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BioForum
Edition 33

Quarter 4 FY10 –
Quarter 1 FY11
November 2010

Will those that have held steady during testing times be rewarded with growth?

pwc

What would you like to grow?

Consolidation continues for biotechs

The Life Sciences Index underperformed the broader ASX All Ordinaries in the first quarter of 2011, as consolidation continued in the sector. The pruning taking place within biotech ranks will prepare the sector for new growth but companies will need to exhibit grit and show clear value to survive the current cycle.

The All Ordinaries rose by 7.2 per cent over the three months to September 30 while the Life Sciences Index fell 0.9 per cent. The NASDAQ composite and NASDAQ Biotech indices rose 12.3 per cent and 11.9 per cent respectively, in contrast to the Australian result.

The Medical Devices (ex majors) sector, which grew strongly over the past three quarters, posted a 4.6 per cent loss in the September quarter. Still, reduced volatility, shorter commercial timeframes and smaller risk profiles suggest there is underlying strength in the sector.

The Pharma/Biotech Index posted a modest 1.9 per cent gain after dropping 16.5 per cent in Q4FY10. This may have been due to a number of companies either leaving the index or changing their activities.

Investors take profits

Major medical device stocks lost ground during the September quarter. Heartware International's stellar performance (78 per cent gain) in the June quarter was not sustained as investors took profits. The share prices of Cochlear and Resmed also came off the boil.

There were no Australian IPOs during the three months to September 30, continuing the trend of the previous quarter. This is in line with the US, where there was only one IPO.

Secondary raisings have been the lifeblood of the industry but the total raised in the September quarter reinforces the notion that only the strong will survive. Just $27 million was raised, down from $56 million in the June quarter, while the number of raisings increased from 32 to 42.

In the US, the total of secondary capital raised was down 62 per cent, in contrast to the NASDAQ Biotech's 11.9 per cent gain.

Anecdotally the biotech market is patchy but there are some positive signs. US venture capital market investors are reaching out abroad and Australia's smaller venture capital sector is also seeking worthwhile opportunities.

Feature articles

This edition features an article on how life science businesses can manage risk to create value for shareholders.

We also interview Garry Redlich from Implicit Bioscience to discuss his thoughts on the current market and investment trends in the life sciences sector.

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Quarterly key findings

Market performance	Q1FY11	Page
Total market cap of the life sciences industry at end of quarter	A$33,381m	16
Quarterly change in the life sciences industry	-0.9%	16
Total market cap of the pharma/biotech sector at end of quarter	A$21,950m	16
Quarterly change in the pharma/biotech sector	1.9%	16
Total market cap of the medical device sector at end of quarter	A$11,431m	16
Quarterly change in the medical device sector	-5.8%	16
Individual company performance		
Top individual performer	Anteo Diagnostics Ltd	20
Change in market cap over the past four quarters	467%	
Bottom individual performer	Acuvax Limited	21
Change in market cap over the past four quarters	-87%	
Financing		
Number of Australian life sciences companies that IPO'ed	0	17
Total market cap injected into the Australian life sciences index through IPOs	A$0m	17
Number of US life sciences companies that IPO'ed	1	17
Total capital raised in US life sciences IPOs	A$7m	17
Number of Australian life sciences companies that had secondary raisings	42	19
Total capital raised in Australian life sciences in secondary raisings	A$27m	19
Number of US life sciences companies that had secondary raisings	11	19
Total capital raised in US life sciences in secondary raisings	A$156m	19

	Q4FY10	Page	Q1FY11	Page
Announcements – Australia				
Total number of partnerships formed this quarter	7	35	26	23
Total number of mergers and acquisitions	9	35	10	25
Total announcements for clinical trials				
Pre-clinical	0	36	1	26
Phase I	1	36	1	26
Phase II	0	36	3	26
Phase III	4	36	2	26
Total number of regulatory announcements	7	36	15	28
Announcements – US				
Total number of partnerships formed this quarter	32	47	2	41
Total number of mergers and acquisitions	21	48	2	41
Total announcements for clinical trials				
Pre-clinical	4	50	1	41
Phase I	6	50	2	41
Phase II	18	50	3	41
Phase III	19	51	6	41
Total number of regulatory announcements	118	54	44	42

02

Feature articles

Using risk management to create value

Life sciences businesses face a myriad of operational, regulatory and compliance risks. However, by implementing the right frameworks, they can develop the knowledge and culture that treats risk as a tool to grow.

At a glance

By viewing the risk management process as an opportunity to create value and realise opportunities, businesses in this sector can improve performance and gain an edge over competitors.

The life sciences industries in Australia and worldwide are undergoing profound change. Stricter regulation and intensifying competition are just two of the developments combining to challenge current business models or even make them redundant.

To survive, life sciences businesses – including pharmaceutical, biotechnology and medical device firms – must change their structure and direction. This includes reviewing their appetite for and treatment of risk.

Too many firms look only at the downside of risk. However, for life sciences companies, risk is inherent in just about all important decisions. By viewing the risk management process as an opportunity to create value and realise opportunities, businesses in this sector can improve performance and gain an edge over competitors.

Establishing risk appetite: difficult but rewarding

A life sciences business should first review its risk management framework to ensure it is flexible enough to support change and allows the board to determine what level of risk it is prepared to accept when pursuing its objectives – setting the risk appetite.

This needs to be done with a view towards different planning horizons. For example, when developing a five-year strategy, a board may need to decide whether its risk appetite allows it to support the long lead times needed to develop some new treatments. On a more operational level, the risk appetite has to be articulated in such a way as to facilitate day-to-day business decisions that reflect the tactical plan for the financial year.

The risk appetite must then be embedded in operations to ensure staff do not expose the business to excessive – or even insufficient – risk.

Establishing risk appetite and reviewing it to reflect changing circumstances is not an easy task.

How does the board of a life sciences company ensure its risk appetite is consistently reflected and applied across the business?

A board must balance the often conflicting perspectives of its own members, senior management, shareholders, regulators and other stakeholders. Directors must also account for external factors such as demand and economic outlook, as well as internal factors such as changes to management or departures of key staff.

But the rewards of doing so are considerable. Managers and staff can continue to make informed decisions about whether a particular activity is in line with the objectives of their business.

So how does the board of a life sciences company ensure its risk appetite is consistently reflected and applied across the business?

Using risk profiling to increase transparency

As a first step, businesses need to fully understand the risks they face – now and into the future.

They can do this by developing a risk profile that:

- provides a complete view of business processes
- outlines the key risks facing the firm
- evaluates these risks for frequency and impact
- details the measures applied to manage the risk, and
- assesses the residual risks and the measures to treat them.

The profile should include all relevant information and feature what-if and worst-case scenarios.

It should also be refreshed continually and used by directors and senior managers to review risk strategy and risk appetite.

A firm's risk profile is only as useful as the quality and depth of the information used to develop it.

We recommend that businesses review their IT systems to ensure they can extract the insight necessary to build an effective risk profile.

A firm's risk profile is only as useful as the quality and depth of the information used to develop it.

Adopting a risk-smart culture

To ensure that its risk appetite drives the execution of its strategy, a business should strive to create a risk-smart culture. This enables individuals across most levels of the business to make decisions based on the firm's risk appetite. In turn, decisions are made quickly, are in line with strategic objectives and are not held up by evaluation at multiple levels of organisational hierarchy.

The risk function of a business is a key player in creating a risk-smart culture.

Risk professionals should work with directors and senior managers to review whether the way they deliver services supports this approach. The review should establish what risk service model is most appropriate for the company, accounting for cultural, geographical and other factors.

For example, one risk function may operate as an internal 'policeman' directing staff to implement risk management processes, while another may act as an adviser, providing input when required around managing certain risks. Another risk function may act as an enabler to ensure that the risk function is integrated into strategic and tactical planning.

The advantage of this last model is that it builds a risk-smart culture by ensuring the strategic objectives of a business are reflected in day-to-day operations.

For life sciences businesses that wish to grow, risk management is not optional. Businesses must improve their ability to use risk management to set objectives and adopt new and smarter techniques to remain ahead of the competition. They can do this by building a strong risk profile, forging a risk-smart culture and reviewing their risk service model to make sure it is performing as effectively as possible.

Those businesses that take a proactive – but disciplined – approach to risk are more likely to thrive in the new environment than those that continue to treat risk as a negative.

To have a deeper conversation about any of the issues in this paper, please contact:

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Interview with Garry Redlich, Implicit Bioscience

Interviewer – Craig Lawn, PwC

Garry, how do you see the Australian economy at the moment and what are the implications for your company?

It is clear that the Australian economy is on a roll but it is a two speed economy. Retail investors continue to avoid biotechs and therefore we need to be agile and identify new sources of capital. In particular, I see new mining money as a potential opportunity. There is a great recent example of Fortescue Metals chief executive Andrew Forrest making an investment in a UniQuest-related company.

We need to continue to pursue the pockets of enthusiasm for life sciences in the Australian market, identify new sources of capital, and invest in areas where our industry has clear leadership, such as immunology and vaccine development.

We also need to recognise that even though the GFC has had a very significant impact, there are still deep pockets in the US and parts of Europe. Companies in these dominant markets will continue to buy companies and products that we develop and to commercialise our technologies.

Patent expiry and huge demand for products for the ageing population are the big challenges for these markets and we need to continue to focus on them. Our experience in our most recent capital raisings is that US private equity is still very active and we have been successful in raising significant capital. By and large, risk money is still seeking good homes.

Given that there is a tighter market, what are the trends for investment within the life sciences sector?

Regulators are lengthening and tightening their approval processes. There is less patience from investors for longer-timescale life science development, and capital is restricted. We cannot ignore these trends but at the same time let's not lose sight of the fact that it is a market desperate for solutions and with a huge demand for what we are producing. As leaders we therefore need to focus on how we can reduce time, scientific risk and our capital needs.

Regulators are lengthening and tightening their approval processes. There is less patience from investors for longer-timescale life science development, and capital is restricted.

The market has responded in different ways, for example, there is increasing evidence of success from pursuing the device route where there is a shorter development and approval process (Craig: I agree, Garry. There is a clear trend in our BioForum analysis over the past 18 months of investor support for device-based companies).

Similarly, there seems to be more acceptance that developing consumer health supplements and complementary medicines is a viable, less risky path than pure drug development. The regulatory restrictions are generally less but it is a different market than the broader retail market. It was interesting to note that a significant portion of all the health care employees in Queensland were actually involved with complementary medicine and development of consumer-based life science products. The reality is that a lot of people are spending more on supplements and taking care of their diet to prevent health issues. This is a trend that we need to be aware of. I also note, however, that this area generally has limited grant and VC support and investors tend to be angel and family investors with only a small number of larger players.

Implicit's response to these trends is to identify existing compounds that have been partially developed and refocus these in high value markets. We have already identified two compounds which others have spent more that $50 million developing and which have extensive human data and trial results. With our core skills in immune development, we have been successful in refocusing these existing compounds to obtain a high value-add outcome. We look to the frontiers of the mechanism in compounds that are already relatively safe and have an existing manufacturing process. By taking a fresh approach, we can achieve commercially attractive applications. This also means that we plan to provide a value up-tick within a three-year window with a significant return of capital to our investors.

We will continue to identify, harvest and refresh these existing compounds to address high value-add markets.

Have you got any other tips for companies addressing a market that is largely capital starved?

It is imperative that you maintain your global networks, not only for private equity, but also for alternative sources of capital. I have already made mention of new mining money. We also spend a lot of time and effort in maintaining contact with networks that can provide non-dilutive capital, such as philanthropic groups that offer grants. We need to have a broad view of the relevant stakeholders interested in our products. What are the universities, foundations, charities and government departments that are interested in our core areas and can we develop relationships to tap into their non-dilutive capital? This year we have already been able to source more than $1 million of this sort of money from the US.

It is imperative that you maintain your global networks, not only for private equity, but also for alternative sources of capital.

Garry, you have shown how to live in both Australia and the US on a sustainable basis. What are some of your practical learnings?

Travel light and leave a small footprint. We travel frugally. We have a small rented office in Seattle. I leave a bike there and we have a minimalist view operating in both markets. Don't try to replicate operations in both places. I also find Skype extremely valuable. We use this extensively for business and personal purposes to maintain our relationships.

I also note that Australia has a good reputation in the US. I found that the Australian accent is accepted. Once you demonstrate your personal credibility the US will support you given our history and scientific reputation, and our US alliance. In the early stages there is no need to appoint three US VPs for marketing and development and spend a huge amount of money to penetrate the US market. Inevitably this will need to occur at a key time, but for now we can have a small US footprint and still be effective in that market.

Thank you, Garry, for your time. We appreciate your fresh insights. Stay fit, keep buying your supplements and travel light. Well done!

03

Market performance

Performance overview

Figure 1: Weekly performance over the quarter of the Australian life sciences sector compared to major indices (Quarter 4 FY10)

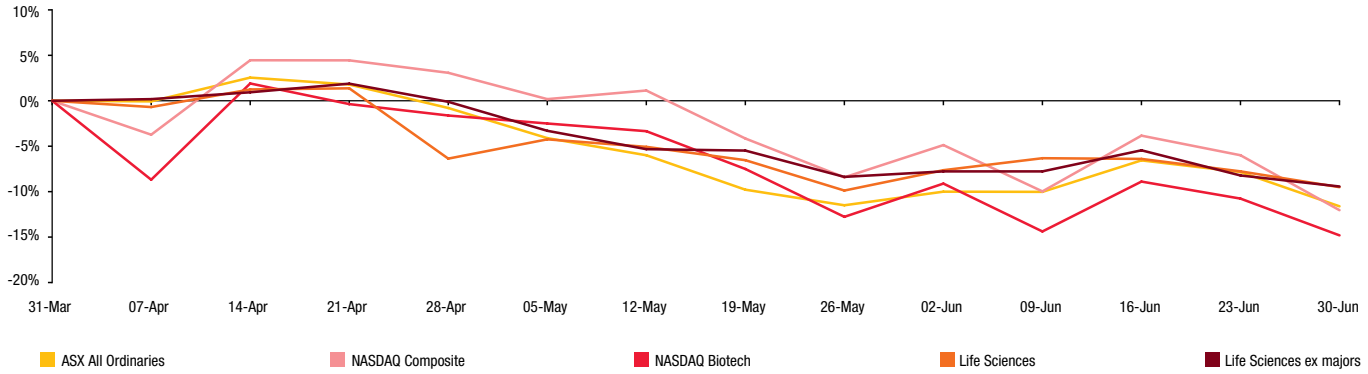
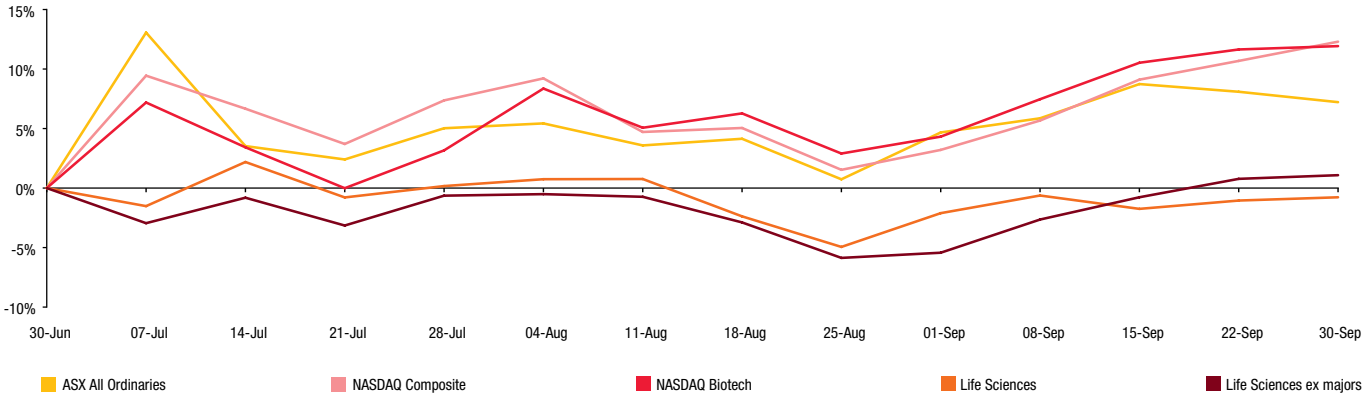


Figure 2: Weekly performance over the quarter of the Australian life sciences compared to major indices (Quarter 1 FY11)



Graph 1: Quarterly movements of the Australian life sciences sector compared to major indices

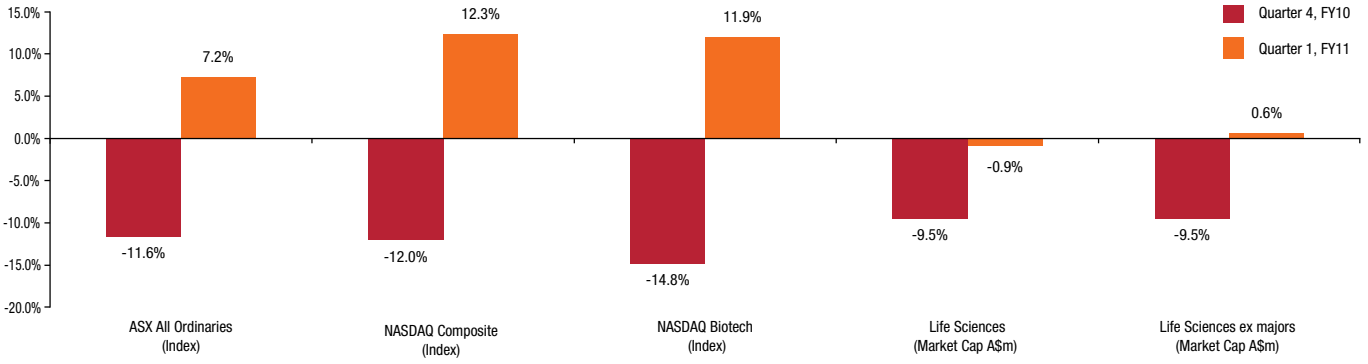
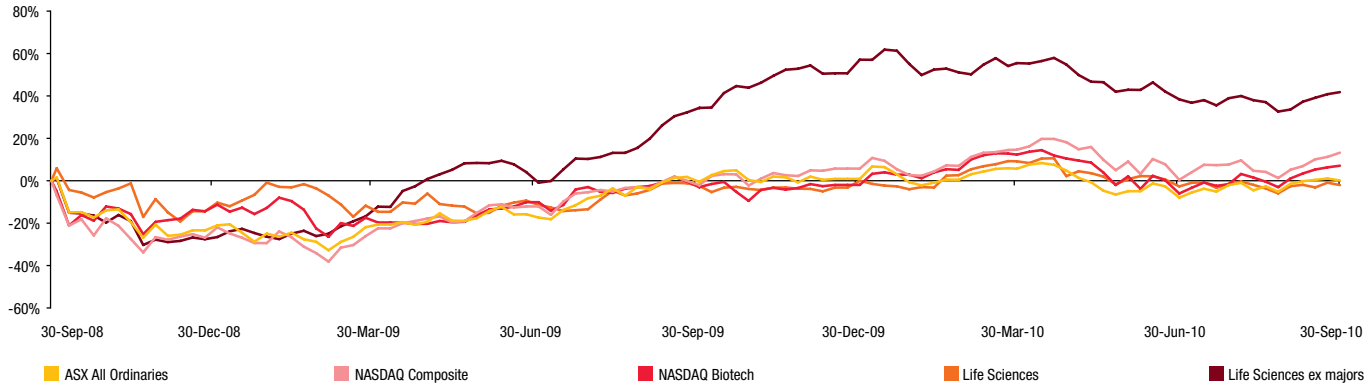


Table 1: Quarterly movements of the Australian life sciences sector compared to major indices

	Value				
	31-Mar-10	30-Jun-10	30-Sep-10	% Change (Mar-Jun)	% Change (Jun-Sep)
ASX All Ordinaries (Index)	4,893	4,325	4,637	-11.6%	7.2%
NASDAQ Composite (Index)	2,398	2,109	2,369	-12.0%	12.3%
NASDAQ Biotech (Index)	939	800	895	-14.8%	11.9%
Life Sciences (Market Cap A$m)	37,211	33,671	33,381	-9.5%	-0.9%
Life Sciences ex majors (Market Cap A$m)	6,714	6,078	6,114	-9.5%	0.6%

Performance overview (cont.)

Figure 3: Two-year comparison of the Australian life sciences sector by market capitalisation compared to major indices



Graph 2: Yearly movements of the Australian life sciences sector by market capitalisation compared to major indices

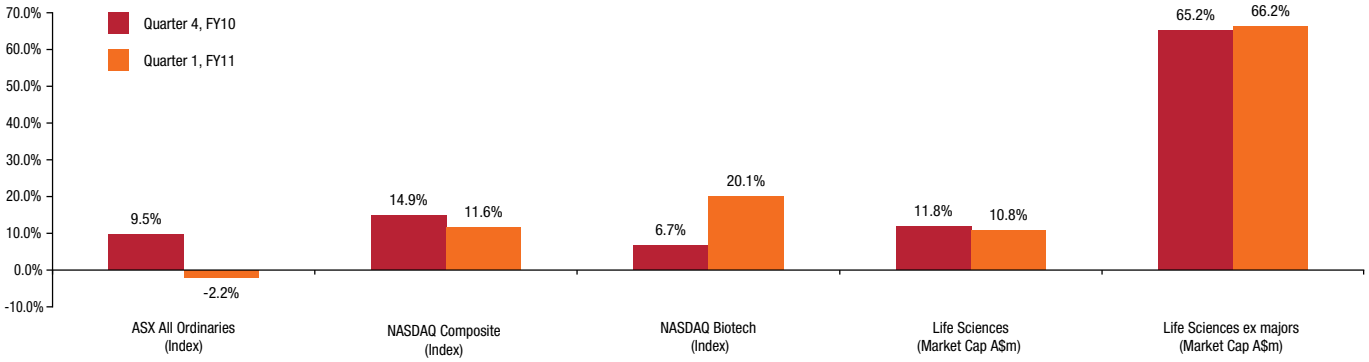


Table 2: Yearly movements of the Australian life sciences sector by market capitalisation compared to major indices

	Value			Value		
	30-Jun-09	30-Jun-10	% Change	30-Sep-09	30-Sep-10	% Change
ASX All Ordinaries (Index)	3,948	4,325	9.5%	4,739	4,637	-2.2%
NASDAQ Composite (Index)	1,835	2,109	14.9%	2,122	2,369	11.6%
NASDAQ Biotech (Index)	750	800	6.7%	745	895	20.1%
Life Sciences (Market Cap A$m)	30,115	33,671	11.8%	30,115	33,381	10.8%
Life Sciences ex majors (Market Cap A$m)	3,678	6,078	65.2%	3,678	6,114	66.2%

Figure 4: Quarterly performance of the Australian life sciences sector and subsectors (Quarter 4 FY10)

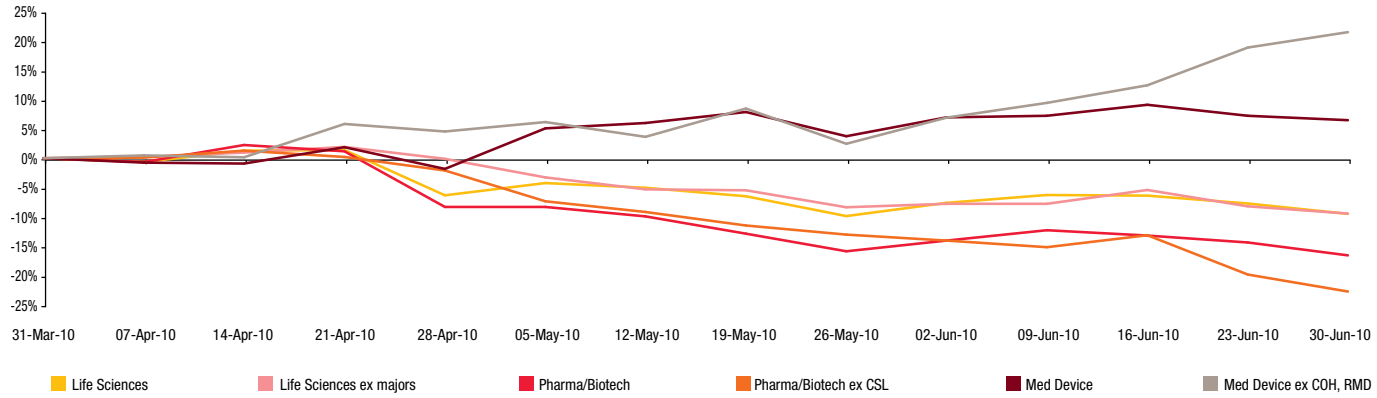


Figure 5: Quarterly performance of the Australian life sciences sector and subsectors (Quarter 1 FY11)

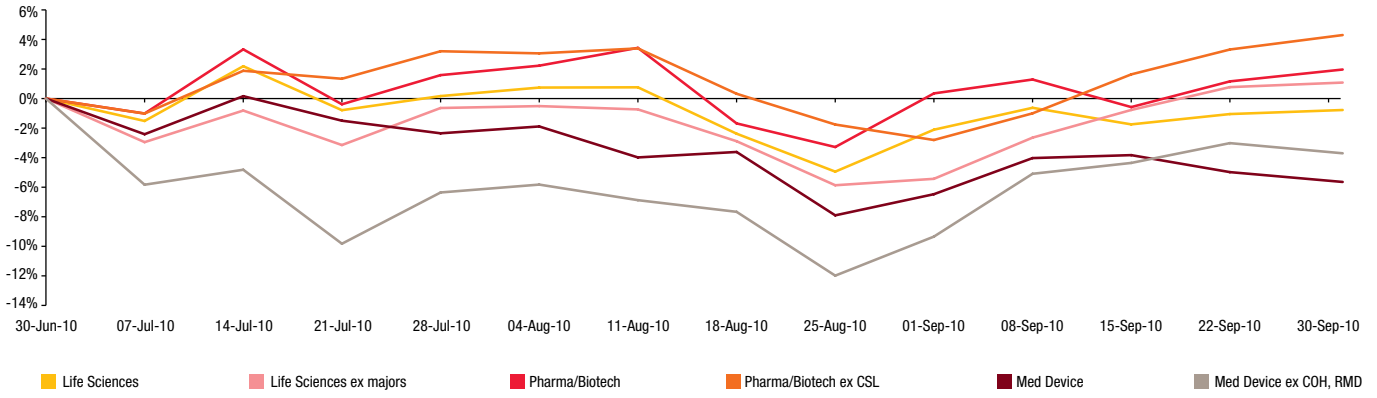


Table 3: Quarterly summary of the Australian life sciences sector's performance (Quarter 4 FY10)

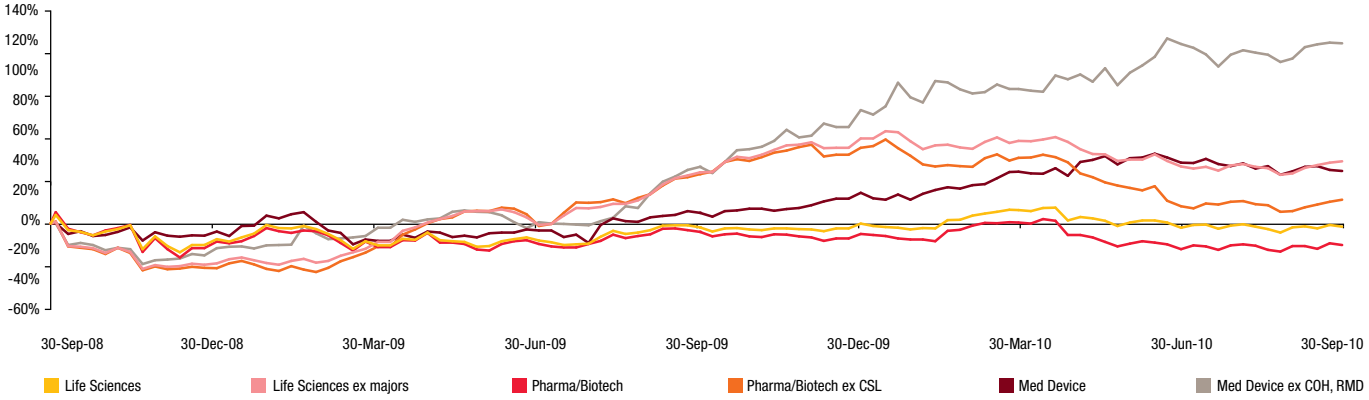
	MCap (A$m)	% of total value	Companies with share price gains	Proportion of subsector up	Companies with share price losses	Proportion of subsector down	Companies with share price flat	Proportion of subsector flat	Total number of companies
Pharma/Biotech	21,533	64%	5	8%	56	85%	5	8%	66
Pharma/Biotech ex CSL	3,624	60%	4	6%	56	86%	5	8%	65
Med Device	12,138	36%	10	25%	27	68%	3	8%	40
Med Device ex COH, RMD	2,454	40%	8	21%	27	71%	3	8%	38
Life Sciences	33,671	100%	15	14%	83	78%	8	8%	106
Life Sciences ex majors	6,078	100%	12	12%	83	81%	8	8%	103

Table 4: Quarterly summary of the Australian life sciences sector's performance (Quarter 1 FY11)

	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
Pharma/Biotech	21,950	66%	27	41%	34	52%	5	8%	66
Pharma/Biotech ex CSL	3,773	62%	26	40%	34	52%	5	8%	65
Med Device	11,431	34%	13	33%	22	55%	5	13%	40
Med Device ex COH, RMD	2,341	38%	13	29%	20	58%	5	13%	38
Life Sciences	33,381	100%	40	38%	56	53%	10	9%	106
Life Sciences ex majors	6,114	100%	39	36%	54	54%	10	10%	103

Performance overview (cont.)

Figure 6: Two-year comparison of the Australian life sciences sector's performance by market cap



Graph 3: Quarterly movements of the Australian life sciences sector and subsectors by market cap

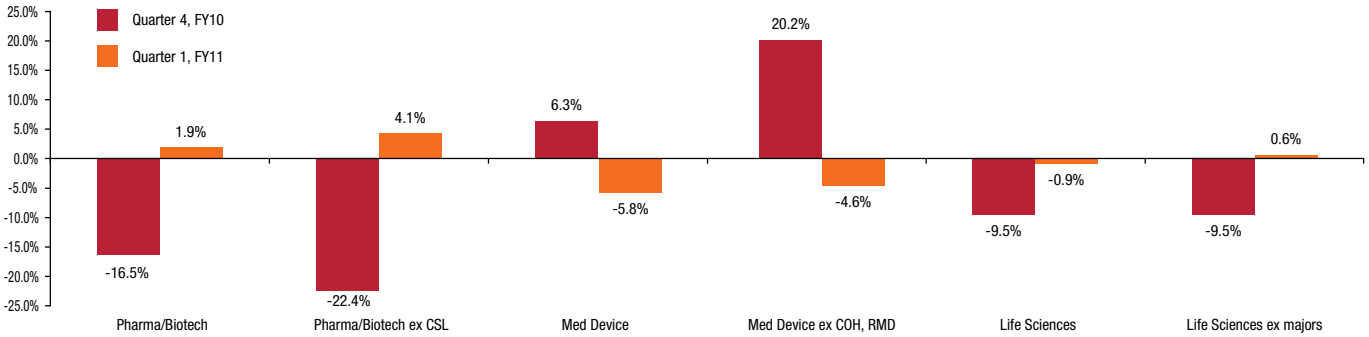
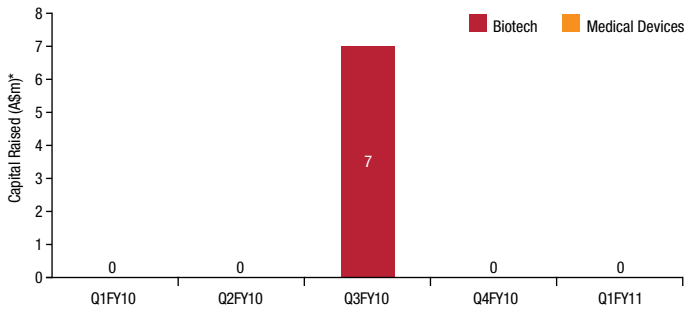


Table 5: Quarterly movements of the Australian life sciences sectors

	Market Capitalisation (A$m)				
	31-Mar-10	30-Jun-10	30-Sep-10	% Change (Mar-Jun)	% Change (Jun-Sep)
Pharma/Biotech	25,790	21,533	21,950	-16.5%	1.9%
Pharma/Biotech ex CSL	4,672	3,624	3,773	-22.4%	4.1%
Med Device	11,421	12,138	11,431	6.3%	-5.8%
Med Device ex COH, RMD	2,042	2,454	2,341	20.2%	-4.6%
Life Sciences	37,211	33,671	33,381	-9.5%	-0.9%
Life Sciences ex majors	6,714	6,078	6,114	-9.5%	0.6%

Quarterly financing

Figure 7: Quarterly comparison of IPOs in Australia



** Amount shown is total market cap addition to the Life Science Index from IPOs on first day of trading*

Table 6: Number of Australian IPO listings

	Biotech	Med Devices	ASX
Q1FY11	0	0	9
Q4FY10	0	0	16
Q3FY10	1	0	7
Q2FY10	0	0	27
Q1FY10	0	0	3

Figure 8: Quarterly comparison of IPOs in the US

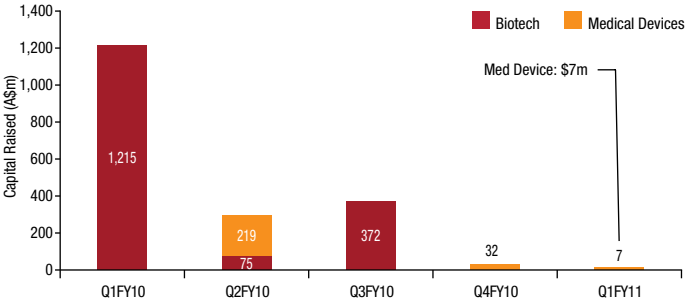


Table 7: Number of US IPO listings

	Biotech	Med Devices
Q1FY11	0	1
Q4FY10	0	1
Q3FY10	4	0
Q2FY10	1	1
Q1FY10	2	0

Table 8: Total of quarterly US IPO listings

Company	Quarter	Capital Raised (A$m)
Electromed Inc	Q1FY11	$7 million
GenMark Diagnostics Inc	Q4FY10	$32 million
Total		**$39 million**

IPO financing (cont.)

Yearly financing

Figure 9: Annual comparison of IPOs in Australia

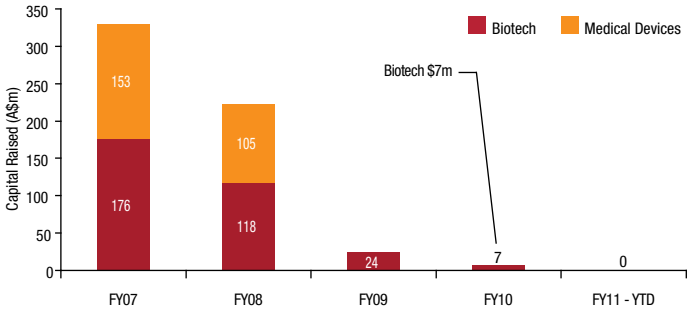


Table 9: Number of Australian IPO listings

	Biotech	Med Devices	ASX
FY11 – YTD	0	0	9
FY10	1	0	53
FY09	1	0	24
FY08	4	3	79
FY07	6	7	245

Figure 10: Annual comparison of IPOs in the US

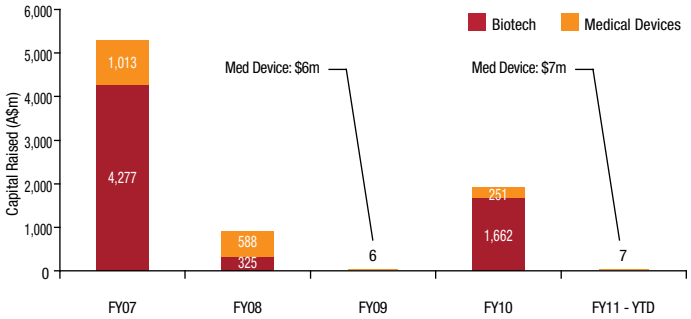


Table 10: Number of US IPO listings

	Biotech	Med Devices
FY11 – YTD	0	1
FY10	7	2
FY09	0	1
FY08	8	8
FY07	42	12

Secondary finance market

Quarterly financing

Figure 11: Quarterly comparison of secondary financing in Australia

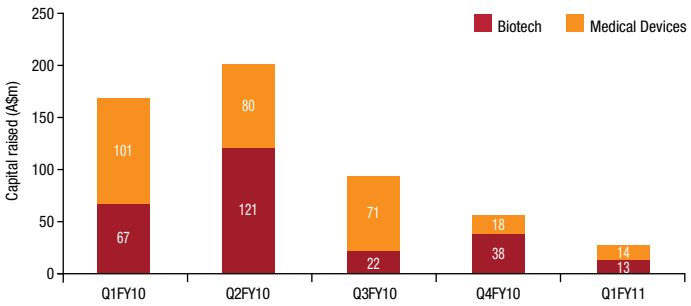


Table 11: Number of Australian secondary raisings

	Biotech	Avg. amount raised ($m)	Med Devices	Avg. amount raised ($m)
Q1FY11	31	0.4	11	1.3
Q4FY10	26	1.5	6	3.0
Q3FY10	18	1.2	4	17.9
Q2FY10	33	3.7	18	4.4
Q1FY10	30	2.2	11	9.2

Figure 12: Quarterly comparison of secondary financing in the US

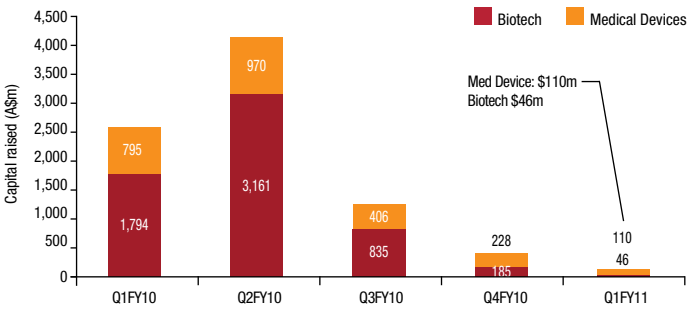


Table 12: Number of US secondary raisings

	Biotech	Med Devices
Q1FY11	2	9
Q4FY10	6	11
Q3FY10	47	13
Q2FY10	29	16
Q1FY10	40	17

Yearly financing

Figure 13: Annual comparison of secondary financing in Australia

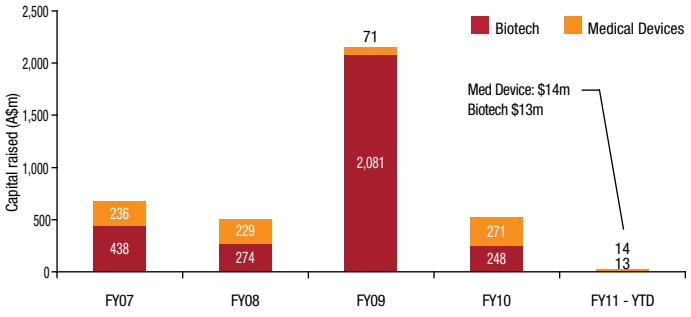


Table 13: Number of Australian secondary raisings

	Biotech	Med Devices
FY11 – YTD	31	11
FY10	107	39
FY09	87	41
FY08	99	66
FY07	98	75

Figure 14: Annual comparison of secondary financing in the US

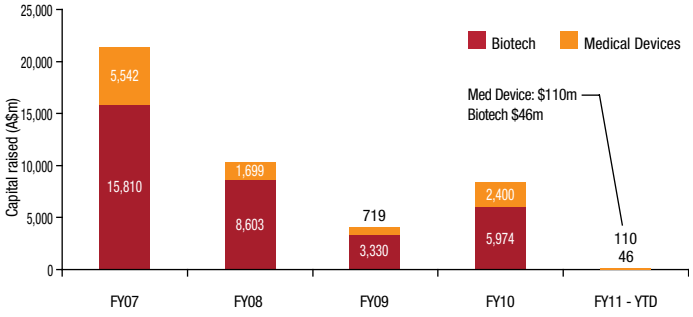
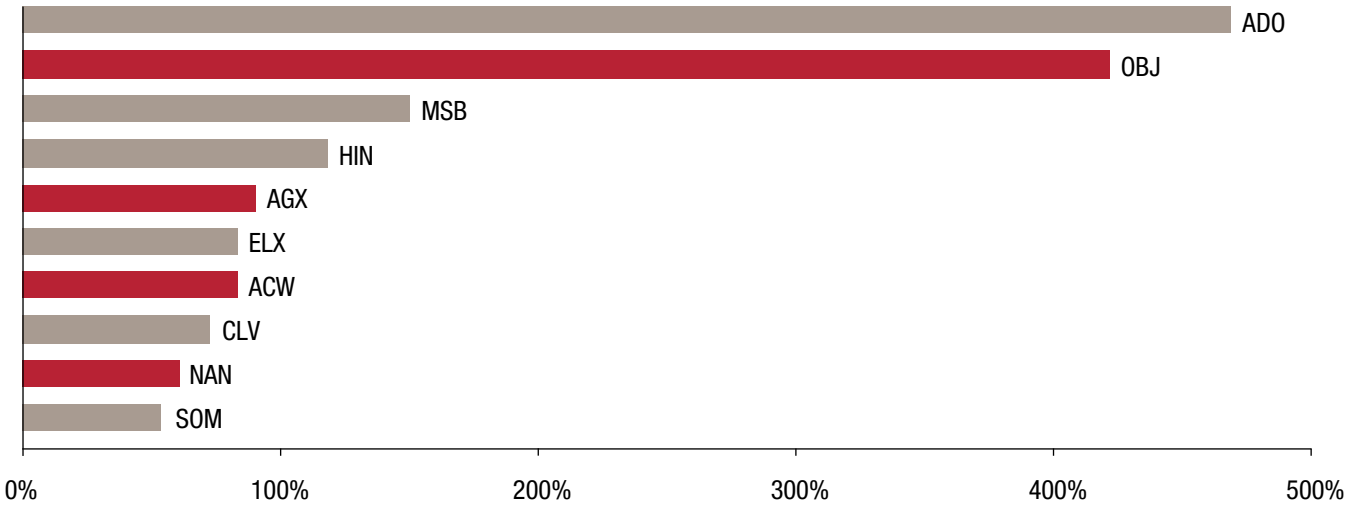


Table 14: Number of US secondary raisings

	Biotech	Med Devices
FY11 – YTD	2	9
FY10	122	57
FY09	48	24
FY08	80	29
FY07	258	59

Top 10

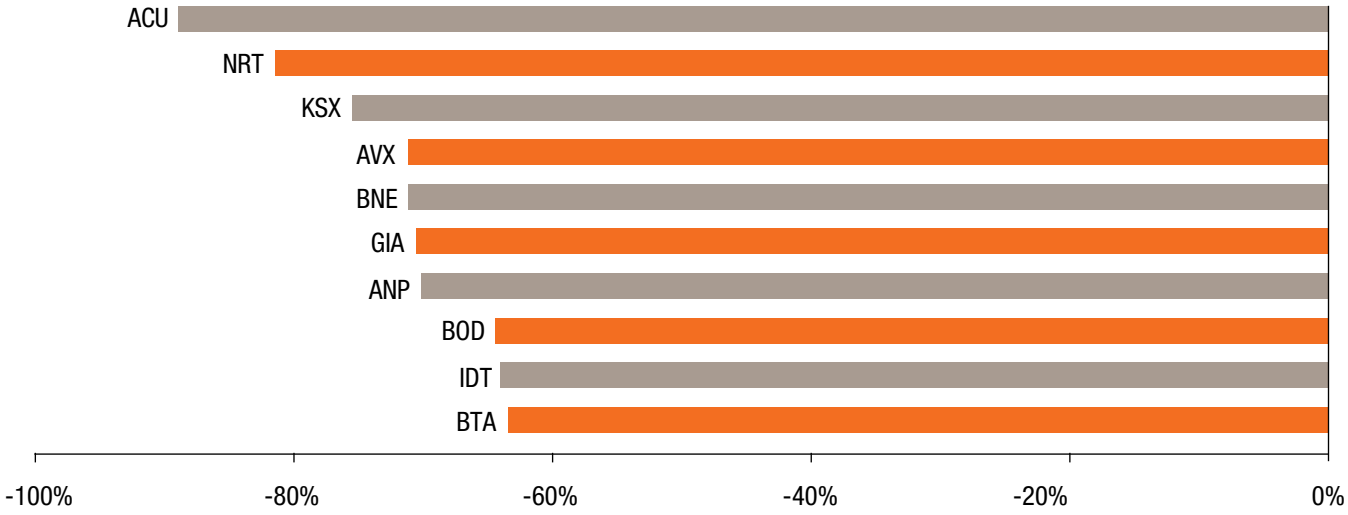
Performers over past four quarters



01 ANTEO DIAGNOSTICS LIMITED (ADO)	Return: 467% Closing price: $0.051 MCap: A$27.76m	Anteo announced that it has agreed on the terms of a four year supply agreement with Merck Chimie SAS to manufacture two new bead-based products for Merck to package and sell. The new product launch is anticipated within the next two months.
02 OBJ LIMITED (OBJ)	Return: 420% Closing price: $0.026 MCap: A$30.16m	OBJ has lodged six additional field of use patents covering the major commercial areas of interest to OBJ's partner companies.
03 MESOBLAST LIMITED (MSB)	Return: 150% Closing price: $2.570 MCap: A$398.20m	The company announced that it has received TGA regulatory approval to commercially manufacture adult stem cell products.
04 HEARTWARE INTERNATIONAL, INC (HIN)	Return: 118% Closing price: $2.090 MCap: A$991.52m	An application regarding data from Heartware's 'bridge-to-transplant' study was chosen by the American Heart Association late-breaking clinical trial session.
05 AGENIX LIMITED (AGX)	Return: 90% Closing price: $0.033 MCap: A$21.64m	On 30 June 2010, the company has received RMB 2.8m (approximately A$477k from its Chinese wholly owned enterprise in relation to a failed 2007 transaction. Total payments received now are RMB 20.9m (approximately A$ 3.6m).
06 ELLEX MEDICAL LASERS LIMITED (ELX)	Return: 83% Closing price: $0.330 MCap: A$28.02m	Profit of $3.6 million was announced as opposed to a guidance of $3.5 million.
07 ACTINOGEN LIMITED (ACW)	Return: 83% Closing price: $0.110 MCap: A$4.39m	The company announced that it has discovered a new method to produce Anacardic acid in pure form from an actinomycete, under defined culture conditions.
08 CLOVER CORPORATION LIMITED (CLV)	Return: 73% Closing price: $0.345 MCap: A$56.99m	Clover Corp announced that due to continued disappointing results of its 50% owned JV FFI, it has fully impaired its investment in, and loans advanced to, FFI. As at 30 June 2010 Clover's investment in FFI stood at $.07m and loans to FFI totalled $2.3m The JV partners have also decided to investigate options for the sale of FFI's business.
09 NANOSONICS LIMITED (NAN)	Return: 61% Closing price: $0.790 MCap: A$179.04m	The company announced a distribution agreement with GE Healthcare whereby GEHC will have exclusive rights to Nanosonics' Trophon EPR ultrasound probe disinfector and its consumables in USA and Canada. The agreement also provides GE Healthcare non-exclusive OEM co-sales of the Trophon EPR with GEHC ultrasound consoles in other countries outside the USA and Canada.
10 SOMNOMED (SOM)	Return: 57% Closing price: $0.940 MCap: A$37.90m	Somnomed announced revenue growth of 34% to $10.99m for 2010 bolstering the year end position to a profit of $788k compared with a $1.9m loss in the prior year.

Bottom 10

Performers over past four quarters



01 ACUVAX LIMITED (ACU)	Return: -87% Closing price: $0.003 MCap: A$2.50m	The company announced that Merck Sharp & Dohme made a successful bid for the HBI assets which the US bankruptcy courts have approved. While the terms of the deal are yet to be finalised, it has been reported that Merck Sharp & Dohme will pay US $3.1m A$3.5m.
02 NOVOGEN LIMITED (NRT)	Return: -83% Closing price: $0.125 MCap: A$12.77m	Novogen Limited's subsidiary Marshall Edwards announced the appointment of Christine A White, MD to its board of directors. Dr White replaces Professor Paul J Nestel, who has served as a director since April 2001.
03 KARMELSONIX LIMITED (KSX)	Return: -78% Closing price: $0.013 MCap: A$8.93m	The US FDA has granted 510k market clearance for the WHolterTM Recorder, the third acoustic respiratory monitoring product in the KarmelSonix product range, along with the PulmoTrack and the Personal WheezoMeter.
04 AVEXA LIMITED (AVX)	Return: -73% Closing price: $0.031 MCap: A$26.28m	Avexa engaged The Bioadvisory Group to undertake an independent review of its programs. The independent review will encompass existing drug development assets in Avexa's portfolio and will consider potential strategic options. In parallel with the independent review, Avexa is exploring options for its lead asset apricitabine.
05 BONE MEDICAL LIMITED (BNE)	Return: -73% Closing price: $0.055 MCap: A$5.42m	Bone Medical announced the signing of a non-binding convertible note facility worth $6 million.
06 GIACONDA LIMITED (GIA)	Return: -72% Closing price: $0.028 MCap: A$2.19m	The company announced that it has signed an agreement to sell its Myoconda, Heliconda and Picoconda patents to RedHill Biopharma Ltd.
07 ANTISENSE THERAPEUTICS LIMITED (ANP)	Return: -72% Closing price: $0.014 MCap: A$8.29m	Antisense reported that revenues were down 59.8% to $102,594 when compared with 30 June 2009.
08 BIOMD LIMITED (BOD)	Return: -70% Closing price: $0.021 MCap: A$2.71m	The company announced that Caroline Bentley has resigned as company secretary and Darren Bromley will succeed her.
09 INSTITUTE OF DRUG TECHNOLOGY AUSTRALIA LIMITED (IDT)	Return: -66% Closing price: $0.600 MCap: A$25.92m	The company appointed Mr Roman Najdecki as its new CFO. He has held senior financial roles for over 25 years and has extensive experience in an ASX environment, health and pharmaceutical sector. Outgoing CFO Mr Adrian McKenzie will continue at the company until the end of October to ensure a smooth transition.
10 BIOTA HOLDINGS LIMITED (BTA)	Return: -65% Closing price: $0.955 MCap: A$171.78m	The company announced the commencement of a phase II clinical trial of the antiviral drug BTA798 in patients with chronic asthma. BTA798 is orally administered and active against human rhinovirus, a virus often associated with the common cold.

04

Announcements

Australia
First quarter FY11

Partnerships

Company	Pharma/biotech partner	Application	Value (A$m)	Comments
Biotechnology			**Total**	**15**
Agenix Limited (AGX)	Institute of Medicinal Biotechnology (IMB) of the Chinese Academy of Medical Sciences	HIV	A$2.72m (RMB17m)	Collaboration to complete the regulatory requirements and obtain the product licence for AGX-1009.
Alchemia (ACL)	Dr Reddy	Marketing fondaparinux sodium for injection in all territories outside of North America	Dr Reddy's will pay Alchemia a royalty on sales at an agreed proportion	Alchemia announced the agreement of terms with Dr Reddy's Limited for marketing fondaparinux sodium for injection. This agreement does not in any way alter the existing arrangements between the companies for the manufacture and North American marketing of fondaparinux.
Avexa (AVX)	Shanghai Institute of Organic Chemistry (SIOC)	HIV	SIOC will bear all future development cost and Avexa will receive 50% of any net commercialisation revenues	The company announced that it has licensed one of its HIV integrase programs to its Chinese partner. Avexa to retain all development and marketing rights for the rest of the world.
Avita Medical Limited (AVH)	US Armed Forces	Treatment of scars and dispigmentation	US$1.8m	The goal of the program is to advance, "…technologies that return wounded personnel to active duty, restore their limb, muscular and skin form or function…" and includes the conduct of successful FDA clinical trials for those validated technologies. This contract recognises the contribution ReCell Spray-On Skin can make in the treatment of indications involving scarred, damaged or discoloured skin.
Calzada (CZD)	ATOS Wellness		Not disclosed	Calzada and ATOS Wellness have today terminated the conditional agreement under which Calzada was to invest $500,000 and vend its 100% owned subsidiary Metabolic Pharmaceuticals Pty Ltd, plus all intellectual property associated with Metabolic's drug development assets, into ATOS Wellness Ltd.
Circadian Technologies (CIR)	Cincinnati Children's Hospital Medical Centre (CCHMC)	LAM diagnosis	Not disclosed	This partnership will develop and market a blood test to diagnose LAM, a serious lung disease that strikes women, usually in their child bearing years.
Clinuvel Pharmaceuticals (CUV)	SurModics	Afamelanotide – Skin pigmentation induction	Not disclosed	Clinuvel Pharmaceuticals has entered into a long term manufacturing agreement with SurModics, a leading provider of drug delivery technologies to the healthcare industry.
HalcyGen Pharmaceuticals (HGN)	Pan-Malayan Pharmaceuticals	DORYX, ASTRIX and ERYC	Not disclosed	The company has signed a distribution agreement with Pan-Malayan Pharmaceuticals.
HealthLinx Limited (HTX)	Millipore Corporation	Monoclonal antibody	Not disclosed	The worldwide non-exclusive licence agreement allows Millipore to market and sell the monoclonal antibody for research purposes only, with upfront fees and royalties to flow back to HealthLinx.
Novogen (NRT)	Marshall Edwards	Isoflavone	Not disclosed	Novogen has reached an agreement with its subsidiary Marshall Edwards to acquire Novogen's entire isoflavone-related intellectual property portfolio in a stockbased transaction.
Prima BioMed (PRR)	Bioceros	Cancer	Not disclosed	Prima BioMed announced that its subsidiary, Oncomab Pty Ltd, has entered into a licensing agreement with Bioceros. The licensing agreement paves the way for the further development of Oncomab's technology to create a Cripto-1 mAB as an immunotherapy treatment for cancers.
Progen Pharmaceuticals Ltd (PGL)	Lund University in Sweden	Data from a joint research effort was published in the journal Anti-Cancer Drugs	Not disclosed	The study showed that PG11047 targeted the cancer stem cell population of this tumour line specifically by interfering with several stem cell-related properties, such as self-renewal, differentiation, motility, and the cancer related mesenchymal phenotype.

Company	Pharma/biotech partner	Application	Value (A$m)	Comments
QRxPharma (QRX)	Aoxing		Not disclosed	Strategic alliance with Aoxing in which Aoxing will fund clinical development of MoxDuo IV in exchange for exclusive marketing rights in China.
Select Vaccines Limited (SLT)	Artes		Not disclosed	Artes will acquire Select's Anavax virus-like-particle technology. Artes will offer the technology to clients primarily in conjunction with its proprietary yeast based expression systems.
Stirling Products Limited (STI)		Inflammatory and immunodeficiency conditions	Not disclosed	Stirling has agreed to proceed with a collaborative research study of its unique botanical immunomodulator, ImmunoXel, to be conducted at a US government institute.
Medical Devices			**Total**	**11**
Advanced Surgical Design and Manufacture (AMT)	AllVascular and its principal, Professor Rodney Lane	Saving limbs threatened with amputation due to gangrene	Not disclosed	Advanced Surgical Design and Manufacture has signed a landmark peripheral access device (PAD) licensing deal allowing ASDM direct access to an annual global market worth in excess of $5.0B.
Anteo Diagnostics (ADO)	Merck Chimie SAS		Not disclosed	Anteo has agreed on the terms of a four year supply agreement with Merck Chimie SAS to manufacture two new bead-based products for them to package and sell.
AtCor Medical (ACG)	Not disclosed		US$1.77m	The company signed a new agreement to supply SphygmoCor systems and clinical trial support services to a major international pharmaceutical company.
ATOS Wellness (ATW)	Calzada	The partnership will provide exposure to a drug which is targeted at providing a treatment obesity	Not disclosed	ATOS Wellness and Calzada have signed an agreement under which Calzada will invest $500k cash and vend into ATOS its 100% owned subsidiary Metabolic Pharmaceuticals Pty Ltd, plus all intellectual property associated with Metabolic's drug development assets, primarily focused on AOD9604.
ImpediMed (IPD)	US managed care organisation	For treatment of female breast cancer patients	Not disclosed	The company announced its first contract with a US managed care organisation for use of its L-Dex technology as an aid in the clinical assessment of lymphoedema in female breast cancer.
Medtech Global (MDG)	Zydacron Austria		Not applicable	Medtech Global and Zydacron Austria have signed a memorandum of understanding to represent Zydacron's tele-health products in the following countries: Australia, New Zealand, South east Asia and South Africa.
Medtech Global (MDG)	Datam Ltd		NZ$1m	An agreement to provide software services in relation to an important national health project for the Ministry of Health in New Zealand.
Nanosonics (NAN)	GE Healthcare (GEHC)	Not disclosed	Not disclosed	The company announced a distribution agreement with GE Healthcare.
OBJ Limited	FMCG Company	Drug delivery technologies	Not disclosed	For the design and development of a range of consumer products incorporating OBJ's micro-array and FIM drug delivery technologies.
Sunshine Heart (SHC)	Hydrix Services and Design + Industry	Cardiac care	Not disclosed	The company has entered into joint development programs with two leading Australian-based international firms to develop a smaller, quieter and lighter single-control system for use in a US clinical trial.
Cogstate (CGS)	Quixole		Not disclosed	The company has officially launched Axion Sports, its joint venture with Quixote Investment.

Mergers, acquisitions and divestments

Dominant company	Target company	Type of deal	Value (A$m)	Comments
Biotechnology			**Total**	**4**
Giaconda (GIA)	RedHill Biopharma	Divestment	Not disclosed	The company announced that it has signed a contract to sell its Myoconda, Heliconda and Picoconda patents to RedHill Biopharma Ltd.
Mesoblast (MSB)	Angioblast Systems	Acquisition	Not disclosed	The company approved the acquisition of its United States associate company, Angioblast Systems Inc.
Stirling Products (STI)	TeleMedCare Holdings	Acquisition	$7m	Stirling Products announced that it has acquired a 65% controlling interest in TeleMedCare Holdings Pty Limited.
Stirling Products (STI)	Halcion Pty Ltd	Acquisition	$3.3m	The company announced that it has conditionally acquired the business and assets of Halcion Pty Ltd.
Medical Devices			**Total**	**6**
AquaCarotine (AQL)	Farmacule BioIndustries	Merger	Not disclosed	AquaCarotine announced that the settlement of the Aurora transaction was finalised.
ATOS Wellness (ATW)	Metabolic Pharmaceuticals	Acquisition and divestment	Not disclosed	The company has divested itself of several dormant entities and proposed the aquisition of Metabolic Pharmaceuticals.
CathRx (CXD)	AscaMed Gmbh	Acquisition	Not disclosed	CathRx's partner Pioneer Medical devices has acquired AscaMed Gmbh.
Eastland Medical Systems (EMS)	Narson Pty Ltd	Divestment	$294k	Eastland Medical Systems has accepted an unconditional offer for its Portland Surgical Products Ltd property from Narson Pty Ltd.
Medical Australia (MLA)	Care Essentials	Acquisition	$3.9m	Medical Australia has signed contract to buy Care Essentials.
NeuroDiscovery (NDL)	Neurosolutions	Sale of subsidiary	Not disclosed	The sale of the wholly owned subsidiary Neurosolutions has been completed with the receipt of funds and the transfer of securities now finalised.

Clinical trials

Company	Drug	Application	Comments
Pre-clinical		**Total**	**1**
Agenix Limited (AGX)	AGX-1009	Hepatitis B	AGX received independent confirmation that AGX-1009 does not inhibit Cytochrome P450 at concentrations well above its likely effective antiviral dose.
Phase I		**Total**	**1**
Immuron (IMC)	Bovine colostrum powder, Imm122-I and Imm124-E	For the treatment of the liver disease non alcoholic steatohepatitis (NASH)	The company reported successful results of an open label phase I/II clinical trial of two oral formulations of hyper-immune bovine colostrum powder, Imm122-I and Imm124-E. Immuron is working towards an FDA compliant multisite trial.
Phase II		**Total**	**3**
Living Cell Technologies (LCT)	Diabecell	Insulin dependent diabetes	The company announced following results from its Diabecell clinical trial :- (1) 8 patients in New Zealand have received Diabecell implants according to schedule, (2) All 4 patients given 10,000 islet equivalents/kg showed reduction in episodes of clinically significant hypoglycaemia (low blood glucose), (3) Improved blood glucose control shown with reduction in insulin requirements, and (4) Second group of 4 patients have received 15,000 IEQ/kg.
QRxPharma (QRX)	MoxDuo IV	For the treatment of moderate to severe post-operative pain in patients following hip replacement surgery	QRxPharma announced positive phase 2 proof-of-concept data for MoxDuo IV.
Virax Holdings (VHL)	VIR201 immunotherapy vaccine	For treatment of HIV	The company announced the following achievements in relating to VIR201 clinical trial :- (1) Final Data Safety Monitoring Board meeting completed, (2) Immunological analysis and database lock being finalised, (3) Increased dose of more highly purified vaccine utilised in trial to boost the immune response and (4) Peer reviewed paper to be published in AIDS Journal.
Phase III		**Total**	**2**
Clinuvel Pharmaceuticals (CUV)	Scenesse	Phototoxic reactions following exposure to sun and light	The company announced that it obtained positive results in a study which investigated Scenesse (afamelanotide) as a systemic photoprotectant in a 12 month, multicenter, randomised, double-blind, placebo controlled phase III crossover study (CUV017) in erythropoietic protoporphyria (EPP).
Chemgenex Phamaceuticals Ltd (CXS)	Omapro	Chronic myeloid leukemia (CML)	Initial indications are promising with two completed phase 2/3 clinical trials with 103 and 100 patients respectively.
Other		**Total**	**14**
Actinogen (ACW)	Anacardic acid	Anacardic acid is used in various industries	The company announced that it has discovered a new method to produce anacardic acid in pure form from an actinomycete, under defined culture conditions.
BioDiem Limited (BDM)	BDM-E	Retinitis pigmentosa	The US FDA granted orphan drug designation to BDM-E. Preclinical work has demonstrated BDM-E's potential for the treatment of retinitis pigmentosa.
Biotron (BIT)	BIT225	To prevent HIV infection	The company announced that as per the latest data available, its investigational drug BIT225 has the potential to prevent the establishment of HIV infection in the first cells to encounter the virus at the point of infection.
HeartWare International		Patients with end–stage heart failure	The company's bridge–to–transplant study had been chosen by the American Heart Association for a clinical trial session.
NeuroDiscovery (NDL)	NSL – 101 and NSL – 043	Used in dental pain	The company announced that :- (1) NSL-101 has successfully completed a phase II trial, and (2) NSL-043 has successfully completed two phase I trials, and (3) NSL-043 and NSL-101 have consistently demonstrated results in 'gold standard' models of pain.

Company	Drug	Application	Comments
Prima BioMed (PRR)	CVac	Ovarian cancer	The company announced that first patient has been enrolled in a phase IIb clinical trial of the cancer therapy vaccine. The randomised trial will be conducted with 60 patients across multiple global clinical sites wwand clinical assessments will be performed every 4 weeks and imaging via CT or MRI will be performed every 12 weeks.
ResMed (RMD)	CPAP device	Sleep apnoea	The company announced the results of a clinical study confirming efficacy of ResMed's new CPAP device. The study showed an improvement of 30 minutes in average daily usage, from a mean of 6 hours 35 minutes on the patient's usual CPAP device, to 7 hours 5 minutes, when using the new S9 Series.
Sirtex Medical (SRX)	Resirt therapy	Primary kidney cancer	The company announced that it would invest in a new clinical study in relation to the treatment of primary kidney cancer. This new study will be the first time in the world the therapy has been used to treat cancer tumours outside the liver.
Sirtex Medical (SRX)	SIR-Spheres microspheres	Inoperable liver cancer	The company announced that the results of two independent studies done in Belgium and Italy and published, reconfirmed that there are significant clinical benefits from the use of targeted radioactive SIR Spheres® microspheres as an effective option for patients with inoperable liver cancer.
Stirling Products (STI)	ImmunoXel	Immunomodulator in the treatment of TB and HIV	The company announced that ImmunoXel continues to demonstrate breakthrough performance as an HIV therapy in US studies.
Sunshine Heart (SHC)	C-Pulse Heart Assist System	Moderate heart failure caused by a failing left ventricle	The company announced that its C-Pulse Heart Assist System has been successfully implanted using a minimally invasive thoracotomy procedure at a leading US hospital.
Tissue Therapies Limited (TIS)	VitroGro	Treatment of chronic venous leg ulcers	Additional results bring the Australian human venous ulcer trial to a total of 30 patients. When the clinical data for the last 3 patients are included, the overall trial results show average venous ulcer healing of 43%.
Tyrian Diagnostics Limited (TDX)	TB Marker	Diagnostic test to detect active TB	TDX has developed an assay using existing molecular technology for direct detection of its lead TB diagnostic marker in sputum samples. For this performance study, analysis of 33 clinical sputum samples positive for active TB infection showed Tyrian's RNA marker to have greater sensitivity compared to the current gold standard marker (16S RNA) for diagnosis of active TB.
Viralytics Limited (VLA)	Cavatak	Treatment of malignant glioblastoma – the most common type of primary brain cancer	Research developments suggest that the anti-cancer activity of a single dose of Cavatak is clearly demonstrated with the elimination of most tumours in mice.

Regulatory

Company	Product	Application	Comments
Biotechnology		**Total**	**11**
Benitec Limited (BLT)	Patent progress	Not applicable	CSIRO and BLT have received a Notice of Allowance issued by the United States Patent and Trademark Office (USPTO) reversing all rejections in the '099 Graham patent appeal.
Benitec Limited (BLT)	Successful patent grant	Not applicable	US patent application for RNAi Expression Constructs has been granted by the United States Patent and Trademark Office (USPTO). The grant covers an RNAi construct solely owned by Benitec with a single promoter for targeting Hepatitis C virus to inhibit the level of Hepatitis C virus in cells, tissues and organs.
BioDiem Ltd (BDM)	Live Attenuated Influenza Vaccine	For the treatment of influenza	BioDiem announced that its lead product, the Live Attenuated Influenza Vaccine (LAIV), has been granted regulatory approval for marketing in India. NasoVac was launched by the Indian vaccine company the Serum Institute of India.
Biota Holdings Limited (BTA)	Inavir	For the treatment of influenza in adults and children	Daiichi Sankyo has received approval to manufacture and market Inavir in Japan. It will be formally launched on 19 October 2010.
Circadian Technologies Limited (CIR)	Patent progress	Not applicable	CIR announced that its subsidiary company, Vegenics Limited, has been granted US Patent 7785803 claiming diagnostic kits for the detection of VEGF-D in human samples such as blood. VEGF-D, a major novel target for cancer and other diseases, has been shown to be a prognostic indicator of survival or disease progression in a number of different cancer types as well as a biomarker for various respiratory diseases.
Mesoblast (MSB)		Not applicable	The company announced that it has received TGA regulatory approval to commercially manufacture adult stem cell products.
Patrys (PAB)	PAT-PM1	Not applicable	The company announced that it has been granted a United States patent for lead product PAT-PM1.
Patrys (PAB)	Change in Executive management team	Not applicable	The company announced the appointment of Dr Marie Roskrow as chief medical officer and president.
Prana Biotechnology (PBT)	PBT2	Not applicable	The company announced that it has secured key PBT2 patents in Europe and the United States. Patents support pipeline opportunities for PBT2 in AD and HD.
Prima BioMed Ltd (PRR)	CVac	Ovarian cancer	CVac has been granted orphan medicinal product designation with the US Food and Drug Administration (FDA).
Stirling Products (STI)	R-Salbutamol	Obesity	The company announced that it has received a patent from the Australian Patents Office for its R-Salbutamol obesity drug candidate.
Medical Devices		**Total**	**4**
HeartWare International (HIN)	HeartWare's Advance clinical trial	Patients with end-stage heart failure	The company announced the US FDA has approved an Investigational Device Exemption Supplement that allows HeartWare to enroll a second allotment of 54 patients in its bridge-to-transplant clinical trial.
KarmelSonix (KSX)	FDA approval	Not applicable	The company announced that the FDA has granted 510k market clearance for the WHolterTM Recorder, the third acoustic respiratory monitoring product in the KarmelSonix product range, along with the award winning PulmoTrack and the Personal WheezoMeter.
Medigard (MGZ)	3mL Safety Vacuum Retractable Syringe	Not disclosed	The company announced that its patent application in the Republic of South Africa for its 3mL Safety Vacuum Retractable Syringe has now been granted. This provides Medigard with exclusive patent protection in South Africa until March 2027.
Unilife Corporation (UNI)	Unitract 1mL Tuberculin Syringe	Drug delivery	The company announced that it has received 510(k) market clearance for its TB syringes from the FDA.

Other news

Company		Comments
Biotechnology	**Total**	**49**
Actinogen (ACW)	Increased levels of production	ACW has been scaling up batch fermentation cultures, producing pure Anacardic acid from a starch base. It is investigating the possibility of increasing both volume and yield with ongoing work.
Acrux (ACR)	Update on female health care products	The company provided an update on its female health products, including the estradiol spray to treat menopause symptoms, the testosterone spray for hypoactive sexual desire disorder and the contraceptive products.
Acuvax (ACU)	Value of US$3.1m (A$3.6m)	The company announced that Merck Sharp & Dohme has made a successful bid for the HBI assets. This bid has been approved by the US Bankruptcy Courts.
Agenix (AGX)	Agenix recoveries in China continue	On 30 June 2010, the company has received RMB 2.8m (approximately A$477k) from its Chinese wholly owned enterprise in relation to a failed 2007 transaction. Total payments received now are RMB20.9m (approximately A3.6m).
Antisense (ANP)	Resignation	Kate Plumridge has resigned from the post of joint company secretary.
Avexa (AVX)	Results of 6 July 2010 General Meeting	Following are the results of the general meeting held on 6 July 2010: (i)Removal of Nathan Drona as chairman and director, (ii) Appointment of Steven Crowley as a director, (iii) Appointment of Bruce Hewett as a director, (iv) Removal of additional directors. (v) Further on 07/07/2010, the board re-appointed Joe Baini to the board, in the role of non-executive chairman.
Avexa (AVX)	Board appointments	The company announced that it has appointed Bruce Hewett and Steven Crowley as non-executive directors at its AGM.
Avexa (AVX)	Resignation of director	David Bottomley has resigned as non-executice Director of the company.
Avexa (AVX)	Board appointments	The company announced the appointments of Dr Jonathan Coates to the role of chief scientific officer and interim CEO and Jet Soedirdja to the board as a non-executive director.
Avexa (AVX)	Board appointment	The company announced the appointment of Mr Iain Kirkwood as a non executive Director.
Avita (AVH)	New Appointments	The company announced the appointment of Andrew Quick as vice president of Research and Technology. Quick
BioDiem Limited (BDM)	Technology featured at conference	The company's Live Attenuated Influenza Vaccine (LAIV) technology for H5N1 (avian) influenza has featured at the Options for the Control of Influenza VII conference in Hong Kong. This conference is the largest international conference devoted exclusively to influenza, covering topics from basic science to health care policy.
BioDiem Limited (BDM)	Appointment	The company appointed Cathy Cropp as projects manager. Her primary responsibilities will be managing the LAIV vaccine vector and BDM-I antimicrobial projects.
BioProspect (BPO)	Update on development agreement with Solagran Ltd	The company announced that it had sought clarification from Solagran in relation to their statement about the Agreement being "in dispute" by way of a formal letter. The directors wish to advise that there has been no response from Solagran up to the date of this letter and are disappointed with their lack of response.
BioProspect (BPO)	Update on legal dispute with Solagran	BioProspect has served a notice on Solagran Ltd of a dispute in connection with the development agreement between them. This is the first step in the dispute resolution process prescribed by the agreement.
BioProspect Limited (BPO)	Resignation	The directors of BPO announced the resignation of non-executive director Leo Elias Khouri after careful consideration and in regards to the current dispute with Solagran Limited.
Biota Holdings (BTA)	Royalties from Relenza for Q4 and F2010	The company announced that it had received written notification from GlaxoSmithKline that indicative royalties from Relenza were $0.9m during the three months ended 30 June 2010, on sales of $12.8m.
CBio Limited (CBZ)	Resignation	Dr Dennis Feeney has resigned as an executive of CBio with effect from 30 September 2010. Dr Feeney will remain on the board as a non-executive director and will provide consulting services to CBio on an ad-hoc basis.

Company		Comments
Clinuvel Pharmaceuticals (CUV)	Resignation	The company announced that Dr Roger Aston has resigned as non-executive director effective September 1.
Clinuvel Pharmaceuticals (CUV)	Strategic update	The company announced several material changes in its operational activities and an expansion of its development program with the launch of a new proprietary molecule, CUV9900.
Genesis Research and Development Corporation Ltd (GEN)	Cash settlement	In 2007 arranged immediate cash payment of $1.9m and future payment of $2m for Pure Power Global (PPG) to acquire the Genesis shareholding in BioJoule Ltd. In March 2010 Genesis agreed to accept a significantly reduced amount. PPG has now settled the outstanding debt and acquired the PPG shares held by GEN for a further payment of $350k which has been paid to GEN.
Halcygen Pharmaceuticals (HGN)	Board change	The company announced that executive director and COO Craig Bottomley has resigned and Lisa Pendlebury would assume the role of investor relations manager.
HalcyGen Pharmaceuticals (HGN)	New management team	The company announced that it has appointed Stuart Mudge, PhD as global regulatory and clinical affairs manager. Dr Mudge has more than 10 years of industry experience in regulatory affairs across European, USA and Australasian markets.
HealthLinx Limited's (HTX)	New distribution base and launch	HTX has signed an exclusive OvPlex licence agreement with Medison Pharma Limited, a leading Israeli marketing company, which will endeavour to register and commercialise OvPlex in Israel.
Hexima (HXL)	New appointment	The company announced the appointment of Ross Dobinson as executive chairman.
Holista Colltech Limited (HCT)	CEO Appointment	The company finalised the appointment of Dato Dr M Rajen as CEO of the company and its subsidiaries.
Holista Colltech Limited (HCT)	Awards received	One of the members of the scientific advisory board Professor Jeya Henry has won two major awards – the 2011 British Nutrition Foundation prize and the Rank Prize Nutrition Lecturer for 2011.
Holista Colltech Limited (HCT)	Patent lodged	HCT has filed a patent that will reduce the absorption of fat when cooking potato fries. The patent is supported by extensive data and trials, which consistently show the "fat pull" into potato fries is reduced by 40%.
Institute of Drug technology Australia Limited (IDT)	CFO appointment	The company appointed Roman Najdecki as its new CFO. Outgoing CFO Adrian McKenzie will continue at the company until the end of October to ensure a smooth transition.
Living Cell Technologies (LCT)	Board appointments	The company announced the appointment of Dr Ross Macdonald to the new position of managing director. Dr Macdonald will work closely with NZ CEO Dr Paul Tan as the company drives to commercialise its lead product Diabecell.
NeuroDiscovery (NDL)	Board changes	The company announced that David McAuliffe resigned as executive director and it appointed Neville Bassett replacement.
Novogen Limited (NRT)	Board change	Novogen Limited's subsidiary, Marshall Edwards, announced the appointment of Christine A White, to its board of directors. Dr White replaces Professor Paul J Nestel, who has served as a director since April 2001.
Novogen Limited (NRT)	Appointment of new directors	The company appointed three new directors – two based in the US and one based in Ross Youngman, Peter White and Josiah T Austin.
Pharmaxis (PXS)	Appointment of acting CEO	The board has appointed Pharmaxis COO, Gary Phillips to the position of acting CEO.
Pharmaxis (PXS)	European marketing deal	The company announced that it has finalised a strategic marketing and sales service agreement for the commercialisation of Bronchitol for cystic fibrosis in Europe.
Phosphagenics (POH)	New Board Appointments	The company has announced the appointment of Stuart James, Sandra Webb and Don Clarke as non-executive directors.
Phylogica (PYC)	Board change	Following the appointment of Nick Woolf as a non executive director, A.P. Barton retired as a non executive director.
Prima BioMed (PRR)	Resignation	The company announced that Ata Gokyildirim, resigned as a director effective from 27 July 2010.
Prima BioMed (PRR)	Board appointments	The company has announced the following appointments (i) Chief medical officer Dr Neil Frazer was appointed as an executive director, (ii) Martin Rogers, Prima's CEO, was reappointed as managing director and (iii) Albert Wong, who was appointed a non-executive director of Prima, was appointed interim chairman.
Prima BioMed (PRR)	Appointment of new senior vice president	The company appointed Dr Sharron Gargosky as senior vice president

Company		Comments
QRxPharma (QRX)	Award for innovation	The company has been awarded the 2010 North American Frost & Sullivan Award for New Product Innovation of the Year for its lead compound MoxDuo IR.
RGM Media (RGM)	Board change	Tim Boyd has resigned as a director and Andrew Hosking has been appointed as a director in his place.
Select Vaccines (SLT)	Appointment of new directors	Messrs Ian Macliver, Mark Titchener and Phil Warren will be joining the board as independent non-executive directors. Ian Macliver was appointed as chairman of Select Vaccines.
Solagran (SLA)	Board change	The company announced that Mr Branko Jovanovic, CEO of Solagran, has resigned as CEO and from the board of the company and David Croll has been invited to join the board as finance director.
Starpharma Holdings (SPL)	New appointments	Malcolm McColl will join the company's business development team as a vice president.
Stirling Products (STI)	New appointments	The company appointed Alan Payne as the interim group CEO and business development manager.
Stirling Products (STI)	TeleMedCare pilot	The company announced that a significant pilot of specialist Health Clinics within two flagship stores of one of the largest pharmacy chains in the UK is underway using the market-leading clinical grade vital signs TeleMedCare telemedicine units. This pilot phase will assess the effectiveness and benefits of the multi-awarded TeleMedCare units from a client, clinical and commercial perspective.
Stirling Products (STI)	New appointment	The company announced that Alan Payne has been appointed as the group CEO and business development manager.
Virax Holdings (VHL)	Results from VIR201 HIV vaccine phase I/IIa clinical trial	The company announced that VIR201 did not meet its primary or secondary immunological endpoints, failing to elicit a statistically significant increase in immune response relative to the control group in both T-cell assay (ELIspot) and assays of antibody isotype. Also the company announced that it is pursuing a significant new clinical program.
Medical Devices	**Total**	**19**
Advanced Surgical Design and Manufacture (AMT)	Board appointment	The company announced the appointment of Michael Spooner as a director.
AquaCarotene (AQL)	Board changes	The company announced change to its board that following the Farmacule merger.
bioMD (BOD)	Change in company secretary	Caroline Bentley has resigned and Darren Bromley has been appointed as company secretary.
CathRx (CXD)	Change in board	The company announced the appointments of Dr Michael Hirshorn and Dr Colin Adam as non-executive directors and the retirement of Andrew Denver.
CogState (CGS)	Change in Company Secretary	The company announced that Claire Newstead-Sinclair has been appointed as company secretary replacing Lauren Delaney.
CogState (CGS)	New appointments	The company announced the appointment of US life science investment manager Richard van den Broek to its board.
Genera Biosystems Limited (GBI)	Appointment of company secretary	Geoff Widmer has resigned and the company's CFO Mr Tony Panther has been appointed as company secretary.
ITL (ITD)	Change in management	Angelo Tsagarakis resigned as CFO.
ITL (ITL)	Board and management changes	The company announced the following changes: (i) William Leonard Mobbs has been appointed as director (ii) Sanjay Sehgal has been appointed as a non executive director (iii) Roy Rose has resigned as a non executive director (iv) Brian Andrews has resigned as a director Management changes:- Brian Andrews has stepped down as CEO and William Mobbs will act as interim CEO while the company searches for a replacement.
ITL (ITL)	Director resignation	The company announced that Dr Mike Hirshorn's resignation will take effect immediately.
KarmelSonix (KSX)	Proposed restructure	The company announced a new CEO and a new board of directors.
Nanosonics (NAN)	Resignation of CFO	CFO and company secretary, Chris Grundy, has resigned.
Nanosonics (NAN)	Appointment	The company announced the appointment of Robert Waring as company Secretary.
NeuroDiscovery (NDL)	Board change	Dr Mark Treherne has resigned as non-executive chairman and Harry Karelis was appointed non-executive chairman.
Safety Medical Products (SFP)	Deed of company arrangement	A deed of company arrangements was entered into for recapitalisation and relisting of the company.

Company		Comments
SomnoMed (SOM)	Change in management	The company announced that EVP North America John Truitt had resigned for personal reasons. In the interim, Mr Barschow has assumed direct responsibility for the US business.
Unilife Corporation (UNI)	Appointment	The company has appointed Marc S. Firestone, executive vice president and general counsel for Kraft Foods, as a new independent director.
Unilife Corporation (UNI)	New appointments	The company has appointed Christopher Naftzger as general counsel, corporate secretary and chief compliance officer.
Universal Biosensors (UBI)	Board change	Mr Morrisson announced his decision to retire as CEO of the company and to resign from the board.

Announcements

Australia
Fourth quarter FY10

Partnerships

Company	Pharma/biotech partner	Application	Value (A$m)	Comments
Biotechnology			**Total**	**6**
Hawkley Oil & Gas Limited (formerly Incitive limited)	Cygnet Capital Pty Limited & Janita Global Limited	Implementation agreement	Not disclosed	Hawkley has signed and completed the implementation agreement with Cygnet and Janita.
Prana Biotechnology Limited	Quintiles		US$2m	Prana has reached a clinical research agreement with Quintiles.
Probiotec (PBP)	Superdrug	Distribution agreement	Not Disclosed	SuperDrug will distribute Probiotec's Celebrity Slim meal replacement range.
Progen Pharmaceuticals Ltd	Medigen Biotech Corp.	Licence and collaboration agreement Cancer	Not disclosed	Progen has signed a licence and collaboration agreement with Medigen for the development and commercialisation of muparfostat.
Stirling Products (STI)	Kidney Health Australia	Address awareness of kidney related disease	$750k	Stirling Products announced that it had entered into a national partnership with Kidney Health Australia.
Stirling Products (STI)	Nature's Firewall Inc & Abbey Foods Limited		Canada	A partnership has been formed between STI, Abbey Doods and Nature's Firewall Inc, to develop a product combining honey and STI's botantical products.
Medical Devices			**Total**	**1**
Medigard (MGZ)	Manufacturer not disclosed. Distributer – Outcome Solutions	Blood collection	Not disclosed	The company has entered into 5 year manufacturing and distribution agreements that will commercialise its Blood Collection Device.

Mergers, acquisitions and divestments

Dominant company	Target company	Type of deal	Value (A$m)	Comments
Biotechnology			**Total**	**6**
Strides Acrolab Limited	Ascent Pharmahealth (APH)	Share acquisition	$0.35/share	APH has undertaken a preliminary assessment of the proposal of Strides to acquire outstanding minority shares in APH, at a price of $0.35 cash per share.
Giaconda Limited	Redhill Biopharma Limited	Binding term sheet	US$500k	Giaconda has signed a binding term sheet for the sale of Myoconda, Heliconda and Picoconda to Redhill.
Hawley Oil & Gas Limited (Formerly Incitive limited)	Not disclosed	Demerger	Not disclosed	Shareholders approved the demerger of the company's biotechnology assets, subject to various conditions.
Incitive Limited	Hawkley Oil & Gas Limited	Reverse takeover	$5.5m	Incitive completed their reverse takeover of Hawkley.
Mesoblast (MSB)	Angioblast Systems	Share acquisition	$24m	Mesoblast announced that it will acquire Angioblast Systems. A capital raising of $37m has been completed.
Probiotec (PBP)	Celebrity Slim brand	Brand acquisition	$3.8m	The company has acquired 50% of Celebrity Slim, resulting in 100% brand ownership.
Medical Devices			**Total**	**3**
Aquacarotene (AQL)	Farmacule Bioindustries	Merger	15m AQL shares	AQl has signed an agreement to merge with Farmacule Bioindustries.
Neurodiscovery Limited	University of Warwick	Sale of subsidiary	$850k	The wholly owned subsidiary of NeuroSolutions will be sold to the University of Warwick.
Safety Medical Products (SFP)		Liquidation		The administrators of the company have advertised for expressions of interest in the recapitalisation of Safety Med and/or purchase of its business and/or assets.

Clinical trials

Company	Drug	Application	Comments
Pre-clinical		**Total**	**0**
Phase I		**Total**	**1**
QRxPharma	MoxDuo	Chronic pain	QRxPharma has commenced the phase I clinical trial of MoxDuo.
Phase II		**Total**	**0**
Phase III		**Total**	**4**
Eastland Medical Systems Ltd (EMS)	ArTiMist	Malaria	Positive results have been announced from the recently completed phase IIa clinical trial of ArTiMist
Novogen (NRT)	Phenoxodiol	Recurrent ovarian cancer	NRT subsidiary Marshall Edwards announced that its phase 3 Ovature trial did not show a statistically significant improvement in its primary or secondary endpoints and hence the trial was closed.
Pharmaxis Ltd	Bronchitol	Cystic Fibrosis	Favourable top line results were produced in the phase III clinical trial of Bronchitol.
Prima BioMed	CVac	Ovarian cancer	Prima BioMed has been granted orphan drug designation in Europe for its lead product, the ovarian cancer therapy vaccine CVac.
Other		**Total**	**1**
Tissue Therapies Limited	Vitro Gro	Ulcers	Tiisue Therapies have released favourable results from a clinical trial of VitroGro.

Regulatory

Company	Product	Application	Comments
Biotechnology		**Total**	**5**
CSL (CSL)	Appendix 3E and 3F		CSL filed Appendix 3F informing the market that 54,863,000 shares were bought back for a total consideration of $1.775bn.
Genetic Technologies Limited	NASDAQ market regulations		Genetic Technologies has transferred its current listing to the current market to comply with NASDAQ listing rules.
Incitive (ICV)	Capital restructuring		ICV announced that should the shareholders approve the demerger of company's biotechnology assets, shareholders will receive 26.67 shares in Sarantis Ltd for every one share held in Incitive Ltd.
Pharmaxis (PXS)	Resubmission of new drug application		A new drug application for Aridol has been resubmitted to the FDA.
Progen Pharmaceuticals Limited	NASDAQ securities		Progen NASDAQ securities will be delisted due to a minimum bid price deficiency.
Medical Devices		**Total**	**2**
KarmelSonix Ltd	Approval of CPT codes	Respiratory monitoring technology	The American Medical Association has awarded 2 new Category III Current Procedural Terminology.
Unilife Corp	Lodgement of S-1		Unilife has lodged an S-1 resale registration statement with the US SEC.

Other news

Company			Comments
Biotechnology		**Total**	**40**
Acuvax (ACU)	Non-renounceable right issue		ACU shareholders have been offered a non-renounceable rights issue of one new share at $0.005 for every share to raise a maximum of $3.3 million.
Analytica (ALT)	Change of company secretary		Ben Graham has resigned and Jennie Yuen has been appointed in his place.
Apollo Consolidated (AOP)	Expiry of options		Apollo announced that 30,000 unlisted options over ordinary shares have expired unexercised.
Ascent Pharmahealth Ltd (APH)	Resignation		Dr Roger Aston resigned as a chairman of the Board and as a director of Ascent.
Avexa (AVX)	Changes in company's operations		The company announced the closure of its lead HIV program, resignation of its CEO resignation and a staff cut.
Avexa (AVX)	New appointment		Non-executive director Joe Baini has resigned and Uri Ratner has joined the board as an independent non-executive director effective.
Avita Medical (AVH)	Convertible note facility		Avita Medical has signed a convertible note facility with La Jolla Cove Investors, Inc. which will provide up to US$6m in funding.
Benitec (BLT)	Capital funding		Benitec has signed a convertible note facility with La Jolla Cove Investors to provide up to US$6m in funding.
Benitec (BLT)	New appointment		The company announced the appointment of Iain Ross to the board.
Benitec (BLT)	Appointment of CEO		Dr Peter French has been appointed CEO of Benitec.
BioDiem (BDM)	Changes in board		The following changes have been made to the board of directors:- (1) appointment of Julie Phillips (CEO), (2) appointment of Professor Arthur Li (non-executive director) and (3) the resignation of Dr John Brown (non-executive director).
BioProspect Limited	Resignation		Kamran Shamsi has formally resigned as non-executive director of the company.
Biotron (BIT)	New appointment		Dr Denis Wade has been appointed as a director of BIT.
Biotron (BIT)	Resignation		Peter G. Scott has resigned as a non-executive director.
Biosignal (BOS)	Consolidation of capital		The 25:1 consolidation of Biosignal's issued capital has been completed.
Bone Medical (BNE)	Appointment		Viriathus Capital has been appointed as investment banker, financial adviser and consultant to the company.
Circadian (CIR)	Resignation of CFO		Natalie Korchev has resigned as the CFO, head of operations and company secretary.
Circadian Technologies (CIR)	Appointment of company secretary		Susan Madden has been appointed as secretary of the company and its subsidiary companies.
Clinuvel Pharmaceuticals (CUV)	Appointment of chairman		Stan McLiesh, formerly general manager, has been appointed non-executive chairman.
Genesis Research and Development Corporation (GEN)	Retirement		Jim Mclean has retired from the board.
Genesis Research and Development Corporation (GEN)	Suspension of NZ operations		GEN has suspended operations in New Zealand due to lack of funding.
Genetic Technologies (GTG)	Appointment		Lewis Stuart was appointed as general manager of Genetic Technologies, North Amercian molecular diagnostics business.
Giaconda (GIA)	Termination of contract		Giaconda has terminated its asset purchase agreement for the sale of Myoconda to Australian Medical Therapy Investments Pty Limited.

Company		Comments
Hawkley Oil and Gas Limited (formerly Incitive Limited)	Appointment and resignation of key staff	The following staff were appointed: Paul Morgan (non-executive chairman), Richard Reavley (executive director and CEO), David Riekie (non-executive director), Ian Hobson (company secretary). The following staff resigned: Melvyn Bridges (executive chairman), Eric de Mori (non-executive director) and Winton Willesee (non-executive director and company secretary).
HealthLinx (HTX)	Cancellation of options	Unquoted options were not exercised by their expiry date of 31 March 2010 being well out of money and have now lapsed.
HealthLinx (HTX)	Notice u/s 807A(6)	The company filed notice u/s 807A(6) informing that 1,062,699 ordinary fully paid shares were issued without disclosure to investors.
HealthLinx (HTX)	Stonebridge private placement	HTX will receive new investment funding of $750k via share placement through Stonebridge Securities of 7.5m shares.
IDT Australia (IDT)	Bonus option offer	The company announced a fully franked dividend of 1% per share and also its intent to proceed with a pro-rata offer of free option for every 10 IDT shares held.
Incitive Limited	Change of Name	Incitive Limited has formally changed its name to Hawkley Oil and Gas Limited after a reverse takeover and $5.5m capital raising.
Medical Developments International (MVP)	Appointment of CEO	John Sharman has been appointed as CEO.
Novogen (NRT)	New appointments	Dr Daniel Gold has been appointed as the new president and CEO of the company.
Novogen (NRT)	Appointment of CFO	Mr Thomas Zech was appointed CFO and company secretary.
NuSep (NSP)	Rights issue	Nustep raised $4.5m through a rights issue that closed on 21 May 2010.
Phosphagenics (POH)	Retirement and appointment of a new Chairman	Independent director and chairman Andrew Vizard has advised POH of his intention not to seek re-election as a director. Consequently J L Addison has been appointed as the chairman.
Progen Pharmaceuticals (PGL)	Appointment	Sue MacLeman (CEO) and John Chiplin (director), have both been appointed as Directors of Progen Pharmaceuticals Pty Ltd.
Progen Pharmaceuticals (PGL)	Resignation	Lee Horobin has resigned as company secretary.
Phylogica (PYC)	Appointment	Nick Woolf was appointed as Non Executive Director.
Prima Biomed Ltd	Resignation	Martin Rogers has resigned from the board but he will remain as Prima's CEO.
Probiotec (PBP)	Settlement	The long running legal dispute between a subsidiary and Pfizer Australia Pty Limited has been settled for the payment of $600k plus legal costs.
Sirtex Medical (SRX)	Judgement from legal proceedings	Justice Barker delivered a judgement in favour of Sirtex on its damages claim against Dr Bruce Gray (former director).
Medical Devices		**Total 15**
AquaCarotene (AQL)	Change in company secretary	Susan Leach has resigned as company secretary and Stephene Denaro has been appointed in her place.
CathRX (CXD)	Resignation	Non-executive director Dr Carrie Hillyard has resigned.
Fluorotechnics (FLS)	Rights issue	The company's non-renounceable rights issue has closed with the total amount raised of $1.625m, with a shortfall of 3,720,864 shares.
Genera Biosystems (GBI)	Release of securities from escrow	7,276,723 ordinary fully paid shares, 330,000 options with an exercise price of $0.50/share option and 1,100,000 options with an exercise price of $0.40/share option were be released from escrow on 11 June 2010.
Heartware International (HIN)	Appointment of chairman	C Raymond Larkin Jr has been appointed chairman of the board of directors.
Impedimed (IPD)	Share Issue	The company announced an equity raising of up to A$20.1m at an offer price of A$0.65 per share.
Innovative Technologies for Life (ITD)	Warning notice to shareholders	The company announced that it does not endorse any unsolicited offer from and has no connection with National Management Consultants Pty Ltd.

Company		Comments
Medivac (MDV)	Judgement debt	Diakyne Pty Ltd (MediVac subsidiary) has received its judgement debt of $136k from former director Paul Ralph and associated entity Colorado Investments Pty Limited.
MediVac (MDV)	Resignation	Nick Gatsios has resigned from the company as managing director.
Probiotec (PBP)	Appointments	Robert Maxwell Johnston and Wesley Stringer are appointed as directors of PBP.
Prima BioMed (PRR)	Appointment	Albert Yue-Ling Wong has been appointed to PRR's board as a non-executive director.
Phosphagenics (POH)	Appointment	Dr Esra Ogru has been appointed as joint CEO
Safety Medical Products (SFP)	Appointment of administrators	Sam Davies and Rob Kirman of McGrathNicol have been appointment as voluntary administrators of the company.
Stirling Products (STI)	Appointments	The company announced the appointment of following key personnel: (1) John Diasinos (company secretary), (2) Alex Della Mora (manager of the Stirling Pharma pharmaceutical manufacturing plant at Cape Breton) and (3) Wayne Miller (senior brand, sales and management executive).
Unilife Corporation (UNI)	Appointments	The company has appointed Mary Kate Wold to its board of directors and R Richard Wieland II as chief financing officer.

05

Announcements

United States of America
First quarter FY11

Partnerships

Company	Pharma/biotech partner	Application	Value (US$m)	Comments
Biotechnology			**Total**	**2**
Orexigen	Takeda	Takeda could commercialise Orexigen's obesity drug Contrave in North America	Up to $1bn	The agreement includes a $50m upfront payment and a $100m payout prior to launch upon Contrave's approval.
Pharming Group NV	Santarus	Santarus obtained the rights to commercialize Rhucin in North America	$20m	Rhucin is for the treatment of acute angioedema attacks in patients. Pharming is also eligible to receive additional payments upon the completion of clinical and commercial milestones. Santarus will purchase its commercial supply of Rhucin from Pharming at a tiered supply price.

Mergers, acquisitions and divestments

Dominant company	Target company	Type of deal	Value (US$m)	Comments
Biotechnology			**Total**	**2**
Lab Amazon Group	Data Call Technologies	Acquisition	Not disclosed	DCLT signed a letter of intent to be acquired by Lab Amazon Group. Upon completion of the acquisition, Lab Amazon will become the public company with Data Call becoming a wholly owned subsidiary of Lab Amazon.
Evotec	DeveloGen	Acquisition	Not disclosed	It augments and complements Evotec's high-end drug discovery platform and capability with DeveloGen's target discovery, validation and in vivo/in vitro pharmacology expertise.

Clinical trials

Company	Drug	Application	Comments
Pre-clinical		**Total**	**1**
Perseid Therapeutics	CTLA4-Ig	Improved protein drug	Perseid has received a $5m dollar payment from Astellas for co-developing and commercialising next-generation CTLA4-Ig therapeutics.
Phase I		**Total**	**2**
Limerick BioPharma	LIM-0705	A calcineurin inhibitor used as an immunosuppressant for transplant surgery	Dr Michael Chang, Limerick's VP of research and development said, "This new data is the first evidence from human trials that the use of our drug can reduce unwanted physiological consequences of tacrolimus."
Protalex Inc	PRTX-100	Treatment for patients with active rheumatoid arthritis on methotrexate therapy	The primary objective of this phase Ib randomised, multiple-dose, dose-escalation study is to assess the safety and tolerability of intravenous PRTX-100 administered weekly in patients.
Phase II		**Total**	**3**
Can-Fite BioPharma	CF101	Treatment of patients with moderate to severe dry eye syndrome	The randomised, double-masked trial will compare two doses of CF101 to placebo. Approximately 240 patients will be enrolled at multiple centres; they will be treated for 24 weeks.
Novartis	Afinitor (Everolimus)	Treatment for advanced pancreatic neuroendocrine tumours	Everolimus extended median progression-free survival from 4.6 to 11 months and reduced risk of cancer progression by 65%.
Santaris Pharma	Miravirsen (SPC 3649)	Treatment of chronic hepatitis C virus (HCV) genotype 1 infection	There will be the initiation of a randomised, double-blind, placebo-controlled phase IIa trial in up to 55 treatment-naive patients with HCV genotype 1 infection. The multiple ascending dose trial aims to assess the safety and tolerability of the agent following weekly or fortnightly subcutaneous injections for four weeks.
Phase III		**Total**	**6**
D-Pharm	DP-b99	Treatment for ischemic stroke	FDA approved phase III clinical trial for DP-b99 is being conducted on 770 patients in 100 medical centres globally.

Company	Drug	Application	Comments
Genentech	Avastin	Treatment of ovarian cancer	Phase III, international study showed that the combination of Avastin and chemotherapy, followed by the continued use of Avastin alone, increased the time women with previously untreated ovarian cancer lived without the disease worsening.
GlaxoSmithKline and Genmab	Ofatumumab	Treatment of indolent B-cell non-Hodgkin's lymphoma	A total of 338 patients in this phase III open label study will be randomised to receive either ofatumumab in addition to bendamustine or bendamustine alone.
Nabi Biopharmaceuticals	NicVAX	Vaccine being developed to treat nicotine addiction and prevent smoking relapse	Both phase III studies for NicVAX are double-blinded, placebo-controlled studies enrolling approximately 1,000 patients each.
NPS Pharmaceuticals	Gattex	Treatment for parenteral nutrition (PN) dependent short bowel syndrome (SBS)	The double-blind, placebo-controlled safety and efficacy study, which is known as Steps, is being conducted in 86 patients.
Pro-Pharmaceuticals	Davanat and 5-FU	Treatment of advanced, metastatic colorectal cancer	Numoda will oversee the phase III clinical trial of Davanat and 5-FU compared with the standard of care in the treatment of patients and will be responsible for helping to manage the Pro-Pharmaceuticals clinical trial.
Other		**Total**	**3**
Amarin	AMR101	Treatment for those with very high triglyceride levels, which is a risk factor in heart disease	The company's 12-week study, which finished recruitment of 229 patients, will look at the effect of AMR101.
DiaMedica	DM-99	Treatment of rheumatoid arthritis and other autoimmune diseases	Company released positive results. DM-99 was found to reduce joint swelling by up to 90% in a collagen induced animal model of rheumatoid arthritis (RA) during the peak of the disease.
Roche Holding	Taspoglutide	Diabetes drug	Roche has halted late-stage trials of taspoglutide, an experimental diabetes drug, because of side effects, such as hypersensitivity.

Regulatory

Company	Drug	Application	Comments
Biotechnology		**Total**	**43**
Abbott	FDA approval obtained	Molecular diagnostics test for measuring the viral load of hepatitis B	Abbott RealTime HBV assay is the first automated molecular test for assessing HBV viral load to be cleared by the FDA.
Abbott	FDA approval obtained	A test that can detect both HIV antibodies and antigen simultaneously	Abbott's new test – Architect HIV Ag/Ab Combo assay – identifies the HIV p24 antigen, making it possible to diagnose infections days before antibodies appear.
Actelion Pharmaceuticals	FDA approval of brand name	Treatment of moderate to severe pulmonary arterial hypertension (PAH) and PAH associated with the scleroderma spectrum of disease	Veletri is an improved formulation of epoprostenol that offers greater convenience to patients than other epoprostenol formulations.
Alimera Sciences	FDA grants priority review	A fluocinolone acetonide intravitreal insert	Review time for Iluvien is reduced from 10 months to six months.
Alkermes Inc	FDA approval of a second use of a drug	Prevent relapse in recently detoxified opioid-dependent patients	Voting was in regards to Vivitrol which first gained FDA approval for alcohol dependence in 2006.
Amneal Pharmaceuticals	Drug approved by FDA	Used in the management of primary hyperaldosteronism, edematous conditions, essential hypertension, hypokalaemia and severe heart failure	Spironolactone HCl is a synthetic 17-lactone drug that is a renal competitive aldosterone antagonist in potassium-sparing diuretics.
Amsterdam Molecular Therapeutics	Orphan drug designation granted by FDA	A gene therapy for Duchenne muscular dystrophy	The FDA's orphan drug designation, which includes AMT-080, is designed to encourage the development of new treatments for diseases affecting fewer than 200,000 US residents.
Arcion Therapeutics	Fast track status granted by FDA	Treatment of pain associated with painful diabetic neuropathy (PDN)	Arcion recently announced positive top-line results from a phase IIb double-blind, randomised, placebo controlled clinical trial of ARC-4558 in adult patients with PDN.

Company	Drug	Application	Comments
Arena Pharmaceuticals	Drug rejected by FDA	Weight loss pill	Lorcaserin was rejected by the FDA panel recommendation.
Athersys	Orphan drug designation granted by FDA	Prevention of graft vs host disease (GvHD)	MultiStem seeks to prevent GvHD – a common condition associated with a bone marrow transplant.
Baxter Healthcare Corporation	Drug approved by FDA	Used to treat poisoning by organophosphate pesticides and chemicals	Approval is for paediatric use of Protopam Chloride. The drug is approved to be administered either by intravenous or intramuscular injections and was FDA approved in 1964 for adult use.
Biofrontera	Drug approved by EMA	Treatment of actinic keratosis	BF-200 ALA passed the first stage of the approval process.
BioMimetic Therapeutics Inc	Completed 100 day Premarket Approval Application (PMA) meeting with the FDA	Treatment of foot and ankle fusions	If the panel determines the product to be safe and effective, the company expects approval of Augment Bone Graft by the FDA in mid-2011.
Catalyst Pharmaceutical Partners	Orphan drug designation granted by FDA	Treatment of infantile spasms	CPP-115 is an investigational drug.
Cornerstone Therapeutics	Seeks FDA approval	Treatment for cold symptoms	Cornerstone is seeking approval for generic Tussionex.
CSL Behring	Drug approved by FDA	For the treatment of primary immunodeficiency	The FDA has approved a supplemental biologics licence application to extend the shelf life of Hizentra, from 18 months to 24 months.
EraGen Biosciences	Secured FDA 510(k) market clearance	DNA detection and typing test intended to aid in the diagnosis of genital herpes infection	Market clearance was for MultiCode-Rtx HSV 1&2 Kit.
Genentech Inc	Supplemental approval by the FDA	Therapy for adult kidney transplant patients at high risk of cytomegalovirus (CMV) disease	FDA approved increasing the length of therapy with Valcyte.
Genentech Inc	Drug approved by FDA	Treatment of macula oedema which occurs as a result of vessel blockages in the retina of the eye	Genentech carried out clinical phase III studies with 789 participants for Lucentis (ranibizumab).
Genzyme	Drug approved by FDA	Treatment of the late onset of Pompe's disease for patients aged 8 years and older	Genzyme already manufactures Myozyme, a different form of alglucosidase alfa which is also approved for the treatment of Pompe's disease.
Gilead Sciences	Submitted an abbreviated new drug application (ANDA) to the FDA	A generic version of Hepsera, or adefovir dipivoxil	Are requesting permission to manufacture and market a generic version of this drug.
GlaxoSmithKline and Human Genome Sciences	FDA has granted a priority review designation	A potential treatment for systemic lupus erythematosus	Priority review designation to Benlysta due to the results of two pivotal phase III clinical trials.
iCo Therapeutics	Orphan drug status granted by FDA	Treatment of Visceral Leishmaniasis	iCo plans to develop iCo-009 for both fungal and parasitic diseases in the developed and developing world.
Jazz Pharmaceuticals	FDA advisory panel has voted against label approval	Treatment of the chronic pain condition fibromyalgia	Citing the risk for abuse as the molecule is the oral liquid form of gammahydroxybutyrate (GHB), a drug used recreationally for euphoric effects or sedating women in 'date rapes'.
Kamada	Drug approved by FDA	Treatment of Alpha 1 deficiency	Glassia is the first and only liquid, ready to use, Alpha-1-Proteinase Inhibitor on the market.
Lannett Company	Drug approved by FDA	For the prevention of postoperative nausea and vomiting and for the prevention of chemotherapy-induced nausea and vomiting	Approval for Ondansetron Injection, USP, 2 mg/mL, Single-Dose Vials. It is the generic version of GlaxoSmithKline's Zofran Injection, 2 mg/mL.
MannKind	FDA approved the resubmission of its new drug application	For treatment of Type 1 diabetes	Application for Afrezza classified as a class 2 resubmission.
Momenta Pharmaceuticals	FDA approval issued	A complex protein-based anticoagulant derived from the blood thinner heparin	FDA issued a long-awaited approval of the company's generic Lovenox.
N30 Pharmaceuticals	Drug approved by FDA	New treatment for acute exacerbations of asthma, chronic obstructive pulmonary disease and inflammatory bowel disease	N30 Pharma will now begin a first-in-man, phase I, dose escalation trial of N6022 – its investigational new drug application in healthy subjects.
NicOx	Drug rejected by FDA	Anti-inflammatory medicine	The FDA recommended long-term studies concerning Naproxcinod's cardiovascular and gastrointestinal safety.

Company	Drug	Application	Comments
Noscira	Fast track status granted by FDA	Treatment of Progressive Supranuclear Palsy (PSP)	A phase II trial with Tideglusib in PSP commenced in December 2009 and is currently in progress.
Novartis	Drug approved by FDA	Treatment of multiple sclerosis	Gilenya is the first oral treatment for relapsing remitting multiple sclerosis.
Optimer	First section of a new drug application submitted to the FDA	Treatment of clostridium difficile infection	Optimer anticipates completing the submission for fidaxomicin in the fourth quarter of 2010.
Pathwork Diagnostics	Received FDA clearance	Formalin-fixed, paraffin-embedded (FFPE)-based cancer test	The test compares the degree of commonality between the RNA expression patterns in a tumour specimen as against RNA expression patterns in a database of 15 tumour types.
Progenics Pharmaceuticals	Drug approved by FDA, EMA and Health Canada	Treatment of opioid-induced constipation (OIC)	Pre-filled syringes of Relistor provide a simplified dosing option for the treatment of OIC.
pSivida	New drug application submission to FDA	Treatment for for diabetic macular oedema	Iluvien, developed by pSivida and licensed to Alimera Sciences, is a sustained release drug delivery system releasing the steroid flucocinolone acetonide.
Quindel	Drug approved by FDA	Detects antigens associated with acute respiratory syncytial virus	QuickVue RSV 10 is a nasal swab test.
Quindel	FDA marketing approval received	Rapid pregnancy test	The three-minute RapidVue human chorionic gonadotropin (hCG) test is used with urine samples.
Roche/Genentech	FDA approval decision postponed	Treatment of advanced breast cancer	FDA postponed its decision on whether the approval of Avastin will be revoked based on new data.
Roche	Accelerated approval refused by the FDA	A targeted anticancerial based on antibodies	The phase III registration study will be continued. Development is being undertaken as a collaboration with ImmunoGen and Genentech.
Savient Pharmaceuticals	Drug approved by FDA	Treatment for gout	Krystexxa is for people who have not responded to or tolerated conventional therapies.
Teva Pharmaceutical Industries Ltd	Declined application by the FDA	Treatment of severe neutropenia	The FDA declined to approve and is seeking more data on Teva's copy of Amgen's Neupogen. Main European patents on Neupogen expired in 2006 but only expire in the US in 2013.
Vivus	Drug rejected by FDA panel	Diet drug	The panel narrowly rejected recommending Qnexa.
Medical Devices		**Total**	**1**
Orthovita	FDA approved new facility	Orthovita will use the new facility to process the highly purified form of collagen used in its Vitagel Surgical Hemostat product	The approval of the new facility gives Orthovita an opportunity to develop, manufacture and market additional collagen-based products.

Other

Company	Product	Application	Comments
Biotechnology		**Total**	**13**
Actelion	Experimental drug clazosentan fails trial	Not applicable	Clazosentan is unlikely to make it to market after it failed in a late-stage study.
Arena Pharmaceuticals	Licensing deal obtained as FDA approval is awaited	Treatment for obesity	Arena sold US rights of lorcaserin to Eisai for $50m upfront.
Biogen Idec	Agreed to develop experimental drug	Not applicable	Biogen, known for its multiple-sclerosis treatments, agreed to develop closely held Knopp Neurosciences' experimental treatment for amyotrophic lateral sclerosis, also known as Lou Gehrig's disease.
Genentech	Accelerated approval denied	Not applicable	FDA denied accelerated approval for its investigational breast cancer treatment trastuzumab-DM1 (T-DM1), pushing the drug's potential market entry back at least two years.
Predictive Biosciences	Executive appointments	Not applicable	Appointment of Thomas M Ross as chief commercial officer and Randal Vader as VP of clinical and regulatory affairs.
Salix Pharmaceuticals Ltd	Legal proceedings	Not applicable	Salix filed a Form 8K – Entry Into a Definitive Agreement – with the Securities and Exchange Commission on September because Novel was seeking FDA approval to market a generic version of Salix's OsmoPrep product. On 30 September 2010 the parties agreed to a confidential settlement of the OsmoPrep lawsuit.
Sanofi-Aventis SA	Proposed takeover	Not applicable	Sanofi recently went public with its $18.5bn all cash bid for Genzyme Corp.
Seattle Genetics	Drug phase II trial failed	Not applicable	A key trial of its experimental drug lintuzumab showed that the biotechnology treatment did not extend the lives of patients with acute myeloid leukaemia.
Sinclair Pharma	Licensing deal completed	Not applicable	Licensed the range of patented fast-drying transparent silicone scar-reduction gel and spray wound dressings marketed under the Kelo-Cote brand.
SpineAlign Medical	First patient enrolled in treatment registry	Not applicable	It has enrolled its initial patient in an observation study to further assess the ability of the VerteLift System to treat the pain and dysfunction associated with osteoporotic vertebral compression fractures, while providing clinically measurable height restoration.
Teva Pharmaceuticals Industries	Legal proceedings	Not applicable	Teva has filed a second lawsuit against Mylan accusing the company of infringing patents on its multiple sclerosis drug Copaxone. A trial date has not yet been scheduled in that case.
Vical	Drug failed in late stage clinical trial	Not applicable	The genetic drug, which aims to encourage the growth of new blood vessels, did not reach its main goal in a late-stage clinical trial. Vical was developing the drug with Sanofi-Aventis.
Vivus	Data disclosed	Not applicable	Vivus, as one of three companies seeking regulatory approval for an obesity drug, disclosed two-year data that showed strong and sustained weight loss for the majority of patients using its Qnexa product and no new side effects.

Announcements

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Partnerships

Company	Pharma/biotech partner	Application	Value (US$m)	Comments
Biotechnology			**Total**	**27**
Abbott Laboratories	Neurocrine Biosciences	Partnership	$75m	Abbott's investment in Neurocrine per the partnership agreement will give Abbott rights to elagolix.
Allergen	Serenity Pharmceuticals	Development and commercialisation of Ser-120	Not applicable	Allergen and Serenity have entered into a global agreement.
AMAG Pharmaceuticals	Takeda Pharmaceuticals Company Ltd	License/development agreement	Not disclosed	AMAG and Takeda have entered into a development agreement for Feraheme.
BioDelivery Sciences International	Kunwha Pharmaceutical Co	License and supply agreement	$1.275m	BioDelivery Sciences International has entered into an agreement with Kunwha Pharmaceutical Co for the exclusive rights to develop and commercialise BEMA Fentanyl in the Republic of Korea.
Cardium Therapeutics	Devro Medical Limited	Supply agreement	Not disclosed	Cardium has entered into a multi-year supply agreement with Devro for the supply of Excellagen.
Diamyd Medical AB	Ortho-McNeil-Janssen Pharmaceuticals (OMJPI)	Development agreement	US$45m	Diamyd has signed an agreement with OMJPI to develop and commercialise Diamyd diabetes therapy.
Dyax Corp	Sigma-Tau SpA	Strategic partnership	$2.5m	Dyax has signed an agreement with Sigma-Tau to develop and commercialise subcutaneous DX-88.
China Kangtai Cactus Biotech.	Yongkangmen Health & Drug Chain Store Group Ltd	Sales and marketing agreement	Not applicable	A 3 year sales and marketing agreement to sell patented cactus-based products has been signed.
Clinical Data	Santen Phamaceutical Co	Licence agreement	$2m	Clinical data has signed a licence agreement with Santen Pharmaceutical for adenosine A(2A) agonist compound.
Clovis Oncology	Ventana Medical Systems	Collaboration agreement	Not disclosed	Clovis has entered into a collaboration agreement with Ventana to develop hENT1.
Genzyme Corp	Relational Investors	Mutual cooperation agreement	Not applicable	Genzyme Corp. and Relational Investors announced they have amended their mutual cooperation agreement with Ralph Whitworth elected to Genzyme's board of directors, effective immediately.
GTC Biotherapies	Bio Sidus S.A.	Agreement to obtain sales authorisations	Not applicable	GTC and Bio Sidus have entered into a registration licence agreement.
Guided Therapeutics	Konica Minolta Opto	Licensing agreement	$750k for one year	Konica Minolta Opto Inc has extended its licensing agreement with Guided Therapeutics to codevelop non-invasive cancer detection products.
Hawaii Biotech	Advanced BioScience Laboratories	Pre - development agreement	Not applicable	Hawaii Biotech and Advanced BioScience Laboratories have entered into a partnership.
Hemisphex Biopharma	Max Neeman	Collaborative research effort	Not applicable	Hemispherx and Max Neeman have entered into a partnership to create a research platform for Alferon N Injection.
iBio	Fraunhofer USA Centre for Molecular Biotechnology	Licence agreement	Not disclosed	iBio has announced an agreement with Fraunhofer for the development and manufacture of global health vaccines.
International Business Systems	Farmacie Comunali Riunite	Core Business Applications	Not disclosed	Farmacie Comunali Riunite has switched to IBS Enterprise for all of its core business applications.
IRX Therapeutics	National Cancer Research Centre (NCRC)	Strategic agreement	Not disclosed	IRX has entered into a strategic agreement with NCRC to evaluate cancer vaccines.
Life Technologies Corporation	Stanford University School of Medicine and other institutions	R&D in breast cancer	Not disclosed	Life Technologies Corporation announced its scientists have teamed with researchers from Stanford University School of Medicine.
Merck Pharmaceuticals	Ariad Pharmaceuticals	Development of potential cancer drug	$50m	Merck and Ariad have revised their partnership, with Merck now covering all development costs.
Optimer Pharmaceuticals	Biocon	Manufacturing and supply agreement	Not mentioned	Optimer Pharmaceuticals and Biocon have entered into a long-term supply agreement for the commercial manufacturing of fidaxomicin.
Penwest Pharmaceuticals	Alvogen	Development agreement	Not disclosed	Penwest has signed a development and collaboration agreement with Alvogen.

Company	Pharma/biotech partner	Application	Value (US$m)	Comments
Pfizer	Stemgent	Collaboration and research licensing agreement	Not applicable	Stemgent and Pfizer announced an agreement that will lead to availability of Pfizer research to the global community.
Pfizer	MDRNA	Research agreement	Not disclosed	Pfizer has entered into a study effort with MDRNA.
Radient Pharmeuticals Corp	Jaiva Technologies	Collaboration agreement	Not applicable	Radient and Jaiva have entered into an exclusive 5 year collaboration agreement.
Response Genetics	PCR analysis technology	Exclusive licence agreement	Not mentioned	Response Genetics announced that it has signed a non exclusive licence agreement granting GlaxoSmithKline certain rights to its PCR analysis technology.
UnitedHealth Group	YMCA	Prevent and control diabetes, prediabetes and obesity	Not applicable	UnitedHealth Group is launching the Diabetes Prevention and Control Alliance, a partnership with YMCA and Walgreens, in the treatment of diabetes.
Medical Devices			**Total**	**5**
Dako	Omnyx	Development agreement	Not disclosed	Dako and Omnyx have entered into a 3 year agreement to develop clinical algorithms for digital pathology.
Eyegate Pharma	GlaxoSmithKline (GSK)	Research collaboration agreement	Not disclosed	Eyegate has entered into a collaboration agreement with GSK to evaluate the delivery of several GSK products.
Exiqon	Becton, Dickinson and Company (BD)	Licence agreement	Not disclosed	Exiqon has signed a licence agreement with BD for its patented LNATM technology.
Medical Alarm Concepts Holding	YesDTC Holdings	Marketing agreement	Not disclosed	Medical Alarm Concepts selected YesDTC as its direct response television (DRTV) marketing representative for MediPendant.
Medrad International	Ev3 Inc.	Supply agreement	Not disclosed	Medrad has entered into a supply agreement with ev3, where Medrad will make Cotavance available to ev3.

Mergers, acquisitions and divestments

Dominant company	Target company	Type of deal	Value (US$m)	Comments
Biotechnology			**Total**	**13**
Allscripts	Eclipsys	Merger	$1.3bn	A definitive agreement was announced to merge Allscripts and Eclipsys. Eclipsys stockholders will receive 1.2 shares of Allscripts for each share of Eclipsys.
Angiotech Pharmaceuticals	Haemacure	Asset acquisition	Not disclosed	Angiotech has completed the acquisition of certain product candidates and technology assets of Haemacure.
AstraZeneca	Pozen Inc	Acquisition of new drug application	$20m	Pozen announced the receipt of a $20m milestone payment from AstraZeneca for rights to Vimovo.
Biotime Inc.	ES Cell International	Acquisition	Not disclosed	Biotime has completed the acquisition of ES Cell International.
Cadence Pharmaceuticals	Incline Therapeutics	Acquisition option	Not disclosed	Cadence has signed an agreement providing Cadence with an exclusive option to acquire Incline Therapeutics.
HealthTronics	Endo Pharmaceuticals	Merger	$223m	HealthTronics and Endo Pharmaceuticals have signed a definitve merger agreement.
Ikaria Holdings	Orphan Therapeutics	Acquisition of assets	Not disclosed	Ikaria has acquired the new drug and investigational new drug application from Orphan.
IntelGenx Technologies	Cary Pharmaceuticals	Acquisition	Not applicable	IntelGenx and Cary have terminated their agreement to assign 50% ownership of CPI-300 to IntelGenx and have further agreed to transfer and assign the device.
Javelin Pharmaceuticals	Hospira	Acquisition	$2.20/share	Javelin has received a binding offer to enter into a merger, loan and intellectual property and security agreement.
Mesoblast (MSB)	Angioblast Systems	Share acquisition	$24m	Mesoblast announced that it will acquire Angioblast Systems after a capital raising of $37m has been completed.

Dominant company	Target company	Type of deal	Value (US$m)	Comments
Power3 Medical Products	StemTroniX	Termination of merger agreement	Not applicable	The company has elected to terminate the merger agreement with StemTroniX previously due to issues solely related to StemTroniX.
Shrink Nanotechnologies	Millennium Cell	Acquisition of trademark	Not disclosed	Notification of the purchase of the PowerSkin trademarks from the bankruptcy estate associated with the Millennium Cell has been received.
Thermo Fisher Scientific	Proxeon A/S	Acquisition	Not disclosed	Thermo Fisher Scientific announced it has acquired Proxeon A/S, an innovative supplier of products for proteomics analysis.
Medical Devices			**Total**	**8**
Agilent Technologies	Varian	Merger	$1.5b	The Federal Trade Commission agreed to the merger of Agilent Technologies and Varian subject to the sale of three product lines, which Agilent and Varian have successfully completed.
CytoSorbents Corporation	Lincoln Park Capital Fund	Funding agreement	$6m	CytoSorbents Corporation enters into funding agreement with Lincoln Park Capital Fund through a 25 month period of CytoSorbents common stock sales to LPC.
C.R. Bard	SenoRx	Acquisition	$200m	The C.R. Bard acquisition of SenoRx has been approved by the boards of both companies, but it is subject to the approval of SenoRx's shareholders.
Gentiva Health Services	Odyssey HealthCare	Merger	$1b	A definitive merger agreement has been announced whereby Gentiva will acquire Odyssey.
Med Gen	Leapfrog Realty	Acquisition	Not disclosed	Med Gen Inc has signed a letter of intent to acquire an interest in a branch office of Leapfrog Realty.
Renal Care	Dialysis Corporation of America	Acquisition of shares	Not disclosed	A definitive agreement has been reached to acquire all of the outstanding shares of common stock of Dialysis Corporation of America.
Tissue Regenix	Oxeco	Reverse takeover	GBP4.5m	Tissue Regenix has performed a reverse takeover of Oxeco to enter into London's junior Alternative Investment Market.
Universal Health Services	Psychiatric Solutions	Acquisition	$3.1b approx	Universal Health Services has entered into definitive agreement to acquire Psychiatric Solutions.

Clinical trials

Company	Drug	Application	Comments
Pre-clinical		**Total**	**4**
Aeolus Pharmaceuticals	AEOL 10150	Radiation of the gastrointestinal tract	A second study of the AEOL drug has been announced, initiated by the NIH and NIAID.
nContact Surgical	Electrophysiologist (EP) catheter	Atrial fibrillation (AF)	nContact enrolled the first patient in an IDE trial of closed chest convergent AF ablation procedure.
Pharmaceutical Co	Gestiva	Prevention of pre-term birth	The clinical trial and consequent patient enrolment for Gestiva has commenced.
Scripps Clinic	The OsseoFix Spinal Fracture Reduction System	Compression fractures of the spine	Scripps Clinic announced that it is enrolling patients in a new clinical study for the OsseoFix.
Phase I		**Total**	**6**
Abbott Laboratories	MitraClip system	Research into the causes of mitral regurgitation	Abbott Laboratories announced new favourable data from the Everest II trial, which provide additional details about the safety and clinical benefit of the MitraClip system.
Achillion Pharmaceuticals	ACH-1625	Hepatitis C	Achillion Pharmaceuticals announced favourable results from the third and fourth cohorts of patients in the phase Ib trial of ACH-1625.
Boston Scientific Corp	Promus Element stent and Xience Prime stent	Comparision of Promus stents	Clinical trial is designed to compare the performance of the stents.
Celsion	ThermoDox	Liver tumours	Celsion has released favourable results from a phase clinical trial of ThermoDox.
Gilead Sciences	GS 9350	Not disclosed	Gilead has dosed its first patient in the phase I trial of GS 9350.

Company	Drug	Application	Comments
Gold Coast Research	Oros	Treatment of opioid-tolerant patients with chronic lower back pain	Investigators published new favourable data for OROS.
Phase II		**Total**	**18**
Baxter International	Gammagard	Alzheimer's disease	Baxter announced favourable results from the phase II clinical trial for Gammagard.
Berkeley Heights	Tesetaxel	Gastric cancer	Berkley Heights has initiated a phase 2b trial of tesetaxel in 2nd-line gastric cancer.
Capstone Therapeutics	AZX100	Keloid scarring	A limited analysis has been completed of the two ongoing AZX100 phase 2a clinical trials in keloid scarring, with all objectives being met.
Celator Pharamceuticals	CPX-351	Acute myeloid leukaemia	Celator announced positive results from its phase II study of CPX-351.
Dyax Corp	Kalbitor	Hereditary angioedema	Dyax has released favourable results from its second phase III placebo-controlled trial.
Dynavax Technologies	Heplisav	Chronic kidney disease	Dynavax has released favourable results from its phase II clinical trial of Heplisav.
GE Healthcare	Flutemetamol	Brain imaging	GE has released positive results from a phase II clinical trial of Flutemetamol.
Genta	Tesetaxel	Gastric cancer	Phase IIb trial has been initiated for tesetaxel.
Generex Biotechnology Corporation	Oral-lyn	Oral insulin spray	Generex Biotechnology Corporation reported favourable preliminary outcomes and trends from the ongoing phase III pivotal study of Generex Oral-lyn.
Neurologix	NLX-P101	Parkinson's disease	Neurologix has announced positive results in its phase II clinical trial for NLX – P101 with improvements of motor scores.
Omeros	OMS103HP	Improve joint function	Omeros released additional positive results from phase II clinical trial.
Oncolytics Biotech	Reolysin	Treatment of platinum-refractory head and neck cancers	Oncolytics Biotech receives approval from the Belgian Federal Agency for Medicines and Health Products to conduct a phase III trial.
Raptor Pharmaceutical	Delayed release cysteamine bitartrate	Non-alcholic steatohepatitis	Raptor received positive results from a phase 2a trial of delayed relase cysteamine bitartrate.
Regeneron Pharmaceuticals	REGN475	Targets nerves	In an interim efficacy analysis of a phase II trial REGN475 demonstrated favourable results.
Provectus Pharmaceuticals	PV-10	Metastatic melanoma	Additional positive data has been announced from Provectus' phase 2 clinical trial of PV-10.
Vical	Allovectin-7	Metastatic melanoma	Vical announced that data from its phase II trial of Allovectin-7 in metastatic melanoma showed favourable results.
Vivus	Qnexa	Obstructive sleep apnoea	Vivus presented favourable results from the Qnexa phase II trial and significant improvements in the apnea/hypoapnoea index.
Vivus	Avanafil	Erectile dysfunction	Vivus presents positive results from a phase III study of avanafil.
Phase III		**Total**	**19**
Ariad Pharmaceuticals	Oral Ridaforolimus	Metastatic sarcomas	The independent Data Monitoring Committee has completed the second interim efficacy analysis and has recommended oral ridaforolimus.
Biolex Therapeutics	Locteron	Hepatitis C	Biolex presents inerim results from a phase IIb study of Locteron.
Delcath Systems	PHP System	Melanoma metastases	Delcath released favourable results from its PHP system clinical trial, meeting the primary endpoint.
Dyax	Kalibitor	Amelioration of HAE attacks	Dyax has released positive results from its Kalibitor clinical trial with an improvement of symptoms in comparison to the placebo.
Eastland Medical Systems (EMS)	ArTiMist	Malaria	Positive results were announced from the recently completed phase IIa clinical trial of ArTiMist.
EyeGate Pharmaceuticals	EPG-437	Dry-eye syndrome	Eyegate has commenced the phase III clinical trial of EPG 437.
Molecular Medicine SpA	NGR-hTNF	Malignant pleural mesothelioma	MolMed has received US clearance for phase III trial.

Company	Drug	Application	Comments
Novartis	Afinitor	Pancratic neuroendocrine tumours	The phase III clinical trial of Afinitor has met its primary endpoint.
Nymox Pharmaceutical	NX-1207	Benign prostatic hyperplasia	Nymox reports positive results from the Phase III Safety Committee Meeting on 30/4/10.
Oncolytics Biotech	Reolysin	Treatment of platinum-refractory head and neck cancers	Oncolytics Biotech has opened enrolment in its phase 3 trial examining Reolysin in combination with paclitaxel and carboplatin.
Repligen	RG1068, synthetic human secretin	Improvement of pancreatic magnetic resonance imaging	Repligen has received the FDA and the EMA's, approval to reanalyse the images from phase III study to establish the utility of RG1068.
Retina Implant	Not disclosed	Vision impairment	Announced positive results for a first clinical trial, allowing patients to view and focus on objects.
Roche	MabThera	Follicular lymphoma	Results of a phase III study showed that the first-line use of MabThera improves progression-free survival by 50% in patients with follicular lymphoma.
Pfizer	Sutent v. Nexavar	Kidney cancer	The phase III clinical trial comparing Sutent to Nexavar has discontinued as a result of safety and efficacy troubles.
Sanuwave Health	DermaPACE Phase III	Diabetic foot ulcers	The patient enrolment for a phase III clinical trial was completed.
Stallergenes	Oralair	Grass Pollen Immunotherapy	Stallergenes reports positive results compared to the placebo for Oralair from a phase III trial in the US
Sucampo Pharmceuticals	Lubiprostone	Chronic idiopathic constipation	The phase III clinical trial for Lubiprostone has met its primary endpoint with statistical significance.
Takeda & Seattle Genetics	SGN-35	Hodgkin's lymphoma	Phase III of the clinical study of SGN-35 has commenced.
Wilex	Redectane	In the diagnosis of renal masses	The data of the phase III study demonstrate favourable results and Wilex is now seeking FDA approval.
Other		**Total**	**55**
Acorda Therapeutics	Ampyra	Improve walking in patients with multiple sclerosis (MS)	Acorda Therapeutics announced four new analyses of clinical trial data on Ampyra (dalfampridine) Extended Release.
Acurian	Not applicable	Not applicable	Acurian announced that its opted-in patient database is an effective resource for patient recruitement in minority populations.
Aeterna Zentaris	Not disclosed	Colorectal cancer	The European health regulator indicated that the data from the late stage trial of its drug would be sufficient to receive regulatory approval.
Angiotech Pharmaceuticals	Zilver PTX drug	Peripheral arterial disease in the superficial femoral artery	Cook Medical, a licence holder of Angiotech, presented fabourable one year data related to Zilver PTX drug.
Apnex Medical	Apnex HGNS	Obstructive sleep apnoea	Data from the Apnex HGNS clinical study showed favourable results.
Asthmatx	Bronchial thermoplasty (BT) with the Alair® System	Asthma	Five-year data presented verifies Bronchial Thermoplasty's ability to provide long lasting control.
AtriCure	Dual epicardial/ endocardial procedure	Atrial fibrillation	Conditional approval from the FDA has been received to evaluate the safety and efficacy of a dual epicardial/ endocadial procedure (DEEP), or hybrid procedure.
Bard	Lifestent	Moderate length lesions in the superficial femoral atery	Bard has published favourable results from a clinical trial showing improved patency and reduced revascularisation rates.
Basilea Pharmaceutica	Zeftera	Skin infections	In consultation with Health Canada the sale of Zeftera was discontinued.
BioInvent and ThromboGenics	TB-403 (RG7334)	Metastatic, treatment refractory, colorectal and ovarian cancer	BioInvent and ThromboGenics announced that their partner Roche will begin an imaging study with the novel anti-cancer antibody TB-403. BioInvent and ThromboGenics will receive $10m from Roche under the terms of the strategic alliance agreement.
Brigham and Women's Hospital	Kidney Injury Molecule-1 (Kim-1)	Tubular toxicity	Brigham Renal Division Research will lead research to identify next generation biomarkers to screen kidney toxicity.
BSD Medical	BSD 2000	Cancer in children	BSD presented favourable results from the clinical study evaluating the use of BSD-2000 with chemotherapy.

Company	Drug	Application	Comments
Cameron Health	Subcutaneous implantable defibrillator	Reviving patients	Cameron Health has commenced its clinical trial of the defibrillator free of leads, after it was approved by the FDA under an investigational device exemption.
Canyon Pharmaceuticals	Iprivask	Heparin-induced thrombocytopenia (HIT)	Canyon Pharmaceuticals presents positive results of Iprivask comparative trial.
Clinical Data	Vilazodone	Major depressive disorder	Clinical Data announced data from clinical trials of vilazodone, which included positive results from the second placebo-controlled phase III clinical trial.
Cohera Medical	TissuGlu	Wound drainage and associated complications in the surgeries	Top-line human clinical study results demonstrate safety and preliminary effectiveness of TissuGlu.
CombinatoRx	Prednisporin	Pinkeye	Sanofi-Aventis unit pays CombinatoRx $500K after starting new mid-stage clinical trial.
Compugen	CGEN-928	Multiple myeloma	Compugen announced the discovery of a new drug, CGEN-928.
Conceptus	Essure(R) procedure	Birth control	Conceptus(R) Receives FDA Approval on Essures Bilateral Placement Rate to 96.9%.
Covidien	Exalgo extended-release tablets/Pennsaid	Chronic pain relief/ oestoarthristis of the knee	Covidien introduced the FDA approved Exalgo extended-release tablets and Pennsaid.
Cytori Therapeutics	Celution	Heart failure	Cytori announced favourable outcomes for the first clinical trial of Celution.
Delcath Systems	PHP System	Liver cancer	Delcath Systems announced that preliminary results from a study of its liver cancer treatment device exceeded expectations.
Echo Therapeutics	Prelude SkinPrep Device	Ablate the skin prior to dermal anesthaesia	The clinical trial for Prelude(TM) SkinPrep Device produced positive results.
Emerging Healthcare Solutions	Camox emergency oxygen system	Oxygen Supply	Emerging Healthcare Solutions has announced favourable completion of its review process for the Camox emergency oxygen system.
Emerging Healthcare Solutions	Mayday emergency escape system	Emergency oxygen supply	The Mayday prototype is complete and ready for pilot scale production.
Endologix	Powerlink system	Heart failure	Englogix has released favourable long term results from its Powerlink clinical trials.
Ev3	EverFlex Self-Expanding Stent System	Superficial femoral artery (SFA) and proximal popliteal lesions	Ev3 announced the completion of patient enrolment in the trial evaluating the EverFlex Self-Expanding Stent System.
Forest Laboratories	Bystolic (nebivolol) tablets	Mild to moderate hypertension	Data from a phase IV study showed significantly reduced sitting systolic and diastolic blood pressure (BP) when used as monotherapy.
Genzyme Corp	Myozyme	Pompe disease	Genzyme reported favourable results from a study with participants averaging an extra 25m of walking after taking Myozyme.
GTx	Toremifene	Prevention of prostate cancer	Shares of GTx tumbled after the company announced its drug candidate toremifene did not meet its goals in a clinical trial.
Hansen Medical	Sensei X Robotic Catheter System and the Artisan Control	Atrial fibrillation	Hansen has received conditional investigational device exemption approval from the FDA authorising a clinical trial to investigate use of its 2 systems.
iCAD	VeraLook computer-aided detection (CAD) technology	Early identification of cancer	iCAD launches a new version of VeraLook computer-aided detection technology for CT colonography at ESGAR, with new technology to review virtual colonoscopy images.
Kinetic Muscles	Teletherapy service	Treatment of stroke survivors in rural areas	Kinetic Muscles received a $2.8m grant from the National Institute of Neurological Disorder and Stroke (NINDS) of the National Institutes of Health (NIH) that will support delivery of KMI's Teletherapy service.
Johnson & Johnson	Nevo Stent	Clogged heart arteries	Johnson & Johnson announced that patient-outcome trends in a key study for Nevo continued to favour the devices after a year.
Lantheus Medical Imaging	Definity	Pulmonary artery pressure	The phase IV clinical trial of Definity showed no significant changes in pulmonary or systemic haemodynamic parameters.

Company	Drug	Application	Comments
Merck & Co	Copycat version of Aranesp	Anaemia	Merck & Co announced it is discontinuing development of a generic version of Amgen's anaemia treatement Aranesp.
Medtronic	Arctic Front	Paroxysmal atrial fibrillation (AF) patients	Medtronic released favourable Artic Front Cardiac CryoAblation Catheter System clinical trial data.
Medtronic	Anti-tachycardia pacing (ATP)	Arrhythmia	Medtronic has released new data from the MVP trial which demonstrated that ATP was favourable compared to shock therapy.
Medtronic	CoreValve replacement heart valve	Heart disease	The CoreValve replacement heart valve has produced favourable results in a clinical trial.
Medtronic	RestoreSensor neurostimulator	Chronic pain	A trial has been initiated for the RestoreSensor neurostimulator, which has received CE Mark approval in Europe and is under investigational use in the United States.
Medtronic	Epilepsy Device	Movement disorders	FDA has said that the implant failed to ensure reduction in the incidence of seizures and has since failed to meet its study goal.
Micrus Endovascular Corporation	Micrus Endovascular Cerecyte and bare platinum microcoils	Cerebral aneurysms	Landmark randomised trial data shows favourable results compared with all published and reported randomised endovascular microcoil clinical trials.
National Health Service	Phakic intraocular lenses	Impaired vision	National Health Service announced a new method of correcting short sight through Phakic intraocular lenses.
NiTi Surgical Solutions	ColonRing	Gastrointestinal surgery	Clinical data for the ColonRing trial supports the device as a safe alternative to surgical staples.
NMT Medical	Closure I	Structural heart disease	The clinical trial for Closure I did not meet its primary end point.
Power3 Medical Products	NuroPro	Alzheimer's disease	Power3 Medical Products announced favourable results from its clinical trial for NuroPro protein biomarkers and has filed for patent protection for these findings.
Regeneron Pharmaceuticals	Experimental drug (name not disclosed)	High cholesterol and treat osteoarthritis	Data from early-stage trials of experimental drugs to cut cholesterol and treat osteoarthritis are showing positive signs.
ReVision Optics	PresbyLens	Presbyopia	US clinical trials of PresbyLens corneal inlay have been initiated.
Roche and Biogen Idec	Ocrelizumab	Rheumatoid arthritis	Development of ocrelizumab has ceased, following deaths in clinical trials and a disappointing risk-benefit assessment, concluding ocrelizumab was not favorable compared with current treatments.
St Jude Medical	Promote Quadra cardiac resynchronisation therapy defibrillator (CRT-D)	Quadripolar pacing system for patients with heart failure	St. Jude Medical announced European launch of a quadripolar pacing system.
St Jude Medical	QuickOpt optimisation feature in cardiac resynchronisation therapy	Resynchronisation of the heart beat	Trial results for the QuickOpt were favourable and show efficiency compared to echo optimisation.
Sunshine Heart	C-PulseTM heart assist system	Moderate heart failure	The University of Alabama Birmingham Medical Centre has successfully completed an implant of the C-PulseTM heart assist system in a patient, during the FDA approved clinical trial.
Teva Pharmaceutical Industries and Active Biotech	Laquinimod	Relapsing remitting multiple sclerosis (RRMS)	The two companies announced results from several studies demonstrating laquinimod may have neuroprotective properties in addition to its anti-inflammatory effects.
Teva	Teva's biosimilar, TL011	Rheumatoid arthritis	Teva is launching a clinical trial of a biosimilar to the monoclonal antibody.
The Whittemore Peterson Institute for Neuro-Immune Disease	Intercept Blood System	To inactivate XMRV, a human retrovirus, in donated platelet components	Favourable results have been announced from a study of the Intercept Blood System.

Regulatory

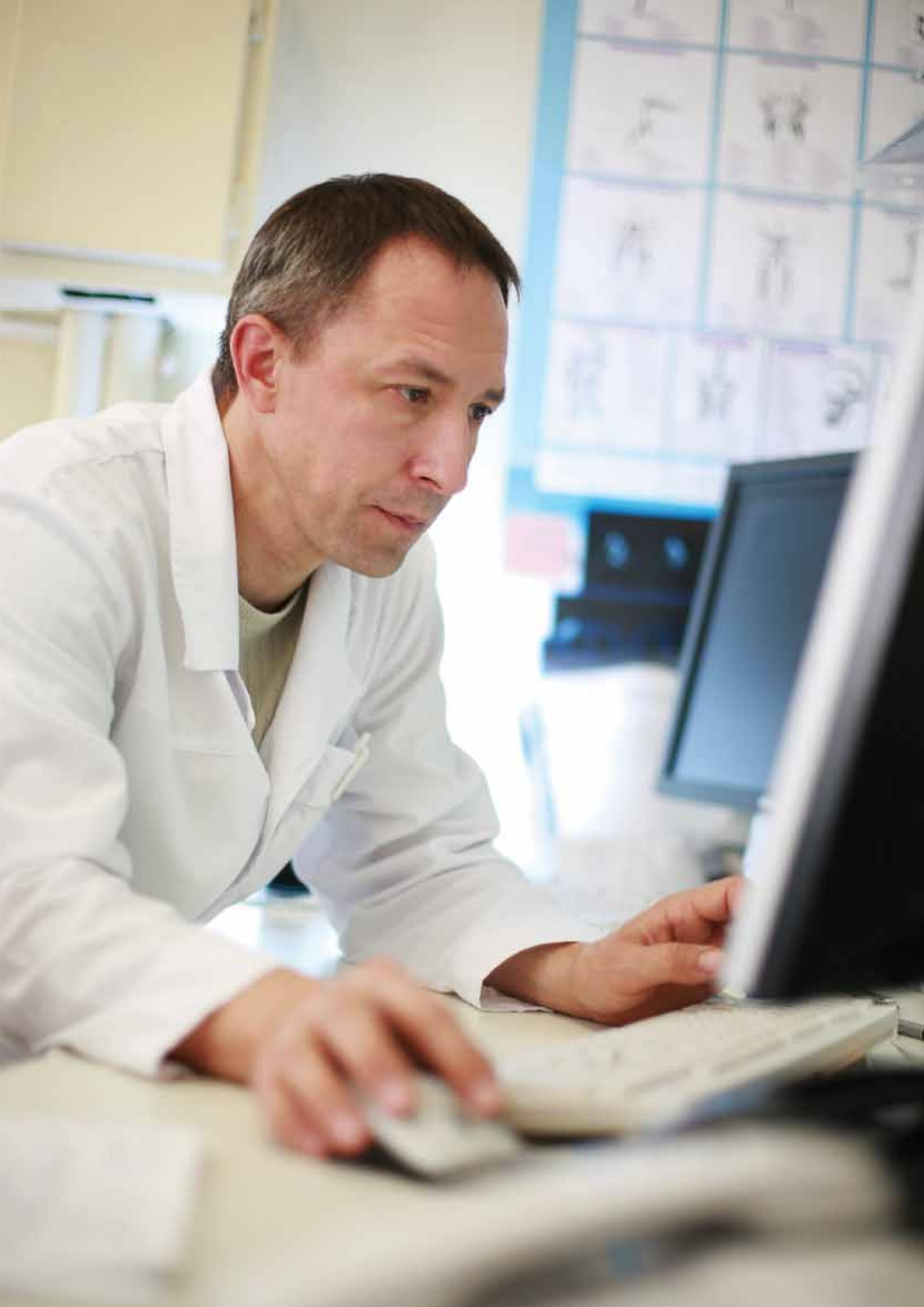
Company	Product	Application	Comments
Biotechnology		**Total**	**63**
Abraxis Bioscience	Abraxane	Mestatic breast cancer	The Scottish Medicines Consortium has accepted Abraxane for restricted use within the National Health Service.
Advanced Medical Solutions	Topical skin adhesives	Closure and protection of surgical incisions	The FDA has approved AMS's topical skin adhesives to be used in the operating theatre.
Akorn	Erythromycin Ophthalmic Ointment USP 3.5 g/ Dilaudid-HP 10mg/ml Injection	Not disclosed	The FDA has granted approval of akom's Abbreviated new drug application (ANDA) supplement for Erythromycin and Dilaudid.
Alkermes	Vivitrol	Treatment of opioid dependence	Alkermes announced that the supplementary new drug application for Vivitrol has been designated as priority review by the US FDA.
Aradigm	Ciprofloxacin	Cystic fibrosis	The FDA has given approval for a Ciprofloacin investigational new drug application.
ARCA biopharma	Bucindolol	Chronic heart failure	ARCA biopharma announced that it has reached agreement with the FDA to assess the safety and efficacy of bucindolol.
B. Braun Medical Inc	Cefepime	Antibiotic injections	The FDA approved Cefepime for use in B. Braun's Duplex System.
Baxter International	TachoSil	Cardiovascular surgery	The FDA granted approval for TachoSil.
Bio-Bridge Science	Vaccine for Papilloma pseudovirus	Papilloma psuedovirus	The Japanese patent office has issued patent number 4472724 for the Papilloma vaccine.
BioDelivery Sciences International	Onsolis (fentanyl buccal soluble film)	Breakthrough pain in opioid-tolerant adult patients with cancer	BioDelivery Sciences International announced the approval of a new drug submission (NDS) by Health Canada for Onsolis.
BioSante Pharmaceuticals	2A/furin technology	Rapid generation of cell lines	BioSante Pharmaceuticals announced the receipt of two US patents directed to its 2A/furin technology for expressing proteins.
Celgene International Sarl	Revlimid	Relasped or refractor multiple myeloma	Revlimid has been granted full marketing authorisation by Japan's Ministry of Health.
ChemGenex Pharmaceuticals Ltd	Omapro	Cancer	In a response letter the FDA approved the development of Omapro.
Clinical Data	Vilazodone	Major depressive disorder	Clinical Data has submitted a new drug application to the FDA for Vilazodone.
Corgenix Medical	AtherOx	Acute coronary syndrome	Corgenix has received a European patent for AtherOx.
CryoLife	CryoValve	Removal of allogeneic donor cells from valves.	Cyrolife has received 510(k) clearance from the FDA for a 5 year shelf life on its device.
DaVita	Not disclosed	In treatment of chronic kidney disease	DaVita received a subpoena from the Dallas office of the Department of Health and Human Services, Office of Inspector General (OIG).
Depomed	DM-1796	Post-therapeutic neuralgia	Depomed announced that its licensee has submitted a new drug application for DM-1796 to the FDA.
Endo Pharmaceuticals and Penwest Pharmaceuticals	Opana ER	Rare disorders of the nervous system	Endo and Penwest have settled litigation with Sandoz regarding the production and sale of a generic version of the drug.
Enzo Biochem	Nucleic acid signal amplification	Direct detection of nucleic acid	United States Board of Patent Appeals denied Siemens Healthcare Diagnostics' request for rehearing on Enzo's pending universal interference patent.
Genentech	Herceptin	Gastro and stomach cancer	Genentech has submitted a supplemental biologics license application to the FDA, based on positive results from the phase III study.
Genzyme Corporation	Lumizyme	Treatment of Pompe disease	Genzyme Corporation received US marketing approval for Lumizyme for Pompe disease.
Geron Corporation	Not disclosed	Not disclosed	The board of patent appeals overturned an earlier decision by the patent office to uphold the claim of patent no. 7029913 held by Wisconsin Alumni Research Foundation.
GlaxoSmithKline	Arzerra	Leukaemia	Arzerra has been rejected by Britain's cost watchdog NICE in preliminary draft guidance.
GlaxoSmithKline	Staxyn	Erectile dysfunction	The FDA has approved Staxyn for the treatment of erectile dysfunction.

Company	Product	Application	Comments
GlaxoSmithKline	Benlysta	Lupus	GlaxoSmithKline has sought European regulators' marketing approval for its experimental drug Benlysta.
HRA Pharma	Ella (Ulipristal)	Emergency contraceptive	The FDA Reproductive Health Drugs Advisory Committee has backed the approval of Ella.
Human Genome Sciences (HGS)	Not disclosed	Hepatitis C	HGS has announced it does not expect FDA approval of its treatment after unfavourable preliminary review results.
Human Genome Sciences (HGS)	Benlysta	Systematic lupus erythematosus	HGS applied to the FDA for approval to market its drug.
Illumina	VeraCode Genotyping Test	Not disclosed	The FDA has granted 510(k) market clearance for the VeraCode Genotyping Test for Factor V (Leiden) and Factor II (Prothrombin).
Keryx Biopharmaceuticals Inc & Aeterna Zentaris	Perifosine	Refractory advanced colorectal cancer	The FDA has given a 'fast track' designation to perifonsine.
Lannett Company	Ondansetron Injection	Not disclosed	Lannett has received FDA approval for its new drug application for Ondansetron.
Lenstec	Softec HD Intraocular Lens Implant	Cataracts	The FDA has granted approval to Softec HD Intraocular Lens Implant (IOL) for treating patients with cataracts.
Neostem	Sterile active pharmaceutical ingredient	Not disclosed	The State Food and Drug Administration (SFDA) in China approve Nestem's subsidiary to manufacture the sterile active pharmaceutical ingredient (API) of the anti-infective cloxacillin.
Merck	Dulera	Acutre bronchospasm	Dulera has been approved by the FDA.
Merck	Fosamax	Osteoporosis in postmenopausal women	The Federel Court has found in Merck's favour (Maley v Merck), rejecting the claims of dental and jaw-related problems from Fosamax use.
Mesoblast	NeoFuse stem cell product	Stem cell therapy	Mesoblast announced that it had received US regulatory approval to start phase two clinical trials of its NeoFuse stem cell product.
Novartis International AG	FTY720	Multiple	Novartis International AG announced that US FDA has extended its review period by three months for the regulatory approval of FTY720.
Oceana Therapeutics and Q-Med AB	Solesta	Fecal (or cowel) incontinence	Oceana Therapeutics and Q-Med AB announced the filing of a premarket approval application with the FDA for Solesta.
Oraya Therapeutics	IRay stereotactic radiotherapy system	Diseases of the eye	Oraya Therapeutics announced that a leading European body has granted Europe's CE mark of approval.
Quark Pharmaceuticals	QPI-1002	Prophylaxis of delayed graft function	The European Commission has granted orphan medicinal product designation for QPI-1002.
Pharming Group	Ruconest	Hereditary angioedema	The European Medicines Agency's Committee for Medical Products for Human Use has adopted a positive opinion on Runconest.
Photocure	Cysview	Bladder cancer	FDA approval means Photocure will therefore receive a payment of EUR 10 M from licence partner GE Healthcare.
Power3 Medical Products	Patent application	Not applicable	Power3 Medical filed two provisional patent applications with the US Patent and Trademark office.
Psivida Corp.	Ophthalmic product	Diabetic macular oedema	Psivida has submitted a new drug application to the FDA for its drug.
Sagent Pharmaceuticals	Mesna injection	Hemorrhagic cystitis	Sagent Pharmaceuticals announced that it has received FDA approval to market its mesna injection.
Solgenix	Oral Beclomethasone Dipropionate	GVHD and leukaemia	Solgenix has been granted a European patent for its drug.
Soligenix	Beclomethasone	To treat irritable bowel syndrome (IBS)	Soligenix announces grant of US patent for the treatment of irritable bowel syndrome with oral beclomethasone dipropionate.
STAAR Surgical Company	Hyperopic Toric ICL	Hyperopia and astigmatism	CE Mark approval for a range of product improvements to the Visian Implantable Collamer Lens (ICL). Including Hyperopic Toric ICL.
Strides Arcolab	Mesna injection	Side effects of chemotherapy	The FDA has approved Stride's generic version of the mesna injection.
SyntheMed	Repel-Gyn	Post-operative adhesion formation in patients undergoing gynaecologic surgery	SyntheMed has CE Mark approval for Repel-Gyn.

Company	Product	Application	Comments
Terumo Medical Corporation	Occlusive/stenotic peripheral artery revascularisation study	Superficial femoral artery	Terumo Medical Corporation announced it has received an investigational device exemption conditional approval from the FDA.
Teva	Cinacalcet HCl 30-, 60- and 90-mg tablets	Hyperparathyroidism	Teva has received tentative CE Mark approval for Cinacalcet HCl 30-, 60- and 90-mg tablets. As well as approval to sell the generic immune system drug tacrolimus.
Teva	Sensipar	Secondary hyperparathyroidism	The FDA has approved the generic Sensipar.
Torax Medical	Linx anti-reflux treatment	Gastro-esophageal reflux disease	Torax Medical has received CE Mark approval for its Linx Anti-Reflux treatment.
Transave	Arikace	Treatment for cystic fibrosis (CF) patients	Transave announced that the US Patent and Trademark Office has issued a key composition of matter patent for Arikace.
Unilife Corp	Unitract 1mL Insulin Syringes	Injection of insulin	Unilife Corp announced that the FDA has gaven additional marketing approval for its Unitract 1mL Insulin Syringes.
Xenoport	XP13512	Not disclosed	The EPO has ruled that the European patent for XP13512 is valid.
Medical Devices		**Total**	**60**
Abbott	FreeStyle Lite	Blood glucose test strips	Abbott has received 510(k) clearance for its device from the FDA.
AGA Medical Holdings	Amplatzer	Heart failure	The FDA has granted conditional IDE approval to study the use of Amplatzer.
American Medical Systems	Miniarc Precise Single-Incision Sling	Female stress urinary incontinence	The FDA has cleared American Medical's Miniarc device.
Applisonix	Selectif	Ultrasound	Applisonix has applied to the FDA to market the company's Selectif ultrasound depilatory device in the US.
Asthmatx	Alair System	Bronchial thermoplasty	Treatment of first patient with bronchial thermoplasty with Alair System following FDA approval.
Atricure	Atriclip System	Not disclosed	Atricure has received 510(k) approval from the FDA for its device.
BioMedix	TRAKnet software	Health records and pratice management	BioMedix TRAKnet software suite was granted American Podiatric Medical Association (APMA) seal of acceptance.
Biotronik	Evia pacemaker	Physiologic pacing	The Evia pacemaker has been cleared by the FDA for distribution in the U.S.
Boston Scientific Corp.	Lead splitters	For the use with the Precision Plus device	Boston Scientific has announced the FDA approval and launch of its device.
Boston Scientific Corp	NC Quantum Apex PTCA	Optimisation of coronary stent deployment	Boston Scientific Corp has announced CE Mark and FDA approval of NC Quantum Apex PTCA Dilation Balloon Catheter.
Boston Scientific Corp	Cognis CRT-Ds and Teligen ICDs	Heart failure	The FDA has granted clearance for two validated manufacturing changes affecting all of Boston Scientific's devices, and they will immediately resume distribution of their devices.
Boston Scientific Corp	Genesys HTA System	Menorrhagia	Boston Scientific has received FDA approval of its Genesys HTA System.
Boston Scientific Corporation	Platinum Chromium Taxus Element Stent System	Diabetes	Boston Scientific has received CE Mark approval for its stent system.
Cambridge Heart	Microvolt T-Wave Alternans OEM module	Cardiac stress tests	Cambridge Heart has received 510(k) clearance from the FDA to begin marketing its Microvolt T-Wave Alternans OEM module.
Cardima	Cardima Surgical Ablation System	Chest surgery	All components of the Cardima Surgical Ablation System are now approved for marketing for the treatment of AF in European countries recognising CE Mark approval.
Cardiovascular Systems	CSI's Diamondback 360 System	Removal of calcific and fibrocalcific plaque in coronary lesions	The FDA has granted approval for ORBIT II Coronary clinical trial.
Cepheid	Xpert SA Nasal Complete	Detection and differentiation of Staphylococcus and Methicillin-resistent staphylococcus	Cepheid received FDA clearance to market its device.
Claros Diagnostics	PSA System	Prostate specific antigen	Claros has received CE Mark approval for its device.
Concentric Medical	Merci Retriever, Merci Microcatheter, and Merci Balloon Guide Catheter	Blood clots as a result of ischemic stroke	The devices have received Shonin approval in Japan.
Cook Medical	Zilver	Peripheral arterial disease	Cook Medical has submitted a pre-approval application to the FDA for its device.

Company	Product	Application	Comments
CorMedix	Neutrolin	Catheter related bloodstream infections	The US Patent and Trademark office has granted a patent for Neutrolin.
Crospon	EndoFLIP	Gastric band surgery	Crospon has launched its EndoFLIP gastric product in the US.
Digirad	Ergo	Medical imaging system	The FDA has granted approval for marketing of Ergo imaging camera.
EDAP TMS SA	Sonolith i-move	Location of urinary stones	EDAP TMS SA announced the European approval of Sonolith i-move.
Embrella Cardiovascular	Embrella Embolic Deflector	Embolisation of the brain	Embrella Embolic Deflector has received CE mark approval.
Envoy Medical	An implantable hearing system	Sensorineural hearing	Envoy's implantable hearing system has receieved FDA approval.
Ethicon	Sedasys System	Sedation during colonoscopy procedures	Ethicon's Endo-Surgery Sedasys System received regulatory approval in Canada and CE Mark approval.
Ev3	Pipeline Embolization Device	Aneurysms	ev3 Inc has filed a pre-market approval application for FDA approval of the Pipeline Embolization Device.
GE Healthcare	Cysview	Papillary cancer of the bladder	The FDA has approved GE Healthcare's device.
Guided Therapeutics	LightTouch Cervical Scanner	Detection alternative/ supplement for pap tests	An FDA trial demonstrated favourable results.
Hansen Medical	Hansen's catheter system	Irregular heartbeat	Hansen has received conditional approval from the US FDA for a clinical trial of Hansen's catheter system for the treatment of irregular heartbeat.
Heartware International	Heartware Ventricular Assist System	Heart failure	The FDA has granted Heartware conditional approval to begin enrolment in an investigational device exemption destination therapy clinical trial for its device.
Hyperbranch Medical Technology	Adherus	Spinal surgeries	Adherus has received a CE Mark.
Illumina	BeadXpress system	Simultaneous detection of multiple analytes in a DNA sample	The FDA has granted 510(k) market clearance for the company's BeadXpress system for multiplex genetic analysis.
Kinetic Concepts	Vacuum Assisted Closure Therapy System	Venous insufficiency ulcers	The FDA has given 510(k) clearance for the marketing of the Vacuum Assisted Closure Therapy system.
Johnson & Johnson	Sedation system	Regulation of the delivery of sedatives	The FDA has rejected the company's application for a computer-assisted sedation system, company is appealing the decision.
Maquet Cardiovascular	Quadrox-iD	Paediatric diffusion membrane oxygenator	Maquet had received FDA 510(k) marketing clearance for Quadrox-iD.
MBiotechnologies	Occlusin 500 Artificial Embolization Device	Unresectable/inoperable hypervascularized tumours	IMBiotechnologies received FDA clearance to market the Occlusin 500 Biodegradable Microspheres in the US.
Medtronic	Revo MRI SureScan Pacing System	MRI safe pacemaker	FDA has recommended approval with conditions for Medtronic's Revo MRI SureScan Pacing System.
Medtronic	SE Vascular Stent System	Not disclosed	The FDA granted approval for the SE Vascular Stent System.
Millennium Dental Technologies	PerioLase MVP-7	Gum disease	Millennium Dental has received CE Mark approval for the device.
Micronics	ABORhCard	An invitro test that provides a simultaneous determination of an individual's ABO blood group and Rh factor	Micronics announced that the FDA has granted the company 510(k) clearance to market its ABORhCard.
Oraya Therapeutics	iRay	Stereostatic radiotherapy	The iRay stereostatic radiotherapy has been granted a CE Mark.
Orasure Technologies	HCV Rapid Antibody Test	Hepatitis C	Orasure has received FDA approval for its device.
Pathway Medical Technologies	Jeststream G3 SF Atherectomy System	Peripheral vascular disease	Pathway Medical has received 510(k) clearance from the FDA to market its device.
Pyng Medical Corp	Cric	Obtaining a surgical airway	The FDA has completed its review of Pying Medical's 510(k) submission for its CRIC Kit Cricothyrotomy device.
Redent Nova	Vatea Irrigation Device	Root canal	Redent has obtained FDA marketing approval for its device.
SpectraScience	Optical biopsy system	Characterisation of tissue	SpectraScience had two patents issued by the Japanese patent office and the European patent office for its device.
Steris	1E liquid chemical sterilant processing system	Prevention and decontamination of infections	The FDA has cleared Steris to market its System 1E liquid chemical sterilant processing system.
Steris	Steris System 1 Processor, or SS1	Sterlisation	The FDA announced that a consent decree has been filed to stop the company from distributing unapproved and misbranded devices.

Company	Product	Application	Comments
St Jude Medical	Epiducer	Neurostimulation therapy	Epiducer has received CE Mark approval.
St Jude Medical	EnSite Derexi module	Sychronisation of patient records	St Jude Medical announced FDA clearance, CE Mark approval as well as the launch of the EnSite Derexi module.
St Jude Medical	Unify and Fortify defibrillators	Irregular heart	The FDA has given clearance for two of St Jude's implantable heart defibrillators.
SurgiVision	ClearPoint System	Minimally invasive procedures on the brain	SurgiVision has received 510(k) clearance to begin marketing its device.
SynCardia Systems	Freedom System	Artificial heart	The FDA has approved an IDE for the clinical study of the Freedom driver system.
Terumo Medical	Misago Self-expanding Stent System	Superficial femoral artery	Terumo Medical has received an investigational device exemption conditional approval from the FDA.
Vasomedical	Biox Model 2301	Combine ECG Holter and blood pressure montoring system	Vasomedical has received an FDA 510(k) clearance for Model 2301.
Volcano	PrimeWire Prestige	Single-Multi vessel disease	Volcano has received 510(k) clearance and CE Mark approval for its device.
WL Gore & Associates	Gore Tag Thoracic Endoprothesis	Aneurysms	WL Gore has received FDA approval for its device.
WL Gore & Associates	The Gore Viabil Biliary Endoprosthesis	Biliary strictures	WL Gore & Associates has received European CE Mark approval for the Gore Viabil Biliary Endoprosthesis.



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Appendix

Companies in the PwC Life Sciences Index

		Closing Mcap (A$m)	Quarterly return
Medical Device			Q1 FY11
ACG	ATCOR MEDICAL HOLDINGS LIMITED	12.05	-9%
ADO	ANTEO DIAGNOSTICS LIMITED	27.76	-6%
AMT	ADVANCED SURGICAL DESIGN & MANUFACTURE LIMITED	13.06	-14%
AQL	AQUACAROTENE LIMITED	4.85	33%
AYX	AUSTOFIX GROUP LIMITED	11.84	0%
BOD	BIOMD LIMITED	2.71	-23%
BRC	BRAIN RESOURCE COMPANY LIMITED (THE)	19.26	-5%
CBB	CORDLIFE LIMITED	41.54	-11%
CGS	COGSTATE LTD	17.29	0%
CLV	CLOVER CORPORATION LIMITED	56.99	23%
CMP	COMPUMEDICS LIMITED	22.68	12%
COH	COCHLEAR LIMITED	3,974.39	-5.5%
CXD	CATHRX LTD	39.40	4%
CYC	CYCLOPHARM LIMITED	11.46	-14%
ELX	ELLEX MEDICAL LASERS LIMITED	28.02	120%
EMS	EASTLAND MEDICAL SYSTEMS LTD	19.65	32%
FLS	FLUOROTECHNICS LIMITED	1.79	-89%
GBI	GENERA BIOSYSTEMS LIMITED	27.57	-2%
HIN	HEARTWARE INTERNATIONAL, INC	991.52	-16%
IPD	IMPEDIMED LIMITED	108.86	42%
ITD	ITL LIMITED	6.58	-12%
KSX	KARMELSONIX LIMITED	8.93	-28%
LBT	LABTECH SYSTEMS LIMITED	8.75	32%
MDG	MEDTECH GLOBAL LIMITED	5.01	0%
MDV	MEDIVAC LIMITED	8.70	0%
MGZ	MEDIGARD LIMITED	4.72	-58%
MLA	MEDICAL AUSTRALIA LIMITED	5.68	-12%
MOD	MEDICAL CORPORATION AUSTRALASIA LIMITED	4.98	0%
MVH	MEDIC VISION LIMITED	14.11	458%
NAN	NANOSONICS LIMITED	179.04	49%
NDL	NEURODISCOVERY LIMITED	2.59	-17%
OBJ	OBJ LIMITED	30.61	18%
OIL	OPTISCAN IMAGING LIMITED	5.71	-15%
RMD	RESMED INC	5,116.21	-7%
SHC	SUNSHINE HEART, INC.	16.17	-24%
SOM	SOMNOMED LIMITED	37.90	18%
TDX	TYRIAN DIAGNOSTICS LIMITED	6.98	56%
UBI	UNIVERSAL BIOSENSORS, INC.	228.25	-6%
UCM	USCOM LIMITED	13.38	-48%
UNS	UNILIFE CORPORATION	344.64	-7%

		Closing Mcap (A$m)	Quarterly return
Pharma and Biotech			Q1 FY11
ACR	ACRUX LIMITED	390.16	32%
ACW	ACTINOGEN LIMITED	4.39	214%
ACU	ACUVAX LIMITED	2.50	-50%
AGX	AGENIX LIMITED	21.64	90%
ACL	ALCHEMIA LIMITED	92.69	-6%
ALT	ANALYTICA LIMITED	9.04	-15%
ANP	ANTISENSE THERAPEUTICS LIMITED	8.29	8%
AOP	APOLLO CONSOLIDATED LIMITED	14.38	163%
APH	ASCENT PHARMAHEALTH LTD	72.34	7%
AVX	AVEXA LIMITED	26.28	-6%
AVH	AVITA MEDICAL LTD	11.14	-13%
BLT	BENITEC LIMITED	17.45	25%
BDM	BIODIEM LIMITED	14.21	27%
BNO	BIONOMICS LIMITED	87.55	2%
BPH	BIOPHARMICA LIMITED	26.23	31%
BPO	BIOPROSPECT LIMITED	5.63	-23%
BTA	BIOTA HOLDINGS LIMITED	171.78	-6%
BIT	BIOTRON LIMITED	7.79	-17%
BNE	BONE MEDICAL LIMITED	5.42	-39%
CBZ	CBIO LIMITED	24.48	-34%
CZD	CALZADA LIMITED	8.32	-4%
CST	CELLESTIS LIMITED	225.96	-15%
CDY	CELLMID LIMITED	6.53	5%
CXS	CHEMGENEX PHARMACEUTICALS LTD	96.34	15%
CIR	CIRCADIAN TECHNOLOGIES LIMITED	25.98	12%
CUV	CLINUVEL PHARMACEUTICALS LIMITED	62.21	-9%
CTE	CRYOSITE LIMITED	4.66	-17%
CSL	CSL LIMITED	18,176.44	1%
GEN	GENESIS RESEARCH AND DEVELOPMENT CORPORATION LIMITED	0.60	0%
GTG	GENETIC TECHNOLOGIES LIMITED	10.52	-26%
GIA	GIACONDA LIMITED	2.19	-10%
HGN	HALCYGEN PHARMACEUTICALS LIMITED	87.84	5%
HTX	HEALTHLINX LIMITED	12.50	-25%
HXL	HEXIMA LIMITED	21.48	20%
HCT	HOLISTA COLLTECH LIMITED4	12.96	-13%
IMC	IMMURON LIMITED	26.41	22%
IMU	IMUGENE LIMITED	12.93	165%
IDT	INSTITUTE OF DRUG TECHNOLOGY AUSTRALIA LIMITED	25.92	-3%
LCT	LIVING CELL TECHNOLOGIES LIMITED	49.66	-19%
MVP	MEDICAL DEVELOPMENTS INTERNATIONAL LIMITED	14.81	-2%
MSB	MESOBLAST LIMITED	398.20	39%
NEU	NEUREN PHARMACEUTICALS LIMITED	6.85	-15%
NRT	NOVOGEN LIMITED	12.77	-27%
NSP	NUSEP LIMITED	14.26	17%
PAB	PATRYS LIMITED	14.42	-25%
PXS	PHARMAXIS LTD	489.91	5%
POH	PHOSPHAGENICS LIMITED	68.79	-7%
PYC	PHYLOGICA LIMITED	14.83	-27%
PBT	PRANA BIOTECHNOLOGY LIMITED	30.16	-19%
PRR	PRIMA BIOMED LTD	72.82	-5%

		Closing Mcap (A$m)	Quarterly return
PCC	PROBIOMICS LIMITED	2.94	0%
PBP	PROBIOTEC LIMITED	52.17	-27%
PGL	PROGEN PHARMACEUTICALS LIMITED.	8.65	-13%
PVA	PSIVIDA CORP.	90.80	28%
QRX	QRXPHARMA LIMITED	102.48	-14%
SIE	SCIGEN LIMITED	96.65	0%
SLT	SELECT VACCINES LIMITED	3.52	0%
SRX	SIRTEX MEDICAL LIMITED	272.71	0%
SLA	SOLAGRAN LIMITED	44.67	20%
SPL	STARPHARMA HOLDINGS LIMITED	134.05	4%
STI	STIRLING PRODUCTS LIMITED	11.49	50%
TEO	TELESSO TECHNOLOGIES LIMITED	0.60	0%
TIS	TISSUE THERAPIES LIMITED	32.48	31%
VLA	VIRALYTICS LIMITED	17.70	-11%
VHL	VIRAX HOLDINGS LIMITED	5.26	-55%
XCD	XCEED CAPITAL LTD	2.40	20%

Notes:

ATW	Removed from index. Suspended from the ASX
BOS	Removed from index. Suspended from the ASX
BZI	Removed from index. Company has moved into Resources sector
CBZ	Cbio added into index.
ICV	Removed from index. Company has moved into Resources sector
PAA	Removed from index. Company has moved into Resources sector
SFP	Removed from index. Suspended from the ASX

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Methodology

Sources

BioForum draws on historical data from the following sources:

- Bloomberg
- Connect 4
- the ASX
- 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:

i. PwC Life Sciences Index

ii. 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:

i. pharmaceutical/biotechnology

ii. 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. 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.

Top and bottom performers

Annual data on these companies is sourced from Bloomberg each quarter. Company announcements are sourced from the ASX or directly 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 our quarterly *PwC Global Pharma and Life Sciences Newsbrief*.

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. Examples of other information include management and board changes, the closing or opening of offices, and successful grant applications.

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

The US announcement data is sourced from our quarterly *PwC Global Pharma and Life Sciences Newsbrief*.

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“Anecdotally the biotech market is patchy but there are some positive signs. US venture capital market investors are reaching out abroad and Australia’s smaller venture capital sector is also seeking worthwhile opportunities.”

Craig Lawn, Partner, PwC

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