Biotech Daily

Wednesday April 4, 2018

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: DIMERIX UP 5%; USCOM DOWN 10%**

*** IDT SELLS 2014'S $21m SANDOZ DRUGS TO ANI FOR $3.55m**

*** EYEPOINT (PSIVIDA) TO DELIST FROM ASX**

*** IMAGION: FDA SUPPORTS DEVELOPMENT PLANS**

*** ONCOSIL: 3rd PANCREATIC CANCER PATIENT SURGERY**

*** CELLMID TO DISTRIBUTE LABO'S FILLERINA**

*** AUSTRALIAN ETHICAL REDUCES TO 9% OF PHARMAXIS**

*** REGAL FUNDS INCREASES TO 11% OF ONCOSIL**

*** MITSUBISHI, MORGAN STANLEY BELOW 5% OF MEDLAB**

*** DR JOHN CULLITY REPLACES RACE DIRECTOR DR BRENDAN DE KAUWE**

*** DR JACK HAMILTON ANTEO CHAIR; JOHN HURRELL, ROLF SICKMAN GO**

MARKET REPORT

The Australian stock market was up 0.17 percent on Wednesday April 4, 2018 with the ASX200 up 9.5 points to 5,761.4 points. Ten of the Biotech Daily Top 40 stocks were up, 22 fell and eight traded unchanged.

Dimerix was the best, up half a cent or 4.55 percent to 11.5 cents with 85,328 shares traded. Oncosil climbed 4.2 percent; Orthocell, Osprey, Telix and Universal Biosensors were up more than three percent; Genetic Signatures rose 2.1 percent; Avita, CSL and Pharmaxis were up more than one percent; with Sirtex up 0.2 percent.

Uscom led the falls, down 2.5 cents or 10.2 percent to 22 cents with 210,790 shares traded. ITL and Psivida lost more than eight percent; Opthea was down 7.1 percent; Factor and Immutep fell more than four percent; Airxpanders was down 3.4 percent; Bionomics, Compumedics, Ellex, Impedimed, Mesoblast, Neuren, Polynovo, Prana and Starpharma shed more than two percent; Admedus was down 1.6 percent; with Clinuvel, Cochlear, Cyclopharm, Medical Developments, Resmed, Viralytics and Volpara down by less than one percent.

IDT AUSTRALIA

IDT says it will sell 23 generic drugs it acquired from Sandoz for $20.6 million to ANI Pharmaceuticals for $US2.73 million ($A3.55 million) and a share of Prazosin profits.
IDT said the net profit share would continue for 60 months post product launch and the company would retain contract manufacturing rights to supply ANI with a number of the generic products.
In 2014, IDT's then chief executive officer Dr Paul MacLeman announced the acquisition of 23 previously marketed US generic drug products for $US18 million ($A20.6 million) addressing a $US460 million market (BD: Nov 3, Dec 18, 2014).
Biotech Daily was later informed that the drugs had been bought from Sandoz.
Today, IDT chairman Alan Fisher told Biotech Daily that the drugs sold were the same 23 acquired in 2014.
Mr Fisher said that generics had very low margins, the generics industry had seen a marked downturn in recent years and there was a significant cost of keeping the drugs.
Mr Fisher said that the company announced an impairment cost for the drugs in its half year report (BD: Feb 26, 2018).
In a media release to the ASX, IDT said that "to advance a selected generics portfolio and to build on the company's existing commercial [active pharmaceutical ingredient] and contract manufacturing businesses, [it had] divested a majority of the company's generic [abbreviated new drug application] product portfolio" to the Baudette, Minnesota-based ANI Pharmaceuticals.
IDT said it would retain the right to manufacture and supply doxazosin mesylate and calcium leucovorin, which were the divested products currently manufactured in its Boronia, Melbourne facilities, on a contract manufacture for profit basis.
The company said that ANI Pharmaceuticals would be responsible for all commercialization costs along with all pharmaco-vigilance and regulatory costs associated with the divested product portfolio.
"This transaction allows IDT to monetize a specific group of non-specialized generic assets and for IDT to focus on developing selected generic products," Mr Fisher said.
"These new products will complement the company's temozolomide product and play to IDT's niche strengths of dealing with cytotoxic drugs and other highly potent high containment products," Mr Fisher said.
"Importantly IDT is able to immediately free itself from the high fixed costs associated with having a portfolio of 19 US generic product filings, many of which have been affected by the changed market conditions for generics in the US," Mr Fisher said.
IDT said its focus would be on increasing revenues, reducing costs "and accelerating the development of a portfolio of high value niche generic products".
IDT was up 0.6 cents or 7.1 percent to 9.1 cents.

EYEPOINT PHARMACEUTICALS (FORMERLY PSIVIDA CORP)

Eyepoint says it has received formal approval to delist from the ASX, with trading suspended on April 30 and removal from the list on May 7, 2018 (BD: Mar 29, 2018).
Eyepoint said its Nasdaq code had been changed from PSDV to EYPT, effective from April 2, 2018, but the ASX code would remain PVA.
The company said Australian Chess depository instrument (CDI) holders could convert their Australian CDIs into US shares to be traded on the Nasdaq, or sell them through the voluntary sale facility, opening on May 21, 2018 and following the close of the voluntary sale facility it would establish a compulsory sale facility for all CDIs not sold or converted.
Eyepoint fell 13 cents or 8.1 percent to $1.48.

IMAGION BIOSYSTEMS

Imagion says the US Food and Drug Administration has generally accepted its development plans for its Magsense technology.

Imagion said it filed a pre-submission document with the FDA in January 2018 to initiate communications on the clinical development plans, with the Center for Devices and Radiological Health confirming the Office of Combination Products' opinion that Magsense was a combination product and that Center was the lead review group.

The company said that the Center accepted its general toxicology study plan based on the view that the nanoparticle formulation was "a low safety risk due to prior known safety profiles of the materials incorporated into the formulation".

Imagion said that the Center agreed with its overall clinical study approach of sequential clinical studies starting with the first-in-human early feasibility study and provided clear guidance for the early feasibility study design.

Imagion said that its next steps would include the manufacture of an initial batch of nanoparticles and a nanoparticle safety and toxicology study.

Separately, the company said it was relocating from Albuquerque, New Mexico to San Diego, California and expected to be fully operational in San Diego by July 2018.

Imagion was up 2.4 cents or 42.9 percent to eight cents.

ONCOSIL

Oncosil says a third patient of the first 20 patients in its trial of Brachysil for pancreatic cancer has undergone surgical resection with curative intent.

Oncosil said a further three patients were being assessed by clinical teams for possible resection.

In March, the company said two patients had undergone the procedure as part of its pancreatic cancer clinical study program (BD: Mar 21, 2018)

Oncosil said surgical resection was not a pre-specified trial endpoint, but the findings were "a clinical milestone", suggesting the potential for down-staging patients from initially inoperable to surgically resectable when its device was used with optimum chemotherapy.

The company said the first study participants in the US and the EU had been implanted with the device, with a total of 40 patients enrolled and 31 implanted.

Oncosil was up half a cent or 4.2 percent to 12.5 cents.

CELLMID

Cellmid says it has agreed to distribute Labo International's anti-aging skincare product Fillerina in Australia and New Zealand for an initial five years.

Cellmid said Fillerina was a dermo-cosmetic filler treatment, that had been scientifically proven to reduce facial wrinkles, deliver measurable filling effect, increase facial volumes and decrease the clinical signs of skin again.

The company said the agreement with the Basel, Switzerland-based Labo included joint distribution and sales targets, as well as a close marketing collaboration.

Cellmid chief executive officer Maria Halasz said the growth strategy for the Advangen subsidiary was "focused on first in class, best in class, clinically-validated, anti-aging products for hair, skin and body".

"Having built a successful distribution network for our FGF5 inhibitor hair [growth] products, Fillerina is an exciting addition to our consumer health business," Ms Halasz said.

Cellmid fell 1.5 cents or 3.4 percent to 43 cents.

PHARMAXIS

Australian Ethical Investment says it has reduced its substantial shareholding in Pharmaxis from 32,424,427 shares (10.16%) to 28,759,640 shares (8.99%).
Australian Ethical said that from October 3 to November 2, 2017 it bought shares, and then sold shares from March 3 until April 3, 2018, when it sold 5,000,000 for $1,646,370, or 32.9 cents a share.
Pharmaxis was up half a cent or 1.6 percent to 32.5 cents.

ONCOSIL MEDICAL

Regal Funds Management says it has increased its substantial shareholding in Oncosil from 36,625,525 shares (7. 51%) to 59,238,620 shares (10.62%).
The Sydney-based Regal Funds substantial shareholder notice said that between February 7, 2018 and March 27, 2018 it sold shares and on March 28 bought 25,521,930 shares for $3,062,631, or 12 cents a share, as part of Oncosil's $12.7 million placement (BD: Mar 21, 2018).

MEDLAB CLINICAL

Mitsubishi UFJ Financial and Morgan Stanley say they have ceased the substantial shareholding in Medlab announced last week.
Last week, the Tokyo, Japan-based Mitsubishi UFJ Financial and New York and Sydney-based Morgan Stanley filed similar substantial share-holder announcements saying they had become substantial shareholders in Medlab with 12,466,662 shares (5.99%) in a large number of trades between November 29, 2017 and March 26, 2018 buying shares and received collateral, with the single largest purchase 6,384,903 shares for $4,054,413 or 63.5 cents a share (BD: Mar 29, 2018).
Today, the companies said they bought shares on March 27 and 28 and sold shares on March 28, 2018 with the single largest sale 8,438,903 shares for $4,219,452 or 50 cents a share.
Medlab fell 4.5 cents or eight percent to 52 cents.

RACE ONCOLOGY

Race says it has appointed US-based Dr John Cullity as a non-executive director,effective April 6, 2018, replacing Dr Brendan de Kauwe.
The company said Dr Cullity had worked as an executive at Schering-Plough and Sanofi-Aventis.
Race said that Dr Cullity previously was a principal for advisory firm Torreya Partners and managed licencing and merger and acquisition transactions.
The company said that Dr Cullity was currently a director of Theraly Fibrosis, Haemalogix, and Ceramedix.
Race said Dr Cullity held a Bachelor of Medicine and, Bachelor of Surgery from the University of Western Australia, a Master of Science from the London School of Economics and a Masters of Business Administration from the Wharton School, University of Pennsylvania.
Race said that Dr de Kauwe had resigned and the company was grateful for his "outstanding service as a director … since the founding of the company."
Race was up half a cent or 1.4 percent to 36.5 cents.

ANTEO DIAGNOSTICS

Anteo says that Dr John (Jack) Andrew Hamilton will replace Dr John Hurrell as independent non-executive chairman, effective from April 1, 2018.

Anteo said that Dr Hurrell and director Rolf Sickman had resigned.

The company said that Dr Hamilton had more than 15 years' experience as an executive with experience in strategy development, commercial marketing, mergers and acquisitions, capital raisings, manufacturing operations and project management in the energy and petrochemical sectors.

Anteo said that Dr Hamilton had more than 10 years' experience as a non-executive director and was currently a director of Calix and an advisor to GHD Advisory.

The company said that Dr Hamilton was formerly a director of Duet Group and chairman of Renu Energy.

Anteo fell 0.1 cents or 6.25 percent to 1.5 cents with 1.2 million shares traded.