

Biotech Daily

Monday November 5, 2018

Daily news on ASX-listed biotechnology companies

* ASX, BIOTECH DOWN: CLINUVEL UP 9%; AIRXPANDERS DOWN 12.5%

* COCHLEAR ORDERED TO PAY \$372m OVER PATENT; APPEAL

- * MACH7 WORKS ON SENTARA RADIOLOGY UPGRADE
- * JAPAN PATENT FOR RESAPP RESPIRATORY DIAGNOSTIC
- * VANGUARD TAKES 5% OF CSL
- * MGC TAKES 'CANNAGLOBAL, MGC DERMA SALE' HALT TO SUSPENSION

MARKET REPORT

The Australian stock market fell 0.53 percent on Monday November 5, 2018 with the ASX200 down 31.1 points to 5,818.1 points.

Eight of the Biotech Daily Top 40 stocks were up, 17 fell, 10 traded unchanged and five were untraded. All three Big Caps fell.

Clinuvel was the best, up \$1.52 or 8.6 percent to \$19.20, with 60,107 shares traded.

Bionomics and Osprey were up more than three percent; Universal Biosensors rose 2.1 percent; Compumedics and Cynata were up more than one percent; with Ellex and Mesoblast up by less than one percent.

Airxpanders led the falls, down 0.8 cents or 12.5 percent to 5.6 cents, with 693,100 shares traded.

Avita and Orthocell fell four percent or more; Cochlear, Neuren and Pro Medicus were down three percent or more; CSL, Impedimed, Oncosil and Reva shed more than two percent; Dimerix, Opthea, Pharmaxis, Prescient, Resmed and Telix lost more than one percent; with Genetic Signatures, Medical Developments, Nanosonics and Starpharma down by less than one percent.

COCHLEAR

Cochlear says it has been ordered to pay Alfred E Mann Foundation and Advanced Bionics LLC \$US268,057,078 (\$A372,148,573) for patent infringement.

Cochlear said it had would appeal the judgment "over a long-expired patent" with the outcome expected in about two years, and said that in 2013-'14 it established a \$21.3 million provision for the liability.

The company said the provision was "based on the view of Cochlear's independent damages expert's assessment of the liability that could result from the dispute" and it would "undertake a review of the current provision of \$21.3 million".

Cochlear said the infringement related to "a long-expired patent and has no ongoing impact to Cochlear's business".

The company said that in January 2014, a jury found that it had infringed four claims in two patents, the infringement was "wilful" and awarded \$US131,216,325 in damages. Cochlear said that on April 1, 2015, a judge in the US District Court in Los Angeles, California held that three of the four patent claims were invalid and Cochlear's infringement of the remaining claim was not "wilful" and the judge vacated the damages awarded because three of the four claims were held to be invalid.

The company said that on April 21, 2015, the Court entered judgment on liability only and stayed a new trial on damages pending the outcome of the appeals by all parties and on November 18, 2016, the Court of Appeals affirmed the judgment as to infringement, affirmed the judgment as to invalidity of one patent, and reversed the judgment of invalidity as to one claim in the other patent.

Cochlear said the Court of Appeals then remanded to the District Court the issue of damages and wilfulness of infringement of two claims in the remaining patent at issue. The company said that the Alfred E Mann Foundation and Advanced Bionics asked the District Court judge to enter judgment against Cochlear for \$US131,216,325 based on the verdict from the jury trial in January 2014, to add an additional amount for post-verdict infringement and to increase those damages for wilful infringement.

Cochlear said it asked the judge to find non-infringement of the second valid claim, to hold a second jury trial on damages and to decline to increase damages for wilful infringement. The company said that today the US District Court granted AMF's and AB's request for entry of the prior jury verdict, upheld infringement of the second claim, added

\$US2,812,214 for post-verdict infringement, increased damages based on the jury's verdict of wilful infringement, and ordered AMF and AB prepare a judgment to be entered against Cochlear for \$US268,057,078.

Cochlear chief executive officer Dig Howitt said the company was "surprised by the decision and do not agree with the reasons given by the judge".

"We will continue to defend this case and the next step in the litigation process is our appeal to the US Court of Appeals," Mr Howitt said.

"The case is likely to take years to finally resolve," Mr Howitt said.

The company said that to stay the execution of the judgment pending the outcome of the appeal, it would need to lodge a \$US335 million insurance bond with the Court within 14 days of the entry of judgment to secure the judgment amount and any interest and costs, and said it had "debt and other facilities available to cover the amount of the insurance bond".

Cochlear said that a provision was expensed in the six months to December 31, 2013 in relation to this dispute and it would review the \$21.3 million provision.

The company said that as the patent at issue had expired, the judgment would not disrupt its US business or customers.

Cochlear fell \$6.83 or 3.8 percent to \$172.73 with 261,004 shares traded.

MACH7 TECHNOLOGIES

Mach7 says it is a co-vendor for the Norfolk, Virginia-based Sentara Healthcare's picture archive communication system modernization project.

Mach7 said it was a co-vendor with the Waterloo, Ontario-based Client Outlook Inc for the picture archive communication system (PACS) upgrade which would incorporate Mach7's Diagnostic Studio and Client Outlook's Eunity radiology reading functionality

The company said the project built on a partnership that began in 2014 when Sentara implemented its vendor neutral archive at its facilities in Virginia and North Carolina. Mach7 said it was currently supporting Sentara with the migration from five separate picture archive communication systems into its vendor neutral archive (VNA).

The company said that Sentara had forecast "substantial annual cost savings from Mach7's and Eunity's diagnostic capabilities", which would improve medical imaging fluidity across sites and increase radiology and clinician workflow efficiency, resulting in better patient care.

Sentara information technology director Trent Conwell said that "Mach7 and Client Outlook provide the architectures that enable us to choose the most advanced and innovative technologies".

"With a proven data platform, solid enterprise viewer and efficient, seamless migration process, Mach7 and Client Outlook have helped Sentara develop our vision of an evolutionary clinical [information technology] ecosystem," Mr Conwell said.

Mach7 chief executive officer Mike Jackman said that Sentara "shares our commitment to innovation and developing solutions that empower physicians and radiologists to access the clinical data they need when and where they need it to support optimal patient care". Mach7 was unchanged at 23.5 cents.

RESAPP HEALTH

Resapp says the Japan Patent Office has allowed a patent covering the use of a coughsound based audio processing pipeline for diagnosing respiratory disease.

Resapp said the patent application, titled 'A Method and Apparatus for Processing Patient Sounds' protected "a key component of [the] Resappdx ... smartphone application for diagnosing acute respiratory disease, until March 28, 2033.

The company said it was the third member of the patent family to be accepted, following US and Australia acceptances, with applications covering similar subject matter pending in Europe, China and South Korea.

Resapp chief executive officer Dr Tony Keating said that an aging population, a shortage of doctors and rising healthcare costs put pressure on Japan's healthcare system, increased the use of telehealth in Japan, accelerated by health insurance deregulation.

"The granting of our core patent ... is an important part of our commercialization strategy in Japan and further strengthens our global intellectual property position," Dr Keating said. Resapp fell half a cent or 4.35 percent to 11 cents with 3.8 million shares traded.

<u>CSL</u>

The Valley Forge, Pennsylvania-based Vanguard Group has become a substantial shareholder in CSL with 22,656,088 shares or 5.002 percent.

The substantial shareholder notice said the shares were held by the group and Vanguard Investments Australia, which bought and sold shares between July 3 and October 31, 2018 in more than 250 trades, at prices ranging from \$174.69 a share to \$230.28. CSL fell \$4.66 or 2.4 percent to \$187.52 with 761,215 shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC has requested a voluntary suspension to follow the trading halt requested on November 1, "pending the release of an announcement … regarding the MGC Derma sale transaction with Cannaglobal" (BD: Nov 1, 2018). MGC last traded at 5.1 cents.