Biotech Daily

Wednesday September 1, 2010

Daily news on ASX-listed biotechnology companies

*** BDI-40 HOLDS 4-YEAR LEAD OVER ASX200**
- COMPUMEDICS UP 26%, VIRAX DOWN 58%, IMMURON JOINS BDI-40

*** TODAY: ASX UP, BIOTECH DOWN: CELLMID UP 11%; OPTISCAN DOWN 13%**

*** NON-BIG CAP BIOTECH PROFIT UP 42.5%, REVENUE UP 9.5%**

*** AVITA REVENUE UP 17% TO $3.9m, LOSS DOWN 47% TO $2.7m**

*** CYCLOPHARM H1 REVENUE DOWN 24% TO $3m, LOSS UP 440% TO 769k**

*** FDA PRIORITY REVIEW FOR PSIVIDA'S ILUVIEN FOR DME**

*** HEALTHLINX PREPARES SOUTH KOREAN OVARIAN CANCER TEST TRIAL**

*** QRX SAYS INTERIM ANALYSIS SHOWS MOXDUO TRIAL ON-TRACK**

*** PROGEN SAYS MEDIGEN HAS APPLIED FOR US SPA FOR PI-88**

*** PLATYPUS TAKES 5% OF SIRTEX**

*** IDT APPOINTS IM MEDICAL'S ROMAN NAJDECKI CFO**

MARKET REPORT

The Australian stock market climbed 2.08 percent on Wednesday September 1, 2010 with the S&P ASX 200 up 91.5 points to 4495.7. Fourteen of the Biotech Daily Top 40 stocks were up, 17 fell, five traded unchanged and four were untraded.

Cellmid was best, up 0.2 cents or 10.5 percent to 2.1 cents with 263,157 shares traded. Living Cell climbed 5.4 percent; LBT, QRX and Sunshine Heart were up more than three percent; Prima and Starpharma rose more than two percent; with Alchemia, Biota, Cellestis, Chemgenex, Cochlear, Mesoblast and Universal Biosensors up more than one percent.

Optiscan led the falls, down 0.6 cents or 12.5 percent to 4.2 cents with 104,451 shares traded, followed by Virax down 10.3 percent to 2.6 cents with 19,800 shares traded. Phylogica and Tissue Therapies both lost 5.26 percent; Benitec, Genera, Immuron and Novogen fell four percent or more; Bionomics, Circadian and Genetic Technologies were down more than three percent, Clinuvel and Phosphagenics shed more than two percent; with Heartware, Nanosonics, Patrys and Pharmaxis down more than one percent.

BIOTECH DAILY TOP 40 INDEX

The Biotech Daily Top 40 Index (BDI-40) has held its one-year and four-year lead over the ASX200, despite falling 3.4 percent in August compared to the ASX200 down 2.0 percent.

The limited good news is that despite easing over the past two months, for the 12 months to August 31, 2010, the BDI-40 was up 12.1 percent, the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) were up 1.8 percent, while the S&P ASX200 fell 1.7 percent.

Over the four years to August 31, 2010, the BDI-40 was up 16.0 percent compared to Australia's 200 largest companies falling 13.9 percent.

The Top 20 biotechnology companies were more even than the Second 20 in August, with seven companies up, 12 down and one untraded. The Second 20 saw just two companies rising with 15 falling and three unchanged. Cochlear, CSL and Resmed collectively fell 2.3 percent in August.

Compumedics was best, up 26.3 percent to a market capitalization of $24 million, followed by LBT Innovations, up 14.3 percent from a low base of $7 million to $8 million.

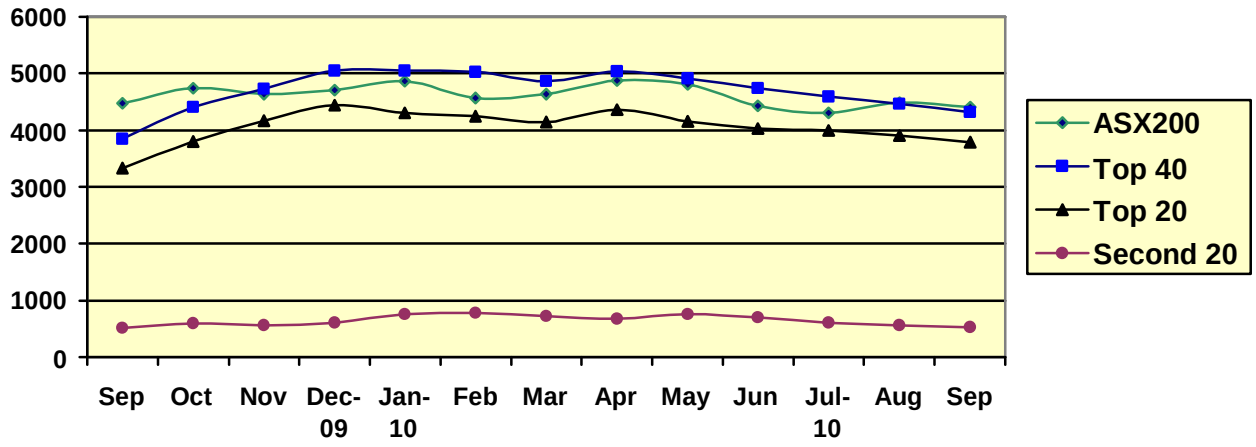
Virax led the falls, down 58.3 percent to $5 million on disappointing phase IIa results (BD: Aug 16, 2010), followed by Phylogica down 27.7 percent to $13 million in the wake of a $100 million licence deal, but having announced a capital raising at five cents when trading at 7.5 cents.

Bone Medical fell 25 percent to a market capitalization of $6 million, followed by Cathrx down21.9 percent to $25 million, Antisense (20%), Living Cell (18.5%).

Bone Medical has an FDA-approved phase III trial but needs to find funds and joins the Third 20. Immuron has trials supported by Israel's Hadasit and its market capitalization has improved over the year - up 19.2 percent in August - and joins the Second 20.

Biotechs raised $17.5 million in August.

Biotech Daily Top 40 ($m) v S&P ASX200 2009-'10



BIOTECH PROFIT, REVENUE 2009-'10

Non-Big Cap revenue for the year to June 30, 2010 was up 9.5 percent to $508.33 million, with profit up 42.5 percent to $97.2 million compared to the previous year.

CSL's eight percent fall in revenue and profit reduced total biotech profit 0.4 percent to $1512.8 million on total revenue down 2.9 percent to $7,079.1 million. Gains by Resmed and Cochlear were not enough to compensate for CSL's fall.

The non Big Cap gains primarily came from Acrux, Biota, Cellestis, Probiotec and Sirtex, with Halcygen and Nusep posting maiden profits and Probiomics seeing a turnaround profit.

Imugene and Resonance posted maiden profits for 2008-'09 but saw a fall in revenue and profits turned to losses.

The companies covered only include those with sales of product and do not include the vast majority of biotechnology companies with minimal revenues from grants or loans and have ongoing losses.

Company	Profit/Loss ($Am)	% move	Revenue ($Am)	% move
Resmed	$207.4	30	$1,200.00	19
Cochlear	$155.2	19	$743.80	6
Phosphagenics	-$0.6	-85	$5.14	252
Nusep	$3.3	maiden	$2.40	17.3
LBT	$1.49	341.5	$3.91	76.3
CSL	$1,053.00	-8.1	$4,627.00	-8.2
Biota	$16.24	-57	$67.60	12
Atcor	-$1.22	-28	$9.25	-19
Probiomics	$0.08	t/round	$1.11	-32
Cellestis	$8.25	0.03	$41.10	17
IDT	-$1.58	-124	$12.24	55
Cogstate	$1.64	15	$9.75	13
Acrux	$46.55	maiden	$56.10	1498
Brain Resource	$2.21	-47	$8.15	11
Probiotec	$9.48	6.5	$74.84	-14.1
Sirtex	$16.08	-11.8	$72.09	-2.4
Medical Develop	$0.88	8.5	$8.30	-4.9
Ellex	$3.82	117	$47.42	-19
Compumedics	$0.45	-83.5	$32.37	-15.6
Resonance	-$0.10	-117	$2.01	-16
Halcygen	$3.26	maiden	$36.71	8638
Fluorotechnics	-$4.47	-20	$3.49	7
Uscom	-$1.76	-59.8	$1.02	47
Imugene	-$0.02	-336	$0.04	-99
Avita	-$5.89	-16	$3.88	17
Advanced Surgical	-$0.46	-54.7	$7.47	16.6
Pharmaust	-$0.44	-144	$1.94	-48
Totals	$1,512.8		$7,079.13	

AVITA MEDICAL

Avita says its loss after tax was down 47 percent to $2,708,913 for the 12 months to June 30, 2010 on revenue up 17 percent to $3,881,638.
Avita said that under Australian accounting standards it had to make a $3.18m adjustment for the up to $US6 million convertible note agreement with La Jolla Cove Investors, taking its net loss after tax up 16 percent to $5,889,363.
The company said that its net tangible assets per share was 1.4 cents at June 30, 2010, a 71.4 fall from the 4.9 cents at June 30, 2009.
Avita was unchanged at 11 cents.

CYCLOPHARM

Cyclopharm says its revenue fell 24 percent to $3,272,041 for the six months to June 30, 2010, increasing its loss 440 percent to $769,203.
Cyclopharm said that sales of its Technegas Plus generators and patient administration sets for nuclear imaging were lower than the prior year, while gross profit margins were consistent with the prior period.
The company said that the reduction in profitability was “primarily attributed to the timing of sales and costs incurred during the start up phases of the cyclotron facility at [Macquarie University Hospital] and our imaging joint venture [Macquarie Medical Imaging]”.
Cyclopharm was unchanged at eight cents.

HEALTHLINX

Healthlinx says it has finalized agreements with South Korean collaborators to begin the 220-patient Ovplex study required by the South Korea Food and Drug Administration.
Healthlinx said the trial would be conducted by principal investigator Prof Byoung-Gie Kim of Samsung Medical Center and Sungkyunkwan University School of Medicine.
The company said that Prof Kim assisted in securing other institutions to participate in the trial including the Asan Medical Centre and Seoul National University Hospital.
Healthlinx said that collectively the three hospitals had more than 12,000 beds and supported the three leading gynaecological cancer research centres in the country.
Healthlinx managing director Nick Gatsios said that as well as securing distribution in the South Korean market, the study would “strengthen the scientific validity the Ovplex panel for other jurisdictions we are targeting”.
The company said South Korea had a greater than 10 percent growth rate in newly diagnosed ovarian cancer cases over the past four years.
In 2004 ovarian cancer was not recognized as one of the top 10 cancers in the country and in the five years to 2009 ovarian cancer became the eighth most lethal cancer in South Korea with projections that it could reach number five within the next three years.
Healthlinx said it expected the study would take up to 14 months to complete followed by submissions to the South Korea Food and Drug Administration.
Healthlinx fell 0.2 cents or two percent to 9.8 cents.

PSIVIDA

Psivida says US Food and Drug Administration has granted priority review to licencee, Alimera Sciences for a new drug application for Iluvien for diabetic macular oedema.
Psivida said FDA priority review status was given to therapies that offered major advances in treatment or provided a treatment where no adequate therapy existed.
The company said priority review reduced the review time goal from 10 months to six months.
Psivida chief executive officer Dr Paul Ashton said that with priority review a response from the FDA on Iluvien could be received by the end of 2010.
“Approval of Iluvien would trigger a $US25 million milestone payment to Psivida from Alimera,” Dr Ashton said.
“Under the licence agreement Psivida is also to receive 20 percent of net profits on sales by Alimera,” Dr Ashton said.
Psivida was untraded at $3.51.

QRX PHARMA

QRX says it has conducted a “successful interim analysis of its final Moxduo [immediate release] pivotal phase III trial”, but provided no specific data.
QRX said the trial was required for a new drug application to the US Food and Drug Administration and the analysis “indicated the planned sample size of 140 patients has greater than 90 percent power to detect differences of analgesic effect, indicating there is no need to enrol additional patients”.
QRX said it expected to complete the analysis of the study by the end of 2010 and file a new drug application for Moxduo IR by April 2011.
QRX said it was completing its product registration clinical program for Moxduo IR, which has a three-to-two ratio of morphine to oxycodone, for moderate to severe acute pain.
The company said the comparative study at 10 centres in the US was more than halfway completed, evaluating analgesic efficacy and tolerability of a flexible dose regimen (12mg and 8mg) versus a fixed low dose (3mg and 2mg) of Moxduo IR in 140 patients with moderate to severe pain following total knee replacement surgery.
QRX said the study design included a blinded interim analysis with 70 completed patients to be conducted by an independent statistician for the purpose of sample size confirmation.
The company said the interim analysis “indicated that the projected sample size of 140 patients is likely to provide sufficient power to distinguish the analgesic effects of flexible dose versus fixed low dose of Moxduo IR over a 48 hour study period”.
QRX said the blinded interim analysis was based on how much variability was observed when both dosage groups were combined and did not evaluate the magnitude of the difference between the two treatment groups.
The company said “one must be cautious in drawing conclusions that the expected endpoints will be met”.
This type of interim analysis conducted for the purpose of sample size re-estimation, which was accepted by the FDA, does not result in a statistical penalty in the p-values [significance] of the final analysis to be conducted upon study completion, QRX said.
QRX chief executive officer Dr John Holaday said it was “exciting … that interim analysis of the final pivotal study indicates we’re on track to obtain significant results”.
“In study after study this product has performed consistently, successfully achieving every primary end-point,” Dr Holaday said.
QRX was up three cents or 3.4 percent to 92 cents.

PROGEN, MEDIGEN

Progen says Taiwan licencee Medigen has applied to the US Food and Drug Administration for special protocol assessment for muparfostat or PI-88 for liver cancer.
Progen chief executive officer Sue MacLeman told Biotech Daily that Progen would receive royalties, milestone payments and revenues for the manufacturing of clinical trial stock of PI-88.
Progen said in a media release that through a special protocol assessment the FDA provided official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for a new drug application.
The company said that final marketing approval depended on the results of efficacy, the adverse event profile and an evaluation of the benefit and risk of treatment demonstrated in the phase III clinical program.
Progen said Medigen completed the PI-88 phase II liver cancer trial in six medical centers in Taiwan and the trial showed promising effects on reduction of tumor recurrence in liver cancer patients who had had their tumors resected.
Progen halted its phase III trial of PI-88 in July 2008, precipitating the saga of bids for Progen's then cash reserves of $70 million (BD: Jul 23, Nov 10, Dec 1, 22, 2008; Jan 28, Mar 9, 27, 2009).
Medigen wanted to acquire PI-88 since Progen discontinued the phase III trial, citing slow recruitment and finally did so in June (BD: Jun 30, 2010).
Today Progen said that in the package to the FDA, Medigen said it intended to recruit 500 patients and to use disease free survival as the primary efficacy end-point.
The company said trial sites were likely to include China, Taiwan, Korea, Hong Kong, Singapore, the US, Canada and Europe.
Progen said that a special protocol assessment would save significant cost and time for the PI-88 project.
Progen said PI-88 was a multi-targeted cancer therapeutic which inhibited both angiogenesis or tumor promoting factors such as vascular endothelial growth factor, fibroblast growth factors 1 and 2 and heparanase, an enzyme implicated in metastasis or tumor spread.
Progen was untraded at 32 cents.

SIRTEX MEDICAL

Platypus Asset Management has become a substantial shareholder in Sirtex with the acquisition of 2,854,200 shares or 5.12 percent of the company.
The Sydney-based Platypus said it acquired its most recent parcel of110,889 shares for $545,617 or an average price of $4.92 a share.
Sirtex was up four cents or 0.8 percent to $4.89.

IDT

IDT has appointed former IM Medical chief executive officer and chief financial officer Roman Najdecki as its chief financial officer, replacing Adrian McKenzie.
IDT said Mr Najdecki would take up the position on October 4, 2010.
The company said that before IM Medical Mr Najdecki was chief financial officer ta Lowan Australia and Iatia and had more than 25 years experience in senior financial roles.
IDT was unchanged at 59 cents.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company $Am	**Sep-09**	**Aug-10**	**Sep-10**
Cochlear	3,162	3,996	3,915
CSL	19,441	18,217	18,124
Resmed	4,097	5,594	5,140
Top 20			
Acrux	210	313	324
Alchemia	71	103	93
Antisense	26	10	8
Bionomics	66	102	86
Biota	353	177	167
Cellestis	346	267	227
Chemgenex	164	95	96
Clinuvel	97	71	67
Genera	32	29	31
Heartware	368	976	995
Impedimed	60	86	94
Living Cell	38	65	53
Mesoblast	123	299	283
Nanosonics	89	133	140
Pharmaxis	495	497	458
Sirtex	256	280	270
Starpharma	93	127	117
Sunshine Heart	16	17	14
Tissue Therapies	18	26	26
Universal Biosensors	166	231	239
Second 20			
Benitec	19	12	10
Cathrx	19	32	25
Cellmid (ex-MTY)	6	7	6
Circadian	34	27	27
Compumedics	29	19	24
Genetic Tech	23	14	13
Immuron	12	26	31
LBT Innovations	14	7	8
Novogen	74	15	13
Optiscan	8	6	6
Patrys	23	19	18
Phosphagenics	76	70	73
Phylogica	16	18	13
Prana	49	33	30
Prima	47	68	63
Psivida	60	66	65
QRX Pharma	49	96	91
Uscom	30	14	14
Viralytics	8	18	17
Virax	8	12	5

* Biotech Daily editor, David Langsam, owns shares in Alchemia, Bionomics, Biota, Chemgenex, Impedimed, Neuren, Optiscan, Pharmaxis and non-biotechnology stocks and has an indirect interest via Australian Ethical trusts in Cochlear, Impedimed, Pharmaxis, QRX, Resmed and Tissue Therapies. These holdings are liable to change at any time.

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