

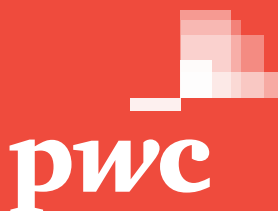
Collaboration as a source of strength for the Life Sciences sector

BioForum

Edition 48

Quarter 4 FY14

Aug 2014



Q4FY14 key statistics

↓3.7%

Life Sciences Index
(up 1.9% in Q3FY14)

↓15.8%

*Life Sciences Index
ex Majors*
(up 7.2% in Q3FY14)

↑0.5%

ASX All Ordinaries
(up 0.9% in Q3FY14)

↑8.8%

Nasdaq Biotech
(up 4.2% in Q3FY14)

↑5%

Nasdaq Composite
(up 0.5% in Q3FY14)

Key Developments

- *The Victorian Government announced development of a new strategy to position Victoria as an internationally competitive developer of medical technology, while also providing new opportunities for the state's advanced manufacturing sector*
- *Malcolm Turnbull announced that the federal government would look to make changes to employee share schemes legislation later in 2014*
- *Parnell Pharmaceuticals, an Australian animal pharmaceutical company, listed on the NASDAQ and raised \$USD50m*
- *Commercialisation Australia is now closed for new applications and will be rolled into the new Entrepreneurs Infrastructure Program*

Introduction

Collaboration as a source of strength for the Life Sciences sector

With external uncertainty continuing to plague the Life Sciences industry, many in the sector are collaborating with other companies and industries to build long term sustainability.

For too long the sector has pinned its hopes on government intervention to create an environment that will enable it to thrive. In many instances the level of support has often fallen short of the promise forcing Life Sciences companies to look at other ways to develop their ideas.

The most recent Federal Budget saw cuts to commercialisation initiatives with the abolition of the Innovation Investment Fund and Commercialisation Australia, no confirmed changes to Employee Share Schemes, a 1.5% reduction in the R&D tax incentive and the introduction of a \$50m over three years Manufacturing Transition Grants Programme.

And while the Medical Research Future Fund is a noble objective, until the details are confirmed and the government successfully pushes the medicare co-payment through the senate, it adds to the uncertainty already felt by the sector.

However, instead of waiting for more opportunities from the public purse, some Life Sciences companies are driving their own success through collaboration.

Collaboration is critical in enabling success at all stages of the lifecycle. Its commonplace to see Life Sciences companies pursue partnerships for discovery, research and development and commercialisation, but beyond these traditional partnerships, collaboration can help businesses access new funding sources, new technologies and promote the advancement of science and research.

One standout collaboration is Panasonic and KKR's joint ownership of Panasonic Healthcare Co Ltd; combining Panasonic's technology, industry knowledge and commercial network with KKR's investment experience and investment network.

And closer to home, Starpharma teamed its antiviral product with Ansell to create a new condom which significantly reduces the risk of transmission of a number of sexually transmitted diseases.

Despite these success stories, why aren't we seeing more collaboration within the Australian sector?

New South Wales Business Chamber, with PwC, recently released a research discussion paper which outlined a set of key recommendations to grow Australian productivity through collaboration between industry, research organisations and government.

Key recommendations included establishing good practice forums on corporate engagement and commercialisation of research, incorporating initiatives into university curriculums to foster long term partnerships and mindsets and creation of a marketplace for research expertise. The full report can be found on the NSWBC website.

We hope that the increased focus on creating collaboration opportunities, in addition to success stories from around the world, translates into long term success for the Life Sciences sector. Collaboration enables the science, the funding and the results. It's the key to creating certainty and support in the Life Sciences sector, and in the broader economy.



Michelle Chiang
Partner
PwC Assurance



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Quarterly key findings

Quarterly key findings

Market performance	Q4FY14	Page
Life sciences industry total MCap	A\$50,132m	9
Life sciences Index	50,269	9
Life sciences Index growth	-3.7%	9
Pharma/biotech sector total MCap	A\$37,125m	9
Pharma/biotech Index	37,782	10
Pharma/biotech Index growth	-7.3%	10
Medical device sector total MCap	A\$13,007m	9
Medical device Index	12,487	10
Medical device Index growth	9.5%	10
Individual company performance		
Top individual performer	Medtech Global Limited	16
Change in market cap over the past four quarters		
Bottom individual performer	Qrxpharma Limited	17
Change in market cap over the past four quarters		
Financing		
Australian IPO count	0	12
Total raised	A\$m	
US IPO count	15	12
Total raised	A\$1,214m	
Australian secondary financing count	20	14
Total raised	A\$79m	
US secondary financing count	37	14
Total raised	A\$1,853m	
Announcements	Q4FY14	Page
Australia		
Partnerships	10	19
Mergers & acquisitions	6	20
Clinical trials	22	21
Regulatory	11	23
Other	5	24

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Market performance

Performance overview

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

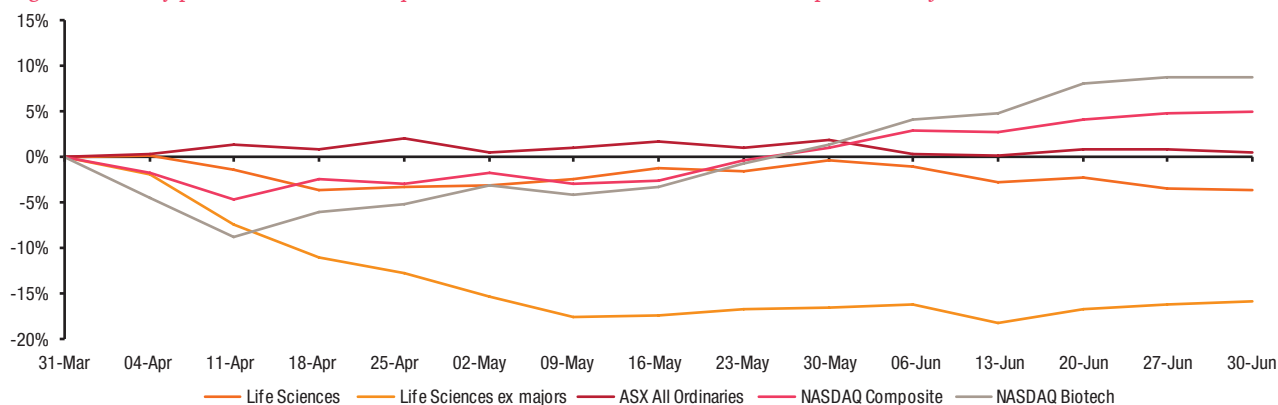


Table 1: Quarterly movements of the PwC Life Sciences Index compared to major indices

	Value			% Change (Dec-Mar)	% Change (Mar-Jun)
	31-Dec-13	31-Mar-14	30-Jun-14		
PwC Life Sciences Index (Index)	51,268	52,175	50,269	1.8%	-3.7%
PwC Life Sciences Index ex majors (Index)	8,507	9,065	7,632	6.6%	-15.8%
ASX All Ordinaries (Index)	5,353	5,403	5,429	0.9%	0.5%
NASDAQ Composite (Index)	4,177	4,199	4,408	0.5%	5.0%
NASDAQ Biotech (Index)	2,370	2,469	2,686	4.2%	8.8%

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

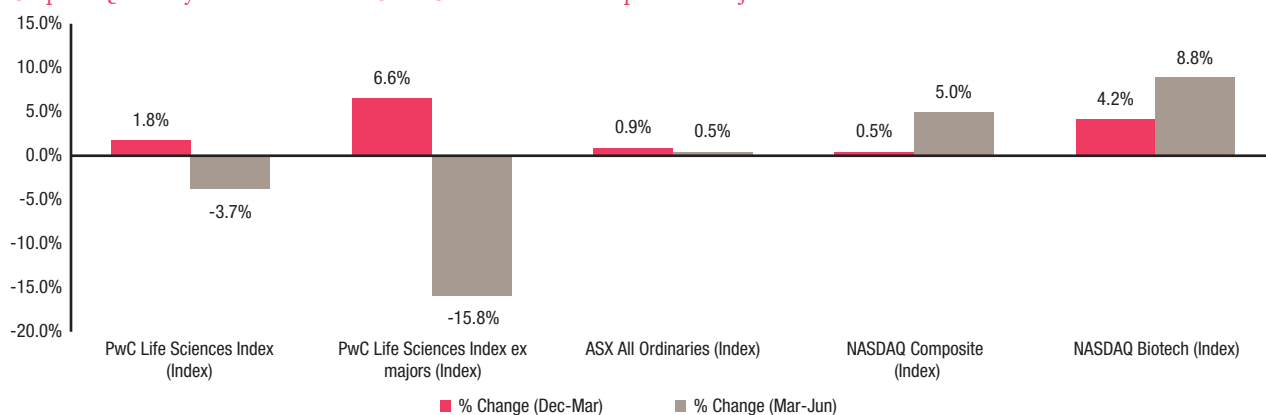


Figure 2: Two-year comparison of the PwC Life Sciences Index compared to major indices

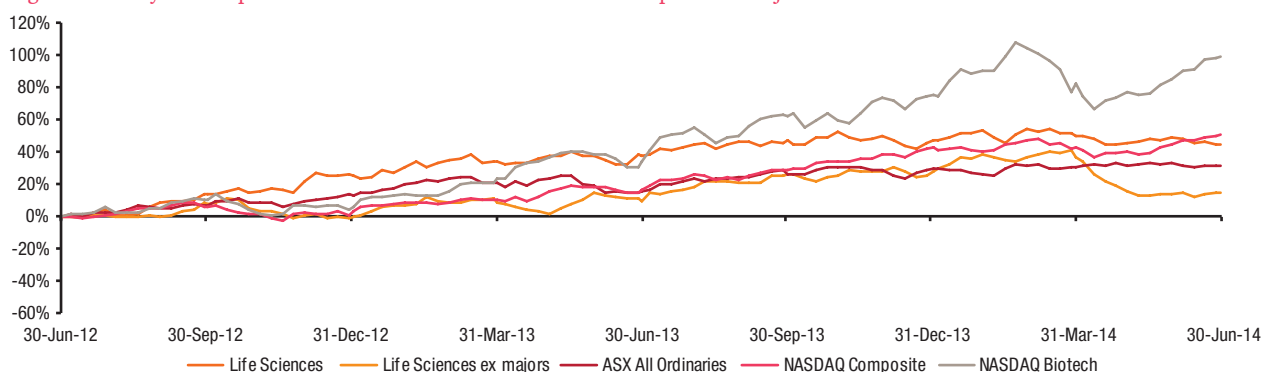


Table 2: Yearly performance of the PwC Life Sciences Index compared to major indices

	% Change (Mar13-Mar14)			% Change (Jun13-Jun14)		
	31-Mar-13	31-Mar-14	% Change	30-Jun-13	30-Jun-14	% Change
Life Sciences (Index)	46,804	52,175	11.5%	47,932	50,269	4.9%
Life Sciences ex majors (Index)	7,207	9,065	25.8%	7,232	7,632	5.5%
ASX All Ordinaries (Index)	4,980	5,403	8.5%	4,775	5,429	13.7%
NASDAQ Composite (Index)	3,239	4,199	29.6%	3,403	4,408	29.5%
NASDAQ Biotech (Index)	1,669	2,469	47.9%	1,813	2,686	48.2%

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

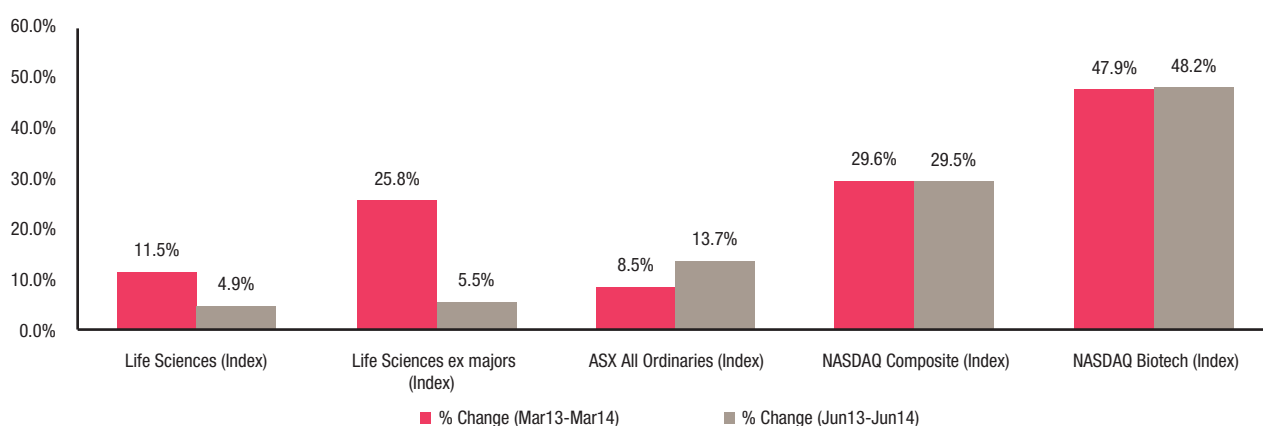


Figure 3: Quarterly performance of the PwC Life Sciences Index and its subsectors

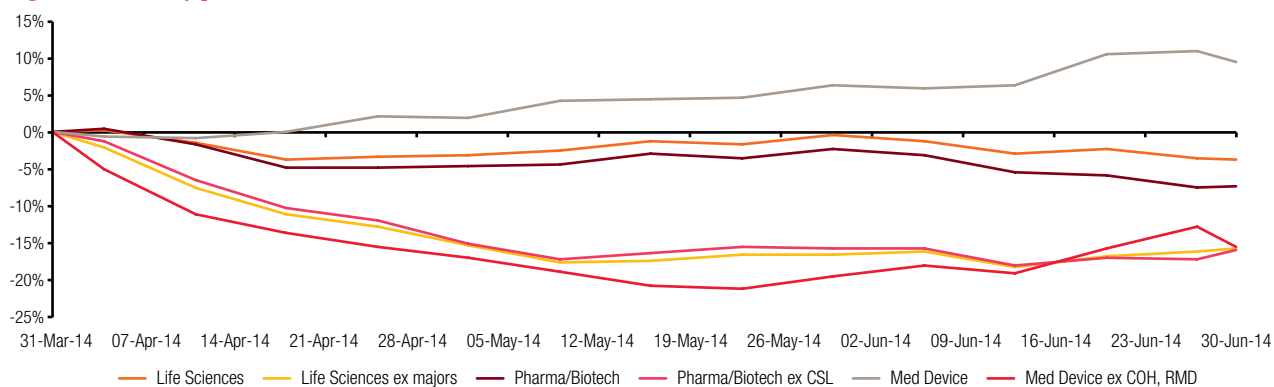


Table 3: Quarterly performance of the PwC Life Sciences Index and its subsectors

	Market capitalisation (A\$m)			% Change (Dec-Mar)	% Change (Mar-Jun)
	31-Dec-13	31-Mar-14	30-Jun-14		
Life Sciences	51,268	52,175	50,269	1.8%	-3.7%
Life Sciences ex majors	8,507	9,065	7,632	6.6%	-15.8%
Pharma/Biotech	40,057	40,769	37,782	1.8%	-7.3%
Pharma/Biotech ex CSL	6,608	7,106	5,976	7.5%	-15.9%
Med Device	11,211	11,406	12,487	1.7%	9.5%
Med Device ex COH, RMD	1,899	1,959	1,656	3.1%	-15.4%

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

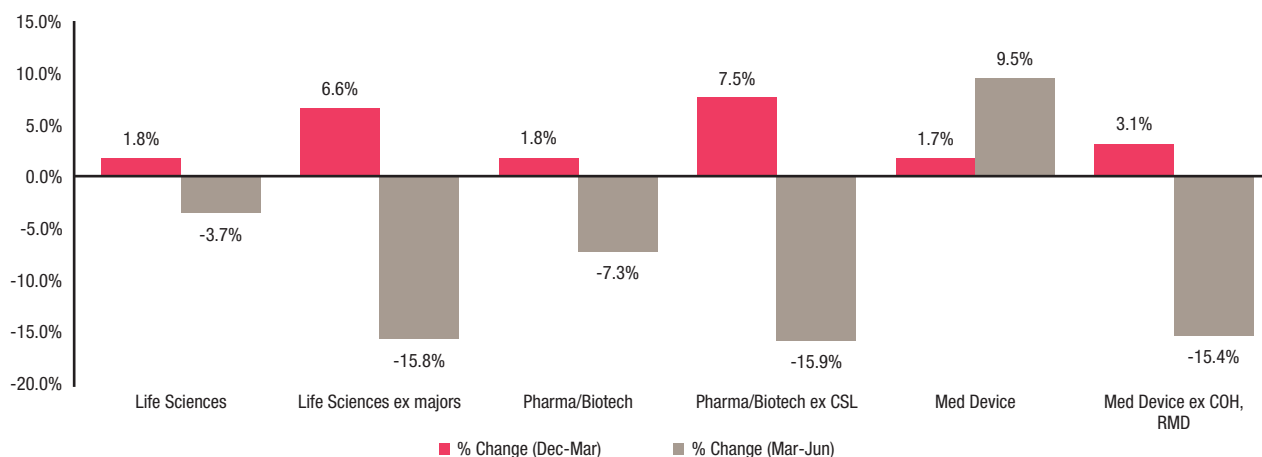


Figure 4: Two-year performance of the PwC Life Sciences Index and its subsectors

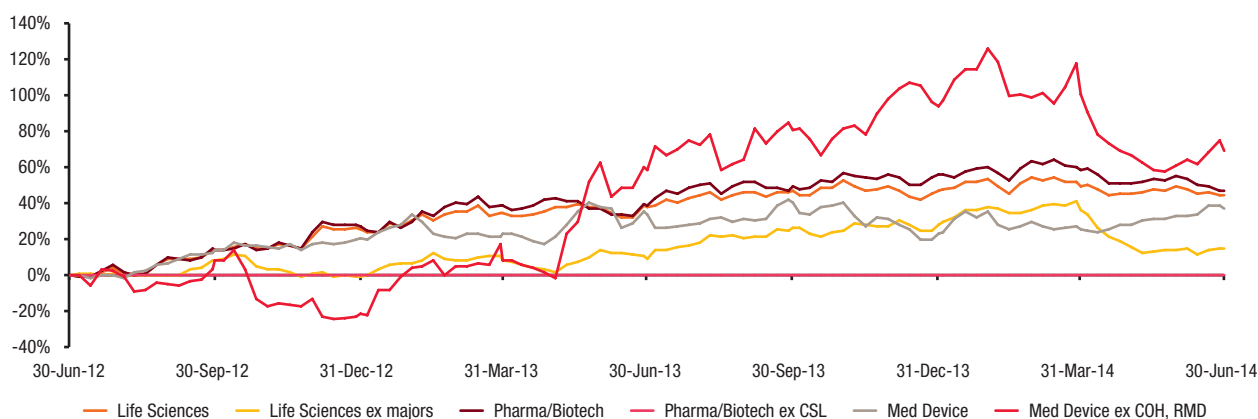


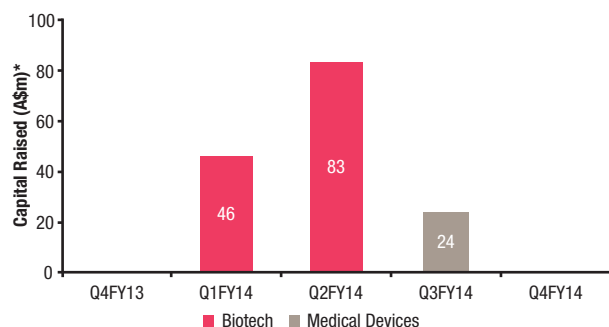
Table 4: Quarterly summary of the PwC Life Sciences Index and its subsectors

	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	50,269	100%	21	24%	65	74%	2	2%	88
Life Sciences ex majors	7,632	100%	19	22%	64	75%	2	2%	85
Pharma/Biotech	37,782	75%	7	13%	46	87%	-	0%	53
Pharma/Biotech ex CSL	5,976	78%	7	13%	45	87%	-	0%	52
Med Device	12,487	25%	14	40%	19	54%	2	6%	35
Med Device ex COH, RMD	1,656	22%	12	36%	19	58%	2	6%	33

IPO financing

Quarterly financing

Figure 5: Quarterly comparison of IPOs in Australia

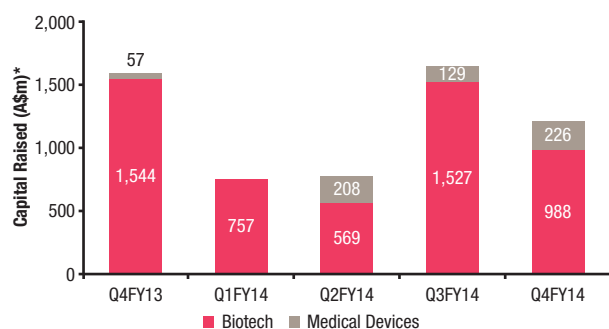


Note: * Amount shown is total company valuation on first day of trading

Table 5: Number of quarterly Australian IPO listings

	Biotech	Med Devices	ASX
Q4FY14	-	-	21
Q3FY14	-	1	4
Q2FY14	2	-	32
Q1FY14	1	-	8
Q4FY13	-	-	11

Figure 6: Quarterly comparison of IPOs in the US



Note: * Amount shown is total amount raised

Table 6: Listing of quarterly Australian IPO listings

Company	Listing date	Capital Raised (A\$m)	Valuation on listing (\$m)	Sector
None				
Total			-	

Table 7: Total of quarterly US IPO listings

	Biotech	Med Devices
Q4FY14	13	2
Q3FY14	21	4
Q2FY14	8	2
Q1FY14	11	-
Q4FY13	9	1

Table 8: Listing of quarterly US IPO listing

Company	Listing date	Capital raised (A\$m)	Sector
Adamas Pharmaceuticals Inc	09/04/2014	52	Biotech
Agile Therapeutics Inc	22/05/2014	59	Biotech
Alder BioPharmaceuticals Inc	07/05/2014	86	Biotech
Aldeyra Therapeutics Inc	01/05/2014	13	Biotech
Amphastar Pharmaceuticals Inc	24/06/2014	60	Biotech
Ardelyx Inc	18/06/2014	64	Biotech
Cerulean Pharma Inc	10/04/2014	64	Biotech
Corium International Inc	02/04/2014	56	Biotech
K2M Group Holdings Inc	07/05/2014	142	Med Devices
Phibro Animal Health Corp	10/04/2014	205	Biotech
Radius Health Inc	05/06/2014	56	Biotech
TriVascular Technologies Inc	15/04/2014	84	Med Devices
Vital Therapies Inc	16/04/2014	58	Biotech
Zafgen Inc	18/06/2014	102	Biotech
ZS Pharma Inc	17/06/2014	114	Biotech
Total		1,214	

Yearly financing

Figure 7: Annual comparisons of IPOs in Australia

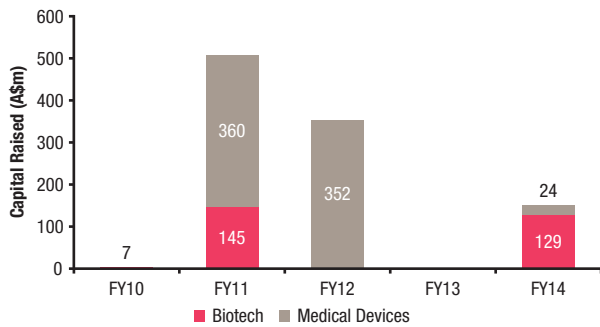


Table 9 Number of IPO listings in Australia

	Biotech	Med Devices	ASX
FY14	3	1	65
FY13	-	-	49
FY12	-	2	75
FY11	1	1	127
FY10	1	-	53

Figure 8: Annual comparison of IPOs in the US

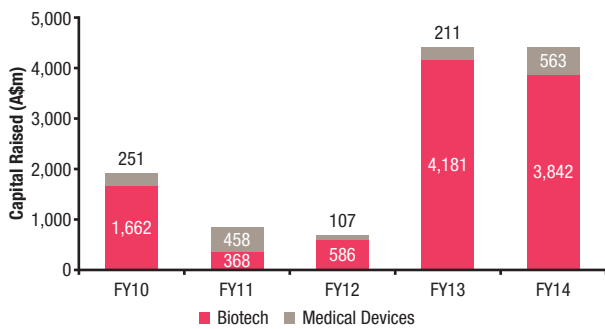


Table 10: Number of IPO listings in the US

	Biotech	Med Devices
FY14	53	8
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

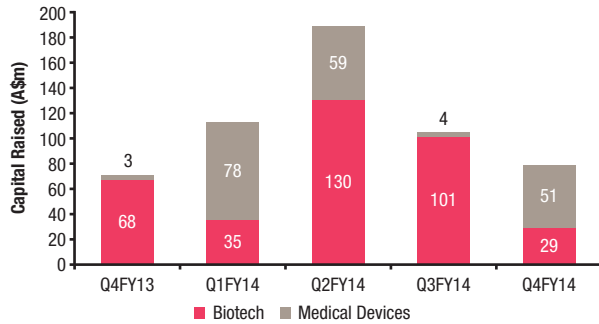


Figure 10: Quarterly comparison of secondary financing in the US

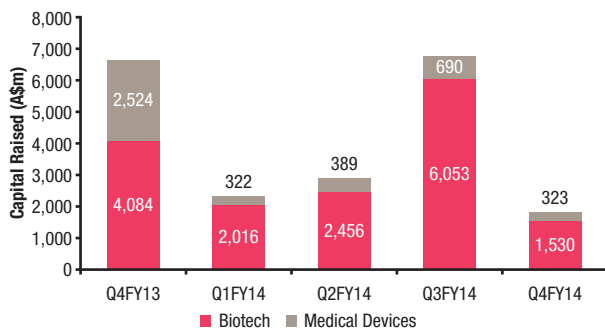


Table 11: Number of secondary deals (AU)

	Biotech	Avg. amount raised (\$m)	Med Devices	Avg. amount raised (\$m)
Q4FY14	10	2.9	10	5.1
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

Table 12: Number of secondary deals (US)

	Biotech	Med Devices
Q4FY14	24	13
Q3FY14	60	20
Q2FY14	41	14
Q1FY14	48	19
Q4FY13	38	22

Yearly financing

Figure 11: Annual comparison of secondary financing in Australia

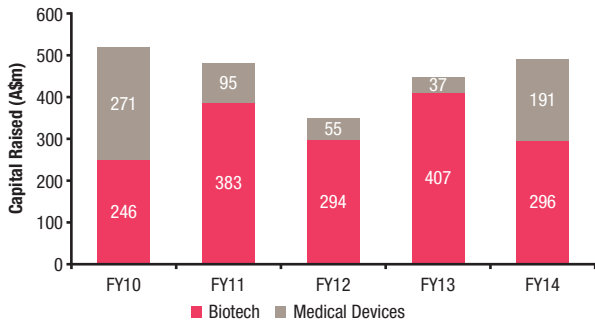


Table 13: Number of Australian secondary raisings

	Biotech	Med Devices
FY14	86	39
FY13	100	29
FY12	99	39
FY11	154	43
FY10	107	39

Figure 12: Annual comparison of secondary financing in the US

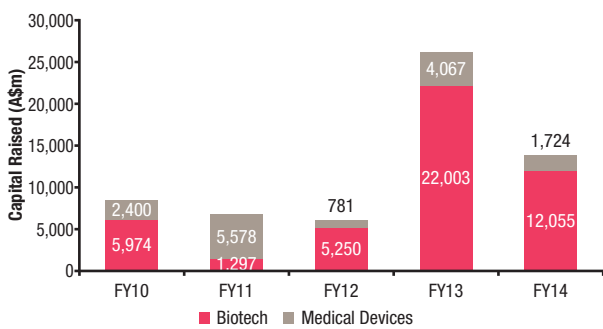
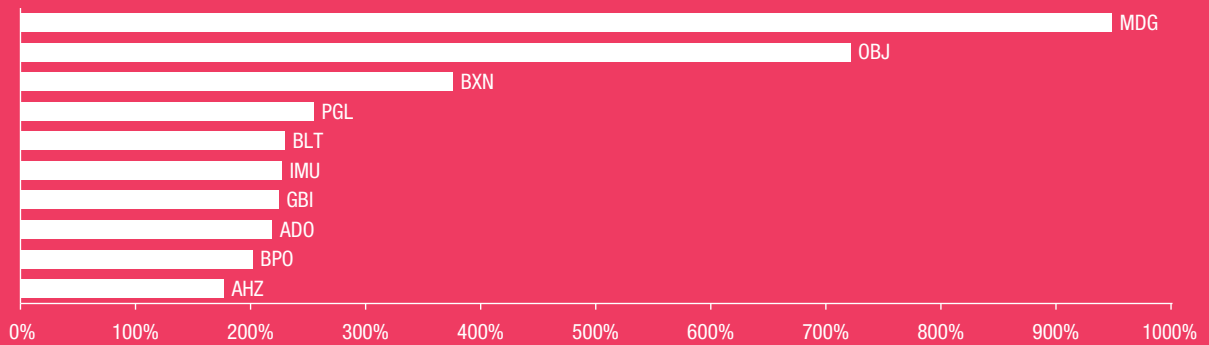


Table 14: Number of US secondary raisings

	Biotech	Med Devices
FY14	173	66
FY13	152	85
FY12	125	43
FY11	66	121
FY10	122	57

Top 10

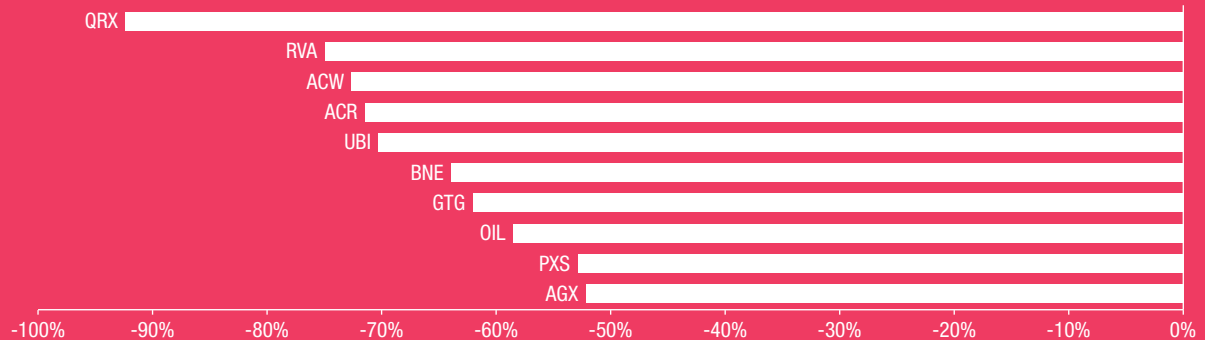
Performers over the past four quarters



01	Medtech Global Ltd	Return: 948% Closing price: \$0.22 MCap: A\$20.05m	Medtech Global received a \$1.6m grant from the Victorian Government. Profit before tax came in at \$2.14m compared to \$251k in the prior year.
02	OBJ Ltd	Return: 720% Closing price: \$0.08 MCap: A\$122.32	OBJ and Procter and Gamble made a series of deals covering product development and licensing to commercialise OBJ's magnetic micro-array technology. OBJ made a second analgesic study agreement with GlaxoSmithKline after completing a phase I trial.
03	Bioxyne Ltd	Return: 375% Closing price: \$0.02 MCap: A\$3.61m	Bioxyne reported that its probiotics business had a record quarter with sales of \$933k and a royalty payment was received from its distributor.
04	Progen Pharmaceuticals Ltd	Return: 256% Closing price: \$0.80 MCap: A\$44.78m	The company's late-stage liver cancer drug PI-88 is on track for New Drug Applications in Asia, with patient enrolment for a phase III trial completed in December.
05	Benitec Biopharma Ltd	Return: 229% Closing price: \$1.15 MCap: A\$133.85m	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.
06	Imugene Ltd	Return: 225% Closing price: \$0.01 MCap: A\$13.25m	Imugene acquired Biolife Science in November 2013 for \$4.5m. The net loss for the half year to December 2013 was up 22% to \$1.5m.
07	Genera Biosystems Ltd	Return: 224% Closing price: \$0.34 MCap: A\$30.16m	Genera Biosystems revealed in June that it was in merger talks with an undisclosed larger international molecular diagnostics business.
08	Anteo Diagnostics Ltd	Return: 217% Closing price: \$0.19 MCap: A\$153.86m	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.
09	Bioprospect Ltd	Return: 200% Closing price: \$0.00 MCap: A\$9.52m	Bioprospect acquired an option to purchase an 80% stake in Invatec Health, which has developed a method for the diagnosis of mental health disorders.
10	Admedus Ltd	Return: 176% Closing price: \$0.14 MCap: A\$194.55m	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.

Bottom 10

Performers over the past four quarters



10	Agenix Ltd	Return: -52% Closing price: \$0.01 MCap: A\$1.70m	Agenix issued shares to Tyrian Diagnostics for licensing of its rapid point-of-care human diagnostic technology. The loss for the half year was \$609k before tax, down from \$2.25m in the prior half-year period.
09	Pharmaxis Ltd	Return: -53% Closing price: \$0.066 MCap: A\$19.81m	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.
08	Optiscan Imaging Ltd	Return: -59% Closing price: \$0.03 MCap: A\$5.37m	Optiscan reported a \$600k loss in 2013, down from \$2.5m in 2012. It raised \$1m via a convertible note issue.
07	Genetic Technologies Ltd	Return: -62% Closing price: \$0.04 MCap: A\$22.71m	Revenues for Brevagen grew 39% over the previous quarter although the number of samples collected fell for the first time. \$5m was raised via a convertible note issue, and some notes have been converted into equity.
06	Bone Medical Ltd	Return: -64% Closing price: \$0.02 MCap: A\$0.42m	Losses for the half year to December 2013 were \$683k. The company raised \$3.82m through a share placement in January.
05	Universal Biosensors Inc	Return: -70% Closing price: \$0.200 MCap: A\$36.00	Universal Biosensors pushed back to the September quarter the release of the blood coagulation device it is developing with Siemens. Losses increased 27% to \$11.6m for year ended December 2013.
04	Acrux Ltd	Return: -71% Closing price: \$1.01 MCap: A\$167.35m	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.
03	Actinogen Ltd	Return: -73% Closing price: \$0.011 MCap: A\$2.23m	Revenues for the half year were down 44% to \$167k and losses increased 756% to \$153k.
02	Reva Medical	Return: -75% Closing price: \$0.14 MCap: A\$45.17m	Reva halted development of its ReZolve product to focus resources on its Fantom product, and hopes to begin human studies later this year.
01	QRxPharma Ltd	Return: -92% Closing price: \$0.080 MCap: A\$13.14m	The US Food and Drug Administration issued a complete response letter in regards to QRx's new drug application for Moxduo, stating there was not sufficient evidence to support approval of the drug.

03

Announcements

Australia – Partnerships

Date	Company	Partner	Application	Value (A\$m)	Comments
02 April 2014	Advanced Surgical Design & Manufacture Ltd (AMT)	University of Sydney	Bone loss	Undisclosed	Advanced Surgical Design and Manufacture announced a global licence agreement with the University of Sydney relating to a composite biocompatible ceramic material known as Sr-HT-Gahnite. ASDM is to facilitate the commercialisation of veterinary and orthopaedic solutions based on the material developed by the university.
24 June 2014	Bionomics Ltd (BNO)	Merck (aka MSD)	Cognitive dysfunction	Bionomics will receive US\$20m upfront and is eligible to receive up to US\$506m, plus undisclosed royalties on any product sales, for meeting certain research and clinical development milestones.	Bionomics entered into an exclusive research and licence agreement with Merck (MSD) for its BNC375 research program, which targets cognitive dysfunction associated with Alzheimer's disease and other central nervous system conditions.
05 June 2014	Compumedics Ltd (CMP)	MedAssets Purchasing Group	Sleep diagnostics and neuromonitoring systems	Undisclosed	Compumedics' subsidiary Compumedics USA reached a three-year agreement to supply sleep diagnostic and neuromonitoring systems to MedAssets, which has as members 2,800 hospitals and 90,000 acute healthcare facilities.
21 May 2014	Immuron Ltd (IMC)	DB Pharm Korea Co	Diarrhoea	Undisclosed	Immuron has signed an exclusive agreement allowing DB Pharm Korea to market, distribute, and sell Travelan in South Korea while complying with specified annual minimum order obligations.
27 May 2014	Imugene Ltd (IMU)	Bachem AG	Cancer	Undisclosed	Australian immuno-oncology company Imugene has appointed Bachem AG to undertake clinical-grade manufacture of the peptide component of its proprietary therapeutic HER-2+ cancer vaccine HER-Vaxx.
02 June 2014	Novogen Ltd (NRT)	Genea Biocells	Super-benzopyran (SBP)	N/A	Novogen will collaborate with Genea Biocells to accelerate testing of their super-benzopyran (SBP) drugs for degenerative diseases of the nervous system and muscles. The partners will test the molecules in laboratory models across a range of degenerative diseases.
28 April 2014	OBJ Ltd (OBJ)	Procter & Gamble	Magnetic micro-array technology	Undisclosed	"OBJ and Procter and Gamble have entered into a suite of agreements including a multi-product development agreement (PDA) and an initial licensing agreement that sets the course to commercialise OBJ's magnetic micro-array technology."
16 May 2014	SomnoMed Ltd (SOM)	JJ Thompson (Orthodontic Appliances) Ltd	Continuous open airway therapy	Undisclosed	SomnoMed signed a deal allowing JJThompson (Orthodontic Appliances) to operate as its service laboratory and logistics hub in the United Kingdom and Ireland. This allows SomnoMed to access a new client base of over 1,000 dentists.
07 April 2014	Starpharma Holdings Ltd (SPL)	AstraZeneca	Cancer	Undisclosed	Starpharma Holdings has signed a second, expanded agreement with AstraZeneca in the field of cancer medicine using Starpharma's proprietary DEP dendrimer drug delivery technology. Under the new agreement, AstraZeneca will provide funding for a preclinical stage cancer research program to be conducted jointly.
05 May 2014	Virax Holdings Ltd (VHL)	Moffitt Cancer Centre and Research Institute	GGTI-2418	Virax paid \$3000 for an exclusive licence	Virax has entered into an option agreement with the Moffitt Cancer Center and Research Institute to license novel technology which allows for the selection of breast and other cancer patients that are likely to respond to Virax's GGTI-2418. This technology can help determine which patients are likely to benefit from the GGTI-2418 treatment, thus improving personalised breast cancer care.

Mergers, acquisitions and divestments

Date	Dominant company	Other company	Type of deal	Value (A\$m)	Comments
19 May 2014	Agenix Ltd (AGX)	Cinkate Pharmaceuticals Intermediates Co Ltd	Sale	US\$2m	Agenix reached a binding definitive agreement for the sale of its AGX-1009 China project to Cinkate Pharmaceutical Intermediates. Under the terms of the sale, Cinkate will take over development of AGX-1009, a tenofovir pro-drug for HBV, patented in China.
14 April 2014	BioProspect Ltd (BPO)	Invatec/Heartlink	Acquisition	Undisclosed	BioProspect agreed to acquire Invatec/Heartlink's Heart Rate Variability technology after completing a highly favourable due diligence exercise. The board has acquired an initial interest in Invatec and will license the Heartlink technology.
25 June 2014	Mayne Pharma Group Ltd (MYX)	HedgePath Pharmaceuticals Inc (HPPI)	Out-licensing	A\$4.0-4.5m	Mayne Pharma completed the out-licensing of its SUBA-Itraconazole intellectual property to US-based HedgePath Pharmaceuticals. HPPI secured funding to develop, register and commercialise the patented oral formulation for the treatment of cancers. Mayne took an equity stake of 41.5% in HPPI in return for granting it exclusive rights to this product in the US.
23 June 2014	Safety Medical Products Ltd (SFP)	3D Medical Ltd	Acquisition	A\$100k	Safety Medical Products agreed to acquire 3D Medical, an Australian unlisted company focused on the commercialisation of 3D printing and holographic projection technology in the medical industry.
27 June 2014	Scigen Ltd (SIE)	Anglo Gulf FZE (AGF)	Sale	US\$7m	SciGen Ltd sold its total interest (50.01% of equity) in SciGen BioPharma to Anglo Gulf FZE for US\$7m in cash. SBPL is a joint venture established in India to manufacture human insulin and the facility is not yet operational.
30 May 2014	Virax Holdings Ltd (VHL)	Pathway Oncology Pty Ltd	Acquisition	60m shares	Virax Holdings acquired specialty oncology company Pathway Oncology and its novel cancer drug candidate GGTI-2418. The drug is expected to move into further clinical trials in breast cancer and multiple myeloma in Q2 2015. As part of the transaction, Paul Hopper will join the board as an executive director.

Clinical trials

Date	Company	Drug	Application	Comments
Phase I				
26 June 2014	Benitec Biopharma Ltd (BLT)	Cal-1	HIV	Benitec Biopharma announced that its licensee in the HIV/AIDS field, privately owned US-based Calimmune, has approval to move ahead with the second patient cohort of its phase I/II clinical trial of Cal-1, an innovative ddRNAi-based therapy.
29 May 2014	Benitec Biopharma Ltd (BLT)	TTT-034	Hepatitis C	Benitec Biopharma said it has dosed the first patient in its 'first in man', phase I/IIa clinical trial for TTT-034, a ddRNAi-based therapeutic designed to treat and potentially cure hepatitis C (HCV) with a single injection.
23 June 2014	Living Cell Technologies Ltd (LCT)	NTCell	Parkinson's disease	Living Cell Technologies said it has received regulatory approval to resume recruitment of the remaining three patients in the phase I/IIa clinical trial of NTCell in Parkinson's disease.
15 May 2014	Progen Pharmaceuticals Ltd (PGL)	PG545	Cancer	Progen completed treatment of the first patient cohort in its PG545 phase 1 clinical trial. Progen, together with an independent medical monitor and the co-ordinating investigator, reviewed the safety data from this cohort and agreed to progress to the next higher dose of PG545.
30 June 2014	Regeneus Ltd (RGS)	Kvax	Canine cancer vaccine	Regeneus and a leading vet health care services group will conduct a US marketing trial of the company's novel autologous canine therapeutic cancer vaccine, Kvax.
Phase II				
28 April 2014	Admedus Ltd (AHZ)	CardioCel	Congenital heart disease	Admedus said results of a six-year follow-up on the first patient from its phase II study show there is still no detectable calcification of CardioCel, with no extra surgery required and no other issues. The patient was implanted at three weeks of age and reached their sixth birthday with no implant issues.
06 May 2014	Clinuvel Pharmaceuticals Ltd (CUV)	Scenesse	Dermatology	Clinuvel announced a phase II study of its drug Scenesse in Singapore had received the necessary regulatory and ethics committee approvals. It will recruit 60 adults with vitiligo for a seven-month, double-blind, placebo controlled study at Singapore's leading dermatology hospital.
31 March 2014	Prana Biotechnology Ltd (PBT)	PBT2	Alzheimer's disease	Prana Biotechnology said results of a 12-month phase II imaging trial showed 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. While there was a reduction in patients treated with PBT2, the results were confounded by an atypical reduction of levels of the PiB PET signal in the placebo group as well.
08 April 2014	Viralytics Ltd (VLA)	Cavatak	Cancer treatment	Viralytics reported positive interim results from the ongoing phase II CALM clinical trial. Investigators reported partial or complete reduction of non-injected tumours in multiple patients who had been on treatment at least eight weeks. These findings provide potential evidence of oncolytic immunotherapy.
Phase III				
30 June 2014	Clover Corporation Ltd (CLV)	Medical foods	The augmentation of DHA levels in premature babies	The Women's & Children's Hospital in Adelaide launched a phase III clinical trial involving 50 hospitals in four countries to test the effectiveness of Clover's proprietary DHA emulsion in reducing the incidence and severity of lung disorders in infants born prematurely. Clover said it would obtain regulatory approval to sell the emulsion once results are available (mid-2015.)
Pre-clinical and other				
18 June 2014	Atcor Medical Holdings Ltd (ACG)	SphygmoCor	Blood pressure monitor	AtCor Medical announced the launch of a new 24-hour ambulatory blood pressure monitor (ABPM) system at the European Society of Hypertension meeting in Athens.
15 May 2014	Avita Medical Ltd (AVH)	ReCell	Hypopigmented scars	Avita Medical said a clinical study showed ReCell gives clinically superior results in treating hypopigmented scars. The ongoing study found that areas treated with ReCell, combined with a scar treatment technique called medical needling, showed statistically significant repigmentation, while the areas treated with medical needling alone and not treated with ReCell, did not.

Clinical trials

Date	Company	Drug	Application	Comments
12 May 2014	Bone Medical Ltd (BNE)	An oral treatment	Osteoporosis	Bone Medical received approval to proceed with its planned human clinical study to compare a potential oral treatment for osteoporosis against commercially available alternatives. The study was expected to begin before the end of May and conclude within three months. Additionally, Peter Young stepped down as CEO and director of the company and is assuming a role as senior consultant and advisor.
07 May 2014	Cellmid Ltd (CDY)	CAB102	Oncology	Cellmid announced it reached key milestone in selecting its lead anti-midkine antibodies for trial. CAB102 has been shown to significantly reduce chemotherapy resistance in preclinical models of lung cancer.
15 May 2014	Ellex Medical Lasers Ltd (ELX)	Retinal rejuvenation therapy (2RT)	Eye disease	Ellex said the 24-month follow-up of the pilot study to investigate the efficacy of its proprietary retinal rejuvenation therapy in the treatment of early age-related macular degeneration has been released and published. This showed a reduced drusen area in 35-40% of the patients tested.
15 May 2014	Gi Dynamics (GID)	EndoBarrier therapy	Type 2 diabetes and obesity	GI Dynamics announced findings that show EndoBarrier Therapy enabled a rapid reduction in, and elimination of, insulin therapy by patients with type 2 diabetes and obesity.
16 June 2014	Gi Dynamics Inc (GID)	EndoBarrier therapy	Type 2 diabetes and obesity	GI Dynamics announced data findings which demonstrate the acute effects of EndoBarrier therapy on glycaemic control, its ability to reduce reliance on diabetes medications, including insulin, and findings that help explain its potential mechanism.
26 June 2014	ImpediMed Ltd (IPD)	L-Dex device	Lymphoedema	ImpediMed said its international post-approval clinical trial has commenced six months ahead of schedule with the enrolment of its first patient. The trial will test the clinical utility of ImpediMed's L-Dex device in early detection of lymphoedema.
25 June 2014	Mesoblast Ltd (MSB)	Left ventricular assist device	Heart failure	Regenerative medicine company Mesoblast Ltd said trial results evaluating a low dose of its proprietary mesenchymal precursor cells in patients with end-stage heart failure, who receive a left ventricular assist device (LVAD), have been published in the June issue of the American Heart Association journal 'Circulation'.
17 June 2014	Novogen Ltd (NRT)	Trx-1	Ovarian cancer	Australian oncology drug development company Novogen and CanTx, its joint venture with Yale University, announced the success of proof-of-concept preclinical studies at the Drug Discovery and Therapy 2014 World Congress. These studies confirmed the potency of an experimental drug, Trx-1, in the treatment of primary ovarian cancer when delivered into the peritoneal cavity.
14 May 2014	Regeneus Ltd (RGS)	HiQCell	Neuropathic pain	Regeneus announced publication of results describing early efficacy data for the use of its stem cell therapy (HiQCell) for neuropathic pain sufferers. This new study confirms that HiQCell appears to offer a viable new strategy for treatment of neuropathic pain that affects up to 6% of the population.
23 June 2014	Uscom Ltd (UCM)	Uscom BP+	Hypertension and heart failure	Uscom Ltd announced the manufacture of the first Uscom BP+ unit at its head office in Sydney.

Regulatory

Date	Company	Product	Application	Comments
07 April 2014	Antisense Therapeutics Ltd (ANP)	ATL1102	Multiple sclerosis	Antisense Therapeutics said it has been granted a patent for the use of the ATL1102 compound to reduce brain lesions in relapsing-remitting multiple sclerosis (RRMS), and progressive forms of MS. This stands until 23 Jun 2029, with potential for an extension of up to five years.
16 April 2014	AtCor Medical Holdings Ltd (ACG)	SphygmoCor	Cardiovascular disease measurement	AtCor Medical has been granted a US patent for its SphygmoCor system, which measures central aortic blood pressure and arterial stiffness non-invasively. This establishes a proprietary position for AtCor in deriving cardiac output from the central aortic pressure waveform and confers intellectual property rights to AtCor until August 2026.
22 May 2014	Clinuvel Pharmaceuticals Ltd (CUV)	Scenesse	Hailey-Hailey disease	Clinuvel Pharmaceuticals said afamelanotide, the active ingredient in its proprietary drug Scenesse, has received orphan-drug designation from the US FDA for the rare Hailey-Hailey disease. Orphan-drug designation is granted to drugs which have the potential to diagnose or treat rare conditions, entitling Clinuvel to technical assistance, potential fee reductions and tax credits, and seven years' market exclusivity if approved for marketing by the FDA.
16 June 2014	Genera Biosystems Ltd (GBI)	Roche cobas 4800 HPV Test	Human papillomavirus	"Health Canada has approved the Roche cobas 4800 HPV test for use as a first-line primary screening test for cervical cancer in women 25 and older."
26 June 2014	Medical Developments International Ltd (MVP)	Penthrox	Inhaled analgesic	Medical Developments International received approval from the Medicines Control Council in South Africa to market and sell its inhaled analgesic product, Penthrox, for pain relief from trauma and surgical procedures.
04 June 2014	Neuren Pharmaceuticals Ltd (NEU)	NNZ-2591	Neurological impairment	The US Patent and Trademark Office has issued a notice of allowance for a new patent covering Neuren's second drug candidate, NNZ-2591. The patent is expected to expire in 2031.
17 June 2014	Osprey Medical Inc (OSP)	Avert (2nd gen.)	Heart surgery	Osprey Medical has received US FDA 510(k) clearance for its 2nd generation Avert System for the controlled infusion of dye.
18 June 2014	Patrys Ltd (PAB)	PAT-SM6	Cancer treatment	Patrys announced that a third PAT-SM6 patent has been granted in United States, providing protection through to November 2024.
23 June 2014	pSivida Corp (PVA)	Iluvien	Vision impairment	pSivida said that the Italian Medicines Agency has granted it authorisation to market Iluvien in Italy for the treatment of vision impairment associated with chronic diabetic macular oedema considered insufficiently responsive to available therapies.
26 May 2014	QRxPharma Ltd (QRX)	Moxduo	Acute pain treatment	The US Food and Drug Administration issued a letter stating regarding there was not sufficient evidence to support approval of Moxduo. It indicated clinical information is needed showing a clear benefit over oxycodone and morphine alone.
24 June 2014	SomnoMed Ltd (SOM)	SomnoDent Classic and Fusion Flex	Obstructive sleep apnoea	SomnoMed Ltd said it received FDA 510(k) approval from the US Department of Health & Human Services for its new SomnoDent Fusion Classic and SomnoDent Fusion Flex oral appliances.

Other news

Date	Company	Product	Application	Comments
19 June 2014	Cellmid Ltd (CDY)	Rodon Biologics	Oncology	Cellmid said it has selected Rodon Biologics, a subsidiary of Biotechnol SA, to manufacture its humanised anti-midkine (MK) antibody CAB102 for clinical trials in multiple oncology indications. Under the agreement, Rodon will engineer a high yielding CHO cell line expressing CAB102, along with the processes necessary to manufacture and formulate the drug for human trials.
02 June 2014	Cochlear Ltd (COH)	Cochlear Nucleus Profile Series	Hearing system	Cochlear said it would be launching the Cochlear Nucleus Profile Series across Europe in Jun.
20 May 2014	Compumedics Ltd (CMP)	Doppler Box X	Sonography	Compumedics said its German-based brain blood-flow Doppler-sonography division, Compumedics Germany GmbH, has secured a €200k deal to supply its Doppler-Box X technology to 10 stroke centres across Brazil.
20 June 2014	Cyclopharm Ltd (CYC)	Cyclotron		The Cyclopharm cyclotron facility suffered significant damage from water used to put out a vehicle fire. The full extent of the damage is yet to be ascertained but the facility is fully insured.
16 June 2014	Uscom Ltd (UCM)	Unetixs Vascular	Cardiovascular disease	Uscom appointed Unetixs Vascular as a US distributor for the USCOM 1A for three years.

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Appendix

Companies in the PwC Life Sciences Index

		Closing MCap (A\$m)	Quarterly return	Annual return
Med Device1				
AHZ	Admedus Limited	194.55	-4%	176%
AMT	Advanced Surgical Design & Manufacture Limited	2.63	33%	-43%
ADO	Anteo Diagnostics Limited	153.86	-22%	217%
ACG	Atcor Medical Holdings Limited	14.96	-22%	34%
BRC	Brain Resource Company Limited (The)	25.94	2%	-6%
CLV	Clover Corporation Limited	72.68	-7%	-29%
COH	Cochlear Limited	3,575.60	8%	0%
CGS	Cogstate Limited	29.69	0%	-17%
CMP	Compumedics Limited	21.70	32%	164%
CYC	Cyclopharm Limited	12.06	0%	20%
ELX	Ellex Medical Lasers Limited	40.37	12%	88%
GBI	Genera Biosystems Limited	30.16	183%	224%
GID	Gi Dynamics Inc	284.28	2%	-3%
IPD	Impedimed Limited	44.15	-16%	106%
ISN	Isona Limited	62.08	12%	-35%
ITD	Itl Limited	19.50	-16%	-25%
LBT	Lbt Innovations Limited	14.38	56%	47%
MLA	Medical Australia Limited	14.29	-39%	-8%
MGZ	Medigard Limited	2.09	15%	-23%
MDG	Medtech Global Limited	20.05	255%	948%
NAN	Nanosonics Limited	205.78	-8%	31%
OBJ	Obj Limited	122.32	61%	720%
OSL	Oncosil Medical Limited	34.67	-23%	133%
OIL	Optiscan Imaging Limited	5.37	-42%	-59%
OSP	Osprey Medical Inc	69.00	-7%	14%
RMD	Resmed Inc	7,361.76	15%	10%
RVA	Reva Medical	45.17	-10%	-75%
SFP	Safety Medical Products Limited	3.73	150%	25%
SVA	Simavita Limited	35.26	-43%	-
SOM	Somnomed Limited	65.49	-6%	60%
SUD	Suda Limited	47.51	-19%	100%
TDX	Tyrian Diagnostics Limited	1.02	-50%	0%
UNS	Unilife Corporation	320.07	-33%	-12%
UBI	Universal Biosensors, Inc.	36.00	-41%	-70%
UCM	Uscom Limited	18.74	-27%	29%

		Closing MCap (A\$m)	Quarterly return	Annual return
Pharma and Biotech				
ACR	Acrux Limited	167.35	-42%	-71%
ACW	Actinogen Limited	2.23	-76%	-73%
AGX	Agenix Limited	1.70	-35%	-52%
ACL	Alchemia Limited	188.16	7%	73%
ALT	Analytica Limited	36.69	54%	115%
ANP	Antisense Therapeutics Limited	21.61	-35%	40%
AVX	Avexa Limited	12.03	-30%	0%
AVH	Avita Medical Limited	35.78	-17%	-23%
BLT	Benitec Biopharma Limited	133.85	-29%	229%
BNO	Bionomics Limited	239.97	4%	62%
BPO	Bioprospect Limited	9.52	-25%	200%
BIT	Biotron Limited	22.83	-5%	28%
BXN	Bioxyne Limited	3.61	138%	375%
BNE	Bone Medical Limited	0.42	-25%	-64%
CZD	Calzada Limited	46.04	-19%	50%
CDY	Cellmid Limited	19.86	-10%	8%
CIR	Circadian Technologies Limited	10.21	-16%	-19%
CUV	Clinuvel Pharmaceuticals Limited	69.95	8%	-6%
CTE	Cryosite Limited	18.28	-28%	-16%
CSL	Csl Limited	31,806.71	-4%	8%
CYP	Cynata Therapeutics Limited	21.98	-2%	-29%
DVL	Dorsarvi Limited	54.65	-15%	9%
GTG	Genetic Technologies Limited	22.71	-32%	-62%
HCT	Holista Colltech Limited	8.48	-19%	0%
IDT	Idt Australia Limited	14.70	-33%	0%
IMC	Immuron Limited	14.98	-38%	25%
IMU	Imugene Limited	13.25	-13%	225%
IIL	Innate Immunotherapeutics Limited	29.32	-34%	-15%
IVX	Invion Limited	38.43	-7%	119%
LCT	Living Cell Technologies Limited	18.21	-36%	24%
MYX	Mayne Pharma Group Limited	501.59	-10%	98%
MVP	Medical Developments International Limited	75.04	-6%	4%
MSB	Mesoblast Limited	1,474.21	-18%	-16%
NEU	Neuren Pharmaceuticals Limited	127.54	-6%	22%
NRT	Novogen Limited	24.44	-19%	-26%
NSP	Nusep Limited	10.45	2%	22%
PAB	Patrys Limited	20.77	-30%	36%
PXS	Pharmaxis Limited	19.81	-31%	-53%
POH	Phosphagenics Limited	91.84	-7%	-33%
PYC	Phylogica Limited	13.03	-50%	-29%
PBT	Prana Biotechnology Limited	107.50	-79%	-10%
PRR	Prima Biomed Limited	50.43	-2%	-41%

		Closing MCap (A\$m)	Quarterly return	Annual return
PBP	Probiotec Limited	23.29	-34%	48%
PGL	Progen Pharmaceuticals Limited.	44.78	-28%	256%
PVA	Psivida Corp.	121.40	-2%	6%
QRX	Qrxpharma Limited	13.14	-90%	-92%
RGS	Regeneus Limited	68.23	-11%	145%
SIE	Scigen Limited	11.05	-20%	0%
SRX	Sirtex Medical Limited	947.67	9%	41%
SPL	Starpharma Holdings Limited	162.51	-24%	-29%
TIS	Tissue Therapies Limited	76.30	-16%	157%
VLA	Viralytics Limited	50.59	-14%	10%
VHL	Virax Holdings Limited	5.53	-50%	-80%

Notes:

Ensure that all name changes, IPO's and companies that have been taken off the model are updated here.

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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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