percent compared to the six months to September 30, 2015.

Mesoblast fell seven cents or 3.4 percent to \$2.00 with 2.1 million shares traded.

AVIRAGEN THERAPEUTICS (FORMERLY BIOTA PHARMACEUTICALS)

Aviragen says its revenue for the three months to March 31, 2016 fell 10.2 percent to \$US5.3 million (\$A7.2 million) compared to the previous corresponding period.

Aviragen said that the revenue came from sales of the influenza products Relenza and Inavir, licenced to Glaxosmithkline and Daiichi Sankyo prior to Biota moving to the US (BD: Jul 21, 2008; Jul 23, 2009; Oct 19, 2010).

The company said the lower royalties were due to "reduced Relenza government stockpiling orders, which were largely offset by higher royalties from Inavir sales in Japan".

Aviragen said there was a \$US400,000 decrease in service revenue, as a result of the termination of the company's 2011 contract with BARDA in 2014 (BD: Apr 1, 2011).

Biota announced the US Biomedical Advanced Research and Development Authority (BARDA) contract in 2011, but in 2014, 17 months after departing the ASX for the Nasdaq in 2012, the contract was terminated by BARDA (Oct 30, Nov 12, 2012).

At that time Biota said it had not been given specific reasons for the initial stop-work order but BARDA director Dr Robin Robinson told Biotech Daily that BARDA had "concerns about the project with regard to the product manufacturing, clinical study enrollment pace, costs, and contractor performance (Apr 30, May 1, May 9, 2014).

Biota chief executive officer Russell Plumb told the US SEC at that time that the company was "surprised by this stop-work order and unfortunately, do not have any additional visibility or understanding at this time as to the nature of ... [the] decision".

Following inquiries by Biotech Daily, Biota filed an "Update on the development of laninamivir octanoate" quoting Dr Robinson's response to Biotech Daily

Today, Biota said that in April it received gross proceeds of \$US20 million from Healthcare Royalty Partners from the sale of an undisclosed portion of the Inavir royalty rights.

Last night on the Nasdaq, Aviragen was unchanged at \$US1.61 (\$A2.20, equivalent to 27.5 cents pre-merger when Biota was trading at \$A1.00) with 21,530 shares traded.

UNILIFE

Unilife says that shareholders passed the extraordinary general meeting consolidation resolution but with 15,364,872 US shares (14.9%) opposing the move.

Unilife said that shareholders voted on the undefined one for three to 10 consolidation, but later released an Appendix 3A consolidation notice saying that the record date would be May 13, 2016 and the US shares and warrants would be consolidated at a rate of one-for-10, while Australian Chess depository instruments (CDIs) would remain unchanged. The company said that 87,830,391 US shares (85.1%) were in favor of the proposal. Unilife's most recent Appendix 3B new issue announcement said the company had the equivalent of 169,710,485 US shares or 1,018,262,910 CDIs on issue, meaning the vote against the resolution amounted to 9.05 percent of all shares on issue, sufficient to call extraordinary general meetings.

Prior to the consolidation there were six Australian CDIs per US share and following the consolidation there would be 60 CDIs per US share.

On December 7, 2015, Unilife posted an announcement to the ASX entitled 'Unilife 8-K' which said the Nasdaq had given the company 180 days to May 31, 2016 to re-comply with the \$US1.00 per share minimum.

Unilife has fallen from a high of \$US3.27 on May 6, 2015 to a low of 46 US cents on December 28, 2015.

Yesterday, Unilife announced that it was investigating "violations of company policies and procedures and possible violations of law" by the former chief executive officer and chairman, Alan Shortall (BD: May 9, 2016).

Last night on the Nasdaq, Unilife fell 14.74 US cents or 29.04 percent to 36.01 US cents with 3,022,258 shares traded.

On the ASX today, Unilife recovered 0.1 cents or 1.15 percent to 8.8 cents with 2.2 million shares traded.

IMMURON

Immuron says it has a distribution agreement with the Melbourne-based Quality Brands International Direct (QBID) for its Travelan and Protectyn products.

Immuron said that QBID specialized in Australia-China electronic commerce and the products would be available from June 1, 2016.

The company said that the agreement provided a two-year exclusivity based on QBID achieving target sales volumes and that QBID had partnerships with JD.com and other Chinese electronic commerce platforms.

Immuron said that Travelan was a natural product for the prevention of traveller's diarrhoea and in 2015, more than 104 million Chinese travelled outside China and "capturing just five percent of these travellers, would represent a \$70 million plus annual revenue stream", while Protectyn targetted liver and gut health and was "ideally positioned to take advantage of current vitamin sales in mainland China".

Immuron said that China had a rapid rise in obesity and fast food consumption, had more than 130 million diabetics, with 35 percent of adults overweight, 7.3 percent obese and about 24 percent that were physically inactive.

The company said that the rise in obesity had led to an increase of fatty-liver diseases, and partly as a result of this epidemic, the value of vitamin sales on the mainland has more than doubled during the past decade to more than \$17 billion and was estimated that more than \$200 million of the market originated through electronic commerce trades of Australian brands.

Immuron was up half a cent or 1.4 percent to 36 cents.

GI DYNAMICS

GI Dynamics says it will reduce its staff by a further 30 percent “to extend its cash runway” following the close of its pivotal US Endobarrier trial (BD: Jul 30, 31, 2015).

Last year, GI Dynamics said it would reduce its staff by about 46 percent and expected to have about 29 full-time employees and sufficient cash to establish new priorities, continue limited market development and research and to evaluate options (BD: Aug 21, 2015).

Today, GI Dynamics said that following the second staff reduction it expected to have 19 employees and it would incur costs of about \$US250,000 for severance and benefit costs and expected to complete the staff reduction by June 30, 2016.

GI Dynamics was unchanged at 1.8 cents.

IMPEDIMED

The Singapore-based UBS AG and related bodies corporate say they have become substantial shareholders in Impedimed with 24,474,732 shares (6.56%).

UBS AG said that between January 16 and May 5, 2016, it bought, sold, borrowed and returned shares in about 300 separate trades

UBS AG has been effectively “day-trading” in a number of biotechnology stocks including Acrux, Cochlear, GI Dynamics, IDT, Mayne Pharma, Neuren and Sirtex and Biotech Daily’s policy is to report the first instance of this form of trading (BD: May 3, 2016).

Impedimed was up 1.5 cents or 1.6 percent to 95 cents.

GI DYNAMICS

GI Dynamics says that it has appointed Brian Callahan as chief compliance officer and executive vice president clinical, regulatory and quality affairs.

GI Dynamics said that Mr Callahan would ensure the company was engaged in an effective dialogue with regulatory bodies in Europe, Australia and the US.

The company said that Mr Callahan had experience as a consultant with the US Food and Drug Administration in remediating serious issues across multiple companies.

GI Dynamics said that Mr Callahan began his career in the US Army as a nuclear weapons specialist and had worked for Johnson & Johnson, Covidien and Quintiles.

GI Dynamics said that in 2002, Mr Callahan founded a compliance consulting company EEC & Assoc and later was Histogenics Corp’s head of clinical, quality and regulatory affairs and was instrumental in raising \$US49 million to restart the Neocart pivotal study.

ADHERIUM

Adherium says that Mark Licciardo has been appointed as joint company secretary, with Rob Turnbull continuing as chief financial officer and joint company secretary.

The company said that Mr Licciardo was the founder of Mertons Corporate Services and was former company secretary of Transurban and Australian Foundation Investment Company and former chairman of the Governance Institute of Australia (Victoria) and the Melbourne Fringe Festival and was currently a director of public and private companies.

Adherium said that Mr Licciardo held a Bachelor of Business from Victoria University and a Graduate Diploma from the Governance Institute of Australia.

Adherium fell two cents or 3.9 percent to 49 cents.