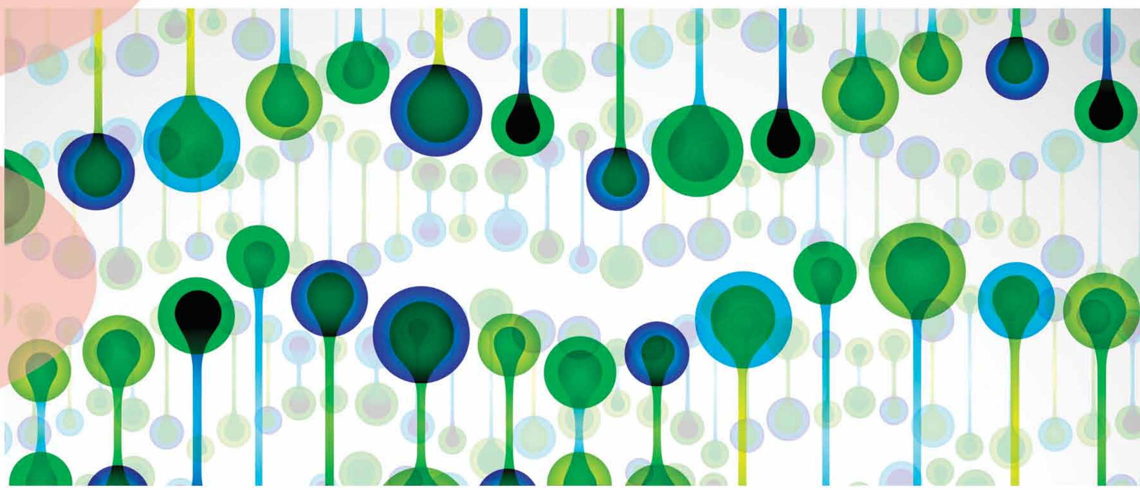
PHARMA HALF-YEAR REVIEW 2013



FOREWORD

Following on from the 2012 Year in Review I would like to welcome you to EP Vantage's Pharma Half-Year Review 2013. In this latest report we have analysed some of the key trends that have defined the industry in the first six months of the year, with a brief nod to what might happen during the remainder of 2013.

The inexorable rise in biotech valuations has best characterised the first half of 2013. Since March the level of Nasdaq Biotechnology Index has consistently exceeded the record highs set during the genomics bubble of 2000; by early September it had surged 50% over the year. Amgen's acquisition of Onyx for $10.4bn last month means investor interest is unlikely to wane any time soon.

This bubble has had both positive and negative knock-on effects for the industry. This report shows that IPO activity has increased in the year, and investors appear more confident about getting a return on their investment. In the first half the year 20 companies floated – compared with just 16 during the whole of 2012 – and raised $1.28bn between them.

Although the pace of IPOs is still slower than before the financial crisis, conditions continue to improve for those braving a listing – "haircuts" or discounts to proposed price ranges are becoming less common, and once on the market share prices are holding up and in many cases rising. One extreme example that will have corporate financiers rubbing their hands with glee is Onconova, which has seen its stock jump 66% since its debut in July.

M&A has also staged a comeback with $29bn worth of deals completed in the first half, topped by Valeant's purchase of Bausch + Lomb for $8.7bn. With Amgen adding to the total since then 2013 is on track to become the best year for acquisitions since 2010, outside the distorting effect of mega mergers.

But companies might want to take advantage of the good times now. With the improving macro-economic environment interest rates could start to rise as early as next year or 2015. The end of cheap money could take the heat out of both the IPO and M&A markets.

One area where there has been a distinct chill is product deals. Just 416 assets were licensed in the first half, meaning 2013 will struggle to match the five-year average of 968. One reason for the brakes being applied could be soaring valuations that have priced assets above buyers' comfort levels.

As for the second half, if the M&A and IPO trends continue, on the surface 2013 could be heralded as the turning point in what has been a grim half decade. But there are still deep-seated issues to deal with, such as productivity, reimbursement and proving the value of products to payers. Only by tackling these successfully will the industry find itself on the real road to recovery.

Regards,

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PHARMA IN THE FIRST HALF OF 2013

If anything illustrates the pharma and biotech industry's mood in 2013, it is this simple fact: On March 5, the Nasdaq Biotechnology Index, a key valuation metric in the small and medium-sized groups that drive innovation, exceeded its previous record of 1,596.93, set almost exactly 13 years earlier. That the previous record was set during the genomics bubble of 2000, which burst spectacularly and from which the sector struggled to recover, should stifle some of the jubilation.

The inflating bubble has had some knock-on effects. Privately held groups are finding it easier to float, with IPOs on a pace not seen in years, for example. They are also benefiting from an increasing flow of venture capital, although this is coming up from a very low base of the financial crash of 2008, as investors' appetite for risk returns. M&A activity is picking up, but will probably not equal the activity that preceded the patent cliff, when pipelines were dry and takeout targets cheap; rising valuations must be limiting big pharma's interest in acquisitions. Likewise, licensing activity has stumbled – the bubble having raised many sellers' expectations out of realistic territories.

As the second half of the year proceeds, the sector will be acutely aware that the biotech bull market will celebrate its second birthday in late November. Expectations are running well ahead of reality, and it might not take much to set a correction in motion. With this in mind, EP Vantage has reviewed the first half of a record-breaking year to provide some perspective on the sustainability of such buoyant trends.

M&A ACTIVITY IS PICKING UP, BUT WILL PROBABLY NOT EQUAL THE ACTIVITY THAT PRECEDED THE PATENT CLIFF, WHEN PIPELINES WERE DRY AND TAKEOUT TARGETS CHEAP; RISING VALUATIONS MUST BE LIMITING BIG PHARMA'S INTEREST IN ACQUISITION

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GOOD TIMES IN PUBLIC EQUITY MARKETS

If the markets in 2012 gave strong returns to pharma and biotech investors, then in the first half of 2013 they have been on steroids. The Nasdaq biotechnology index grew 27% through June 30, nearly equalling the growth through the whole of 2012, with the big-pharma-oriented Dow Jones pharma index showing nearly equal gains at 21%. Compare this with the gains of 14% and 13% for the Dow Jones Industrial Average and S&P 500 respectively, and one can get an idea of how much investment is rushing into the pharma sphere.

Percentage Change in Stock Indices over H1 2013

Stock Index	% Change in H1 2013
NASDAQ Biotechnology (US)	27%
S&P Pharmaceuticals (US)	17%
Dow Jones STOXX Healthcare (EU)	11%
Euro STOXX 50	(1%)
DJIA	14%

As a sign of the buoyant mood, only two big-cap drug developers registered declines in the first six months of the year. It was no surprise when Novo Nordisk slipped 3% – its biggest growth prospect, the long-acting insulins Tresiba and Ryzodeg, were sent back for more clinical work by the FDA. On the positive side, to rank in the top three risers a company's share price gains had to top 40%, a mark achieved by Celgene, Biogen Idec and Gilead Sciences – all groups spurred on by success with newly launched products or by expectation of clinical wins.

Big Pharma Top Risers and Fallers in H1 2013

		Share Price (local currency)			Market Capitalisation ($bn)	
Rank	**Top 5 risers**	**31-Dec-12**	**28-Jun-13**	**Change**	**31-Dec-12**	**28-Jun-13**
1	Celgene ($)	78.47	116.98	49%	33.2	48.8
2	Biogen Idec ($)	146.37	215.20	47%	34.6	51.1
3	Gilead Sciences ($)	36.72	51.27	40%	55.6	78.2
4	Bristol-Myers Squibb ($)	32.59	44.69	37%	53.8	73.4
5	Roche (SFr)	184.00	235.00	28%	170.7	216.4
Rank	**Top 5 fallers**					
1	Novo Nordisk (DKr)	916.50	893.00	(3%)	72.1	69.0
2	Eli Lilly ($)	49.32	49.12	(0.4%)	57.2	55.5

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Outside the realm of big pharma, Vertex made a nimble shift from hepatitis C to cystic fibrosis and managed to nearly double its market capitalisation, while Clovis bounced back from failure in 2012 to clinical success in early 2013, and quadrupled its valuation. Among the smallest of the small, the big story was the dizzying gains of Japanese biotech, lifted by hopes that its government will invest in the sector.

The big fallers consist of some companies that have run across regulatory worries or have found themselves scoring zero in binary events. Indian generics groups Ranbaxy Laboratories and Wockhardt have run into difficulty with US regulators, while Affymax was forced to withdraw its only product, the anaemia drug Omontys, on hypersensitivity concerns. Celsion, Aveo Oncology and Resverlogix all fell on negative clinical data.

Other Significant Risers and Fallers in H1 2013

		Share Price (local currency)			Market Capitalisation ($m)	
Rank	**Top 5 risers**	**31-Dec-12**	**28-Jun-13**	**Change**	**31-Dec-12**	**28-Jun-13**
1	Vertex Pharmaceuticals ($)	41.90	80.06	91%	9,085	17,725
2	Isis Pharmaceuticals ($)	10.44	26.87	157%	1,057	3,001
3	Clovis Oncology ($)	16.00	66.98	319%	418	1,979
4	ACADIA Pharmaceuticals ($)	4.65	18.15	290%	263	1,575
5	Cytokinetics ($)	3.96	11.57	192%	94	311
Rank	**Top 5 fallers**					
1	Ranbaxy Laboratories (Rs)	502.75	309.95	(38%)	4,002	2,414
2	Wockhardt (Rs)	1,572.10	999.50	(36%)	3,242	2,016
3	AVEO Oncology ($)	8.05	2.50	(69%)	352	130
4	Affymax ($)	18.99	1.03	(95%)	706	39
5	Resverlogix (C$)	1.60	0.23	(86%)	120	17

Ranked on Market Cap.

Top 5 risers	**EP Vantage Comment and Analysis**
Vertex Pharmaceuticals ($)	Cystic fibrosis hit takes Vertex back to 2000
Isis Pharmaceuticals ($)	ADA – Knockdown result boosts Isis and antisense alike
Clovis Oncology ($)	Asco Event Analyzer – 2013's winners and losers
ACADIA Pharmaceuticals ($)	Possibility of earlier pimavanserin approval boosts Acadia
Cytokinetics ($)	Amgen's global ambitions for omecamtiv spark renewed interest in Cytokinetics
Top 5 fallers	
Ranbaxy Laboratories (Rs)	Daily Market Movers (24 Jun 2013)
Wockhardt (Rs)	Daily Market Movers (11 Jun 2013)
AVEO Oncology ($)	Aveo reveals fallout of tivozanib failure
Affymax ($)	Affymax faces extinction after Omontys debacle
Resverlogix (C$)	Resverlogix doomed by second failure

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BOOM TIMES GIVE LIFT TO PUBLIC FLOATS

It took some time, perhaps longer than many would have liked, but the biotech IPO candle was lit at last as investor enthusiasm reached fever pitch – 20 floats came in the first six months of 2013, with 16 in the second quarter.

Unlike previous years, when public market aspirants had to rein in expectations of immediate gains, there were some surprising results as floats took off. Bluebird Bio premiered on Nasdaq at a 13% premium to its filed range and proceeded to grow 47% in less than a fortnight. Stemline Therapeutics floated at the low end of its filed range in late January, but more than doubled in price in five months, and Epizyme came close to doubling in value, after floating at a premium, in just a month on public markets.

Top 10 Biotech IPOs on Western Stock Exchanges in H1 2013

Company	Date	Amount Raised	Offering Price	Range	Discount/Premium	Exchange	H1 Change Since Float
PTC Therapeutics	June 20	$125m	$15	$13-16	3%	Nasdaq	0%
Portola Pharmaceuticals	May 22	$122m	$14.50	$13-16	0%	Nasdaq	69%
Chimerix	April 11	$102m	$14	$13- 15	0%	Nasdaq	73%
Bluebird Bio	June 18	$101m	$17	$14- 16	13%	Nasdaq	47%
Epizyme	May 31	$79.8m	$15	$13-15	7%	Nasdaq	88%
Prosensa	June 27	$78m	$13	$11-13	8%	Nasdaq	48%
Tetraphase Pharmaceuticals	March 20	$75m	$7	$10-12	(36%)	Nasdaq	0%
Receptos	May 09	$73m	$14	$14-16	(7%)	Nasdaq	42%
KaloBios Pharmaceuticals	January 31	$70m	$8	$12-14	(38%)	Nasdaq	(29%)
Esperion Therapeutics	June 26	$70m	$14	$13-15	0%	Nasdaq	1%
Average across all 20 IPOs		***$64m***			***(14%)***		***32%***

Source: EvaluatePharma © 2013

The difference between the US and Europe was stark. Only two companies, Sweden's Immunicum and France's Erytech Pharma, went public on European exchanges. If anything, European companies went to America looking for its more specialist biotech investors: Britain's GW Pharmaceuticals added a US listing, while Netherlands-based Prosensa Holding bypassed its domestic market altogether and went straight to the tech-oriented Nasdaq exchange in New York.

Some caution may be thrown into the outlook for second-half floats, however: Regado Biosciences and Sophiris Bio drastically scaled back ambitions during their August IPOs, which should remind companies and investors alike that bubbles cannot be sustained forever.

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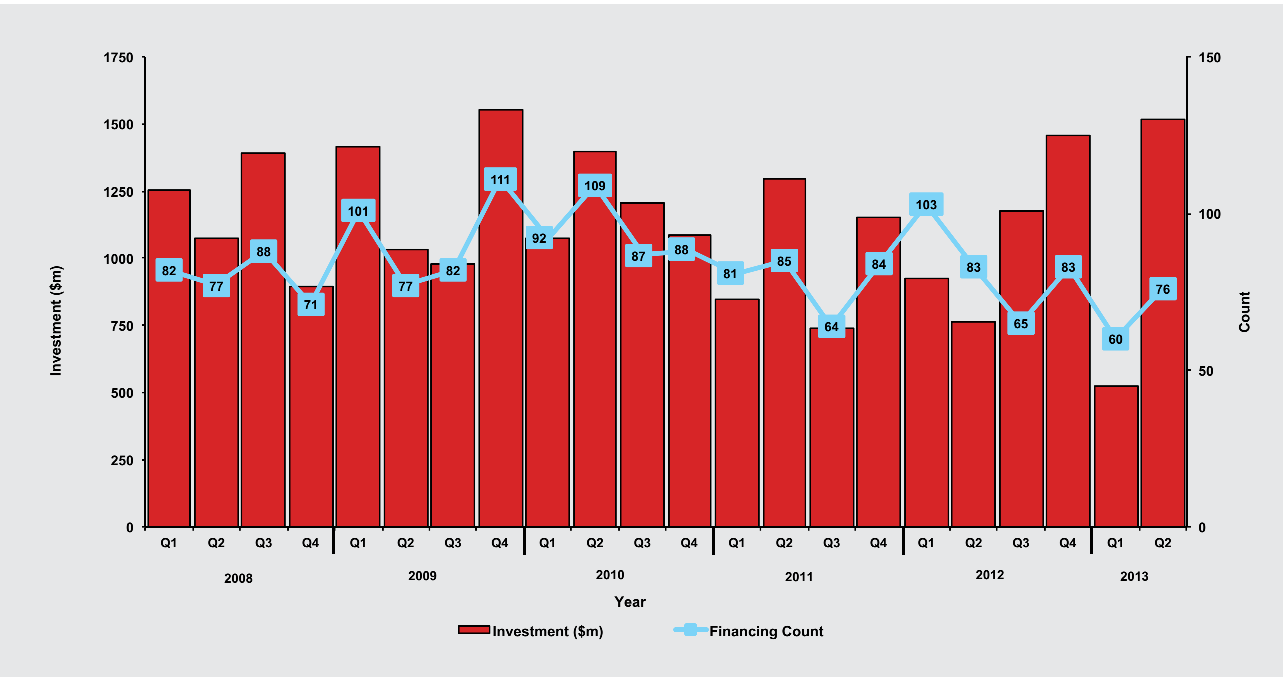
STOPS AND STARTS IN VC FUNDING

Venture capital funding for companies developing human therapeutics was a mixed bag through the first half of 2013, with rounds struggling to get off the ground in the first three months only to see one of the best quarters in years in the second. Some $2bn was raised, two thirds of it in the second quarter as four of the five rounds of $50m or more came between April and the end of June.

Quarterly VC Investments



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It should also be noted that some of the biggest rounds went to companies that were able to execute a public offering shortly afterwards – PTC Therapeutics and Intrexon – a sign that many venture capital investors continue to favour later stage companies.

As far as big fundraisings went, Intrexon outdistanced all other private biotech groups developing human therapeutics when it announced its $150m series F round in May. This coincided with a clear shift towards series C or later rounds, with a concomitant decrease in the number of rounds and an increase in their average size. Another demonstration of this trend: the top 10 rounds in the first half, a ranking that required companies to raise at least $43m, hoovered up one third of all VC funding, up substantially from one-fifth or less in recent years.

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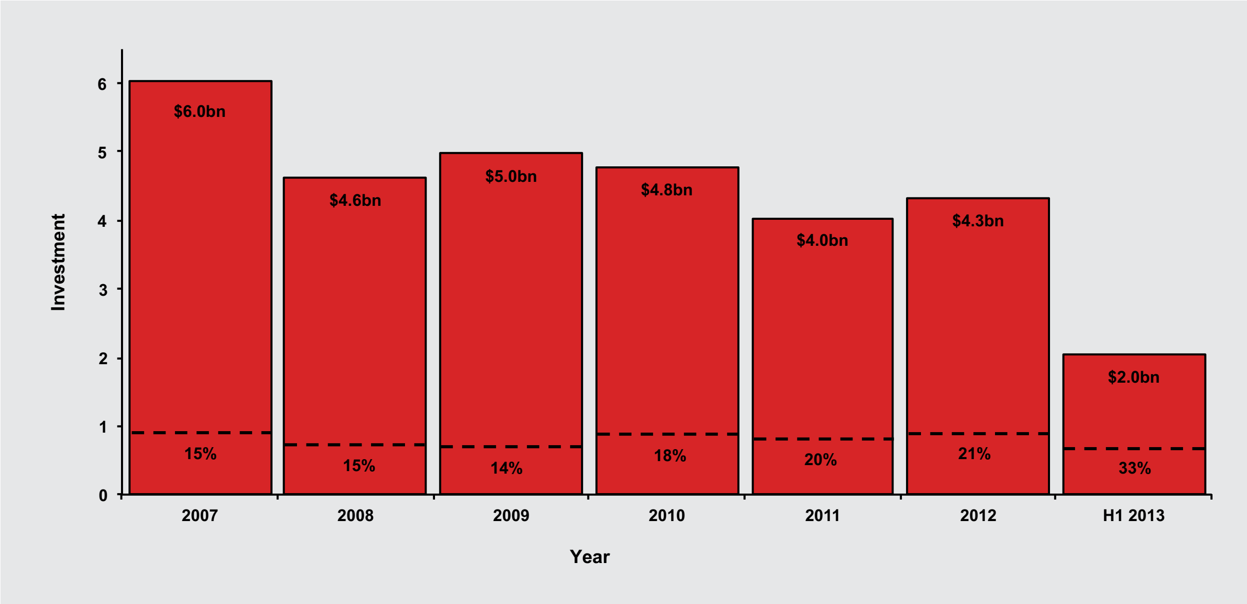
Annual VC Investments with 10 Biggest Rounds Shown as Proportion of Total Raised



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If there is growing comfort with risk, it must be said that VC funders are gravitating towards biotechs whose science has demonstrated some viability, and as PTC and Intrexon have shown it does not hurt to be close to an exit. Unless there are some drastic changes in the financing environment, earlier-stage private biotechs still could struggle to raise the capital to fund clinical work.

Biggest Rounds of H1 2013

Company	Financing Round	Investment ($m)
Intrexon	Series F	150.0
Revance Therapeutics	Series E	104.0
PTC Therapeutics	Series Undisclosed	60.0
Trevena	Series C	60.0
Ophthotech	Series C	50.0

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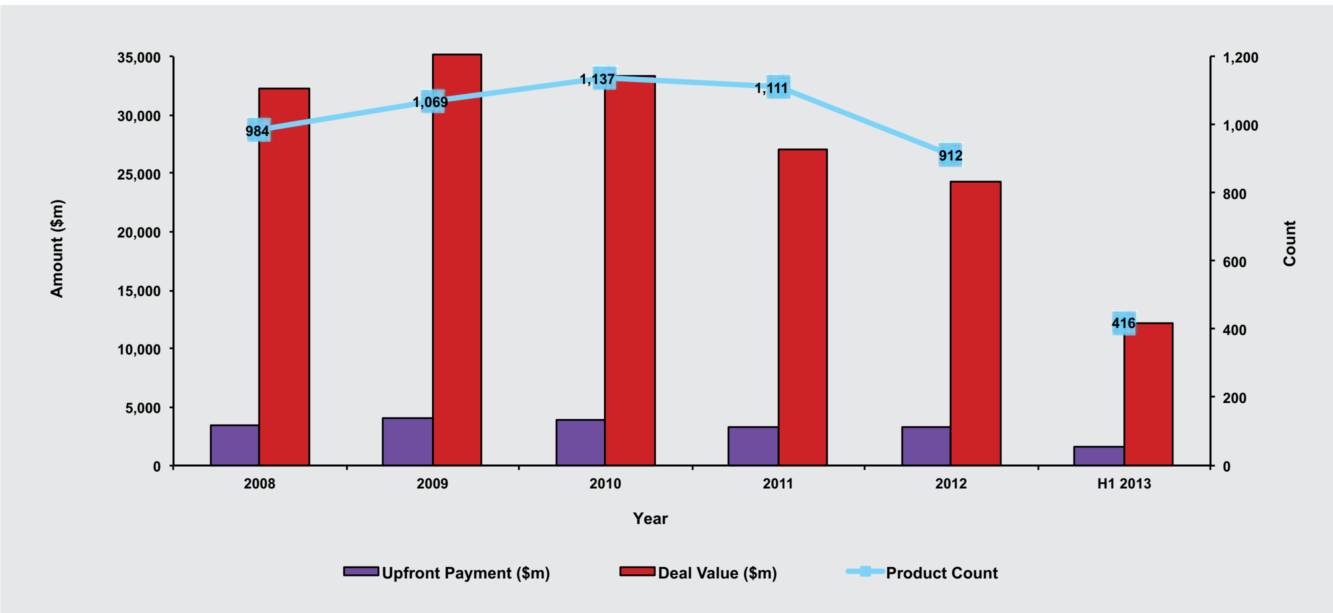
FOOT TAKEN OFF LICENSING ACCELERATOR

Small biotechs should be relieved that the IPO window has opened and venture funding has begun to flow slightly faster because licensing, the other source of cash for drug developers, has slowed substantially from the pre-patent cliff pace that saw big pharma scrambling to fill empty pipelines. With signs that the big companies' R&D engines are beginning to chug along again, the sense of urgency that once pervaded business development departments has gone away.

Annual Product Deals – Total Deal Values, Up-fronts and Product Count



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With 416 deals disclosed as having been struck and $1.59m changing hands immediately in the first half of 2013 the industry may struggle to match the total of 2012, which was the slowest in at least five years. Interest in phase II remained strongest among clinical assets, with 32 deals struck for $434m in up-front payments and $3.2bn in total deal values. The phase II assets were unique among clinical candidates in that they showed a year-on-year improvement in all measures over the first half of 2012. However, there is not necessarily any reason to draw optimism from this; these are all still well short of the second half of 2012.

Outside the clinic, marketed products and research projects have enjoyed significant interest, as both have seen surprising surges in the number of deals struck, up-front payments and bio-dollar deal values – although in the case of preclinical assets the value seems to be buried largely in two deals.

The passing of the patent cliff in 2011 and 2012 eased the pressure on big pharma to generate innovation through canny dealmaking, and the furious activity of 2007-11

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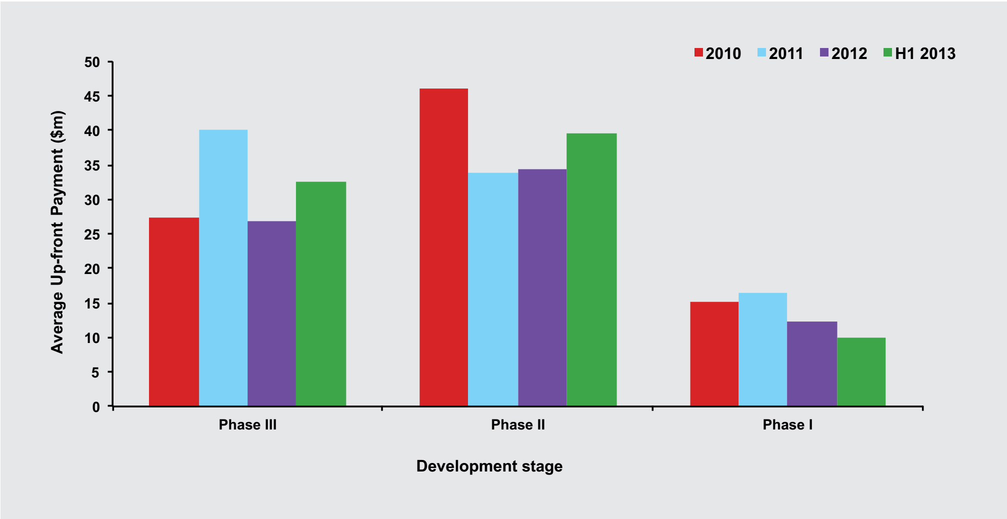
helped to refill dry pipelines. With biotech market valuations reaching sky-high levels, executives' expectations going into partnering meetings will surely also have risen, putting the prices of exciting assets out of the range that big pharma is willing to pay. This could well result in a situation where up-fronts are restrained but deal values rise – at the run rate as of June 30, the total disclosed bio-dollar amount pledged over 416 deals will match 2012, but up-front payments will fall short.

Average Up-front Payment ($m) per Development Stage



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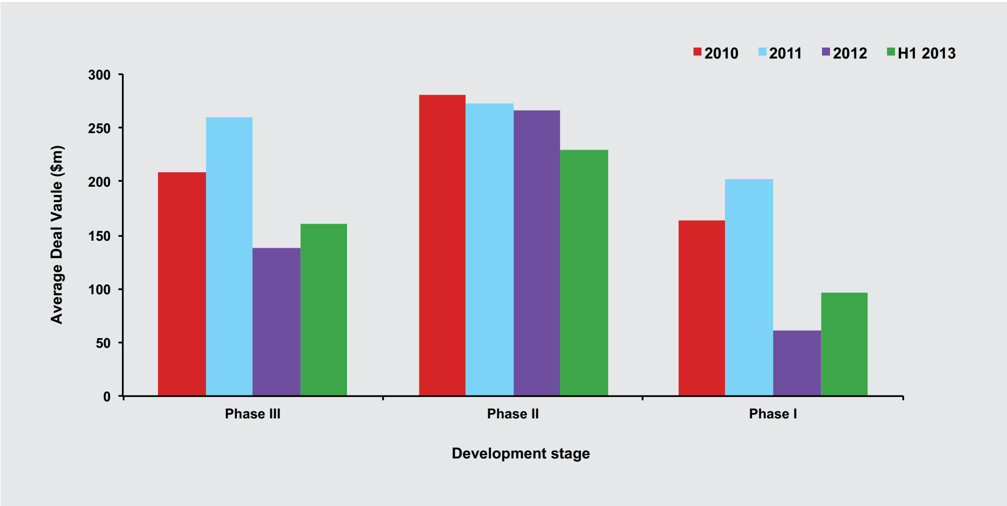
Average Deal Value ($m) per Development Stage



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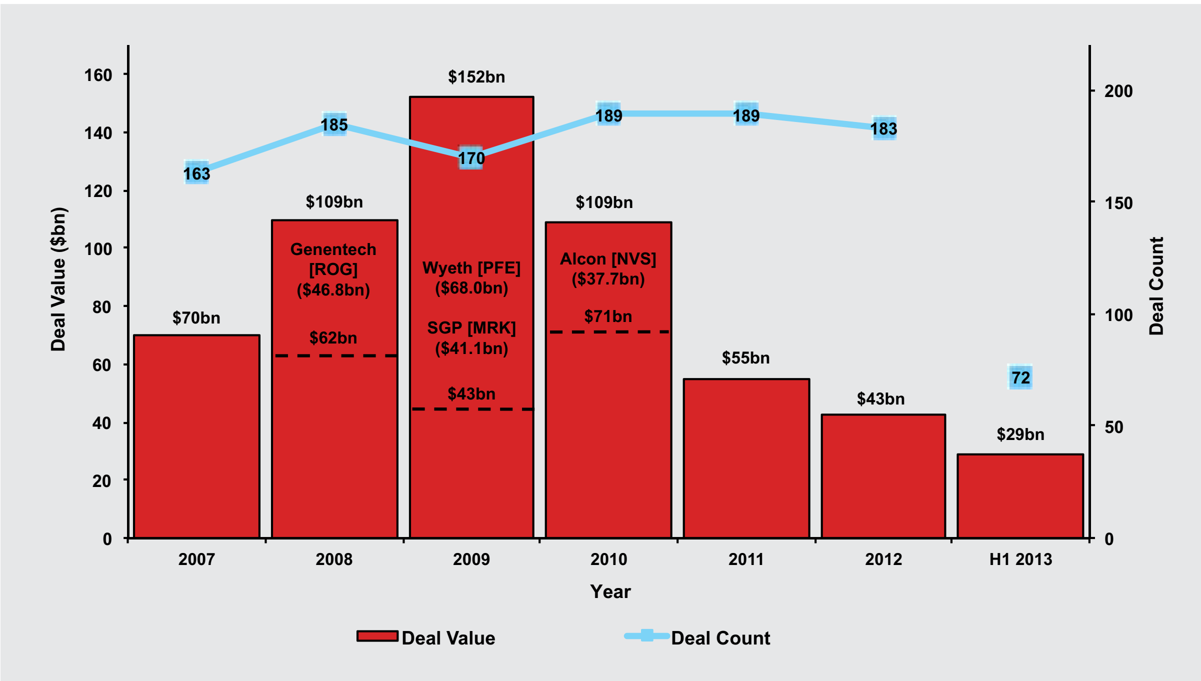
SIGNS OF M&A REBOUND

There have been mixed messages from merger and acquisition activity so far in 2013. At $29bn worth of transactions in the first six months, the year is on track to be the best since 2010 if mega-mergers are excluded from the analysis. If deals like Perrigo-Elan and Amgen-Onyx Pharmaceuticals close in the second half they will push the totals up toward some impressive levels.

Pharma and Biotech M&A Activity



Excludes Terminated Deals
Source: EvaluatePharma © 2013

This activity level is a bit surprising given the valuations of many mid-stage biotechs, so there is no guarantee that the sector can keep up the current rate of deal-making. Yet with many of the sought-after new assets owned by mid- or small-cap companies – think Xofigo in cancer, Kalydeco in cystic fibrosis or Opsumit in pulmonary hypertension – the potential for a takeout is always there.

The big deal of the first half was Valeant's $8.7bn buyout of Bausch + Lomb, followed closely by Actavis's acquisition of Warner Chilcott. Had Royalty Pharma succeeded in swooping on Elan, the industry could have ticked off a third mid-sized deal; Perrigo, the preferred buyer of Elan, will come in at a similar level to the two others, should Elan shareholders continue to back it as Perrigo shares continue to decline.

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Top 5 Pharma/Biotech M&A Deals in H1 2013 and 2012

Year	Rank	Acquiring Company	Target Company or Business Unit	M&A Deal Status	Deal Value ($bn)
H1 2013	1	Valeant Pharmaceuticals International	Bausch + Lomb	Closed	8.7
	2	Actavis	Warner Chilcott	Open	8.5
	3	Royalty Pharma	Elan	Terminated	8.0
	4	Mylan	Agila (division of Strides Arcolab)	Open	1.9
	5	AstraZeneca	Pearl Therapeutics	Closed	1.2
2012	1	Bristol-Myers Squibb	Amylin Pharmaceuticals	Closed	7.0
	2	Actavis	Actavis (pre Watson Pharmaceuticals)	Closed	5.9
	3	GlaxoSmithKline	Human Genome Sciences	Closed	3.0
	4	Dainippon Sumitomo Pharma	Boston Biomedical	Closed	2.6
	5	Valeant Pharmaceuticals International	Medicis Pharmaceutical	Closed	2.6

Source: EvaluatePharma © 2013

A little more surprising is how much less overall deal-making activity there has been. Just 72 transactions occurred in the first six months, a run rate that will put 2013 a bit below activity of the preceding three years, in which at least 180 corporate takeovers were consummated. Mega-mergers are probably largely off the table, as big pharma is spending more time adjusting to corporate divorces, as in the case of AbbVie, or in the case of Pfizer, dividing its operations into three. Still, AstraZeneca continues to make small acquisitions as it tries to restock its failure-prone clinical programmes, and should help to keep the M&A count ticking over.

Outside the top three deals seen in the first half, transactions were substantially smaller, with none topping $2bn – Mylan's acquisition of the Strides Arcolab Agila injectables unit comes in at $1.9bn. Thus, in terms of huge deals 2013 was starting to look a lot like like 2012 – where no deals over $10bn were completed. However, in the second half Amgen bagged Onyx for $10.4bn.

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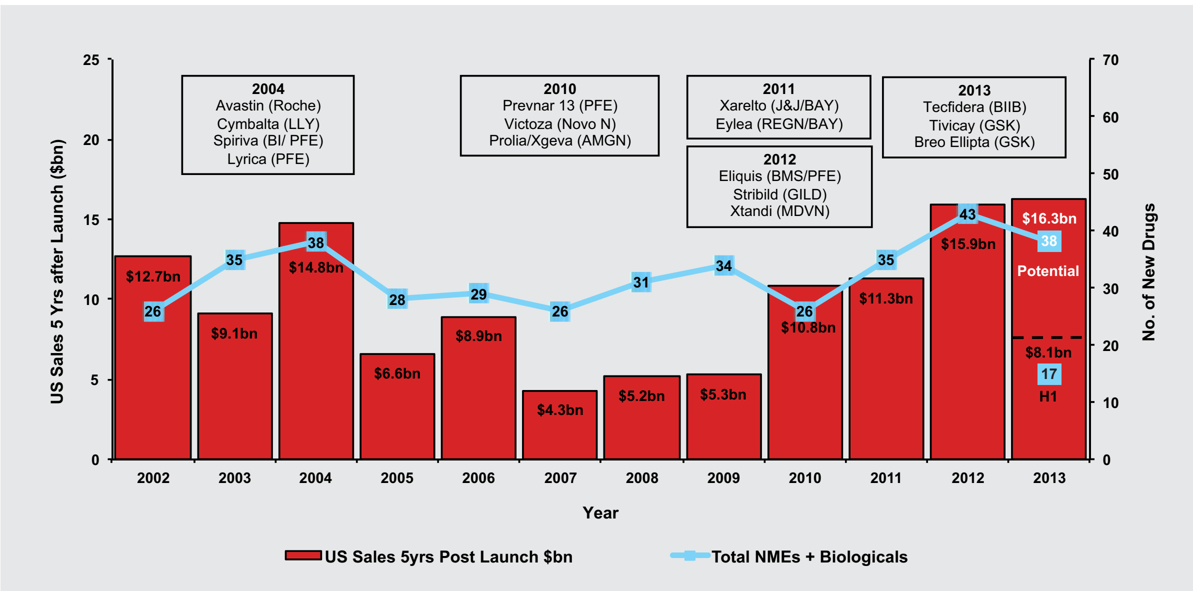
NME APPROVALS FUEL INDUSTRY HOPES

New US product approvals have nearly matched the encouraging pace of 2012, with 17 approved by June 30, two approved since the end of Q2, and another 19 thought to be in the queue for a regulatory win by year's end. At that run rate, 2013 will not quite match the 43 of 2012, but it should do little to discourage the new-found optimism in pharma R&D productivity. New developments like the breakthrough therapy designation and a more open stance taken by FDA officials have given executives new reason to smile.

FDA Approval Count vs Total USA Product Sales 5 Years After Launch



Source: EvaluatePharma © 2013

Without question, the big approval of the year so far is Biogen Idec's multiple sclerosis pill Tecfidera, a product that continues to stoke excitement in the sector – forecasts have risen even after a late March approval as initial prescription numbers have come in. The main risk to achieving its sky-high expectations remains its intellectual property estate in Europe, as the active ingredient has been used to treat psoriasis.

Two big approvals are waiting in the wings – Gilead Sciences' $11bn hepatitis C antiviral sofosbuvir, due a decision in December, and the Pharmacyclics/Johnson & Johnson blood cancer candidate ibrutinib. The latter has received the prized breakthrough therapy designation, and, although it is not clear that approval will happen in the second half of 2013, the positive signals on NME approvals have given many the hope that it will.

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Top 5 Approved Drugs and Potential Approvals for Rest of Year

Biggest 5 approved drugs to date

Rank	Product	Pharmacological Class	Company	Approval date	2018 Annual Sales USA - ($m)
1	Tecfidera	Nuclear factor erythroid 2-related factor (Nrf2) pathway activator	Biogen Idec	27/03/2013	2,657
2	Tivicay	HIV integrase inhibitor	GlaxoSmithKline	12/08/2013*	1,318
3	Breo Ellipta	Long-acting beta 2 adrenoreceptor agonist (LABA) & corticosteroid	GlaxoSmithKline	10/05/2013	1,132
4	Kadcyla	Anti-HER2 (ErbB-2) MAb-DM1 maytansinoid conjugate	Roche	22/02/2013	862
5	Pomalyst	Immunomodulator	Celgene	08/02/2013	679

*Second half approval

Biggest 5 potential approvals

Rank	Product	Pharmacological Class	Company	PDUFA date	2018 Annual Sales USA - ($m)
1	Sofosbuvir	Hepatitis C nucleoside NS5B polymerase inhibitor	Gilead Sciences	08/12/2013	2,997
2	Ibrutinib	Bruton's tyrosine kinase (BTK) inhibitor	Pharmacyclics/Johnson & Johnson	Q4 2013/Q1 2014	1,701
3	Opsumit	Endothelin receptor antagonist	Actelion	18/10/2013	470
4	Obinutuzumab	Anti-CD20 MAb	Roche/Biogen Idec	20/12/2013	465
5	Bridion	Neuromuscular blocker antagonist	Merck & Co	Q4 2013	343

Source: EvaluatePharma © 2013

Should the 29 small molecules and nine biological agents make it to the market, 2013 could be a banner year for the pharma and biotech sector. Projected fifth-year US sales for these 38 products are $16.3bn, above the $15.9bn projected from the class of 2012. Given that 2012 projections exceeded the achievements of 2004, a year that brought big money-spinners like Avastin and Cymbalta, a clean sweep in the second half of 2013 will probably boost optimism even further.

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SECOND HALF OUTLOOK

Pharma had a pretty good year in 2012 on most counts and looks on track at least to equal the expectations that were created for 2013. But success brings its own problems, not least of which is pricing the licensing and M&A transactions that are the lifeblood of the industry. When all parties perceive a seller's market there is a risk of overpaying, while sky-high expectations are rarely met in reality, and investors will waste no time in voicing their displeasure when the inevitable setbacks happen.

Despite the encouraging signs that have emerged recently it seems highly unlikely that the deep-seated productivity problems that had plagued big pharma boardrooms a couple of years ago have been fixed so swiftly. Meanwhile the pressure on drug prices and on companies to prove the value of their high-cost innovations shows no sign of abating.

Meanwhile, some big patents are still left to fall in the next few years, and the threat of biosimilars, albeit still hard to quantify, looms on the horizon. How well the industry performs during the next 16 months as it seeks to extend the lifecycles of important franchises or build up new classes of medicines will go a long way towards determining whether the current optimism is sustained, or if another bust is hiding just beyond this boom. A stumble from one of the highly touted drugs in development risks reversing all the gains of the past two years.

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