# Biotech Daily

Friday April 1, 2011

*Daily news on ASX-listed biotechnology companies*

*** MARCH BDI-40 UP 10.7%, ASX200 UP 0.14%**
**- PRANA UP 60.5%, CHEMGENEX 52.5%, ANTISENSE 50%, BIONOMICS 41%**

*** TODAY: ASX, BIOTECH UP: BIOTA UP 36%; SUNSHINE HEART DOWN 7%**

*** US AWARDS BIOTA $224m FOR 'FLU DRUG REGISTRATION TRIALS**

*** BIOGUIDE BRIEF: BOUQUETS FOR BIOTA, BIONOMICS**

*** 'INVESTOR UPDATE' IMPLIES IMPEDIMED 12-MONTH IMPEDIMENT**

*** EDITORIAL: KEEPING THE MARKET CLEARLY INFORMED**

*** COGSTATE SPORT ADOPTED BY RUGBY LEAGUE FOR BRAIN INJURY**

*** GENERA RIGHTS ISSUE RAISES $2.45m; $506k SHORTFALL**

*** DR BRUCE GRAY SELLS 2.4m SIRTEX SHARES**

*** FLUOROTECHNICS FUND-RAISING REVIVAL AGM**

*** IAIN KIRKWOOD REPLACES AVEXA CHAIRMAN JOE BAINI**

*** AGENIX APPOINTS GARY TAYLOR CFO, CO SEC**

## MARKET REPORT

The Australian stock market climbed 0.49 percent on Friday April 1, 2011 with the S&P ASX 200 up 23.9 points to 4861.8 points. Sixteen of the Biotech Daily Top 40 stocks were up, nine fell, eight traded unchanged and seven were untraded.

Biota was the best, up 37.5 cents or 35.7 percent to $1.425 with 7.9 million shares traded. Genera, Prima and Starpharma climbed more than nine percent; Antisense and Benitec were up more than seven percent; Impedimed, Patrys, Pharmaxis, Phosphagenics and Viralytics were up four percent or more; Acrux was up 3.3 percent; Prana rose two percent; with CSL, Mesoblast and QRX up more than one percent.

Sunshine Heart led the falls, down 0.3 cents or 7.1 percent to 3.9 cents, with 1.1 million shares traded. Bionomics and Virax lost more than three percent; Chemgenex and Phylogica shed more than two percent; with Living Cell and Nanosonics down more than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top 40 Index (BDI-40) returned to its stellar trajectory following February's 3.4 percent stumble, up 10.7 percent in March compared to the S&P ASX200 up 0.14 percent.

The BDI-40 was up 52.9 percent for the year to March 31, 2011 compared to the ASX200 falling 0.8 percent and the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) falling 6.8 percent for the year.

The Big Caps fell 0.13 percent in March with Cochlear up 7.3 percent to $4,709 million, while CSL slipped 0.28 percent to $19,337 million and Resmed lost 6.4 percent to $4,466 million.

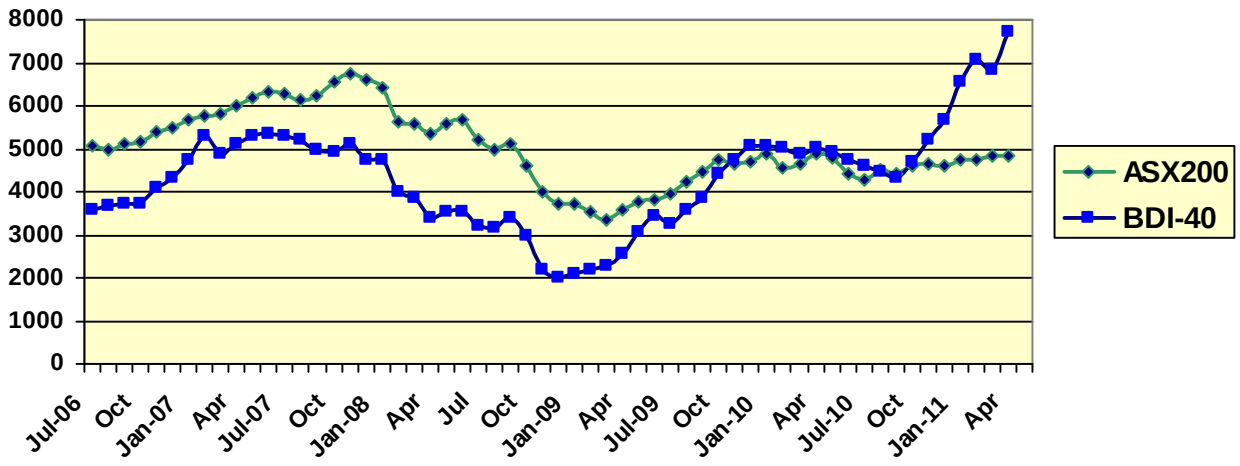
The sector was buoyed by Cephalon's bid for Chemgenex lifting its market capitalization 52.5 percent from $120 million to close the month at $183 million and Bionomics excellent BNC210 results pushing its price up 40.7 percent to a market capitalization of $166 million.

But the best percentage improvement for the month was Prana's $23 million or 60.5 percent rise to $61 million, while the fifth best, Mesoblast, was up 39.4 percent, which added $572 million to its market capitalization taking it to $2,023 million. Antisense was up 50 percent to $12 million followed by Patrys up 26.1 percent to $29 million, Starpharma (21.5%) to $305 million, Psivida (13.7%) to $83 million and Cellestis (11.2%) to $287 million.

Optiscan had the deepest percentage fall, down 25 percent to $6 million, followed by Benitec losing 22.2 percent to $14 million; Genera and Living cell both fell 20 percent to $16 million and $24 million respectively; Clinuvel fell 17.9 percent to $55 million, Virax fell 16.7 percent to $5 million' with Compumedics down 14.3 percent and Acrux easing 11.5 percent to $502 million.

Biotech companies raised $24.406 million in March.

BDI-40 v ASX200 Jul 1, 2006 to Feb 28, 2011



BIOTA HOLDINGS

Biota has been awarded a non-dilutive $US231 million from US agencies for phase III regulatory approval of its laninamivir anti-influenza drug, available in Japan as Inavir.

Biota said today that the Office of Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the US Department of Health and Human Services had awarded up to $US231 million ($A223.7 million) over five years to its wholly owned subsidiary, Biota Scientific Management, for the advanced development of laninamivir.

Biota said the funding over an estimated five year period was contingent on key milestones and was designed to provide US based manufacturing and clinical data to support a new drug application for laninamivir to the US Food and Drug Administration.

In a telephone conference Mr Cook said the funds would cover the US manufacturing, scale up and conduct of phase II and III trials for laninamivir as a therapy for influenza, but not as a preventative.

Mr Cook restated that the funds were not dilutive in any form and there would be no repayment to the Office of Biomedical Advanced Research and Development Authority.

Mr Cook said that the US would have first priority for the product in the case of an emergency.

He said that the funding was contingent on completion within 60 months, but there were other milestones that would have to be met to allow the project to continue.

In a media release Mr Cook said the award provided “visible recognition of the potential medical value of laninamivir to the world’s major market”.

“The BARDA contract will be a major contributor to a timely introduction of the product and will create the opportunity to significantly develop Biota’s business in the US,” he said.

He told the teleconference that ti would further raise the company’s profile in the US but said the company was keeping the question of a Nasdaq listing under review.

In announcing the grant BARDA said laninamivir orCS-8958 was in the same class of drugs as the currently approved influenza antiviral drugs Tamiflu and Relenza, but required “only a single dose for full treatment, as opposed to the five days of twice daily dosing required for Tamiflu and Relenza”.

“CS-8958 also may be effective against influenza viruses known to be resistant to Tamiflu,” the BARD announcement said.

BARDA director Dr Robin Robinson said the award was “another critical step forward in ensuring that safe and effective antiviral drugs are available for the treatment of influenza”.

“The ability to treat influenza by delivering a single dose of medicine would provide real advantages to doctors and patients during an emergency and would be an important addition to our pandemic influenza arsenal,” Dr Robinson said.

BARDA said the contract was part of its implementation of the national pandemic influenza preparedness strategy, which included accelerating the advanced development of new antiviral drugs.

BARDA said it provided a comprehensive, integrated, portfolio approach to the advanced research and development, innovation, acquisition, and manufacturing infrastructure for vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products for public health emergency threats, including chemical, biological, radiological, and nuclear threats, pandemic influenza, and emerging infectious diseases.

Biota said that laninamivir was a long acting neuraminidase inhibitor (LANI) influenza anti-viral drug able to treat an influenza infection, as well as be used preventatively.

Biota said laninamivir was approved for sale in Japan as Inavir but was not approved for sale in other markets.

Biota was up 37.5 cents or 35.7 percent to $1.425 with 7.9 million shares traded.

# MARC SINATRA'S BIOGUIDE BRIEF: BIOTA, BIONOMICS

I must admit I have never been a fan of any of the influenza drugs. Although they were a good idea, they really just didn't provide the patient with enough benefit to justify them putting their hands in their pockets.

The eventual financial success of these drugs, I believe, was due to countries being a bit too proactive when the fear of a global pandemic influenza outbreak became a public fear became a public fear rather than a medical/scientific fear.

Everything I read post bird flu and swine flu, suggested that drugs like Relenza and Gilead's Tamiflu were a bit like turning up at a gun-fight with a pen-knife.

In fact, those that count seemed to being thinking the same thing, with focus shifting to developing drugs for those who were life-threateningly sick from influenza.

Hence, I have been less than bullish about the prospects of Biota's long acting neuraminidase inhibitor, laninamivir (Inavir).

While it made sense for Daiichi Sankyo, Biota's partner, to develop it for Japan, where these types of drugs sell well, I couldn't see the sense in developing it for the rest of the world.

Potential partners, it seems, agreed with me.

But the Office of Biomedical Advanced Research and Development Authority in coming to the laninamivir party with up to $US231 million over five years to take laninamivir to the US Food and Drug Administration is obviously a game changer for laninamivir and shifts the economics of developing the drug for the US well and truly into the "in favor" column.

Congratulations to Biota for sticking to the task. It seems likely that laninamivir's success will now be determined by patients, not straight economics.

While I am handing out bouquets, I need to congratulate Bionomics on its clinical trial results.

Bionomics' BNC210 which is being developed as an anti-anxiety medication, produced some very nice results in two phase Ib trials.

We do need to remember that these were Ib studies and that there is still a long way to go, but you can only jump one hurdle at a time.

With George Jessup's Start-up Australia failing to sell its 28 percent stake in Bionomics, the stock may experience a fairly big over-hang in the not-too-distant future.

Having said that, Start-up did a very nice job of keeping its intention to sell its stake in Bionomics from capping the share price in the lead up to the BNC210 results.

**Marc Sinatra**
**Analyst**

IMPEDIMED

Impedimed appears to have its US commercialization strategy for L-Dex lymphoedema diagnostic set back by about nine to 15 months.

On the last page of a 13 page 'Investor Update' a timeline for insurance coverage of 20 million and 50 million lives provides guidance that they should be achieved by the end of 2011 and by the end of 2012, respectively.

Previous guidance, also on the last page of an 'Investor Presentation', from November 11, 2010 said coverage for 20 million lives was expected by now, with 50 million lives covered by October 2011.

In the November 2010 presentation, Impedimed implied that the filing for the unilateral leg indication would be by the end of 2010, but yesterday's announcement confuses the issue by removing the expression and replacing it with "unilateral limb (arm and leg) FDA clearance by October 2012.

Impedimed chief executive officer Greg Brown told Biotech Daily that the delays were due to "covered life milestones, measured when an insurance policy is posted stating medical necessity for the test, have been pushed out by six months … and the estimated FDA leg clearance has been pushed out by 12 months".

Mr Brown said that delays around coverage were mainly associated with the lack of published outcomes data and accountable care initiatives under the Obamacare health reform legislation.

"The accountable care initiative is influencing medical policy toward oncology strategy around total care packages for a condition (like breast cancer) rather than condition specific coverage (lymphoedema only)," Mr Brown said.

"More decision points are needed to be built into medical policy as a result," Mr Brown said.

Mr Brown said the company had limited control over the regulatory approval and "due to delays seen within the question process and generally across this sector, the company is taking a more conservative position on its estimate".

He said Impedimed wanted to expand the Stanford registry beyond its sponsored program and having Stanford run and manage the registry, with a surgeons governing society support, was a major plus for building the technology's acceptance.

Mr Brown said the registry was likely to be announced in May and start enrollments later this year.

He said a coverage with evidence development (CED) submission to have Medicare sponsor testing for the registry had been delayed by 12 months.

Mr Brown said the CED application would "allow for expanding the registry on a broader scale".

Mr Brown said the presentation provided an update on the L-Dex placement with an increase by 17 devices since November 2010 to 121 in total and that the Australasian Lymphology Association recognized the role of the underlying bio-impedance spectroscopy technology.

Mr Brown said that Impedimed had five managed care contracts in place, and was starting to see coverage in the market on the new reimbursement code, however sporadic.

Impedimed was up three cents or four percent to 78 cents.

## EDITORIAL COMMENT

Whether by accident or intent, significant delays in Impedimed's progress were not disclosed to the market in a transparent manner.

Biotech Daily does not expect the ASX or the Australian Securities and Investments Commission (ASIC) to ensure the market is properly informed, but we will.

The fact that the significant delays to Impedimed's revenue was brought to our attention by a reader who happens to be a fund manager is reprehensible.

A Biotech Daily Top 20 company should understand its obligations to keep the market fully-informed and not on the 13th page of a slide show.

Having previously asked the ASX its view on burying bad news, Biotech Daily is keenly aware that the Listing Rules are, as Captain Barbossa says "more what you'd call guidelines than actual regulations".

If Impedimed had 20 million lives covered six months early, we are certain it would have said so in a stand-alone, plain English announcement.

It is incumbent to do the same when the reverse is true.

When investors discover a company has hidden bad news from them, the company takes a double-hit, first, the impact of the bad news and then, the loss of trust.

Impedimed is the third Top 20 company to try this. We do keep a scorecard.

I own shares in Impedimed.

**David Langsam**
**Editor**

## COGSTATE

Cogstate says its sport system has been adopted by Australia's National Rugby League to be used by all clubs as part of the revised concussion management guidelines.
Cogstate said the League would fund the roll-out of the Cogstate Sport System and all clubs would adopt the system to assist doctors to manage a player's recovery from a concussion.
The company said the League guidelines advised that if a player was diagnosed with a concussion he should not return to the field of play on the day of injury and
Cogstate said the National Rugby League policy followed last weeks concussion management guidelines by the Australian Football League and AFL doctors also recommended use of the Cogstate Sport system by all AFL clubs.
Cogstate said the Sport system allowed an athlete to establish baseline or snapshots of brain speed and accuracy by completing four simple tasks.
The company said that repeating the same tasks after injury identified cognitive changes from the baseline performance helping to indicate whether the brain had fully recovered.
Cogstate said its 15-minute test could be taken from any computer, with athlete profiles and testing data stored securely on-line.
Cogstate was up one cent or 5.6 percent to 19 cents.

## GENERA BIOSYSTEMS

Genera says its one-for-seven rights issue at 33 cents a share has raised $2.45 million from the issue of 6,663,309 shares.
Genera said there was a shortfall of 2,289,588 shares with firm commitments for 755,303 of these shares and it was in discussions to place the remaining shares to raise $506,314.
The company said that each new share came with an attaching option exercisable at 33 cents within two years of the date of issue.
Genera was up 2.5 cents or 9.8 percent to 28 cents.

## SIRTEX MEDICAL

Sirtex founder Dr Bruce Gray has reduced his substantial holding in Sirtex from 14,711,796 shares (26.38%) to 12,328,764 shares (22.11%).
Dr Gray said he had sold 2,383,032 shares for $13,077,809 or an average price of $5.49 a share through two private companies.
Sirtex fell three cents or 0.6 percent to $5.27.

## FLUOROTECHNICS

Fluorotechnics annual general meeting will vote on resolutions to ratify placements and issue shares to raise $1.5 million.
Shareholders will be asked to vote on a $1.5 million raising at a price no lower than 20 percent below the five-day volume weighted average price before the shares are issued.
Fluorotechnics shareholders will be asked to ratify two placements for 7,000,000 shares and a $500,000 convertible note for 16,666,671 shares and options.
The meeting will also vote on the reelection of director Dr Damian Pethica.
The meeting will be held at the Stamford Grand Hotel, Corner of Epping and Herring Roads, North Ryde, Sydney, on May 4, 2011 at 10am (AEST).
Fluorotechnics was untraded at 4.2 cents.

## AVEXA

Avexa says chairman Joe Baini will retire as chairman and a director effective from April 18, 2011 and will be replaced by non-executive director Iain Kirkwood.
Mr Baini continues as Immuron's interim chief executive officer.
Avexa was up 0.3 cents or six percent to 5.3 cents with 7.5 million shares traded.

## AGENIX

Agenix has appointed Gary Taylor as chief financial officer and company secretary, effective immediately.
Agenix said Mr Taylor would replace company secretary Jeffrey Luckins and chief financial officer Graeme Tyshing.
The company said Mr Taylor was an accountant with 30 years experience in early stage, high growth businesses and had worked in Asia, the US, Australia and Europe.
Agenix said Mr Taylor was previously head of private corporate and financial consulting firm Justleigh Holdings and would be based in Melbourne report to executive chairman Nicholas Weston.
Agenix fell 0.2 cents or 10 percent to 1.8 cents.

## BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

| **Company $Am** | **Apr-10** | **Mar-11** | **Apr-11** |
|---|---|---|---|
| Cochlear | 4,119 | 4,386 | 4,709 |
| CSL | 21,118 | 19,391 | 19,337 |
| Resmed | 5,354 | 4,773 | 4,466 |
| **BDI-20** | | | |
| Acrux | 376 | 567 | 502 |
| Alchemia | 117 | 139 | 132 |
| Bionomics | 107 | 118 | 166 |
| Biota | 406 | 194 | 190 |
| Cellestis | 285 | 258 | 287 |
| Chemgenex | 123 | 120 | 183 |
| Clinuvel | 80 | 67 | 55 |
| Genera | 41 | 20 | 16 |
| Heartware | 663 | 1,162 | 1,179 |
| Impedimed | 82 | 119 | 117 |
| Living Cell | 68 | 30 | 24 |
| Mesoblast | 286 | 1,451 | 2,023 |
| Nanosonics | 136 | 220 | 212 |
| Pharmaxis | 638 | 566 | 609 |
| Phylogica | 21 | 21 | 19 |
| Sirtex | 332 | 314 | 296 |
| Starpharma | 164 | 251 | 305 |
| Sunshine Heart | 18 | 43 | 43 |
| Tissue Therapies | 30 | 94 | 98 |
| Universal Biosensors | 270 | 214 | 199 |
| **Second 20** | | | |
| Advanced Surgical | 18 | 11 | 9 |
| Antisense | 13 | 8 | 12 |
| Benitec | 18 | 18 | 14 |
| Bioniche | 94 | 159 | 151 |
| Cathrx | 11 | 27 | 29 |
| Cellmid | 9 | 11 | 9 |
| Circadian | 33 | 32 | 32 |
| Compumedics | 32 | 21 | 18 |
| Genetic Tech | 13 | 40 | 36 |
| LBT Innovations | 9 | 6 | 6 |
| Optiscan | 9 | 8 | 6 |
| Patrys | 27 | 23 | 29 |
| Phosphagenics | 85 | 89 | 91 |
| Prana | 33 | 38 | 61 |
| Prima | 95 | 196 | 218 |
| Psivida | 78 | 73 | 83 |
| QRX Pharma | 94 | 182 | 195 |
| Uscom | 26 | 13 | 15 |
| Viralytics | 22 | 28 | 25 |
| Virax | 14 | 6 | 5 |

* Biotech Daily editor, David Langsam, owns shares in Alchemia, Bionomics, Biota, Chemgenex, Impedimed, Neuren, Optiscan, Sunshine Heart and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in Atcor, Circadian, Pharmaxis, QRX and Tissue Therapies. These holdings are liable to change at any time.

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