Biotech Daily

Wednesday August 24, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: OSPREY UP 12%, OPTHEA DOWN 8%**

*** SIRTEX REVENUE UP 36% to $178m, PROFIT UP 69% TO $40m, DIVIDEND**

*** IMPEDIMED REVENUE UP 21% to $6m, LOSS UP 76% TO $26m**

*** MEDTRONIC TAKES HEARTWARE FOR $1.45b**

*** DRS MAL, STEWART WASHER -THE A TO Z OF MEDICAL MARIJUANA**

*** ACRUX, LILLY TO APPEAL US PATENT DECISION**

*** PROTEOMICS TO DEVELOP ENDOMETRIOSIS DIAGNOSTIC**

*** CRYOSITE REVENUE UP 3% TO $10m, PROFIT DOWN 33% TO $302k**

*** IDT REVENUE UP 8% TO $17m, LOSS UP 34% TO $4m**

*** REGENEUS REVENUE DOWN 9% TO $1.9m, LOSS DOWN 46% TO $3m**

*** RHINOMED REVENUE UP 134% TO $1m, LOSS UP 13% TO $6m**

*** GORDAGEN $1.3m R&D TAX INCENTIVE SETTLES METAMOR LOAN**

MARKET REPORT

The Australian stock market was up 0.14 percent on Wednesday August 24, 2016 with the ASX200 up 7.9 points to 5,561.7 points. Ten of the Biotech Daily Top 40 stocks were up, 14 fell, 14 were unchanged and two were untraded.

Osprey was the best, up four cents or 12.1 percent to 37 cents with 1.5 million shares traded, followed by Sirtex up 12.0 percent to $34.80 with 865,010 shares traded. Acrux recovered 7.3 percent; Living Cell was up 6.9 percent; Actinogen improved 5.6 percent; Benitec and Biotron were up more than four percent; Avita was up 3.3 percent; Pro Medicus and Universal Biosensors were up more than one percent; with Cochlear and CSL up by less than one percent.

Opthea led the falls, down 4.5 cents or 7.6 percent to 55 cents with 45,780 shares traded. Cellmid, Mesoblast and Oncosil lost more than three percent; Airxpanders, IDT, Resmed and Starpharma shed more than two percent; Anteo, Impedimed, Medical Developments, Orthocell and Viralytics were down more than one percent; with Clinuvel and Reva down by less than one percent.

SIRTEX MEDICAL

Sirtex says that record revenue for the 12 months to June 30, 2016 was up 31.9 percent to $234,721,000 with net profit after tax up 32.8 percent to $53,582,000.
Sirtex said that dose sales of its radioactive SIR-spheres for liver cancer increased 16.4 percent to a record 11,931 doses, with sales revenue up 32.0 percent to $232,492,000.
The company said dose sales increased in all regions with the Americas up by 19.0 percent to 8,420 doses; Europe, the Middle East and Africa up 11.2 percent to 2,528 doses; and Asia Pacific up 8.9 percent to 983 doses.
Sirtex said that revenue increased in all regions with the Americas up 35.4 percent to $185.2 million; Europe, the Middle East and Africa up 20.0 percent to $38.9 million; and Asia Pacific up 20.9 percent to $8.4 million.
In a teleconference, Sirtex chief executive officer Gilman Wong said the company expected a “double-digit” increase in dose sales in the coming financial year, but would not be drawn on forecasting revenue or profit.
Mr Wong said the total sales figure was “a significant under-representation of the market opportunity … we have just two percent of the addressable market”.
Mr Wong said the company had 12 consecutive years of increasing dose sales along with 12 consecutive years of increasing revenue and six years of increasing net profit after tax.
Sirtex said that research and development expenditure increased 25.4 percent to $10.8 million, or 4.6 percent to total revenue, down from last year’s 4.9 percent.
Sirtex chief medical officer Dr David Cade said that all five clinical studies were recruited which was a “major achievement” with results from three trials due by July 2017.
“This financial year will be bustling with activity and clinical data,” Dr Cade said.
Dr Cade said that the Sirflox study was published in the Journal of Clinical Oncology in February 2016 and was the most highly read original research article by the Journal’s 26,000 readers in March 2016 and the second most highly read in May 2016.
Dr Cade said that SIR-Spheres were considered a therapeutic option that could be integrated into earlier lines of treatment “including first-line treatment”.
The company said that a partly-franked dividend of 30.0 cents a share would be paid for shareholders on the record date of September 28 on October 19, 2016, an increase of 50 percent over last year’s fully-franked 20.0 cents dividend.
Sirtex said net tangible asset backing per share was up 42.7 percent to $1.933 and diluted earnings per share increased 32.3 percent to 92.2 cents for the year to June 30, 2016,
The company said it had in cash and cash equivalents of $21,025,000 at June 30, 2016, compared to $21,941,000 at the end of the previous financial year.
Mr Wong repeated the company’s three pillars approach to its “2020 vision” of expanding the use of SIR-Spheres, continuing research and development and looking for suitable mergers and acquisitions of commercial-ready technology.
Sirtex climbed $3.72 or 12.0 percent to $34.80 with 865,010 shares traded.

IMPEDIMED

Impedimed says revenue for the year to June 30, 2016, was up 20.7 percent to $5,947,000 with net loss after tax up 75.6 percent to $25,980,000.
Impedimed said that revenue related to increases in medical as well as test and measurement, with total lymphoedema test product revenue up 60 percent.
The company said that diluted loss per share increased 33.3 percent to 8.0 cents at June 30, 2016 with net tangible assets per share up 100 percent to 22 cents and it had $82,254,000 in and cash equivalents cash at June 30, 2016.
Impedimed fell 2.5 cents or 1.5 percent to $1.60.

MEDTRONIC, HEARTWARE INTERNATIONAL

Medtronic says it has completed its acquisition of Heartware for $US1.1 billion ($A1.45 billion) at $US58.00 a share.

The $US58.00 equates to $A76.21, equivalent to $2.18 a share prior to Heartware departing the ASX.

Medtronic said that Heartware would become part of its heart failure business within the Medtronic cardiac rhythm and heart failure division.

The company said that Heartware developed and manufactured miniaturized implantable heart pumps, or ventricular assist devices to treat patients with advanced heart failure and its flagship product, the HVAD system was the world's smallest full-support device, indicated for refractory end-stage left-ventricular heart failure patients in the US awaiting a heart transplant, as well as approved in Europe for long-term use in patients at risk of death from refractory, end-stage heart failure.

Medtronic said the global ventricular assist device market was about $US800 million.

Medtronic head of heart failure Dr David Steinhaus said that the Heartware portfolio expanded “Medtronic leadership across the heart failure continuum” and its product pipeline could result in progressively less-invasive heart pumps that have the potential to benefit even more patients.

Heartware chief executive officer Doug Godshall said that “more than 600 Heartware employees are now part of the broader Medtronic organization”.

“Heartware has delivered incredible advancements for patients suffering from heart failure, through the commercialization of the HVAD system and pipeline development, and I am convinced that being part of Medtronic will allow us to accelerate meaningful innovations even more quickly,” Mr Godshall said.

Medtronic said that Heartware would cease to be traded on the Nasdaq Stock Market.

AUSCANN, ZELDA THERAPEUTICS

Zelda says it expects to raise $4,000,000 at 2.5 cents a share to backdoor list on the ASX to develop marijuana treatments for insomnia, acne and glioblastoma.

Zelda co-founder and executive director Dr Stewart Washer told Biotech Daily that most of the fund-raising had been pledged and the company would expect to list through the Perth, Western Australia-based Gleneagle Gold, by the end of September 2016.

Dr Washer’s father, former Liberal Member of the House of Representatives Dr Mal Washer is the chairman of Auscann which had hoped to backdoor list into TW Holdings to grow marijuana and develop medical cannabis (BD: May 9, 2016).

TW Holdings said in July 2016 that it expected to convene an extraordinary general meeting by the end of September 2016 to approve the acquisition.

Today, Dr Stewart Washer told Biotech Daily that the San Francisco, California-based Aunt Zelda was the major shareholder of Zelda Therapeutics with about 30 percent and company would develop and commercialize sublingual and topical treatments for insomnia, acne and the brain cancer gliobastoma.

A Zelda presentation said that Aunt Zelda was “a pioneering … group supplying customised medical extracts to registered patients” and the company would use the funds to run a series of phase II clinical trials.

Dr Washer said Harry Karelis was Zelda’s executive chairman, with directors including CPS Securities stock broker Jason Peterson and Aunt Zelda founder Mara Gordon.

In July, Gleneagle Gold issued a prospectus for the merger and in July the company voted in favour of a raft of resolutions to become Zelda therapeutics.

Gleneagle Gold was untraded at half a cent.

ACRUX

Acrux says with Eli Lilly & Co it will appeal the US Court decision that granted patents for its Axiron testosterone product were invalid, allowing generic versions.

Yesterday, Acrux fell as much as 44.8 percent to 39.5 cents on the news that the US District Court for the Southern District of Indiana had ruled the formulation and axilla application patents granted by the US Patent Office for Axiron had been invalidated and therefore would not be infringed by the commercialization of generic versions of Axiron by the generic companies that challenged the patents (BD: Aug 23, 2016).

The company said yesterday that its applicator patent was valid but not infringed by the majority of parties.

Acrux said that the decision allowed US Food and Drug Administration-approved generic versions of Axiron to enter the US market “at risk” pending an appeal.

The company said that a favorable ruling would have provided patent protection for Axiron until the formulation and axilla application patents expired in 2017 and 2027, respectively.

Acrux said that at-risk generic launches referred to when FDA approved generics were launched while patent litigation was on-going and if the decision was overturned appeal and the courts determined the patents were valid and infringed, the generics would be withdrawn from the market and the brand company could seek damages.

Acrux said that with Eli Lilly it believed the Axiron formulation and axilla application patents were valid and enforceable and would be infringed by a generic competitor prior to the expiration of exclusivity.

The company said that it and Lilly were “committed to asserting their intellectual property rights for Axiron”.

Acrux recovered three cents or 7.3 percent to 44 cents with 4.4 million shares traded.

PROTEOMICS INTERNATIONAL

Proteomics says it will investigate “protein fingerprints that can diagnose endometriosis from a simple blood test”.

Proteomics said that endometriosis affected one in 10 women in their reproductive years and cost Australia $7.7 billion a year.

The company said that endometriosis occurred when the tissues that lined the uterus spread and surrounded other organs, causing chronic pain and infertility and was often difficult to diagnose because the symptoms were shared by many other gynaecological conditions, taking an average 8.5 years for be diagnosed from first symptoms.

Proteomics said that imaging scans and existing blood tests were inconclusive, so the current gold standard for detection was an invasive laparoscopy, with a camera inserted into the pelvis through a small cut in the abdominal wall.

Proteomics managing-director Dr Richard Lipscombe said each person had a unique make-up of proteins in their blood and the protein fingerprint could be used to diagnose a wide range of conditions and by comparing blood from sick and healthy people it could produce a set of biomarkers that could show whether people had a disease.

“Existing tests fail to serve patient needs and the discovery of new protein-based diagnostics could lead to substantial improvements in treatment,” Dr Lipscombe said.

Proteomics said it would search for proteins associated with endometriosis with the company’s biomarker discovery platform Promarker, which had been used to develop Promarkerd to predict diabetic kidney disease.

The company said that Promarkerd took five years but it believed biomarkers for endometriosis could be identified in 12 months.

Proteomics was up half a cent or 2.1 percent to 24.5 cents.

CRYOSITE

Cryosite says revenue for the 12 months to June 30, 2016 was up 3.0 percent to $10,137,000 with net profit after tax down 33.5 percent to $302,000.
Cryosite said that despite increased revenue from cord blood banking and cryo-preservation, the reduction in profit was a result of “focusing on its long term strategy of investing in sales, marketing and other initiatives to improve competitiveness in its existing operations and to develop additional revenue streams in new markets”.
The company said that an unfranked 0.5 cent dividend per share for shareholders on the record date of September 8 would be paid on October 4, 2016.
The company said that diluted earnings per share fell 33.3 percent to 0.64 cents at June 30, 2016; net tangible asset backing per share was down 10.4 percent to 6.0 cents.
Cryosite said that it had cash and cash equivalents of $3,651,581 at June 30, 2016.
Cryosite was untraded at 22 cents.

IDT AUSTRALIA

IDT says revenue for the 12 months to June 30, 2015 was up 7.6 percent to $16,914,000, with net loss after tax up 33.9 percent to $4,006,000.
The company said that diluted loss per share fell 13.6 percent to 1.9 cents and it had cash and equivalents of $21,000 at June 30, 2016 compared to $129,000 at June 30, 2015.
IDT fell half a cent or 2.1 percent to 23 cents.

REGENEUS

Regeneus says that revenue for the year to June 30, 2016, fell 8.9 percent to $1,878,000 with net loss after tax down 45.9 percent to $3,033,000.
Regeneus said that licence fees were up 35 percent to $1.2 million, costs had been reduced and the results reflected “the shift in strategic focus to clinical development of the groups key programs rather than early commercialization activities for Hiqcell”.
The company said that net tangible asset backing per share fell 42.0 percent from 3.95 cents at June 30, 2015 to 2.29 cents at June 30, 2016, with diluted loss per share down 43.3 percent to 1.7 cents.
Regeneus said that it had cash and cash equivalents of $528,670 at June 30, 2016 compared to $3,012,812 at June 30, 2015.
Regeneus was unchanged at 15.5 cents.

RHINOMED

Rhinomed says that revenue for the year to June 30, 2016, climbed 134.1 percent to $1,012,433 with net loss after tax up 13.3 percent to $6,022,553.
Rhinomed said that revenue comprised sales revenue for its Turbine sports nasal plugs and its Mute anti-snoring nasal plugs.
The company said that net tangible asset backing per share fell 42.0 percent from 3.95 cents at June 30, 2015 to 2.29 cents at June 30, 2016, with diluted loss per share down 15.8 percent to 0.943 cents.
Rhinomed said that it had cash and cash equivalents of $2,612,757 at June 30, 2016 compared to $1,368,621 at June 30, 2015.
Rhinomed fell 0.3 cents or 13.0 percent to two cents.

GORDAGEN PHARMACEUTICALS

Gordagen says it has received a Federal Government R&D Tax Incentive of $1,273,328 for the year to June 30, 2016.

Gordagen said that $1,169,706 of the R&D Incentive would be used to settle a loan facility provided in 2015 by Metamor Capital Partners (BD: Nov 25, 2016).

Gordagen is a private company.