Biotech Daily

Thursday March 16, 2023

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: COMPUMEDICS UP 7%;**
- MEDICAL DEVELOPMENTS DOWN 11%

*** PRESCIENT: 2 COMPLETE PTX-100 LYMPHOMA RESPONSES**

*** CANNATREK SELLS 500k UNITS MARIJUANA T25 TOPAZ FLOWER; $75m**

*** LUMOS EARNS $8.9m FROM 3 HOLOGIC AGREEMENTS**

*** TELIX: US FDA EXPANDS ILLUCCIX NDA**

*** ALTERITY DOSES FIRST US ATH434 MSA PATIENT**

*** CYNATA OPENS 3 MORE DIABETIC FOOT ULCER SITES**

*** INCANNEX TO RUN PSYCHEDELIC PSYCHOTHERAPY CLINICS**

*** PRO MEDICUS CO-FOUNDERS SELL 2m SHARES**

*** LAZARD TAKES 6% OF MAYNE PHARMA**

*** COPIA BELOW 5% IN PROBIOTEC**

*** MICHAEL CARTER, MATTHEW HUDSON REPLACE 4 MEDLAB DIRECTORS**

MARKET REPORT

The Australian stock market fell 1.46 percent on Thursday March 16, 2023, with the ASX200 down 103.4 points to 6,965.5 points. Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, 11 traded unchanged and one was untraded. All three Big Caps were up.

Compumedics was the best, up one cent or 6.7 percent to 16 cents, with 4,000 shares traded. Neuren and Prescient climbed more than four percent; Impedimed improved 3.45 percent; Nanosonics, Resonance, Telix, Universal Biosensors and Volpara rose two percent or more; Cochlear, CSL, Immutep, Pro Medicus and Resmed were up more than one percent; with Cyclopharm, Next Science and Opthea up by less than one percent.

Medical Developments led the falls, down 13 cents or 10.8 percent to $1.075, with 667,678 shares traded. Proteomics lost 8.9 percent; Alcidion shed 7.7 percent; Antisense and Polynovo were down more than five percent; Actinogen, Atomo, Emvision and Micro-X fell more than four percent; Avita, Genetic Signatures and Mesoblast were down more than three percent; Paradigm shed 2.55 percent; with Orthocell down by 1.3 percent.

PRESCIENT THERAPEUTICS

Prescient says an interim analysis of its phase Ib trial of PTX-100 for T-cell lymphomas shows “positive response rates with two new complete responses”.

Last year, the company said it had dosed seven of the up-to 12-patients in the expansion cohort of its phase Ib trial of PTX-100 for T-cell lymphomas, with no serious adverse events (BD: Oct 25, 2022).

At that time, Prescient said that eight patients had been screened, seven had been dosed with 2,000 milligrams per square metre (mg/m2) PTX-100, four patients remained on therapy, and that three patients had left the study for reasons unrelated to the trial, with additional patients to be recruited.

Today, Prescient said that two patients with relapsed and refractory peripheral T-cell lymphoma had “complete responses, complete eradication of cancer, since the prior update… which [was] not generally expected in this disease”.

The company said that PTX-100 continued to “exhibit an excellent safety profile at the highest dose of 2,000mg/m2”.

Prescient said that a total of 13 T-cell lymphoma patients had been dosed with PTX-100, with eight of those with relapsed and refractory peripheral T-cell lymphomas and the remaining with cutaneous T-cell lymphomas (TCL).

Prescient said that of 10 evaluable patients, overall response rates were 40 percent, which had exceeded its target of 30 percent, and that the progression free survival of 8.7 months exceeded its target of five to six months.

The company said that it was planning a subsequent phase II trial in T-cell lymphomas, to be conducted subject to “satisfactory phase Ib outcomes”.

Prescient said that it would seek for “accelerated approval” from the US FDA, which would enable expedited regulatory approval and see the phase II study open within 12 months.

The company said that if it did not gain FDA approval, it would continue to a phase II trial under conventional pathways.

Prescient managing-director Steven Yatomi-Clarke said it was “very exciting to see this clinical data for PTX-100 continue to unfold so favorably, especially in these relapsed and refractory T cell lymphomas, which are particularly difficult to treat and where other therapies have failed”.

“Unlike other TCL therapies, PTX-100 continues to exhibit an excellent safety profile, and the patient responses we are observing are very promising for a phase Ib study,” Mr Yatomi-Clarke said.

“Whilst phase I trials necessarily focus on safety, we have a valuable opportunity to bolster our trial with a small number of additional patients to enable Prescient to have a more meaningful and productive dialogue with the FDA,” Mr Yatomi-Clarke said.

Prescient was up half a cent or 4.2 percent to 12.5 cents with 5.7 million shares traded.

CANNATREK

Cannatrek says it has almost sold its 500,000th unit of its T25 Topaz Flower marijuana prescription drug, which Biotech Daily calculates to be worth a total of $75 million.

Cannatrek chief executive officer Tommy Huppert told Biotech Daily that its T25 Topaz Flower came in 10-gram jars and contained 25 percent delta-9-tetrahydrocannabinol (THC) and less than one percent cannabidiol (CBD).

Mr Huppert said that he believed the recommended retail price was $150 per jar.

Cannatrek said that its T25 Topaz Flower was the most prescribed and “consistent medical cannabis product in Australia”.

Cannatrek is a public unlisted company.

LUMOS DIAGNOSTICS

Lumos says it will receive up-to $US5.9 million ($A8.9 million) from three agreements with Hologic for equipment sales and leasebacks, and extending existing projects.

Last year, Lumos says it would close its facility in Sarasota, Florida as part of its program to reduce its operating cash burn after announcing that it had 1.71 quarters of funding (BD: Jul 29, Aug 2, 2022).

Earlier in July, Lumos said the US Food and Drug Administration had not granted 510(k) clearance to market its Febridx finger-prick blood test to differentiate bacterial from viral infections (BD: Jul 11, 2022).

Today, the company said that the Marlborough, Massachusetts-based Hologic had signed a $US4.2 million sale and leaseback agreement for some of its point-of-care diagnostic manufacturing and development equipment, and an additional two agreements worth up to $US1.7 million to "undertake additional work on existing projects" following the 2022 service agreements.

In 2022, Lumos said it would receive $US1.5 million from Hologic for the development of two women's health tests (BD: Nov 23, 2022).

Today, Lumos chief executive officer Doug Ward said the company was "extremely grateful and appreciative of the ongoing support that Hologic has provided for Lumos through these agreements".

"In addition to providing the company with additional, non-dilutive funding that does not impact on our operational capacity, they further strengthen our strategic relationship with Hologic," Mr Ward said.

Lumos was unchanged at 3.1 cents with 1.5 million shares traded.

TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration has approved a supplementary new drug application for Illuccix for selecting metastatic prostate cancer patients.

In late 2021, Telix said the FDA had approved its Illuccix prostate cancer imaging kit for the preparation of 68-gallium, prostate specific membrane antigen-11 injection (68Ga-PSMA-11) (BD: Jan 16, 2022).

Today, the company said that the supplementary approval applied to patients with metastatic prostate cancer, for whom lutetium-177 (177Lu) prostate-specific membrane antigen (PSMA) directed therapy was indicated.

Telix said that the label expansion meant that Illuccix was approved in the US to "identify and select patients who are candidates for the only FDA-approved prostate-specific membrane antigen (PSMA)-directed radio-ligand therapy (Pluvicto) providing doctors with critical information to guide patient management and help optimize treatment outcomes".

The company said that patients must be imaged with an approved gallium-based PSMA-positron emission tomography agent to qualify for radio-ligand therapy.

Telix Americas chief executive officer Kevin Richardson said the company welcomed the FDA's decision to expand the label indication for Illuccix.

"This additional indication further demonstrates our continued commitment to support patients fighting prostate cancer and to empower the doctors who treat them," Mr Richardson said.

"Clinicians now have the ability to use Illuccix in more stages of the patient journey, to confidently and accurately detect and help manage this disease," Mr Richardson said.

Telix was up 18 cents or 2.7 percent to $6.86 with 1.2 million shares traded.

ALTERITY THERAPEUTICS

Alterity says it has dosed the first US patient in its 60-patient, phase II trial of ATH434 in patients with early-stage multiple system atrophy.
Alterity said the 12-month trial would explore the effect of ATH434 treatment on biomarkers such as aggregating alpha- synuclein and excess iron, both of which it said were important contributors to multiple system atrophy pathology (BD: Jul 6, 2022).
In January, the company said patients would receive one of two dose levels of ATH434 or placebo for 12 months, and the data would inform the design of a planned phase III study (BD: Jan 25, 2023).
Alterity was unchanged at 0.8 cents with 4.7 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has opened three additional sites for its 30-patient trial of CYP-006TK mesenchymal stem cell wound dressing for diabetic foot ulcers.
In 2022, Cynata said a review of safety data has approved the continuation of its diabetic foot ulcers trial, after it had enrolled the first patients in its phase I trial of CYP-006TK wound treatment (BD: Apr 21, Oct 12, 2022).
Today, the company said that all additional sites were based in Perth, including the Royal Perth Hospital, Fiona Stanley Hospital and Sir Charles Gairdner Hospital and it was manufacturing CYP-006TK at the Royal Perth Hospital for use in the trial.
Cynata said that the inclusion of the sites was expected to accelerate enrolment, it hoped to complete recruitment in mid-2023 with top-line data “by the end of the year”.
Cynata was unchanged at 28 cents.

INCANNEX HEALTHCARE

Incannex says it has plans to open psychedelic-assisted psychotherapy clinics and has appointed three directors to an unnamed subsidiary company for the venture.
Incannex said it had been developing the plans for psychedelic clinics for some time and had a partnership with “Australia’s leading clinical psychedelic professionals, all of whom have extensive experience within clinical psychedelic research, treatment, and training”.
The company said it was at “an advanced stage of negotiations” over premises in Melbourne and its first ‘model’ clinical was expected to open before the end of 2023.
Incannex said its director Peter Widdows would lead the subsidiary, with Dr Paul Liknaitzky, Prof Suresh Sundram and Sean O’Carroll appointed directors.
Mr Widdows said the group “intended to use only ketamine-assisted psychotherapy, with the possibility of expanding into psilocybin-assisted psychotherapy for generalized anxiety disorder subject to regulatory approval”.
Mr Widdows said that when the Australian Therapeutic Goods Administration announced the down-scheduling of 3,4-methylene-dioxy-methamphetamine (MDMA) and psilocybin for two indications “we were in a perfect position to expand our plans to cover this wider set of related therapies for certain indications”.
Incannex managing-director Joel Latham said opening the clinics was “a pivotal point in the journey of the company, turning from pure research into service delivery” but would not have an impact on the development of our core clinical assets.
“The implementation of this strategy will in part provide the platform to allow an accelerated path to commercialization for our drug assets, post clinical success,” Mr Latham said.
Incannex fell one cent or 7.4 percent to 12.5 cents with 10.8 million shares traded.

PRO MEDICUS

Pro Medicus says its co-founders, Dr Sam Hupert and Anthony Hall have each sold 1,000,000 shares at yesterday's closing price of $62.22 a share.
Pro Medicus said the shares were less than four percent of chief executive officer Dr Hupert and executive director Mr Hall's respective holdings, and their combined holdings remained more than 50 percent of the company, and they did not intend to sell more shares for "the foreseeable future".
Pro Medicus was up 79 cents or 1.3 percent to $63.01 with 363,204 shares traded.

MAYNE PHARMA

Lazard Asset Management says it has increased its substantial shareholding in Mayne Pharma from 4,539,772 shares (5.29%) to 5,419,443 shares (6.32%).
The Sydney-based Lazard said that it bought shares between March 2 and 14, 2023, with the single largest purchase 181,717 shares for $675,686 or $3.72 a share.
Last year, Mayne conducted a 20-to-one consolidation (BD: Nov 30, 2022).
Mayne fell 21 cents or 5.6 percent to $3.57.

PROBIOTEC

Copia Investment Partners says it has ceased its substantial share-holding in Probiotec.
Melbourne's Copia said that between February 2022, and March 2023 it sold 1,369,681 shares at prices ranging from $2.15 to $2.55.
In 2022, Copia said it had become substantial in Probiotec with 4,455,319 shares or 5.48 percent (BD: Feb 21, 2022).
Probiotec was up two cents or 0.85 percent to $2.37.

MEDLAB CLINICAL

Medlab says Michael Carter and Matthew Hudson will replace chair Michael Hall, and directors Drew Townsend, Cheryl Maley and Mohit Gupta.
Last week, Medlab said it had retrenched 78 percent of its staff and Hall Chadwick had been appointed to assist with a restructure (BD: Mar 7, 2023).
Today, the company said that "stakeholders are assured that the company is not subject to any form of external control, including that it is not subject to voluntary administration".
Medlab said that Mr Carter had 18 years of experience working in corporate advisory roles with ASX-listed companies, was currently a director at CPS Capital Group and European Lithium and was previously a director of Indian Ocean Capital.
Medlab said Mr Carter held a Bachelor of Commerce from the University of Western Australia in Perth.
The company said that Mr Hudson was co-founder and managing-director of Hudson Koch Energy, as well as United Minerals, and had previously worked as an advisor for Credit Suisse and Arthur Anderson.
Medlab was in a suspension and last traded at $6.60.