Biotech Daily

Thursday February 8, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: GENETIC SIGS UP 10%; COMPUMEDICS DOWN 12%**

*** PSIVIDA 2nd PHASE III DURASERT UVEITIS TRIAL MEETS ENDPOINT**

*** FACTOR RECRUITS 100th PATIENT IN VF001 VENOUS LEG ULCER TRIAL**

*** ONCOSIL RECRUITS 1st US PANCREATIC CANCER PATIENT; ASX QUERY**

*** AVIRAGEN (BIOTA) UPS VAXART OFFER FOR MERGER MEETING**

*** HYDROPONICS RESPONDS TO IDES OF MARCH BOARD SPILL; AGM**

*** ADHERIUM H1 REVENUE UP 92% TO $2.7m, LOSS UP 4% TO $5m**

*** PSIVIDA H1 REVENUE DOWN 79% TO $1.7m, LOSS UP 63% TO $15m**

*** INVION PLEADS SCHULTZ TO ASX 22% QUERY**

*** ESENSE RESPONDS TO ASX 9.5m 'PERFORMANCE SHARES' QUERY**

*** INVITROCUE APPOINTS DR ANDREAS LINDNER DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.24 percent on Thursday February 8, 2018 with the ASX200 up 13.9 points to 5,890.7 points. Nineteen of the Biotech Daily Top 40 stocks were up, 14 fell and seven traded unchanged.

Genetic Signatures was the best, up three cents or 10.3 percent to 32 cents with 15,500 shares traded. Actinogen climbed 6.4 percent; Osprey was up 5.2 percent; Dimerix and Immutep (Prima) improved more than four percent; Prana and Universal Biosensors were up more than three percent; Admedus, Mesoblast, Polynovo, Reva and Uscom rose two percent or more; Clinuvel, Nanosonics, Starpharma, Viralytics and Volpara were up more than one percent; with CSL, Cyclopharm, Resmed and Sirtex up by less than one percent.

Compumedics led the falls, down five cents or 11.6 percent to 38 cents with 45,011 shares traded. Optiscan lost 6.7 percent; Airxpanders and Impedimed fell more than four percent; Acrux, Bionomics, ITL, LBT and Telix shed more than two percent; Ellex, Medical Developments, Orthocell and Psivida were down more than one percent; with Cochlear and Neuren down by less than one percent.

PSIVIDA

Psivida says that one-year results from its three-year, 153-patient, phase III trial of Durasert indicate a significant reduction in posterior segment uveitis recurrence.

Psivida said the primary endpoint in the second phase III trial was the prevention of recurrence of posterior uveitis at six months with patients to be followed for 36 months.

The company said that at one-year 36.6 percent of patients treated with Durasert had a recurrence of posterior segment uveitis compared to 71.2 percent of patients who received a sham treatment ($p < 0.001$).

Psivida said there was an average increase of intraocular pressure (IOP) in the treatment group of 2.0mmHg (mercury) from a baseline of 13.3mmHg and no average increase in pressure from patients who received a sham treatment.

The company said that 50.5 percent of patients treated with Durasert required intraocular pressure lowering therapy during the first year after the trial compared to 51.9 percent of patients who received the sham treatment with “only one patient” treated with Durasert, requiring intraocular pressure surgery.

Psivida said that 18.0 percent of the patients with a natural (phakic) lens at baseline treated with Durasert group required cataract surgery during the trial compared to 8.6 percent who received a sham treatment.

Primary clinical investigator and Duke University’s chief of retinal ophthalmology Dr Glenn Jaffe said that "the continued positive efficacy and safety data for Durasert, now confirmed in two separate phase III studies at both six and 12 months, is encouraging for patients that are suffering from posterior segment uveitis”.

“While today’s standard of care treatment options are mainly directed at controlling flares, Durasert is designed to help prevent flares for up to three years with a single injection administered in an office setting,” Dr Jaffe said.

Psivida fell 2.5 cents or 1.85 percent to $1.325 with 375 shares traded.

FACTOR THERAPEUTICS

Factor says it has recruited its one hundredth patient in its 168-patient, phase II trial of VF001 for venous leg ulcers.

Factor said that the trial remained “on track to complete recruitment … potentially in April”.

In November, Factor announced that it reached the halfway mark in recruitment with 84 patients recruited (BD: Nov 29, 2017).

Factor was unchanged at 3.8 cents.

ONCOSIL MEDICAL

Oncosil says it has recruited its first US patient at the University of Texas MD Anderson Cancer Center in its 300-patient global pancreatic cancer trial.

Oncosil said the trial incorporated its 20-patient Conformité Européenne (CE) mark study (BD: Oct 23, 2017).

Oncosil chief executive officer Daniel Kenny said the recruitment of the first US patient brought the number of subjects recruited in the clinical program to 34, and that of these “25 have been successfully implanted with the Oncosil device, and we are in the process of compiling data to be submitted to [British Standards Institute]”.

Separately, Oncosil said in response to an ASX Appendix 4c query that it was “considering options” to fund its ongoing trials after the ASX noted that Oncosil had less than two quarters cash (BD: Jan 29, 2018).

Oncosil was unchanged at 14 cents with 1.1 million shares traded.

AVIRAGEN THERAPEUTICS (FORMERLY BIOTA PHARMACEUTICALS)

Aviragen says it has improved the terms of its merger with Vaxart so that Aviragen shareholders will own 49 percent of the combined company up from 40 percent.
Aviragen said that it was urging investors to vote for the merger at the extraordinary general meeting, planned for tomorrow.
Yesterday, Aviragen postponed its Vaxart merger meeting from February 6 to February 9, 2018 to give voters more time to vote for the proposal (BD: Feb 7, 2018).
The Concerned Aviragen Shareholders Group has told Biotech Daily it hopes to defeat to merger proposal and spill the board at an April 2018 annual general meeting.
The CAS Group has criticized the Aviragen board and management for its “track record of value destruction” citing the loss of the $US231 million BARDA contract and the 90 percent fall in its share value (BD: Oct 31, 2017; Jan 24, 30, 2018).
On the Nasdaq, Aviragen was up four US cents or 6.45 percent to 66 US cents (84.3 Australian cents, equivalent to 10.5 cents before leaving the ASX for the Nasdaq when Biota was trading around $A1.00) with 1.3 million shares traded.

THE HYDROPONICS COMPANY

Hydroponics says it will delay its annual general meeting and has strongly criticized director Alan Beasley who has called a board spill extraordinary general meeting.
In January, Hydroponics said it had received a notice of intention to call the board spill meeting from founding chairman Mr Beasley proposing the removal of directors Ian Mutton, Mary Verschuer, Peter Wallace and Hamish Macdonald and the appointment of Steven Xu, Lou Cattelan and John Radcliff (BD: Jan 21, 2018).
The meeting was proposed to be held at Baker McKenzie, Level 46, Tower One, 100 Barangaroo Avenue Sydney on March 15, 2018 at 11am (AEDT) which was later changed to 9am (AEDT).
Today, Hydroponics said that the Australian Securities and Investments Commission had agreed to an extension of the date for its inaugural annual general meeting from March 15 to March 23, 2018.
The company did not provide an agenda for the meeting or details of location and time.
Earlier this week, Hydroponics published “a complete copy of the EGM notice” from Mr Beasley which said he was “concerned with THC's governance and approach under the majority of the current board”.
“It is my duty to ensure that THC, as a listed company, adheres to the highest level of corporate governance,” Mr Beasley was quoted as saying.
“I intend to ensure that the company consistently operates on the highest level of transparency, communication, fiscal discipline and team approach between all levels of the company, and in its market dealings,” Mr Beasley said.
The notice did not provide any specific details.
Today, Hydroponics chairman Ian Mutton said in a response to Mr Beasley’s notice that he had raised “a range of concerns and comments, most of which have no grounding or basis in truth”.
Mr Mutton said that Mr Beasley was chairman when the rest of the board was appointed and was responsible for their appointments.
Mr Mutton said that under Mr Beasley the board had a “lack of cohesion … [and an] absence of a strategic direction”.
The response and the notice of meeting extension announcements detailed timelines relating to meetings and correspondence between Hydroponics and Mr Beasley.
Hydroponics fell half a cent or 0.7 percent to 75.5 cents.

ADHERIUM

Adherium says that revenue for the six months to December 31, 2017, was up 92.0 percent to $2,661,000 with net loss after tax up 3.5 percent to $4,978,000.
In its January Appendix 4C Adherium said that receipts from customers for the six months were down 26.9 percent to $1,174,000 compared to the previous corresponding period (BD: Jan 31, 2018).
The company said that it had achieved its targets and reaffirmed revenue guidance for the year to June 30, 2018 of between $5.7 million and $7.0 million, with cash of at least $10 million at June 30, 2018.
Adherium said that volumes of its dose meter system for Astrazeneca were meeting previous guidance, device development programs were achieving the targets needed to support both customer roll-outs and its direct-to-consumer program was underway.
The company said that device sales volume was more than double from 7,000 in 2016 to 14,700 in 2017, with the proportion of commercial to clinical volume increasing from 25 percent in 2016, to 95 percent in 2017.
The company said that diluted loss per share was constant at 2.9 cents at December 31, 2016, with net tangible assets per share down 43.2 percent to 10.0 cents.
Adherium said it had cash and cash equivalents of $14,935,000 at December 31, 2017, compared to $29,523,000 at December 31, 2016.
Adherium was up 1.6 cents or 20 percent to 9.6 cents.

PSIVIDA

Psivida says revenue for the six months to December 31, 2017 was $US1,318,000 ($A1,684,260) down 78.9 percent from $US6,248,000 in the previous corresponding period.
Psivida said that in the previous corresponding period it received $US5.6 million of revenue recognized on termination of the Pfizer agreement (BD: Feb 8, 2017).
The company said that excluding the Pfizer payment, revenue for the six months to December 31, 2016 were $US648,000, indicating that, underlying revenue for the six months to December 31, 2017 was up 103.4 percent from the previous corresponding period.
The company said that net loss for the six months to December 31, 2017 was up 62.7 percent to $US11,765,000 ($A15,043,020), compared to $US7,229,000 for the previous corresponding period; with diluted net loss per share of 28 US cents compared to 21 US cents in the previous corresponding period.
Psivida said that cash, cash equivalents and marketable securities at December 31, 2017 were $US12,876,000, down from $US17,532,000 at December 31, 2016.

INVION

Invion has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company’s share price rose 21.7 percent from 2.3 cents to 2.8 cents today, February 8, 2018 and noted a “significant increase” in the volume of the company’s shares traded.
Invion was up 0.5 cents or 21.7 percent to 2.8 cents with 113.3 million shares traded.

ESENSE-LAB

Esense has told the ASX that a $1.1 million IC Access distribution deal triggered the vesting and conversion of 9,537,503 performance shares (BD: Jan 21, 2018).

In its 'Aware' query, the ASX asked Esense to clarify which of its deal announcements triggered the vesting milestone, which was reported in an Appendix 3B announcement on January 29, 2018.

The ASX said that a listed entity was required to immediately provide the ASX any information that a reasonable person would expect to have a material effect on the price or value of the entity's securities.

Esense cited its January $1.1 million distribution deal with the Saudi Arabia-based IC Access (BD: Jan 21, 2018), along with a commercial agreement with Allor Vaporizers, order of $US85,000 ($A108,657).

The company said that other deals it had previously announced had not resulted in any "orders delivered" or "revenue earened".

Esense said it was testing the formulation for a deal announced with Healthy Chocolate Florida; no definitive agreement had been signed with the White City, Oregon-based Wild Rogue Extracts; and Singapore's Advanced Technology Management was required to order between $US540,000 to $US600,000 ($A690,127 to $A766,808) but no orders had been received (BD: Jan 22, 2018).

The company said IC Access had committed to $1.1 million over three years with at least $366,000 each year but the first order was not required until September 30, 2018.

In December, the company said it had an agreement with Sydney's Young Henry's Brewing Co to development a marijuana terpene infused line of beer, but did not state a target value and in November, Esense said it had a joint venture with the Sarasota, Florida-based Healthy Chocolate and had finalized its beta chocolate formulation, but did not provide details on the venture (BD: Nov 16, Dec 12, 2017).

In July, the company said it had a memorandum of understanding with Wild Rogue Extracts to develop and market a new line of cannabidiol-based products including but not limited to vapors and vape pens, including oils and concentrates, tinctures, salves and other topical applications and concentrates (BD: Jul 25, 2017).

In June, Esense said it had a memorandum of understanding with New York-based product development and marketing firm Beyond Brands for its terpenes plant extract-based products, but did not mention value (BD: Jun 19, 2017).

The ASX said that conversion of class C performance rights to CDIs was "pursuant to performance milestones … being satisfied" namely that the company signs binding distribution contracts for its reconstructed terpene profiles with a cumulative value of $1 million within 12 months from the date of listing on the ASX, February 14, 2017 and once converted the rights would be escrowed to February 14, 2019.

Esense said it was satisfied the class C milestone had been satisfied.

In January, Esense said it had received a request under Israeli Companies Law from shareholders Romfal Sifat Pty Ltd, Buzz Capital Pty Ltd and Attollo Investments Pty Ltd calling for a meeting to remove directors Haim Cohen, Eran Gilboa and Ilan Saad; and appoint as directors current chairman Dr Brendan de Kauwe, if he is not re-elected at the annual general meeting, as well as MMJ Phytotech chief executive officer Andreas Gedeon and Faldi Ismail (BD: Jan 29, 2018).

The company's most recent Appendix 3B new issue announcement said it had 36,277,999 Chess depository instruments (CDIs) quoted on the ASX with a further 44,398,808 CDIs in escrow until January 30, 2019, meaning that the performance shares amount to 11.8 percent of the company.

Esense fell 1.5 cents or 6.7 percent to 21 cents.

INVITROCUE

Invitrocue says it has appointed Dr Andreas Lindner as a non-executive director.

Invitrocue said Dr Lindner had experience in healthcare and technology and was a founding partner of healthcare company Medi-Globe, a supplier of equipment and services for minimally invasive surgery and urology, as well as hospital supplies.

The company said that Dr Lindner had established a private venture capital business, which invested across a number of industries and had founded Health Complete, a material supply company specializing in biodegradable cleaning products.

Invitrocue said Dr Lindner had a Doctorate of Philosophy from Munich's Ludwig-Maximilian University.

Invitrocue was unchanged at 9.6 cents.