Biotech Daily

Friday December 9, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: MEDICAL DEVELOP UP 8.5%, SIRTEX DOWN 37%**

*** SIRTEX TUMBLES 52.5% ON FORECAST LOWER SALES GROWTH**

*** RESAPP STARTS PIVOTAL US PAEDIATRIC RESPIRATORY TRIAL**

*** MESOBLAST WELCOMES US '21st CENTURY CURES ACT'**

*** SIENNA APPOINTS SWISS DISTRIBUTION PARTNER**

*** ADHERIUM 'SMARTINHALER INCLUDED IN EU MYAIRCOACH PROGRAM'**

*** DORSAVI REQUESTS CAPITAL RAISING HALT**

*** PARADIGM SHARE PLAN RAISES $494k OF HOPED-FOR $1m**

*** PARADIGM M-D PAUL RENNIE, KZEE, EAR, INCREASE, DILUTED TO 22%**

*** TDM TAKES 11% OF SOMNOMED**

*** CLARIFICATION: IMMURON**

MARKET REPORT

The Australian stock market climbed 0.31 percent on Friday December 9, 2016 with the ASX200 up 17.0 points to 5,560.6 points. Eleven of the Biotech Daily Top 40 stocks were up, 17 fell, 10 traded unchanged and two were untraded.

Medical Developments was the best, up 36 cents or 8.5 percent to $4.61 with 202,101 shares traded on no news, but a research report with a target price of $6.20. Mesoblast and Osprey climbed more than six percent; Benitec was up five percent; Actinogen, Neuren and Orthocell were up more than three percent; Genetic Signatures and Nanosonics rose more than two percent; Pharmaxis and Resmed were up more than one percent; with Compumedics up 0.7 percent.

Sirtex led the falls, down as much as 52.5 percent to $12.20, closing down $9.49 or 37.2 percent to $16.00 with 10.9 million shares traded. Universal Biosensors lost 8.8 percent; Prana fell 7.4 percent; Avita and Cellmid shed more than three percent; Airxpanders, IDT, Oncosil, Prima and Uscom fell more than two percent; Acrux, Clinuvel, Impedimed, Pro Medicus and Starpharma were down more than one percent; with Cochlear, CSL, Ellex and Opthea down by less than one percent.

SIRTEX MEDICAL

Sirtex tumbled as much as 52.5 percent from last night's $25.49 close, to $12.20 in early trading, following forecast lower sales growth.

According to ASX and Commsec data, Sirtex hit an all-time high of $41.33 on November 30, 2015, having fallen from a previous high of $39.20 on March 13 to a low of $17.41 on March 17 on news that SIR-Spheres with chemotherapy did "not result in a statistically significant improvement in the overall progression-free survival" (BD: Mar 17, 2015).

Sirtex said at that time that the 500-patient trial compared its SIR-Spheres with the current standard-of-care, oxaliplatin, leucovorin and 5- fluorouracil (Folfox) to standard-of-care alone for non-resectable metastatic colorectal cancer.

The company said the primary endpoint was progression-free survival, with secondary endpoints including overall survival, tumor response rate, quality of life and surgical resection rate and while the Sirflox study did not show a statistically significant improvement in overall progression-free survival, it did show "a statistically significant improvement in progression-free survival in the liver".

Today, Sirtex said that sales growth for the six months to December 31, 2016 was expected to be between four and six percent compared to growth in the prior corresponding period of 15.7 percent.

The company said that constant currency profit before interest, taxation, depreciation and amortisation for the six months to December 31, 2016 was expected to be in the range of $30 million to $32 million, a 16 percent to nine percent decline.

Sirtex said that for the year to June 30, 2016 dose sales growth was expected to be five to 11 percent compared to 16.4 percent in the year to June 30, 2016.

In August, Sirtex posted record dose sales, record revenue and record profit and 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 (BD: Aug 24, 2016).

Today, Mr Wong said that "trading conditions have been volatile and impacted by a number of factors, including increased competition for patients with liver-directed therapies, a new drug approval in salvage metastatic colorectal cancer and restrictions in reimbursement".

"We have implemented a range of strategic initiatives across the regions to address the disappointing first half, which we anticipate will result in an improved second half and full year dose sales performances, irrespective of the results from our three major clinical studies that are due to report findings in the first half of calendar year 2017," Mr Wong said.

Sirtex said that in the Americas, the company "experienced increased competitive pressures in the medical oncology referral market as well as the interventional oncology market … [with] a significantly higher level of sales and marketing activity around liver-directed therapies including drug-eluting beads, embolization beads and the alternate Yttrium-90 radio-embolization beads …impacting on sales growth".

The company said that in Europe, the Middle East and Africa lower growth was principally related to unexpected tightness and delays in reimbursement, and Germany had experienced funding restrictions for SIR-Spheres in several German States, leading to negligible dose sales growth in that market during the first half.

Sirtex said that across Asia, growth had generally been within management expectations, with the key market of Singapore performing to plan and additional investment in sales and marketing infrastructure in Australia seeing a marked improvement in SIR-Spheres microspheres growth.

Sirtex closed down $9.49 or 37.2 percent to $16.00 with 10.9 million shares traded.

RESAPP HEALTH

Resapp says it has begun its US Smartcough-C study to evaluate the efficacy of the Resappdx mobile software for the diagnosis of paediatric respiratory conditions.
Resapp said that the 1,111-patient, prospective, double-blind, multi-site clinical study would recruit children between the ages of 29 weeks and 12 years.
The company said that the primary efficacy endpoints were the diagnosis of pneumonia compared to radiologic and clinical diagnosis.
Resapp said that secondary endpoints were the diagnosis of other common childhood respiratory diseases such as upper respiratory tract infection, croup, bronchiolitis and asthma compared with a clinical diagnosis.
The company said that the US Smartcough-C trial built on its Australian paediatric clinical study "which demonstrated accurate diagnosis of pneumonia, asthma/viral wheeze, bronchiolitis, croup and upper respiratory tract infections".
Resapp said that analysis of the Australian data was progressing and it would release enhanced results early in the new year.
Resapp chief executive officer Dr Tony Keating said that the company had "devoted key resources to our pivotal US paediatric clinical study to ensure that it commenced during the onset of winter and we are very pleased to announce that our first patients have been enrolled on schedule".
Resapp fell 1.5 cents or 4.35 percent to 33 cents with four million shares traded.

SIENNA CANCER DIAGNOSTICS

Sienna says it has appointed the Muttenz-based Biosystems Switzerland AG to distribute its telomerase-based adjunct diagnostic for bladder cancer in Switzerland.
Sienna said that Biosystems Switzerland was a Swiss laboratory equipment distributor, specializing in equipment and consumables for pathology laboratories focussed on cytology, immunopathology and histology.
Sienna chief operating officer Matthew Hoskin said that Biosystems had "secured significant market share for their clients and has established sales channels, which they will leverage to penetrate the market with the Sienna product".
Sienna is a public unlisted company

MESOBLAST

Mesoblast says it has welcomed the US congress support for the 21st Century Cures Act.
According to the US Congress website, the 21st Century Cures Act is yet to receive Presidential approval but if approved would establish the NIH and Cures Innovation Fund "for biomedical research, including high-risk, high-reward research and research conducted by early stage investigators" as well as develop and implement a strategic plan for biomedical research.
Mesoblast said that when enacted, the Act would provide "an accelerated approval pathway for cell-based medicines designated as regenerative advanced therapies".
Mesoblast chief executive Silviu Itescu said that a number of his company's cell therapy candidates met the Act's criteria for regenerative advanced therapies based on their intended use to treat, modify, reverse, or cure a serious or life-threatening condition.
"We will work closely with the US Food and Drug Administration on the appropriate regulatory pathways for our product candidates that could meet the Act's criteria for the new regenerative advanced therapy designation," Prof Itescu said.
Mesoblast was up eight cents or 6.5 percent to $1.31 with 1.1 million shares traded.

ADHERIUM

Adherium says its Smartinhaler has been included in the European Union's Horizon 2020 Framework for Research and Innovation Myaircoach program.
Adherium said that the Myaircoach program was funded through the Horizon 2020 Framework, which was the largest EU research and innovation program, with nearly EUR80 billion ($A113.7 billion) available over the seven years from 2014 to 2020.
The company said that the Myaircoach program would establish whether home monitoring and mobile health systems could be used to predict asthma control and the occurrence of asthma exacerbations.
Adherium has developed a medication measurement device which attaches to asthma puffers or inhalers.
The company said that one of the goals was to help patients manage their health through user-friendly tools that would increase awareness of their clinical state as well as the adherence and effectiveness of the medical treatment they follow.
Adherium said that the program was expected to set the basis for the adoption of sensor-based self-management systems across the spectrum of respiratory diseases.
Adherium was up two cents or 6.1 percent to 35 cents.

DORSAVI

Dorsavi has requested a trading halt "pending an announcement … in relation to a proposed capital raising".
Trading will resume on December 13, 2016 or on an earlier announcement.
Dorsavi fell three cents or 5.6 percent to 51 cents with 2,000 shares traded, prior to the 11.50am trading halt.
Earlier this week, Dorsavi traded as high as 59.5 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm said in an Appendix 3B new issue announcement saying that its share plan raised $494,000 of which managing director Paul Rennie acquired $200,000 in shares.
Paradigm did not formally report the results of the share plan, but said in the Appendix 3B that apart from Mr Rennie's subscription a further 612,500 shares were issued at 48 cents a share, raising $294,000.
In October, Paradigm said it raised $6,210,000 in an oversubscribed placement at 48 cents a share and offered a share plan to raise a further $1 million (BD: Oct 18, 2016).
Paradigm fell two cents or 4.55 percent to 42 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm managing-director Paul Rennie says he has increased, but been diluted from 21,547,876 shares (24.60%) to 22,104,543 shares (21.78%).
The Adelaide-based Mr Rennie said that the investment was with Kzee Pty Ltd and Ear Investments and on December 8, 2016 the group acquired 140,000 shares in an employee share plan for $46,368 or 33.1 cents a share and bought 416,667 shares for $200,000 in a placement at 48 cents a share.

SOMNOMED

TDM Asset Management says it has increased its holding in Somnomed from 5,454,666 shares (9.62%) to 6,247,419 shares (10.88%).

The New York-based TDM said it acquired 792,753 shares on December 8, 2016, but again failed to state the price paid as required under the Corporations Act, instead saying it paid “market prices”.

The TDM substantial shareholder notice was signed by company secretary Jason Sandler and said that associated entities included TDMAM Pty Ltd, Madleowill Investments Pty Ltd, Zoolander Investments Pty Ltd, Thomas Cowan, Rebecca Cowan, Hamish Corlett and Benjamin Gisz.

Somnomed was up three cents or 0.8 percent to $3.61.

IMMURON

Last night’s edition reported Grandlodge and Immuron executive vice president Peter Anastasiou saying in a substantial shareholder notice that “through Advanced Clinical Systems International and with Kristine Patricia Anastasiou and the Anastasiou Super Fund the group “acquired 546,875 shares at no cost as approved by the November 7, 2015 annual general meeting” and acquired a further 2,418,129 shares for $604,532 or 25 cents a share in the rights issue on July 7, 2016 (BD: Dec 8, 2016).

Mr Anastasiou has told Biotech Daily that the 546,875 shares were issued by Immuron to Advanced Clinical Systems “for provision of all logistical and customer support services in lieu of cash payment”.

Biotech Daily apologizes unreservedly for any confusion.

No sub-editors were hurt, very much, in making this clarification.

Immuron was unchanged at 28.5 cents.