

Biotech Daily

Monday September 21, 2015

Daily news on ASX-listed biotechnology companies

* ASX, BIOTECH DOWN: ANALYTICA UP 17%; ATCOR DOWN 8%

* PM TURNBULL PUTS INNOVATION, CHRIS PYNE CENTRE OF AGENDA

- * COMPUMEDICS \$1m, 3-YEAR SHANGHAI SLEEP CONTRACT
- * EMA STUDY TAKES CLINUVEL CLOSER TO EUROPEAN ROLL-OUT
- * OPTISCAN REQUESTS 'COLLABORATION NEGOTIATION' TRADING HALT
- * DORSAVI RIGHTS OFFER RAISES \$2m, \$1m UNDERWRITTEN SHORTFALL
- * INNATE PLACEMENT TO RAISE \$3.4m
- * CVC DILUTED TO 18% OF CYCLOPHARM

MARKET REPORT

The Australian stock market lost 2.02 percent on Monday September 21, 2015 with the ASX200 down 104.3 points to 5,066.2 points. Ten of the Biotech Daily Top 40 stocks were up, 14 fell, 11 traded unchanged and five were untraded. All three Big Caps fell.

Analytica was the best, up 0.1 cents or 16.7 percent to 0.7 cents, with 1.1 million shares traded.

Genetic Technologies climbed 9.5 percent; Prana was up 7.7 percent; Oncosil was up 3.7 percent; Benitec, Ellex and Starpharma rose more than two percent; Compumedics and Reva were up more than one percent; with Impedimed up by 0.5 percent.

Atcor led the falls, down two cents or 7.8 percent to 23.5 cents with 54,305 shares traded.

Actinogen lost six percent; Orthocell and Pharmaxis fell more than four percent; Acrux, Bionomics and Tissue Therapies were down more than three percent; Osprey and Universal Biosensors shed more than two percent; Anteo, Cochlear, Mesoblast, Nanosonics and Prima were down one percent or more; with CSL, Resmed and Sirtex down by less than one percent.

FEDERAL GOVERNMENT

Prime Minister Malcolm Turnbull says innovation is the centre of one of the Government's most important agendas.

In announcing the new Ministry, Mr Turnbull began with the appointment of Scott Morrison as Treasurer, with Christopher Pyne as the Minister for Industry, Innovation and Science second on his list.

"Christopher is going to be at the centre – as is the whole Government – of one of our most important agendas," Mr Turnbull said.

"If we want to remain a prosperous, first world economy, with a generous social welfare safety net, we must be more competitive, we must be more productive, above all, we must be more innovative.

"We have to work more agilely, more innovatively. We have to be more nimble in the way we seize the enormous opportunities that are presented to us.

"We are not seeking to proof ourselves against the future, we are seeking to embrace it. And this is a government and a ministry that has that as its focus.

"Christopher's department, the Ministry for Industry Innovation and Science, will drive the Government's focus on investing in science, promoting science, technology, engineering and mathematics, education, supporting start-ups and bringing together innovation initiatives right across Government.

"He will continue as Leader of the Government in the House [of representatives]," Mr Turnbull said.

"... the honorable Kelly O'Dwyer MP will be appointed the Minister for Small Business and the Assistant Treasurer, a position which has been elevated to Cabinet," Mr Turnbull said.

"Of course the Assistant Treasurer is, in effect, the 'minister for revenue' and is responsible for the tax system which is at the very centre of our whole productivity agenda - indeed at the very centre of the small business agenda.

"It is vital that we have a tax system that is fair, efficient and creates the right incentives so that we can get the gains in productivity we need. "She will also be appointed to the expenditure review [committee] of cabinet," Mr Turnbull said.

Mr Turnbull appointed Wyatt Roy as Australia's first dedicated Assistant Minister for Innovation and Karen Andrews as Assistant Minister for Science.

In accepting her new role, Ms Andrews said "the commercialization of science research and development of... science, technology, engineering and maths skills in the Australian workforce were both drivers of economic growth for the future".

"There's an economic imperative to ensuring science and research is at the forefront of our agenda and I'm very heartened that Prime Minister Turnbull has signalled an emphasis on innovation and creating a 21st Century economy," Ms Andrews said.

BIOTECH DAILY COMMENT

Biotech Daily very much welcomes Prime Minister Turnbull's promise to support innovation, but Mr Pyne's appointment as the Minister is a great concern.

Mr Pyne has demonstrated a very combative and 18th Century "laissez-faire" approach to his previous portfolio, worsened by failed proposals to increase and uncap university fees, and the "successful" re-introduction of religious education in Government schools.

The University of Melbourne's School of Social and Political Sciences' Prof Sarah Maddison said she would like "a clear statement that research funding won't be cut".

Prof Maddison said that there had been discussion of a loans system to fund research and noted that as Education Minister Mr Pyne and the Government "had walked away from Gonski" - the secondary school reform package agreed between the previous Gillard Labor Government and the majority of States.

Prof Maddison also noted that both incoming Education and Training Minister Senator Simon Birmingham and Mr Pyne were from South Australia, where the Liberal Party was not performing well and noted that submarines were "not very innovative".

Biotech Daily welcomes the appointments of Karen Andrews as Assistant Minister for Science and Wyatt Roy as Assistant Minister for Innovation. Along with previous commitments by Ms O'Dwyer to protect research funding, these appointments strengthen Mr Turnbull's promise to deliver on innovation.

But innovation means funding the sunrise industries of biotechnology, renewable energy and information and communications technology, none of which benefitted in the two years since the Liberal National Party Government came to office.

Indeed, the out-going Minister, Ian Macfarlane, was respected for his work on innovation in the Howard Government and was said to understand and support our sector, but appeared to have little influence in the Abbott Government. Most of his Department's media releases were on cars, submarines and existing programs.

Last week's agreement with the National Party not to put a price on carbon bodes poorly for open research on renewables and investment in alternative energy sources. Given the synergies in funding sunrise industries, this is a concern for us, as well.

Finally, the need to add a commercialization component to the proposed \$20 billion Medical Research Future Fund, to ensure that discoveries are developed in, and return revenue to, Australia rather than being exported like coal to off-shore pharmaceutical companies, has been, thus far, ignored by the Government, Labor and the Greens.

It is difficult to believe that Treasurer Morrison will dig deep into the Federal Budget to fund incentives for innovation, or even reverse the penny-pinching 1.5 percent cut to the Research and Development Tax Incentive. Setting aside 25 percent of the MRFF allocation for commercialization could be a no-cost innovation win for the Government.

We wish them well in keeping their promises, this time.

David Langsam, Editor

COMPUMEDICS

Compumedics says it has a \$1 million contract with China partner Zhi Nuo to distribute its sleep diagnostic and monitoring systems across provinces in and around Shanghai. Compumedics said that the three-year contract "locks in at least 10 percent growth per annum, over the three-year contract period" and was complementary to arrangements for the distribution of its sleep and neurological monitoring range in other provinces in China, announced in June (BD: Jun 15, 2015).

Compumedics executive chairman Dr David Burton said his company had "spent more than a decade, with our Chinese partners, building a foundation for future growth in one of the world's most challenging but highest growth markets".

"Compumedics is now the number one premium supplier of sleep diagnostic and neurological research systems in China," Dr Burton said.

"As a result, Compumedics is well positioned to capture growth, not only in sleep diagnostics, but also in neurological monitoring, a relatively new and untapped market for the Company in China and other parts of Asia," Dr Burton said.

Compumedics was up half a cent or 1.9 percent to 27 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says a European Medicines Agency approval of a post-authorisation study has allowed Scenesse to be sold to adults with erythropoietic protoporphyria.

Clinivel said that Scenesse was granted European marketing authorization last December, but it has taken a further nine months to gain agreement from the EMA's

Pharmacovigilance and Risk Committee for a post-authorisation safety study protocol. The company said that the protocol determined the collection of patient medical data for the assessment of long-term safety as well as "real-life effectiveness" of Scenesse (afamelanotide 16mg).

Clinuvel said it had established a centralised European erythropoietic protoporphyria (EPP) disease registry for the electronic collection and processing of encrypted medical data for periodic analyses and it would provide information on the controlled distribution of Scenesse and the long-term use of Scenesse in Europe.

The company said it had "committed to provide periodic safety updates at a defined frequency and annual reports on the safety and use of Scenesse from data collected in the disease registry".

Clinuvel said that prior to treatment it would train each eligible medical centre and its staff on the use of Scenesse and the handling of data register.

The company said that market access, pricing and reimbursement of Scenesse was subject to review by national competent authorities and insurers in each individual European country, a step which must be taken before Scenesse was made available. Clinuvel acting chief scientific officer Dr Dennis Wright said that with the agreement with the EMA "we can focus on implementing processes which enable EPP patients to gain access to a much needed treatment".

Clinuvel was unchanged at \$2.85.

<u>OPTISCAN</u>

Optiscan has requested a trading halt pending an announcement "concerning the renegotiation of some aspects of a significant development collaboration".

Trading will resume on September 23, 2015 or on an earlier announcement. Optiscan last traded at 4.4 cents.

DORSAVI

Dorsavi said that it received acceptances for 8,370,550 shares raising \$2,176,343 before costs and expenses.

In August, Dorsavi raised \$4,000,000 through a placement at 26 cents a share and announced the Canaccord Genuity fully underwritten \$3.2 million through a one-for-10 rights offer, with the proceeds to be used for working capital (BD: Aug 26, 2015). Dorsavi said that it welcomed "the strong support it received from its shareholders", with about 68.5 percent of entitlements taken up by more than 220 shareholders including major shareholder, Starfish Technology Fund II subscribing for its full entitlements. The company said that the balance of 3,859,450 shortfall shares would be issued pursuant to the underwriting arrangements.

Dorsavi was unchanged at 27.5 cents.

INNATE IMMUNOTHERAPEUTICS

Innate says it has planned a placement of up to 25,000,000 shares at 17.0 cents a share and has commitments for 20,288,824 shares to raise a minimum of \$3,449,100. Innate said that the placement to sophisticated and institutional investors was pending shareholder approval and the funds would be used for additional working capital. The company said that the issue price of 17.0 cents a share was a 2.0 cent premium over the 20-day volume weighted average price to September 18, 2015. Innate said that the proceeds would assist the continuing 90-patient Australia and New Zealand phase IIb trial of MIS416 in patients with secondary progressive multiple sclerosis, applications for patents to protect the use of MIS416 in certain other applications and pre-investigational new drug meetings with the US Food and Drug Administration.

Innate was unchanged at 17.5 cents.

CYCLOPHARM

CVC has increased its holding in Cyclopharm from 6,452,875 shares to 10,636,242 shares but has been diluted to 17.85 percent in the July employee share issue. Sydney-based venture capital firm CVC said that through its subsidiary Stinoc Pty Ltd between May 20, 2010 and September 14, 2015 it bought and sold shares including the 2010 acquisition of 200,000 shares for \$100,401 or 50.2 cents a share and the 2015 sale of 482,475 shares for \$235,953 or 48.9 cents a share.

In July 2015, Cyclopharm issued 2,203,590 shares under its long term incentive plan. Cyclopharm fell two cents or 3.6 percent to 53 cents.