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Walking the tightrope: policy and the Life Sciences sector

BioForum
Edition 47
Quarter 3 FY14
April 2014

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Q3FY14 Key statistics

↑1.9%
Life Sciences Index
(down 0.1% in Q2FY14)

↑7.2%
Life Sciences Index ex Majors
(up 1.7% in Q2FY14)

↑0.9%
ASX All Ordinaries
(down 2.6% in Q2FY14)

↑4.2%
Nasdaq Biotech
(up 8.3% in Q2FY14)

↑0.5%
Nasdaq Composite
(up 10.7% in Q2FY14)

Key developments

- *The US IPO market boomed, with 27 IPOs in a single quarter*
- *There was one Australian IPO: incontinence management company Simavita which is now dual listed on the ASX and the Toronto Stock Exchange*
- *The Australian Federal Government called for comment on its review of employee share schemes*
- *The Federal Government will create three new Cooperative Research Centres and extend four others including the Hearing CRC and Cancer Therapeutics CRC in a $186m effort to drive practical research and innovation.*

Introduction

Time for action: policy and the Life Sciences sector

With the first budget of Australia's new Federal Government rapidly approaching it seems a good time to reflect on how current policies are affecting technology rich, high risk and high reward areas of the economy like Life Sciences companies.

There have always been differing views on the role of Government in supporting industry and the extent to which free market forces should be allowed to dictate outcomes. This debate is particularly important to the Life Sciences sector.

Life Sciences companies are unique in many ways. To start, they operate in a constantly changing technological, scientific and regulatory environment, they require substantial amounts of capital very early on in their lifecycle and they are inherently risky for investors. When you add to this mix the sector's public importance in driving enhancements in the quality and longevity of life there are difficult decisions to be made as to the role Governments should play in supporting the sector.

Those who support a free market stance point to economies such as the US as an example of a flourishing sector where Government support is not required to facilitate growth. This edition of Bioforum confirms that the US capital market for Life Sciences firms is firing. Exit markets are at highs with 27 Life Sciences IPOs this quarter and PwC's Moneytree report finds continued strong venture capital investment. This boom in Life Sciences investment is yet to flow to Australia. There's been a notable increase in Australian IPOs and it's looking like a strong year for secondary raisings, but we're a long way behind the US sector's capital market success. So how can we bridge this gap?

Our reality is that Australian investment will not suffice for the medium term in its current state. Our public markets do not have the same sophisticated understanding of Life Sciences companies as the US and have a lesser appetite for risk - making an Australian IPO feel like a bridge too far for most companies. Our Venture Capital (VC) sector continues to improve but remains too risk averse to be a sufficient source of investment on its own. To top it off, Australia's largest pool of capital, the superannuation industry, largely avoids illiquid venture capital investments and the proposed Stronger Super reforms which come into effect on 1 July could worsen the situation.

These challenges demand a clear and consistent position from Governments: either help narrow the vital investment gap to aid Australian Life Sciences' innovation and success, or act to open the floodgates to foreign capital. If the Government chooses to go down the first route, it needs to commit to a new round for the Innovation Investment Fund and establish a larger, ongoing program for investment in innovation amongst other things. Uncertainty around public programs stifles longer term investment - the Commercialisation Australia grants which have again been frozen until after the May budget are a prime example.

If additional public funding is not an option then the Government could alternatively adjust its policy settings to further encourage the flow of investment funds to those sectors in need. So what hurdles exist in the current structure and at what cost? AVCAL highlighted in their pre-budget submission, VC and Private Equity investments aren't included in the Significant Investor Visa Programme, let alone encouraged. This is a large potential source of capital for unlisted firms that could be accessed with minor modifications to an existing program. Other opportunities include lifting restrictions on the use of Early Stage Venture Capital Partnerships and reducing red tape and compliance costs for young, innovating firms.

Early stage Australian life sciences companies are already looking to the US for capital. PwC is working with a number of firms seeking a future on international markets and exchanges. Are there opportunities to encourage the flow of investment from these areas, which should increase the faith and risk appetite of domestic investors in the longer term?

Whatever avenue the Government takes, perhaps more important is that it does so clearly and consistently. The established role of Government is to promote confidence to enable long term investment. We think there are exciting opportunities for sustainable innovation and success for the Life Sciences sector and encourage Governments to continue to take the steps necessary to guarantee Australia remains a successful base for Life Sciences companies and can capitalise on future opportunities.

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Quarterly key findings

Quarterly key findings

Market performance	Q1 or Q2	Page
Life sciences industry total MCap	A$51,835m	11
Life sciences Index	52,233	
Life sciences Index growth	1.9%	
Pharma/biotech sector total MCap	A$40,109m	11
Pharma/biotech Index	40,826	
Pharma/biotech Index growth	1.9%	
Medical device sector total MCap	A$11,726m	11
Medical device Index	11,406	
Medical device Index growth	1.7%	
Individual company performance		
Top individual performer	Benitec Biopharma Limited	16
Change in market cap over the past four quarters	398%	
Bottom individual performer	Bone Medical Limited	17
Change in market cap over the past four quarters	-76%	
Financing		
Australian IPO count	1	12
Total listed	A$24m	
US IPO count	27	12
Total raised	A$1,685m	
Australian secondary financing count	27	14
Total raised	A$105m	
US secondary financing count	81	14
Total raised	A$6,759m	

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Australia		
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02

Market performance

Performance overview

Figure 1: Weekly performance over the quarter of the PwC Life Sciences Index compared to major indices

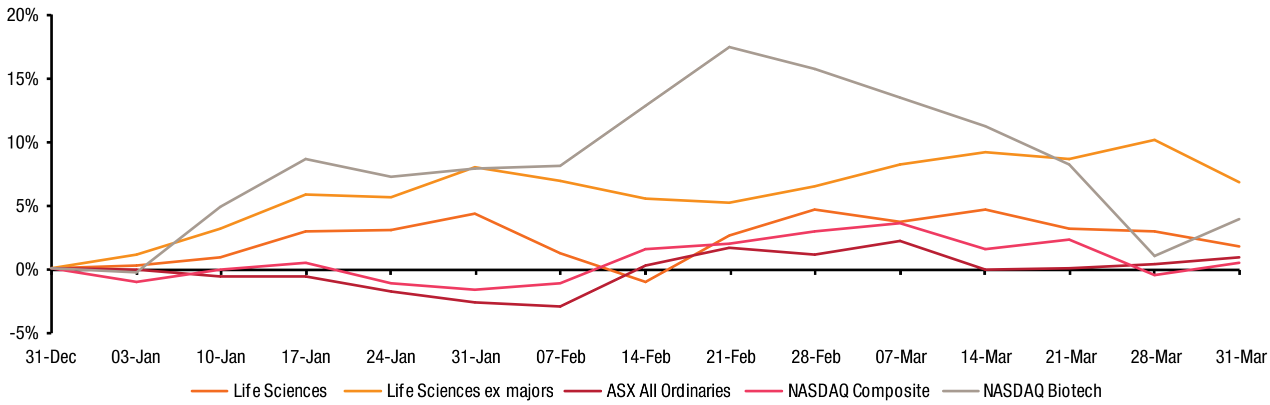


Table 1: Quarterly movements of the PwC Life Sciences Index compared to major indices

	Value				
	30-Sep-13	31-Dec-13	31-Mar-14	% Change (Sep-Dec)	% Change (Dec-Mar)
PwC Life Sciences Index (Index)	51,310	51,268	52,233	-0.1%	1.9%
PwC Life Sciences Index ex majors (Index)	8,367	8,507	9,122	1.7%	7.2%
ASX All Ordinaries (Index)	5,218	5,353	5,403	2.6%	0.9%
NASDAQ Composite (Index)	3,771	4,177	4,199	10.7%	0.5%
NASDAQ Biotech (Index)	2,189	2,370	2,469	8.3%	4.2%

Graph 1: Quarterly movements of PwC Life Sciences Index compared to major indices

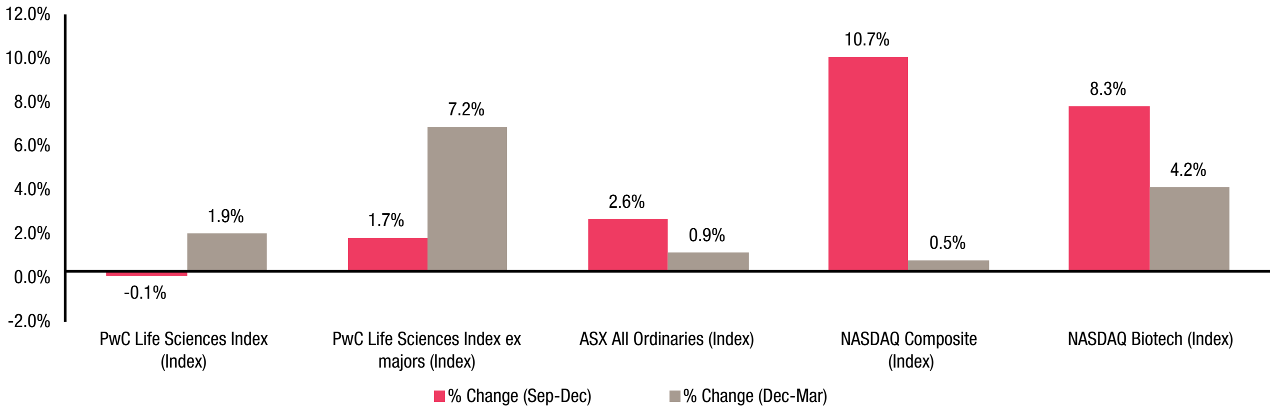


Table 2: Yearly performance of the PwC Life Sciences Index compared to major indices

	% Change (Dec12-Dec13)			% Change (Mar13-Mar14)		
	31-Dec-12	31-Dec-13	% Change	31-Mar-13	31-Mar-14	% Change
Life Sciences (Index)	43,672	51,268	17.4%	46,804	52,233	11.6%
Life Sciences ex majors (Index)	6,586	8,507	29.2%	7,207	9,122	26.6%
ASX All Ordinaries (Index)	4,665	5,353	14.8%	4,980	5,403	8.5%
NASDAQ Composite (Index)	3,020	4,177	38.3%	3,239	4,199	29.6%
NASDAQ Biotech (Index)	1,431	2,370	65.6%	1,669	2,469	47.9%

Graph 2: Yearly performance of the PwC Life Sciences Index compared to major indices

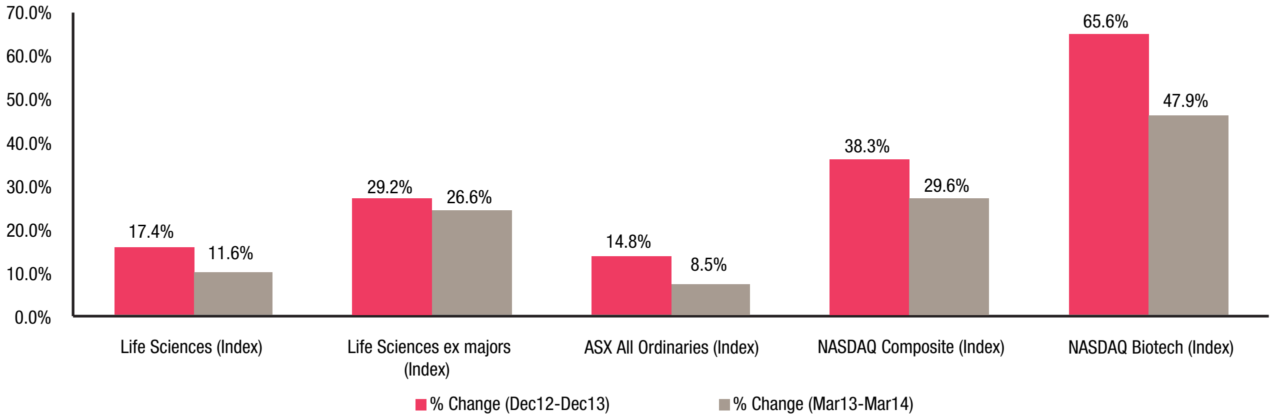


Figure 2: Two-year comparison of the PwC Life Sciences Index compared to major indices

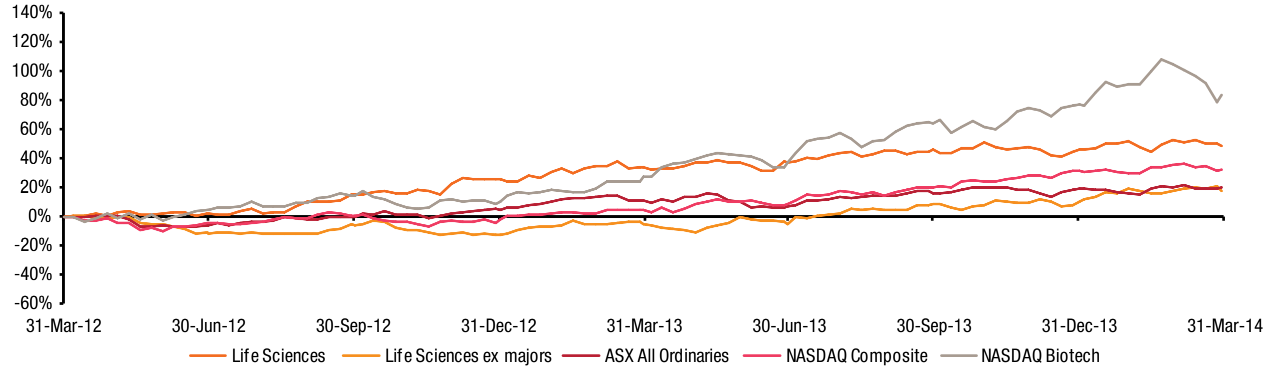


Figure 3: Quarterly performance of the PwC Life Sciences Index and its subsectors

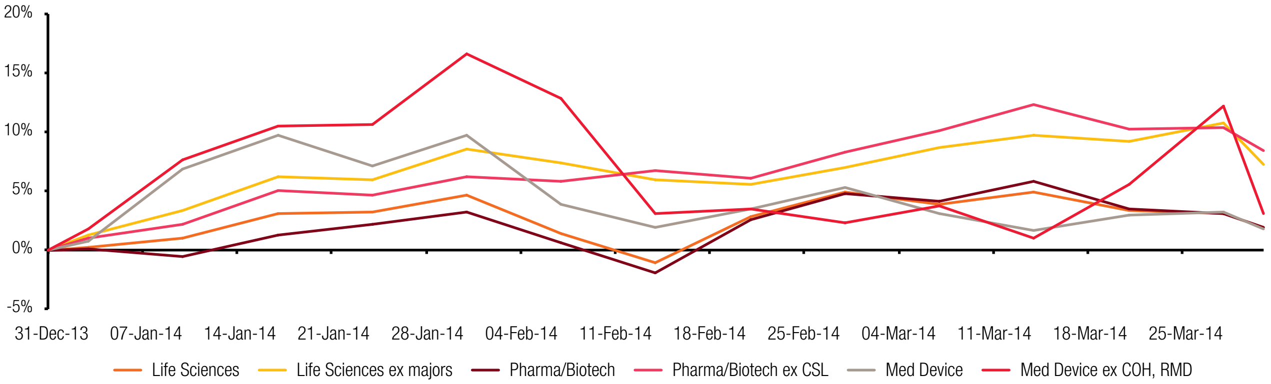


Table 3: Quarterly performance of the PwC Life Sciences Index and its subsectors

	Market capitalisation (A$m)				
	30-Sep-13	31-Dec-13	31-Mar-14	% Change (Sep-Dec)	% Change (Dec-Mar)
Life Sciences	51,310	51,268	52,233	-0.1%	1.9%
Life Sciences ex majors	8,367	8,507	9,122	1.7%	7.2%
Pharma/Biotech	38,513	40,057	40,826	4.0%	1.9%
Pharma/Biotech ex CSL	6,601	6,608	7,163	0.1%	8.4%
Med Device	12,797	11,211	11,406	-12.4%	1.7%
Med Device ex COH, RMD	1,766	1,899	1,959	7.5%	3.1%

Graph 3: Quarterly performance of the PwC Life Sciences Index and its subsectors

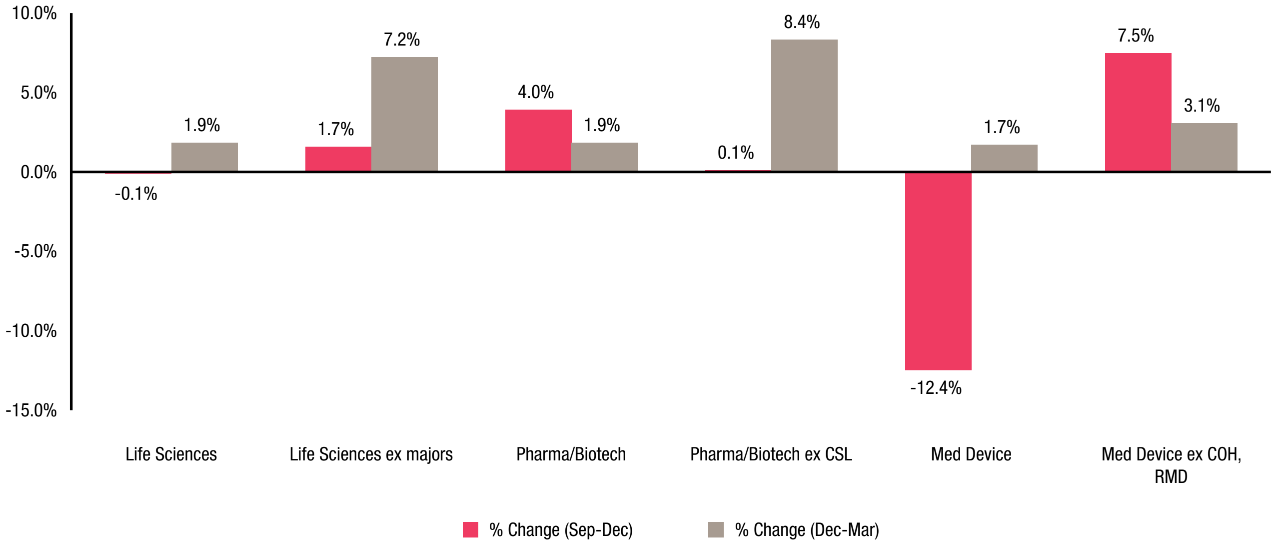
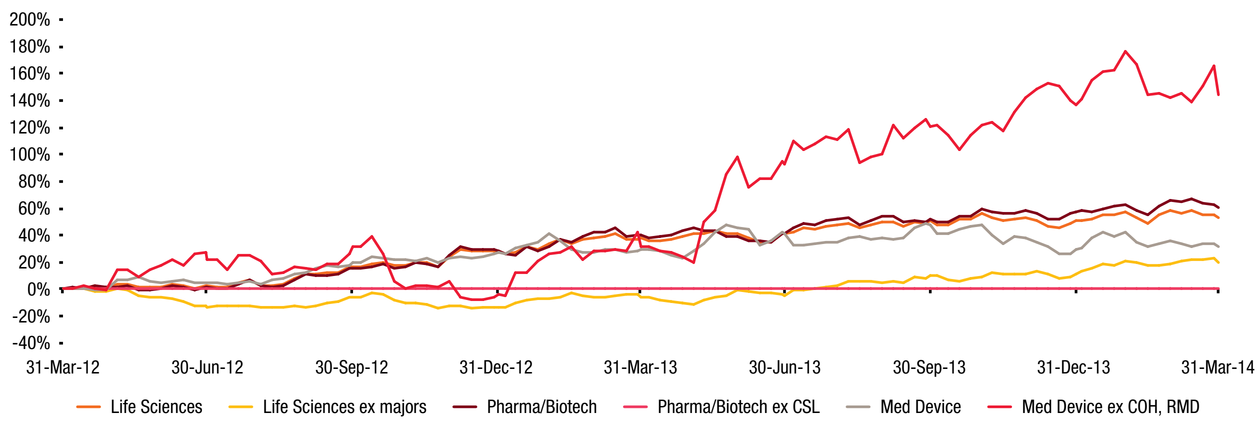


Table 4: Quarterly summary of the PwC Life Sciences Index and its subsectors

	MCap (A$m)	% of total value	Companies with share price gains	Proportion of subsector up	Companies with share price losses	Proportion of subsector down	Companies with share price flat	Proportion of subsector flat	Total number of companies
Life Sciences	52,233	100%	36	41%	46	52%	6	7%	88
Life Sciences ex majors	9,122	100%	35	41%	44	52%	6	7%	85
Pharma/Biotech	40,826	78%	26	49%	25	47%	2	4%	53
Pharma/Biotech ex CSL	7,163	79%	25	48%	25	48%	2	4%	52
Med Device	11,406	22%	10	29%	21	60%	4	11%	35
Med Device ex COH, RMD	1,959	21%	10	30%	19	58%	4	12%	33

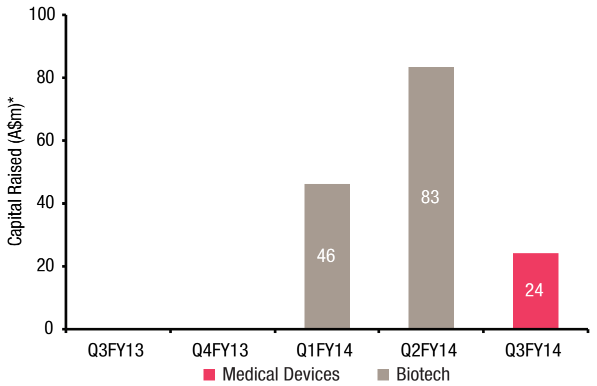
Figure 4: Two-year performance of the PwC Life Sciences Index and its subsectors



IPO financing

Quarterly financing

Figure 5: Quarterly comparison of IPOs in Australia



Note: * Amount shown is total company valuation on first day of trading

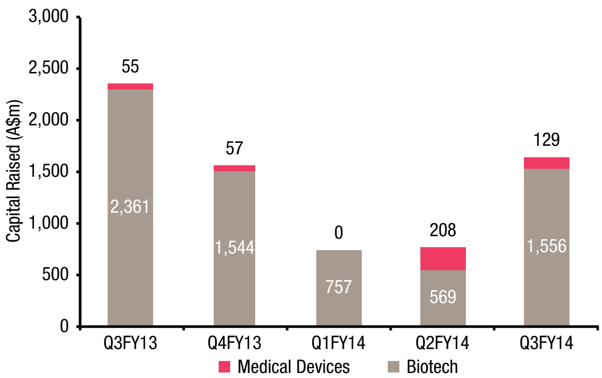
Table 5: Number of quarterly Australian IPO listings

	Biotech	Med Devices	ASX
Q3FY14	-	1	4
Q2FY14	2	-	32
Q1FY14	1	-	8
Q4FY13	-	-	11
Q3FY13	-	-	12

Table 6: Listing of quarterly Australian IPO listings

Company	Listing Date	Capital Raised (A$m)	Valuation on listing ($m)	Sector
Simavita Limited	20/02/2014	14	24	Med Dev
Total			**24**	

Figure 6: Quarterly comparison of IPOs in the US



Note: * Amount shown is total amount raised

Table 7: Total of quarterly US IPO listings

	Biotech	Med Devices
Q3FY14	23	4
Q2FY14	8	2
Q1FY14	11	-
Q4FY13	9	1
Q3FY13	6	2

Table 8: Listing of quarterly US IPO listings

Company	Listing Date	Capital Raised (A$m)	Sector
GlycoMimetics Inc	09/01/2014	63	Biotech
Retrophin Inc	10/01/2014	45	Biotech
Dicerna Pharmaceuticals Inc	29/01/2014	102	Biotech
Cara Therapeutics Inc	30/01/2014	62	Biotech
Ultragenyx Pharmaceutical Inc	30/01/2014	137	Biotech
Trevena Inc	31/01/2014	73	Biotech
Auspex Pharmaceuticals Inc	04/02/2014	94	Biotech
Egalet Corp	05/02/2014	56	Biotech
Eleven Biotherapeutics Inc	05/02/2014	56	Biotech
Revance Therapeutics Inc	05/02/2014	107	Biotech
Argos Therapeutics Inc	06/02/2014	50	Biotech
Eagle	11/02/2014	56	Biotech
Flexion Therapeutics Inc	11/02/2014	73	Biotech
NephroGenex Inc	11/02/2014	42	Biotech
Concert Pharmaceuticals Inc	12/02/2014	94	Biotech
Recro Pharma Inc	06/03/2014	33	Biotech
Achaogen Inc	11/03/2014	79	Biotech
Dipexium Pharmaceuticals LLC	12/03/2014	36	Biotech
Akebia Therapeutics Inc	19/03/2014	110	Biotech
Ruthigen Inc	20/03/2014	21	Biotech
BioLife Solutions Inc	20/03/2014	17	Biotech
Versartis Inc	20/03/2014	139	Biotech
Amedica Corp	12/02/2014	22	Med Devices
Inogen Inc	13/02/2014	79	Med Devices
Semler Scientific Inc	20/02/2014	11	Med Devices
Total		**1,657**	

Yearly financing

Figure 7: Annual comparison of IPOs in Australia

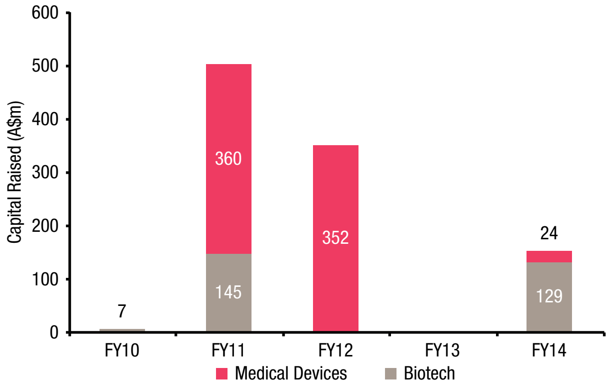


Table 9: Number of IPO listings in Australia

	Biotech	Med Devices	ASX
FY14	3	1	44
FY13	-	-	49
FY12	-	2	75
FY11	1	1	127
FY10	1	-	53

Figure 8: Annual comparison of IPOs in the US

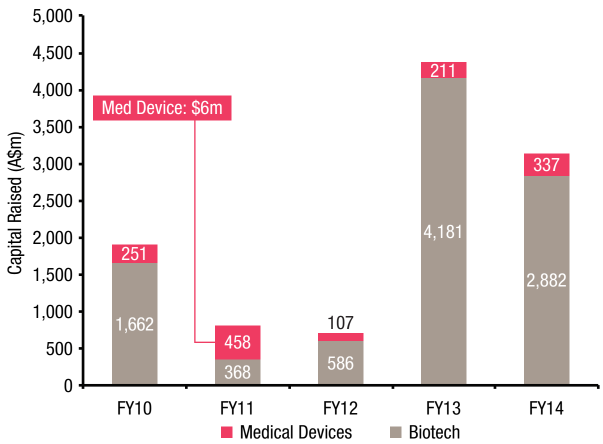


Table 10: Number of IPO listings in the US

	Biotech	Med Devices
FY14	40	6
FY13	19	5
FY12	12	4
FY11	6	8
FY10	7	2

Secondary finance market

Quarterly financing

Figure 9: Quarterly comparison of secondary financing in Australia

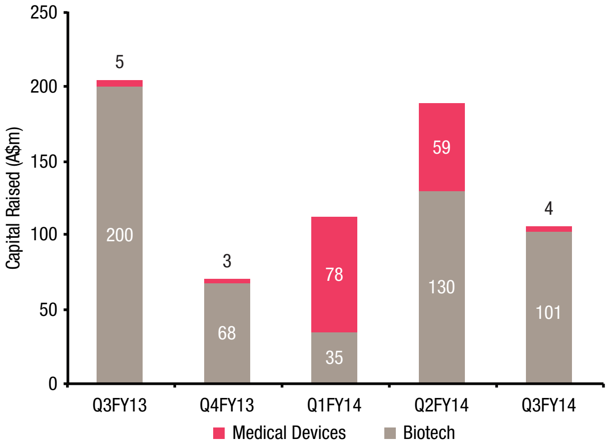


Table 11: Number of secondary deals (AU)

	Biotech	Avg. amount raised ($m)	Med Devices	Avg. amount raised ($m)
Q3FY14	21	4.8	6	0.6
Q2FY14	33	3.9	13	4.5
Q1FY14	22	1.6	10	7.8
Q4FY13	32	2.1	4	0.8
Q3FY13	22	9.1	5	1.0

Figure 10: Quarterly comparison of secondary financing in the US

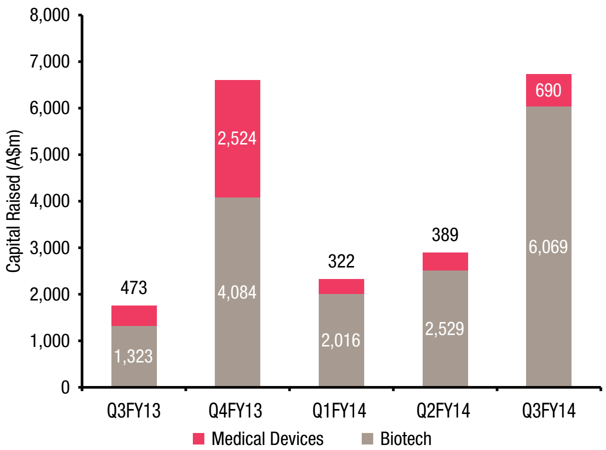


Table 12: Number of secondary deals (US)

	Biotech	Med Devices
Q3FY14	60	20
Q2FY14	41	14
Q1FY14	48	19
Q4FY13	38	22
Q3FY13	33	24

Yearly financing

Figure 11: Annual comparison of secondary financing in Australia

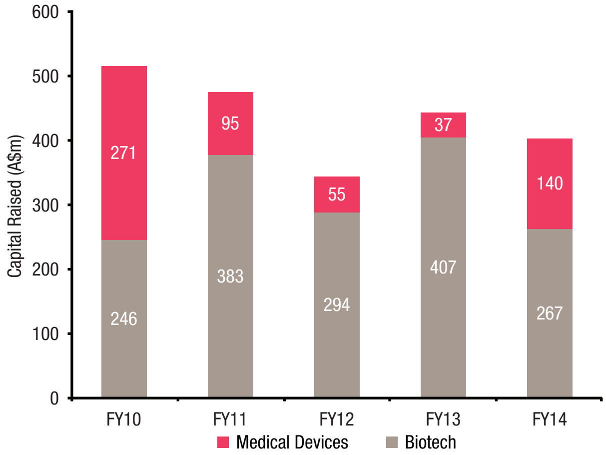


Table 13: Number of Australian secondary raisings

	Biotech	Med Devices
FY14	76	29
FY13	100	29
FY12	99	39
FY11	154	43
FY10	107	39

Figure 12: Annual comparison of secondary financing in the US

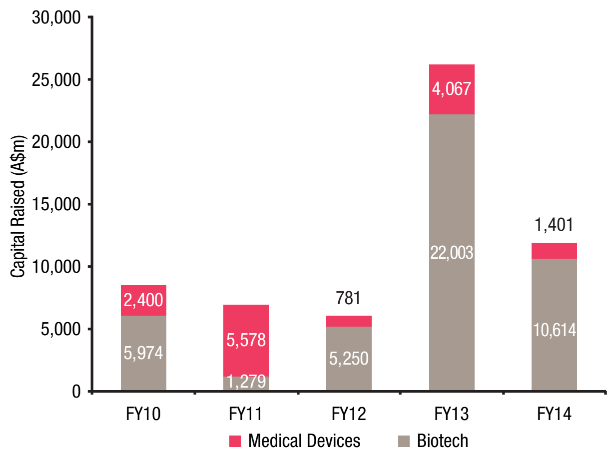
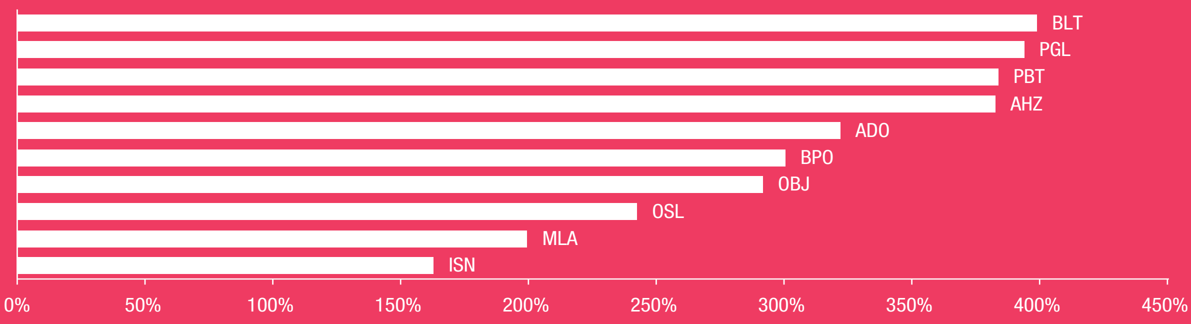


Table 14: Number of US secondary raisings

	Biotech	Med Devices
FY14	149	53
FY13	152	85
FY12	125	43
FY11	66	121
FY10	122	57

Top 10

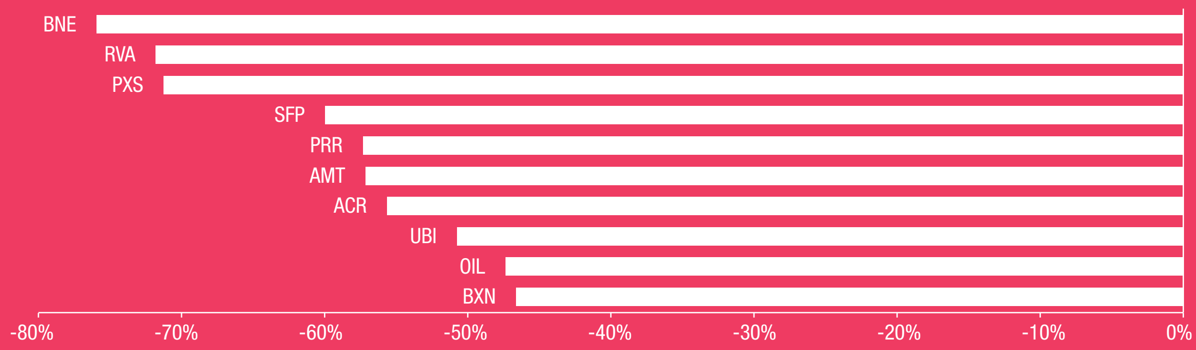
Performers over past four quarters



01	*Benitec Biopharma Ltd*	Return: 398% Closing price: $1.62 MCap: A$179.82m	Benitec Biopharma announced it will seek $31.5m in a US private placement to fund a hepatitis C trial and other trials in patients with lung cancer, age-related macular degeneration and hepatitis B.
02	*Progen Pharmaceuticals Ltd*	Return: 393% Closing price: $1.12 MCap: A$67.45m	The company's late-stage liver cancer drug PI-88 remains on track for New Drug Applications in Asia, with patient enrolment for the phase III trial completed in December.
03	*Prana Biotechnology Ltd*	Return: 384% Closing price: $1.04 MCap: A$446.65m	The share price of Prana Biotechnology rocketed in anticipation of positive results of two phase II trials for its Alzheimer's and Huntington's disease drug PBT2. After the end of the quarter, the Alzheimer's trial failed to meet its primary endpoint and the share price fell 80%.
04	*Admedus Ltd*	Return: 383% Closing price: $0.14 MCap: A$182.23m	Admedus won FDA approval and a CE mark for its cardiovascular tissue patch CardioCel. Coridon, in which Admedus owns a 47% stake, was approved to begin a phase I trial for its herpes simplex virus vaccine.
05	*Anteo Diagnostics Ltd*	Return: 322% Closing price: $0.25 MCap: A$207.54m	Anteo Diagnostics completed a $5.5m capital raising in December. The company was granted a patent for its Mix&Go product in Japan and it signed a deal with BBI Solutions to investigate the manufacturing and performance benefits of Mix&Go technology on BBI particles used in lateral flow applications.
06	*Bioprospect Ltd*	Return: 300% Closing price: $0.00 MCap: A$11.59m	Bioprospect acquired an option to purchase an 80% stake in Invatec Health, which has developed a method for the diagnosis of mental health disorders.
07	*OBJ Ltd*	Return: 292% Closing price: $0.05 MCap: A$73.19m	OBJ executed a second analgesic study agreement with GlaxoSmithKline after it successfully completed a phase I trial. Share price rises in March are as yet unexplained.
08	*Oncosil Medical Ltd*	Return: 242% Closing price: $0.13 MCap: A$41.78m	Oncosil acquired UK-based cancer company Enigma Therapeutics in February and appointed Dr Neil Frazer as CEO in early July. Multiple capital raisings were heavily oversubscribed.
09	*Medical Australia Ltd*	Return: 200% Closing price: $0.27 MCap: A$26.54m	Medical Australia agreed to acquire animal healthcare company Medivet for $11m, and it completed a $4m capital raising in December.
10	*Isonea Ltd*	Return: 163% Closing price: $0.21 MCap: A$60.79m	After a $13.5m capital raising in late June, Isonea launched its flagship Airsonea wheeze monitoring device in Australia in September and later in the US. A poll of 100 medical professionals showed 80 recommended Isonea's iPhone-based wheeze monitoring system for asthma sufferers.

Bottom 10

Performers over past four quarters



10	*Bioxyne Ltd*	Return: -47% Closing price: $0.01 MCap: A$1.60m	Bioxyne completed the sale of its subsidiary Hunter Immunology for a mixture of cash, shares and royalties. A strict cost management program meant the company posted a profit of $170k, up from a loss of $1.045m in the prior calendar year.
09	*Optiscan Imaging Ltd*	Return: -47% Closing price: $0.050 MCap: A$8.30m	Optiscan reported a $600k loss in 2013, down from $2.5m in 2012. It raised $1m via a convertible note issue.
08	*Universal Biosensors Inc*	Return: -51% Closing price: $0.34 MCap: A$64.98m	The company's product LifeScan was subject to a worldwide recall in March 2013. Universal Biosensors posted a 49% drop in revenue and a 27% higher loss, but exceeded some analyst expectations.
07	*Acrux Ltd*	Return: -56% Closing price: $1.72 MCap: A$283.09m	The FDA is investigating a possible link between testosterone replacement therapies and stroke, heart attack and death, which Acrux maintains is just a procedural review. A special dividend of $0.12 a share was announced after Acrux received a milestone payment from Eli Lilly.
06	*Advanced Surgical Design & Manufacture Ltd*	Return: -57% Closing price: $0.05 MCap: A$1.97m	Half-year losses were down 68% to $90k from the prior half-year period and revenues were up 18%. The company continues to pay down debt.
05	*Prima Biomed Ltd*	Return: -57% Closing price: $0.041 MCap: A$51.61m	Prima's share price slumped after an early stage study found its ovarian cancer treatment produced no observed difference in the control group, although the study was not sufficiently powered to detect statistical significance.
04	*Safety Medical Products Ltd*	Return: -60% Closing price: $0.00 MCap: A$1.49m	FY13 losses totalled $940k, more than double those of the prior year. The company purchased a gold company in May and it has sold all non-Australian patents relating to its SecureTouch syringe.
03	*Pharmaxis Ltd*	Return: -71% Closing price: $0.095 MCap: A$30.64m	A committee advised the FDA against recommending the company's drug Bronchitol for use in cystic fibrosis patients in the US. The FDA also added Aridol to its import alert list, effectively stopping imports of the product until removal.
02	*Reva Medical*	Return: -72% Closing price: $0.16 MCap:A$73.61m	Reva halted development of its ReZolve product, choosing instead to focus resources on its Fantom product, and hopes to begin human studies later this year.
01	*Bone Medical Ltd*	Return: -76% Closing price: $0.024 MCap: A$58.40m	Losses for the half-year to December 2013 were $683k. The company raised $3.82m through a share placement in January.

03

Announcements

Australia – partnerships

Date	Company	Partner	Application	Value (A$m)	Comments
5/03/2014	**Alchemia Ltd (ACL)**	Cancer Research Technology	Anti-cancer drugs	Undisclosed	Alchemia licensed two early-stage novel anti-cancer drug candidates from Cancer Research Technology. Alchemia will evaluate the pre-clinical Focal Adhesion Kinase inhibitors, which originate from the Australian Cancer Therapeutics CRC, in various cancer and cancer stem cell models. Formal pre-clinical and clinical development will follow.
27/02/2014	**Actinogen Ltd (ACW)**	Curtin University	Cancer stem cell research	N/A	Actinogen announced that it has signed a research service agreement with Curtin University to conduct further studies on cancer stem cells.
24/03/2014	**Bone Medical Ltd (BNE)**	William Harvey Research Ltd	Rheumatoid arthritis	N/A	William Harvey Research and Bone Medical agreed to further study the company's novel anti-inflammatory molecule for rheumatoid arthritis, BN006, and support its progress towards clinical studies.
29/01/2014	**Cellmid Ltd (CDY)**	Beijing Huana Likang Biotechnology	Hair loss	N/A	The Japanese branch of Cellmid's wholly owned subsidiary Advangen signed a Chinese distribution agreement. The deal with Beijing Huana Likang Biotechnology Co covers Advangen's Lexilis Black and Jo-Ju brands.
14/01/2014	**Circadian Technologies Ltd (CIR)**	Selexis SA	Macular degeneration	Undisclosed	Through its 100% owned subsidiary Opthea, Circadian signed a commercial licence agreement with Selexis SA. It covers the use of the CHO-M cell line and related technologies for the production of Opthea's lead molecule OPT-302.
10/02/2014	**Cynata Therapeutics Ltd (CYP)**	Waisman Biomanufacturing	Stem cell technology	N/A	Cynata signed a deal under which Waisman Biomanufacturing will develop, scale up and make clinical grade quantities of Cynata's proprietary Cymerus off-the-shelf stem cells.
28/03/2014	**Nanosonics Ltd (NAN)**	Miele Professional	Ultrasound probe disinfection	N/A	Nanosonics entered into a strategic partnership with Miele Professional for the distribution of Trophon EPR in Germany.
18/02/2014	**Optiscan Imaging Ltd (OIL)**	MR Solutions	Research endomicroscopy system	N/A	Optiscan executed an exclusive OEM supply agreement with UK-based MR Solutions for its second generation research endomicroscopy system, or the FIVE-2.
22/01/2014	**Regeneus Ltd (RGS)**	Lonza	Cell therapy	N/A	Regeneus announced that Lonza, the world's largest manufacturer of stem cells, will manufacture Regeneus's off-the-shelf cell therapy, CryoShot Canine, for registration in the US.
24/03/2014	**Sirtex Medical Ltd (SRX)**	Guerbet	SIR-Spheres	N/A	Sirtex Medical and Guerbet SA announced they will collaborate on major clinical studies of primary and secondary (metastatic) liver cancer to test how Sirtex's SIR-Spheres microspheres and Guerbet's Lipiodol may work together. The aim is to address the significant unmet clinical need in patients with hepatocellular carcinoma, metastatic colorectal cancer, metastatic neuroendocrine tumours, and a range of other primary and secondary liver cancers.
27/02/2014	**Uscom Ltd (UCM)**	MedCaT	Neurologic and cardiovascular devices	N/A	Uscom announced the appointment of MedCaT as an Uscom 1A distributor for the Netherlands.

Mergers, acquisitions and divestments

Date	Dominant company	Other company	Type of deal	Value (A$m)	Comments
12/02/2014	**Mayne Pharma Group Ltd (MYX)**	Forest Laboratories	Asset purchase	US$12m	Mayne Pharma has acquired selected brands from Forest Laboratories for US$10m plus a US$2m performance-based earn-out. The brands include ESGIC tablets and capsules, used to treat tension headaches, and Lorcet pain relief tablets.
17/03/2014	**Virax Holdings Ltd (VHL)**	Pathway Oncology	Acquisition	60m shares on settlement, plus 180m shares upon milestone achievements	Virax Holdings is to buy Pathway Oncology from Yale University and the University of South Florida. Pathway holds exclusive worldwide licences to intellectual property including anti-cancer technology developed at the university in New Haven, Connecticut and the Moffitt Cancer Center in Florida, the third largest cancer centre in the US.

Clinical trials

	Company	Drug	Application	Comments
	Phase I			
3/02/2014	**Admedus Ltd (AHZ)**	Therapeutic vaccine	Herpes simplex virus	Admedus announced that its phase 1 trial of a vaccine for herpes simplex virus (HSV-2) achieved the primary endpoint of being safe in the study subjects. In addition, the study has shown that the vaccine was able to generate a T-cell response.
3/02/2014	**Bionomics Ltd (BNO)**	BNC105	Ovarian cancer	Bionomics received positive results in the phase I clinical trial of its cancer drug candidate BNC105 in women with ovarian cancer. After completing the enrolment of 15 patients for the phase I portion of the trial during 2013, data to date has found 10 of the patients had a positive response according to the RECIST 1.1 and/or GCIG CA125 criteria.
27/03/2014	**Patrys Ltd (PAB)**	PAT-SM6	Refractory or relapsed multiple myeloma	Patrys announced the final results from its phase I/IIa, open-label study in patients with refractory or relapsed multiple myeloma showed PAT-SM6 was well tolerated and 33% of patients showed evidence of stable disease.
	Phase II			
6/03/2014	**Biotron Ltd (BIT)**	BIT225	HIV and hepatitis C	Interim results from a phase II trial of BIT225 showed analysis of blood samples from patients indicated that all of the HCV genotype 3 patients completing treatment are virus-free at 24 weeks. This extends previous data that showed patients had undetectable virus levels at 12 weeks.
19/03/2014	**Bionomics Ltd (BNO)**	BNC105	Metastatic renal cancer	Bionomics announced the results of the Disruptor 1 trial of BNC105 in patients with metastatic renal cancer. The study did not meet its primary endpoint but highlighted which patients BNC105 was most effective in and potential uses with other cancer types.
31/01/2014	**Prana Biotechnology Ltd (PBT)**	PBT2	Alzheimer's disease	A 12-month phase II imaging trial in Alzheimer's disease using Prana's PBT2 did not meet its primary endpoint of a statistically significant reduction in the levels of beta-amyloid plaques in the brains of prodromal/mild Alzheimer's disease patients, as measured using PiB-PET standardised uptake value ratio.
18/02/2014	**Prana Biotechnology Ltd (PBT)**	PBT2	Huntington's disease	Prana Biotechnology announced the results of its Reach2HD phase 2 clinical trial investigating PBT2 as a treatment for Huntington's disease. The double-blind, placebo-controlled study was conducted in the US and Australia and met its primary endpoint, showing PBT2 was safe and well tolerated.
	Pre-clinical and other			
29/01/2014	**Mesoblast Ltd (MSB)**	Mesenchymal precursor cells	Back pain	Mesoblast announced positive 12-month results from the 100-patient phase 2 clinical trial of its proprietary allogeneic, or off-the-shelf, mesenchymal precursor cells in patients with chronic moderate to severe discogenic low back pain. The results showed that a single injection of MPCs into degenerating intervertebral discs reduced low back pain and improved function for at least 12 months.
18/03/2014	**Novogen Ltd (NRT)**	Trx-1	Anti-cancer	An animal model for ovarian cancer showed that Trx-1 was effective in demonstrating an anti-cancer effect on mice xenografted with human ovarian cancer stem cells.
2/01/2014	**Osprey Medical Inc (OSP)**	Avert system	Imaging	Osprey said published results from a 21-patient pilot clinical trial demonstrated that the Avert System produced a highly significant 40% reduction in dye injection compared with standard imaging techniques, while maintaining image quality.
6/03/2014	**Regeneus Ltd (RGS)**	Kvax	Cancer vaccine	Regeneus announced that a paper describing safety and early efficacy data for the Kvax vaccine has been published in *Cancer Immunology Research*, showing that the vaccine led to remission rates of 30-60%.
24/02/2014	**Uscom Ltd (UCM)**	Uscom BP+	Blood pressure measurement	Uscom announced a new validation study comparing the Uscom BP+ measurements of central blood pressure with the SphygmoCor in children. The study concluded that the BP+ was at least as accurate as the reference gold standard, but was quick, and easy to use, well tolerated by children and suitable for clinical practice.

Regulatory

	Company	Product	Application	Comments
30/01/2014	**AtCor Medical Holdings Ltd (ACG)**	SphygmoCor	Blood pressure measurement	The company's SphygmoCor XCEL system has been approved by Health Canada, allowing its sale to Canadian customers.
14/01/2014	**AtCor Medical Holdings Ltd (ACG)**	SphygmoCor	Blood pressure measurement	The SphygmoCor Xcel system has been approved by the China Food and Drug Administration. AtCor's Chinese distributor, Angy (China) Medical Ltd, is now able to sell SphygmoCor XCEL to clinicians and researchers in mainland China.
16/01/2014	**Agenix Ltd (AGX)**	ThromboView	Radio-labelled monoclonal antibody imaging agent	Agenix announced that it has been granted a key patent in Canada. The patent for "Humanised antibodies derived from DD-3B6/22, specific for the D-Dimer fragment of Fibrin" is the basis of the company's lead diagnostic product, ThromboView.
10/02/2014	**Admedus Ltd (AHZ)**	CardioCel	Regenerative tissue product	Admedus announced it has received FDA clearance to market CardioCel in the US. CardioCel is the group's lead regenerative tissue product to repair and treat a range of cardiovascular and vascular defects. The company will now look to complement its product launch in Europe with preparation for initial sales in the US.
13/02/2014	**Biotron Ltd (BIT)**	BIT225	HIV	Biotron received a notice of allowance from the US Patent and Trademark Office for its patent application 11/922,281 entitled "Antiviral Compounds and Methods".
9/01/2014	**Bone Medical Ltd (BNE)**	Lexcicon	Musculoskeletal diseases	Bone Medical said the European Patent Office has approved its Lexcicon patent. The platform technology is used to provide a molecular framework for novel peptides generated from the company's Mozaic discovery technology.
13/02/2014	**Bone Medical Ltd (BNE)**	Lexcicon	Musculoskeletal diseases	Bone Medical said its Lexcicon patent has been approved in Japan.
10/02/2014	**Cellmid Ltd (CDY)**	N/A	Prevention of surgical adhesions	The US Patent and Trademark Office has approved Cellmid's patent application 13/539,247 entitled "Preventative for Adhesion Following Abdominal Surgery". This patent protects the use of midkine (MK)-specific DNA and RNA antisense molecules that disrupt MK expression and prevent the formation of surgical adhesions.
21/03/2014	**Cochlear Ltd (COH)**	Nucleus	Hearing system	The US Food and Drug Administration approved Cochlear's Nucleus Hybrid Implant System for commercial release.
6/03/2014	**Calzada Ltd (CZD)**	NovoPore	Foam dressing	Calzada announced that its subsidiary PolyNovo Biomaterials has been granted a 510(k) clearance from the US Food and Drug Administration for its topical negative pressure foam dressing NovoPore.
11/03/2014	**Innate Immunotherapeutics Ltd (IIL)**	MIS416	Acute radiation injury	The company has been granted an EU patent application for the use of MIS416 to treat or prevent acute radiation injury and to also mitigate the toxic effects of cancer-related radiotherapy treatment.
24/03/2014	**Imugene Ltd (IMU)**	HER-Vaxx	Cancer vaccine	Imugene has received notice that the Israeli Patent Office has approved the company's proprietary cancer vaccine HER-Vaxx.
19/02/2014	**Mesoblast Ltd (MSB)**	Mesenchymal precursor cells	Cardiac and vascular conditions	Mesoblast said the European Patent Office has approved a key patent covering use of its proprietary adult mesenchymal precursor cells in the treatment of cardiac and vascular conditions.
27/03/2014	**pSivida Corp (PVA)**	Iluvien	Eye disease	pSivida announced it has resubmitted its New Drug Application for Iluvien, for the treatment of chronic diabetic macular oedema.
14/03/2014	**Starpharma Holdings Ltd (SPL)**	VivaGel coated condom	HIV/HPV	Starpharma said it has received regulatory approval to market its VivaGel-coated condom in Japan, the world's second largest condom market.
4/02/2014	**Uscom Ltd (UCM)**	BP+	Blood pressure measurement	Uscom announced receipt of the CE Mark for the BP+, allowing the Uscom BP+ device to be sold into the European Economic Area.

Other news

	Company	Product	Application	Comments
24/02/2014	Alchemia Ltd (ACL)	N/A	N/A	Alchemia announced the appointment of Thomas Liquard as chief executive officer following the departure of Charles Walker. Mr Liquard recently served as a senior director of portfolio development in lead emerging markets for Pfizer in New York.
12/02/2014	Analytica Ltd (ALT)	N/A	N/A	Analytica Ltd has appointed Geoff Daly as chief executive officer.
21/02/2014	Circadian Technologies Ltd (CIR)	N/A	N/A	Circadian announced the appointment of Dr Megan Baldwin to the position of chief executive officer and managing director, effective February 24 2014.
24/01/2014	Cochlear Ltd (COH)	N/A	N/A	A jury has reached a verdict in the patent infringement lawsuit brought against Cochlear by the Alfred E. Mann Foundation for Scientific Research and Advanced Bionics. The jury awarded damages of US$131.2m against Cochlear, which is seeking to appeal against the decision.
11/02/2014	Nusep Ltd (NSP)	N/A	N/A	Prakash Patel's employment as chief executive officer of Nusep ceased on 10 February 2014 and Alison Coutts, the chairman, has been appointed interim CEO while the company seeks to fill the role permanently.

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Appendix

Companies in the PwC Life Sciences Index

		Closing Price	Closing Mcap	Quarterly Return	Annual Return
Medical device					
AHZ	Admedus Limited	0.140	182.23	-10%	383%
AMT	Advanced Surgical Design & Manufacture Limited	0.045	1.97	-10%	-57%
ADO	Anteo Diagnostics Limited	0.245	207.54	53%	322%
ACG	Atcor Medical Holdings Limited	0.120	19.68	-29%	29%
BRC	Brain Resource Company Limited (The)	0.250	25.43	0%	-4%
CLV	Clover Corporation Limited	0.440	72.68	-15%	-29%
COH	Cochlear Limited	57.000	3,259.04	-3%	-16%
CGS	Cogstate Limited	0.300	31.67	-17%	-23%
CMP	Compumedics Limited	0.110	16.69	28%	96%
CYC	Cyclopharm Limited	0.210	12.06	-16%	75%
ELX	Ellex Medical Lasers Limited	0.335	36.06	-7%	76%
GBI	Genera Biosystems Limited	0.120	10.78	-17%	26%
GID	Gi Dynamics Inc	0.570	222.07	-24%	-11%
IPD	Impedimed Limited	0.220	43.52	-10%	150%
ISN	Isonea Limited	0.210	60.79	-37%	163%
ITD	Itl Limited	0.250	20.86	-14%	4%
LBT	Lbt Innovations Limited	0.090	8.98	15%	91%
MLA	Medical Australia Limited	0.270	26.54	10%	200%
MGZ	Medigard Limited	0.020	2.28	-29%	33%
MDG	Medtech Global Limited	0.062	6.22	3%	77%
NAN	Nanosonics Limited	0.860	225.55	2%	79%
OBJ	Obj Limited	0.051	73.19	55%	292%
OSL	Oncosil Medical Limited	0.130	41.78	0%	242%
OIL	Optiscan Imaging Limited	0.050	8.30	-7%	-47%
OSP	Osprey Medical Inc	0.600	73.93	-12%	20%
RMD	Resmed Inc	4.750	6,217.46	-10%	9%
RVA	Reva Medical	0.155	73.61	-68%	-72%
SFP	Safety Medical Products Limited	0.002	1.49	0%	-60%
SVA	Simavita Limited	0.800	41.60	0%	#DIV/0!
SOM	Somnomed Limited	1.560	70.44	42%	63%
SUD	Suda Limited	0.062	59.19	-21%	94%
TDX	Tyrian Diagnostics Limited	0.002	2.04	100%	100%
UNS	Unilife Corporation	0.750	482.49	-7%	114%
UBI	Universal Biosensors, Inc.	0.340	64.98	-26%	-51%
UCM	Uscom Limited	0.300	22.70	114%	50%

		Closing Price	Closing Mcap	Quarterly Return	Annual Return
Pharma and Biotech					
ACR	Acrux Limited	1.720	283.09	-33%	-56%
ACW	Actinogen Limited	0.045	9.05	105%	114%
AGX	Agenix Limited	0.017	2.10	-6%	-23%
ACL	Alchemia Limited	0.520	171.94	-9%	58%
ALT	Analytica Limited	0.028	17.24	4%	27%
ANP	Antisense Therapeutics Limited	0.215	31.70	43%	115%
AVX	Avexa Limited	0.020	18.51	67%	18%
AVH	Avita Medical Limited	0.120	39.04	-11%	4%
BLT	Benitec Biopharma Limited	1.620	179.82	182%	398%
BNO	Bionomics Limited	0.530	229.53	-30%	39%
BPO	Bioprospect Limited	0.004	11.59	33%	300%
BIT	Biotron Limited	0.110	22.60	45%	-4%
BXN	Bioxyne Limited	0.008	1.60	-20%	-47%
BNE	Bone Medical Limited	0.024	58.40	-76%	-76%
CZD	Calzada Limited	0.130	60.54	65%	160%
CDY	Cellmid Limited	0.029	20.60	0%	-15%
CIR	Circadian Technologies Limited	0.225	9.73	10%	-17%
CUV	Clinuvel Pharmaceuticals Limited	1.570	60.77	65%	-35%
CTE	Cryosite Limited	0.500	21.09	9%	-6%
CSL	Csl Limited	69.560	33,662.92	1%	17%
CYP	Cynata Therapeutics Limited	0.410	23.61	-18%	-18%
DVL	Dorsarvi Limited	0.540	67.90	29%	5%
GTG	Genetic Technologies Limited	0.053	35.60	-4%	-29%
HCT	Holista Colltech Limited	0.074	9.18	-26%	14%
IDT	Idt Australia Limited	0.300	24.18	-20%	22%
IMC	Immuron Limited	0.008	23.88	-11%	90%
IMU	Imugene Limited	0.015	13.25	-12%	67%
IIL	Innate Immunotherapeutics Limited	0.250	39.67	25%	0%
IVX	Invion Limited	0.075	39.17	-11%	67%
LCT	Living Cell Technologies Limited	0.080	28.56	3%	67%
MYX	Mayne Pharma Group Limited	0.945	560.25	28%	97%
MVP	Medical Developments International Limited	1.400	81.39	21%	-24%
MSB	Mesoblast Limited	5.470	1,719.22	-6%	-11%
NEU	Neuren Pharmaceuticals Limited	0.088	134.36	-23%	159%
NRT	Novogen Limited	0.180	30.34	-10%	0%
NSP	Nusep Limited	0.060	10.28	-19%	-8%
PAB	Patrys Limited	0.043	29.07	-17%	39%
PXS	Pharmaxis Limited	0.095	30.64	-10%	-71%
POH	Phosphagenics Limited	0.094	101.03	-18%	-28%

		Closing Price	Closing Mcap	Quarterly Return	Annual Return
PYC	Phylogica Limited	0.024	24.05	41%	4%
PBT	Prana Biotechnology Limited	1.040	446.65	35%	384%
PRR	Prima Biomed Limited	0.041	51.61	5%	-57%
PBP	Probiotec Limited	0.630	31.76	50%	85%
PGL	Progen Pharmaceuticals Limited.	1.115	67.45	346%	393%
PVA	Psivida Corp.	4.320	113.41	-5%	95%
QRX	Qrxpharma Limited	0.770	128.89	3%	-34%
RGS	Regeneus Limited	0.440	82.98	-4%	70%
SIE	Scigen Limited	0.025	13.81	-55%	-38%
SRX	Sirtex Medical Limited	15.520	857.34	32%	40%
SPL	Starpharma Holdings Limited	0.760	220.62	-12%	-30%
TIS	Tissue Therapies Limited	0.350	92.00	15%	119%
VLA	Viralytics Limited	0.315	59.79	3%	5%
VHL	Virax Holdings Limited	0.010	5.51	0%	#DIV/0!

Notes:

BNC	**Company removed from index following delisting from ASX**
SVA	**Company added to index after dual listing on ASX**
VHL	**Company re-added to index after emerging from voluntary administration**

05

Methodology

Methodology

Sources

BioForum draws on historical data from the following sources:

- Capital IQ
- Connect 4
- The Australian Stock Exchange
- Company websites
- *PwC Global Pharma and Life Science Quarterly Newsbriefs*

Market performance

The Australian life sciences sector's market performance is tracked through two indices:

1. PwC Life Sciences Index
2. PwC Life Sciences Index ex majors (CSL, ResMed and Cochlear)

Analysis is provided without the large-capitalisation stocks (majors) so the performance of smaller-capitalisation stocks can be observed.

The PwC Life Sciences Index is based on the performance of life sciences companies listed on the Australian Securities Exchange (ASX). It comprises two subsectors:

1. Pharmaceutical/Biotechnology
2. Medical devices

These sectors have been classified according to the Global Industry Classification Standard. The index includes life sciences companies primarily involved in research, development, commercialisation and manufacturing of pharmaceutical and biotechnology products and medical devices. It excludes healthcare, medical software and distribution companies. Companies included in the PwC Life Sciences Index are listed at the end of each issue of BioForum.

The PwC Life Sciences Index is based on the combined market capitalisation of the listed companies and calculates the change of their value over the quarter and change over the previous year. Only the changes in market capitalisation of companies are reflected in the index to ensure that companies entering or leaving the index do not bias the results. Due to methodology changes it is not appropriate to compare current values of the PwC Life Sciences index with values calculated in previous Bioforum reports.

These changes are compared to the changes in the market performance of the following indices:

- ASX All Ordinaries
- NASDAQ Composite
- NASDAQ Biotech

Different formulae are used to calculate the value of these indices and track their performance. These formulae use a combination of company market prices and a weighted average of market capitalisation. Because of these different methods of calculating value, the absolute value of the indices cannot be directly compared. Only their changes over time can be sensibly compared.

The Life Sciences index is designed as a measure of the health and performance of the industry, not as a measure of returns to investors.

Top and bottom performers

Annual data on these companies is sourced from Capital IQ each quarter. Company announcements are sourced from company websites.

IPO and secondary finance markets

IPO and secondary financing data is sourced from the Connect 4 database's health-care industry category. We include data from companies on the PwC Life Sciences Index only. Data on options, rights and bonus issues is excluded. The US IPO and secondary financing data is sourced from Thompson Reuters.

Announcements

These are from companies listed on the PwC Life Sciences Index only. They are sourced from Connect 4 using the health-care industry category. We include announcements on partnerships, mergers and acquisitions and divestments, clinical results, regulatory activity and other information.

Announcements on the following are excluded:

- trading halts
- capital raisings
- proposed (versus actual) mergers, acquisitions and partnerships
- progress reports on clinical trials (results only are included)
- market registration approval

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