Biotech Daily

Tuesday September 27, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PHARMAXIS UP 4%, DIMERIX DOWN 6%**

*** RUSSIA APPROVES PHARMAXIS BRONCHITOL FOR CYSTIC FIBROSIS**

*** GENETIC SIGNATURES EASYSCREEN STI TEST VALIDATION TRIAL**

MARKET REPORT

The Australian stock market fell 0.47 percent on Tuesday September 27, 2016, with the ASX200 down 25.5 points to 5,405.9 points.

Eight of the Biotech Daily Top 40 companies were up, 24 fell, seven traded unchanged and one was untraded.

Pharmaxis was the best, up one cent or 3.8 percent to 27.5 cents with 1.9 million shares traded.

Actinogen and Cellmid climbed more than three percent; Viralytics was up 2.3 percent; Atcor, Avita, Cochlear, Compumedics and CSL were up more than one percent; with Sirtex up by 0.3 percent.

Dimerix led the falls, down 0.1 cents or 6.25 percent to 1.5 cents with 1.9 million shares traded.

Bionomics, Oncosil, Osprey, Prana and Psivida fell four percent or more; Anteo and Factor Therapeutics were down more than three percent; Clinuvel, Impedimed and Prima shed more than two percent; Acrux, Benitec, Ellex, Living Cell, Medical Developments, Mesoblast, Nanosonics, Orthocell and Reva were down more than one percent; with Airxpanders, Opthea, Pro Medicus, Resmed and Starpharma down by less than one percent.

PHARMAXIS

Pharmaxis says that Russia has approved the marketing of Bronchitol for the treatment of both paediatric and adult cystic fibrosis, with first sales expected this year.

Pharmaxis said that Russia was the largest market accessed to date for Bronchitol and the decision made Bronchitol the first medicine to be processed under new Russian laws to provide patients access to innovative medicines.

The company said that new orphan drug legislation was announced by the Russian Ministry of Health in January 2016 and Bronchitol was designated as an orphan drug the following month.

Pharmaxis said that there were about 7,400 cystic fibrosis patients on the Russian Cystic Fibrosis Registry, but it was estimated there were between 3,000 and 6,000 cystic fibrosis patients in rural regions not included on the registry.

The company said that in 2015 the Russian market for cystic fibrosis drugs to deal with mucus clearance was about $US29 million.

Pharmaxis chief executive officer Gary Phillips said the approval was “an important milestone for the company and a noteworthy achievement for Australian innovation”.

“Bronchitol will be manufactured and exported to Russia from our purpose-built factory in Sydney,” Mr Phillips said.

“It will be used to treat children aged six and above and adults throughout Russia who are suffering from the debilitating symptoms of cystic fibrosis,” Mr Phillips said.

“We have successfully translated an Australian clinical discovery into an approved therapy for patients in the [European Union], Australia and now Russia,” Mr Phillips said.

“I am also proud of the work we have done in having Bronchitol become the first drug to be granted marketing approval under the new Russian legislation,” Mr Phillips said. “We were instrumental in demonstrating the need for the new legislation and this will ultimately mean better access to a range of medicines for Russian patients in need.”

Pharmaxis said that Russia’s Ministry of Health Orphan Committee would consider Bronchitol’s application for reimbursement under a program for guaranteed funding of seven orphan diseases known as the Seven Nosologies Program, with cystic fibrosis drugs purchased by the Russian Ministry of Health through an annual tender.

Pharmaxis chairman Malcolm McComas said that accessing the Russian market was led by Mr Phillips “whose experience and long standing relationships in Eastern Europe were a key factor in successfully navigating the complexities involved in achieving this milestone”.

The company said that Russia had 40 cystic fibrosis centres for children and three for adults, along with small centres were located within the pulmonology departments of paediatric hospitals.

The Russian Association of Patients with Cystic Fibrosis president Prof Nikolay Kapranov said that the staff of the Russian and Moscow centres of cystic fibrosis were “very pleased that Bronchitol has state registration in Russia and that our patients will have access to a new innovative product”.

Pharmaxis said that Bronchitol was a spray-dried form of mannitol, delivered to the lungs by a portable inhaler.

The company said that Bronchitol was approved for patients aged six years and over in Australia and for patients aged 18 years and over throughout the European Union.

Pharmaxis said it had been supported in its Russian application by its Russian distributor the Moscow-based Irwin-2, which would provide logistical support for Bronchitol.

The company said it would engage the services of four cystic fibrosis medical specialists to support the use of Bronchitol in the clinic.

Pharmaxis was up one cent or 3.8 percent to 27.5 cents with 1.9 million shares traded.

GENETIC SIGNATURES

Genetic Signatures says it has begun a validation trial of its Easyscreen sexually transmitted infection detection kit with an unnamed Australian clinical partner.

Genetic Signatures said that the trial would examine clinical patient specimens and compare the Easyscreen results with those obtained through current testing standards.

The company said it expected results by the end of 2016.

Genetic Signatures said that sexually transmitted infections (STIs) had a significant impact on sexual and reproductive health with the World Health Organisation reporting that more than one million infections were contracted per day, with the STI testing market estimated at $US550 million.

The company said the Easyscreen STI detection kit was developed over 15 months and leveraged its molecular diagnostic 3Base platform technology and could simultaneously identify 12 of the most significant and commonly encountered infections.

Genetic Signatures said that the trial data would be used to support regulatory approvals.

Genetic Signatures chief executive officer Dr John Melki said the validation trial was “an important step in our Easyscreen product range expansion strategy”.

“Clinical validation data will allow us to progress toward market release and regulatory approval for this product,” Dr Melki said.

“Our 3base technology allowed us to develop a panel that covers a broad range of significant pathogens for genuine STI screening,” Dr Melki said.

“As many STIs are asymptomatic and require screening for diagnosis, our test will allow clinicians to detect a broad range of STIs with a single molecular diagnostic assay,” Dr Melki said.

Genetic Signatures was unchanged at 48 cents.