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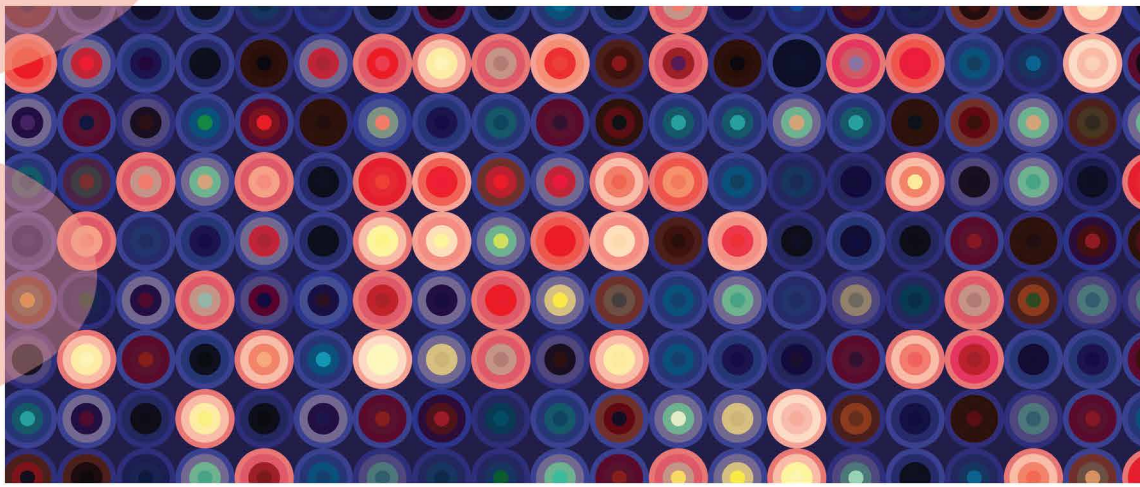
PHARMA & BIOTECH HALF-YEAR REVIEW 2014



EvaluatePharma®

PHARMA & BIOTECH HALF-YEAR REVIEW 2014

If there is one word to sum up the mood in the pharma and biotech sector in 2014 so far, it is "volatile". Make no mistake: there are gains to be made by investing in drug developers, helped along by an M&A frenzy that saw nearly $90bn of equity swallowed up in the first half of the year. However, the key indicator of interest, Nasdaq's biotechnology index, topped out in February as the generalist investors who piled in during 2012 grew nervous about the sustainability of drug pricing. And then a summer bounce back was cut short by growing US ire over the M&A-aided migration of companies to overseas domiciles to cut their tax bills. Meanwhile, the pace of IPOs slowed over the first half, a sign that an exuberant market might have begun to sober up.

This is, of course, the pessimist's view. The optimist can look at companies like Actelion and InterMune, both of which have flourished in this uncertain market by executing flawlessly on their long-term strategies and were rewarded handsomely by investors. For every deflating bubble like Pharmacyclics' performance in the first half, there seemed to be another implausible success story like Intercept Pharmaceuticals. And, no matter how many doubters were willing to call the top of the market in February, there is one fact that cannot be denied: at the time of writing the Nasdaq index stands at more than two and a half times its previous peak in 2000.

FOR EVERY DEFLATING BUBBLE LIKE PHARMACYCLICS' PERFORMANCE IN THE FIRST HALF, THERE SEEMED TO BE ANOTHER IMPLAUSIBLE SUCCESS STORY LIKE INTERCEPT PHARMACEUTICALS.

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PHARMA & BIOTECH HALF-YEAR REVIEW 2014

As we enter the second half of the year it will be useful to watch for some early indicators of the sector's coming direction: Will biotechs successfully float and will discounts become deeper? Will the rhetoric on drug pricing and US corporate inversions get more heated in the midst of a hard-fought congressional campaign? Will a softening market allow a resurgence in licensing activity and M&A in the biotechnology sector? With this in mind, EP Vantage has reviewed the first half of a changeable year to set the stage for the next six months.

Unless stated, all data are sourced to EvaluatePharma® and were accessed in July 2014.

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SUSTAINABILITY OF THE BIOTECH BULL MARKET IN DOUBT

By every measure, the broad pharma and biotech markets are on a winning streak in 2014, if only just in Japan. In Europe, where traders failed to match the exuberance of their US counterparts in 2013, the markets have begun to take off, with the broad gains more or less at parity with the US.

Percentage Change in Stock Indices Over H1 2014

Stock index	% Change in H1 2014
NASDAQ Biotechnology (US)	13%
Dow Jones STOXX Healthcare (EU)	12%
S&P Pharmaceuticals (US)	11%
Euro STOXX 50 (EU)	4%
DJIA (US)	2%
TOPIX Pharmaceutical Index (Japan)	1%

But the six-month gains mask the market volatility since February's peak. At one point in April the Nasdaq biotechnology index was in negative territory for the year and it took until the end of May to build upward momentum again. By contrast, the Dow Jones pharmaceutical index, which primarily comprises big cap companies, has not suffered quite the swings of the Nasdaq grouping and over the six months has been very nearly its equal.

Big Cap Top Risers and Fallers in H1 2014

	Share price (local currency)			Market capitalisation ($bn)	
Top 3 risers	**YE 2013**	**H1 2014**	**Change**	**End H1 2014**	**Change H1**
AstraZeneca	$59.37	$74.31	25%	93.8	19.3
Eli Lilly	$51.00	$62.17	22%	69.6	12.1
Merck & Co	$50.05	$57.85	16%	169.1	22.9
Top 3 fallers					
Bristol-Myers Squibb	$53.15	$48.51	(9%)	80.4	(7.1)
Pfizer	$30.63	$29.68	(3%)	189.1	(9.4)
GlaxoSmithKline	£16.12	£15.64	(3%)	126.1	(3.9)

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In terms of individual winners among the big caps, there were three surprising names: AstraZeneca, Eli Lilly and Merck & Co. Pfizer takeout target Astra took full advantage of the moment to talk about its pipeline extensively, and the acquisition thesis for the UK group has not gone away, even if its declared US suitor is forced to sit it out until November. Lilly has been boosted by its biggest launch since 2004 in the cancer drug Cyramza, and has another forecast blockbuster in the diabetes drug Trulicity waiting in the wings for the second half of the year. Merck is being supported by the expected approval of its immuno-oncology agent pembrolizumab, which could see it become the first to enter the hotly contested anti-PD-1 space.

Merck's gain has come at Bristol-Myers Squibb's expense: That group led the fallers as investors took the view that it had squandered the lead established by its PD-1 agent, nivolumab. Pfizer's miscues in its pursuit of Astra contributed to its fall, and the news on GlaxoSmithKline has been dominated by its continuing difficulties in China and question marks over its respiratory franchise.

Other Large Cap: Top Risers and Fallers in H1 2014

	Share price (local currency)			Market capitalisation ($bn)	
Top 3 risers	**YE 2013**	**H1 2014**	**Change**	**End H1 2014**	**Change H1**
Shire	$141.29	$235.49	67%	46.3	18.7
Allergan	$111.08	$169.22	52%	50.4	17.3
Actavis	$168.00	$223.05	33%	38.9	9.7
Top 3 worst performers					
CSL	AUS$68.96	AUS$66.55	(3%)	30.1	(1.7)
Takeda	¥4,825	¥4,699	(3%)	36.4	(2.6)
Fresenius	€111.91	€109.09	(3%)	27.1	(0.3)

Outside the realm of traditional big pharma, the large cap category's biggest gainers were driven solely by M&A: Shire and Allergan, both targets of takeovers, and Actavis, which snared Forest Laboratories.

In the realm of the small caps, the hope for M&A is almost always a background factor in valuation, and strongly influences the highest-profile gainers. Idenix Pharmaceuticals, of course, leads the way after its acquisition by Merck & Co. Intercept Pharmaceuticals was in the right place at the right time with unexpectedly good news in non-alcoholic steatohepatitis for its one product, obeticholic acid. InterMune returned to favour with better-than-expected data in its US confirmatory study for its idiopathic pulmonary fibrosis drug Esbriet.

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Other Significant Risers and Fallers in H1 2014

	Share price (local currency)			Market capitalisation ($m)	
Top 5 risers	**YE 2013**	**H1 2014**	**Change**	**End H1 2014**	**Change H1**
Actelion	SFr75.35	SFr112.2	49%	15,325	5,284
Salix Pharmaceuticals	$89.94	$123.35	37%	7,822	2,164
Intercept Pharmaceuticals	$68.28	$236.63	247%	5,003	3,683
InterMune	$14.73	$44.15	200%	4,366	3,062
Idenix Pharmaceuticals	$5.98	$24.10	303%	3,636	2,834

	Share price (local currency)			Market capitalisation ($m)	
Top 5 fallers	**YE 2013**	**H1 2014**	**Change**	**End H1 2014**	**Change H1**
BioMarin Pharmaceutical	$70.35	$62.21	(12%)	9,078	(927)
Pharmacyclics	$105.78	$89.71	(15%)	6,731	(1,066)
United Therapeutics	$113.08	$88.49	(22%)	4,245	(1,435)
ThromboGenics	€ 20.15	€ 9.43	(53%)	470	(522)
Active Biotech	SKr69.50	SKr29.60	(57%)	346	(467)

Ranked on Market Cap.

Top 5 risers	**EP Vantage Comment and Analysis**
Actelion	Selexipag hit puts Actelion back on the buyout radar
Salix Pharmaceuticals	Salix's persistence pays off with IBS confirmation
Intercept Pharmaceuticals	Boom! Trial halt turns Intercept into an improbable midcap company
InterMune	InterMune draws up battle lines for IPF space following strong Esbriet data
Idenix Pharmaceuticals	Biotech bull market charges with Merck's Idenix takeout
Top 5 fallers	
BioMarin Pharmaceutical	BioMarin needs to turn a small market into big sales numbers
Pharmacyclics	Asco Event Analyzer – 2014's winners and losers
United Therapeutics	Selexipag hit puts Actelion back on the buyout radar
ThromboGenics	ThromboGenics turns to plan B after fruitless search for buyer
Active Biotech	With EU knockback laquinimod's irrelevance is all but assured

The huge fears from a few years ago about Actelion being unable to sustain its pulmonary arterial hypertension (PAH) franchise as Tracleer's patent expired turned out to be dead wrong as first Opsumit and then selexipag came good. Salix Pharmaceuticals benefited from the bio-run up leading to approval of an expanded label for its hepatic encepholoapthy drug Xifaxan into the diarrhoea-predominant irritable bowel syndrome indication.

Among the fallers, Active Biotech's long efforts to get to the multiple sclerosis market have come to naught. ThromboGenics suffered a reverse of the M&A thesis when it said it had given up on finding a buyer. Speaking of reversals, Actelion's gain was United Therapeutics' loss, as the latter's PAH franchise built around treprostinil sodium now looks unsustainable. Pharmacyclics and BioMarin Pharmaceutical both suffered from the post-launch blues as the view turns from approval to sales catalysts.

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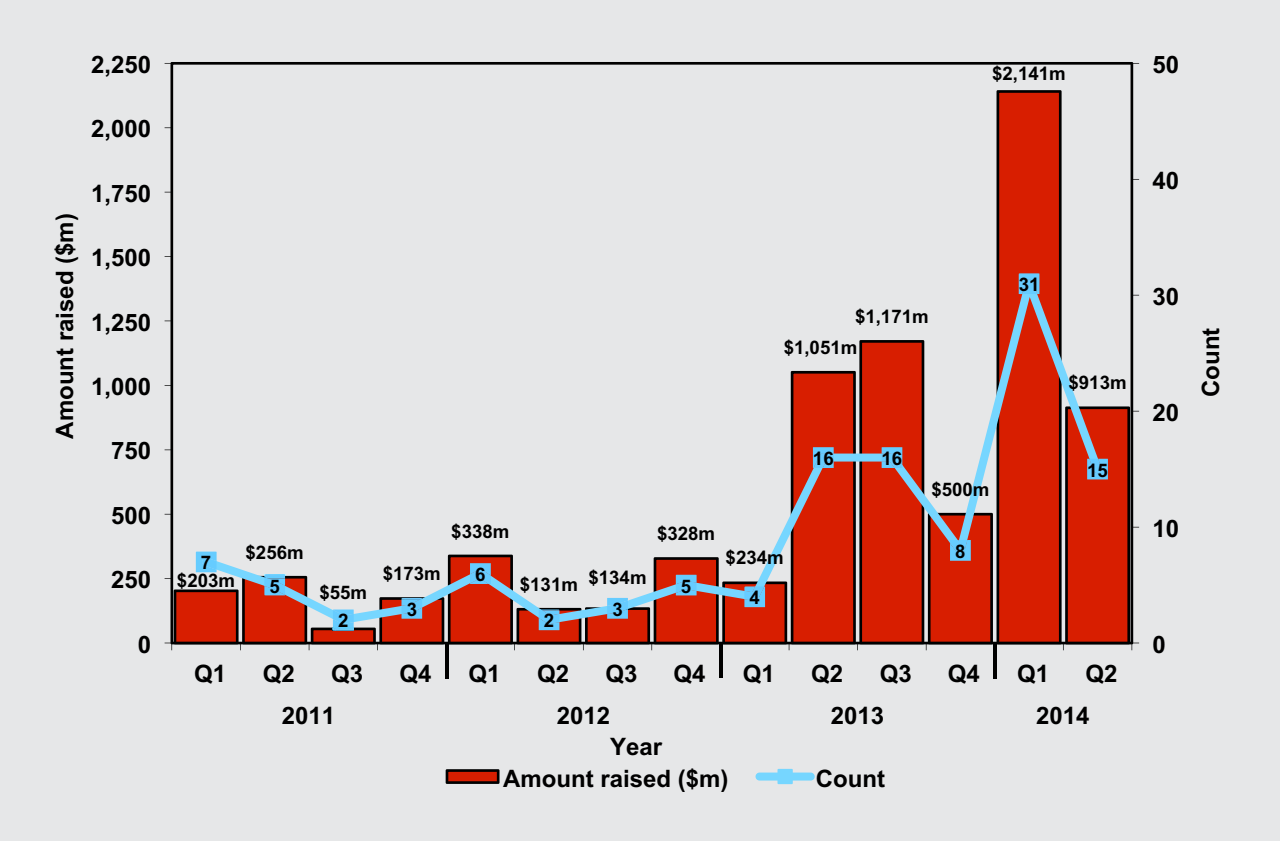
IPO OPPORTUNITY CLOSING?

The uncertainty has flowed through to biotech flotations, which, after having peaked at $2.1bn in the first three months of the year fell back to a more pedestrian $913m in the second quarter. This trend presages a slow third quarter, as the July 4 US holiday serves as an informal deadline for getting a mid-year IPO away. "Some are dusting off alternative financing strategies," says Stephen Thompson, managing director of Brandon Capital Partners in Australia.

Initial Public Offerings by Quarter on Western Exchanges



Source: EP Vantage

If the multibillion-dollar tally was not enough to convince that the first quarter was the best period to have floated, a look at the prices at which IPOs got away is also persuasive: the average haircut was 9%, second best of the last three years. This was a sign that the 31 pharma and biotech companies that listed on the public market were not overwhelming investors' appetites.

Fifteen IPOs occurred in the second quarter, a number that would have delighted the sector a couple of years ago but is now among the harbingers of possible slower times to come – and the 18% average discount seen in the three-month period took the first-half average discount to 10%. Yet the average IPO raised $66m, nearly identical to the $67m raised in 2013, which ought to be taken as some sign of continuing health.

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Top 10 Biotech IPOs on Western Stock Exchanges in H1 2014

Company	Date	Amount raised	Offering price	Range	Discount/ premium	Exchange	H1 change since float
Circassia	13-Mar-14	£200m ($332m)	310p	250p-310p	11%	LSE (main market)	(11%)
Kite Pharma	20-Jun-14	$128m	$17	$12-14	31%	Nasdaq	70%
Versartis	21-Mar-14	$126m	$21	$19-21	5%	Nasdaq	34%
ZS Pharma	17-Jun-14	$123m	$18	$15-17	13%	Nasdaq	60%
Ultragenyx Pharmaceutical	31-Jan-14	$121m	$21	$19-20	8%	Nasdaq	114%
Zafgen	19-Jun-14	$110m	$16	$14-16	7%	Nasdaq	24%
Akebia Therapeutics	20-Mar-14	$100m	$17	$14-17	10%	Nasdaq	63%
Revance Therapeutics	6-Feb-14	$96m	$16	$14-16	7%	Nasdaq	113%
Dicerna Pharmaceuticals	30-Jan-14	$90m	$15	$11-13	25%	Nasdaq	50%
Auspex Pharmaceuticals	5-Feb-14	$84m	$12	$10-12	9%	Nasdaq	86%
Average across all 46 IPOs		***$66m***			***(10%)***		***22%***

Source: EP Vantage

The most encouraging sign of the first half had to be evidence that US investors' enthusiasm for biotech had crossed the Atlantic to European exchanges, which lack the specialist investors of America. That migration was made clear when the biggest float of the year took place not on Nasdaq but on the London stock exchange's main market as the UK-based allergy specialist Circassia raised £200m ($332m) in March. Other European companies floating included Oncodesign, Genticel, TxCell, 4D Pharma and Venture Life Group.

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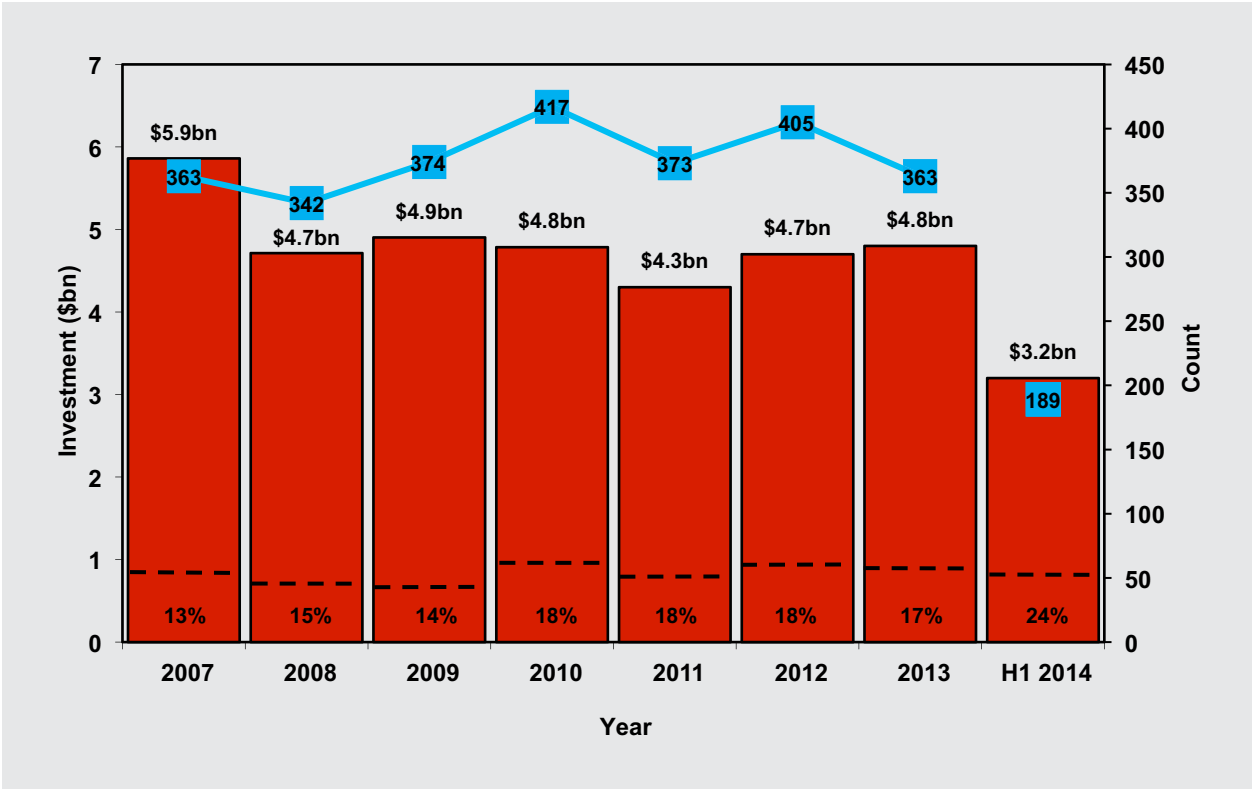
VENTURE CAPITAL ON RECORD PACE

Investment in closely held, venture capital-backed companies mirrored the excitement surrounding publicly traded groups and new listings. At more than $3bn raised in the first six months, the sector is on a run rate that could exceed the $5.9bn of 2007, the last year before the global financial crisis suppressed riskier investments.

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



The money is beginning to migrate to later, bigger rounds and away from early-stage funding. The 190 fund-raisings averaged $17m apiece, a jump up on the averages of the immediate post-crash years. Rounds like Intarcia Therapeutics' $210m series H certainly help inflate the numbers, but this was not the only big one of the first half – the top 10 all were in excess of $50m. This was at the expense, somewhat, of earlier-stage companies; most fund-raising rounds were at series C or later.

Intarcia's fund-raising acumen is a sign of the pattern in venture capital migration. Its raise came less than two years after a $160m fund-raising and is being used to support a phase III trial of its GLP-1 eluting implant ITCA 650. This is a stage where most companies have either partnered, gone public or been acquired. While not necessarily a sign of how drug development will be financed in the future, Intarcia does tell us that the VC world has an increasing appetite for lower-risk, if chunkier, late-stage investments.

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Biggest VC Rounds of H1 2014 ($ Unless Specified)

Company	Investment ($m)	Financing round	Date
Intarcia Therapeutics	200.0	Series H *	Apr
Glycotope Group (€)	74.9	Series Undisclosed	Mar
Spark Therapeutics	72.8	Series B	May
Melinta Therapeutics	70.0	Series G *	Feb
NovImmune (Sfr)	66.0	Series B	Feb
C3 Jian	60.5	Series D	Mar
Kolltan Pharmaceuticals	60.0	Series D	Mar
ProNAi Therapeutics	59.5	Series D	Apr
NuCana BioMed	57.0	Series B	Apr
Advanced Accelerator Applications (€)	55.8	Series Undisclosed	Feb

* series assumed

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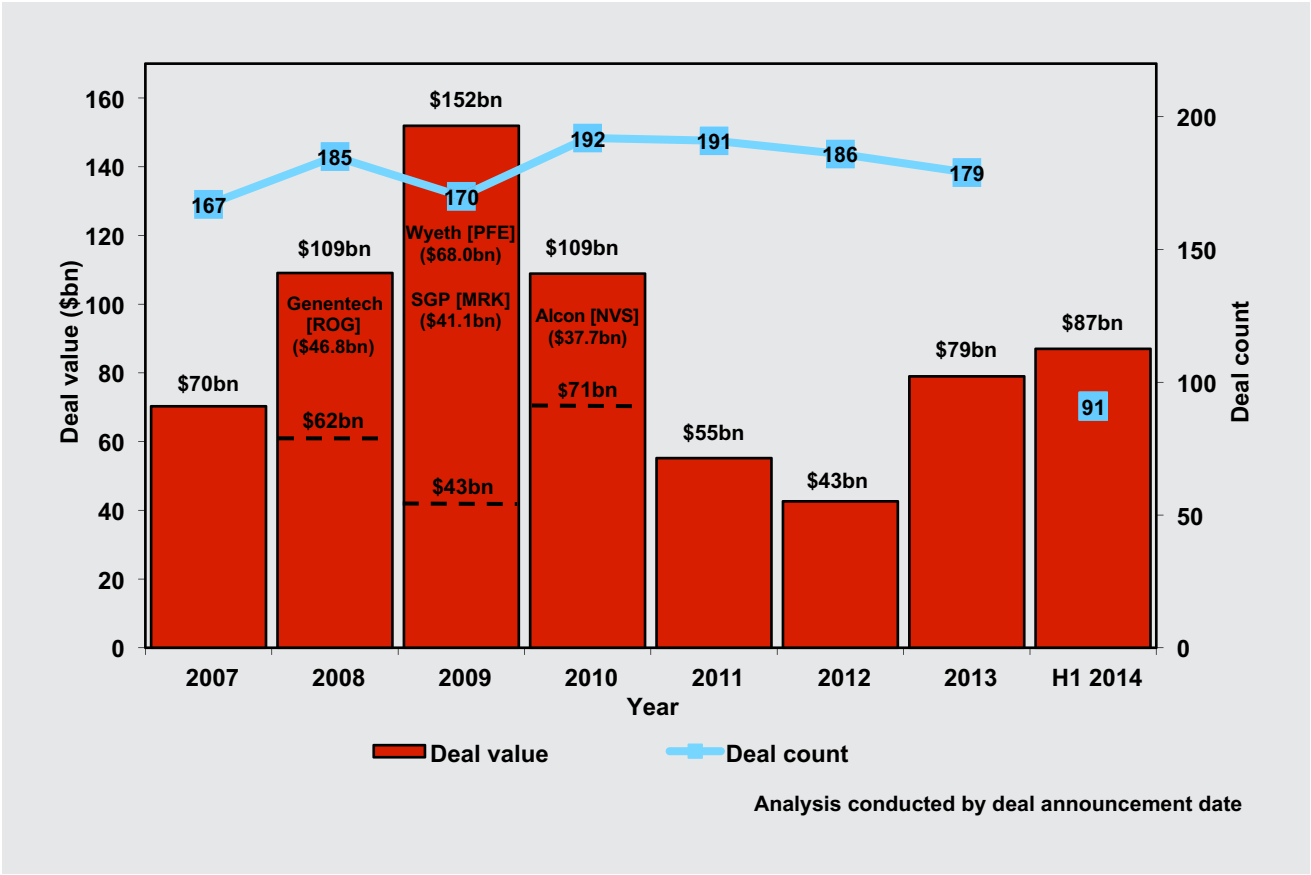
FEVER PITCH IN M&A

The strongest sign of life in pharma and biotech has to be in M&A activity. An astonishing $87bn in transactions took place in the first six months of 2014, exceeding the total for all of 2013 and closing in on the totals of mega-merger-driven 2008 and 2010. Even without AbbVie's $55bn acquisition of Shire in July in this analysis, 2014 is already nipping at the heels of double-mega-merger 2009, with the second half still to conclude.

Pharma and Biotech M&A Activity



As with venture capital funding, transactions seem to be tilted heavily in the direction of fewer, bigger deals. These include the $25bn Actavis shelled out for Forest Laboratories; the Novartis-GlaxoSmithKline asset swap, in which a total of $23bn changed hands; and Mallinkrodt's takeout of troubled Questcor Pharmaceuticals.

Mallinkrodt's M&A activity also illustrated one of the trends of the year: a rush by US companies to buy overseas companies to "invert", or establish a non-US domicile and cut their tax bills, something Mallinkrodt achieved with a February buyout of Cadence Pharmaceuticals, presaging a rush later in the year. Other transactions driven by this in the first half included Auxilium Pharmaceuticals' takeover of Canada's QLT and Horizon Pharma's buyout of Vidara.

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Top 5 Pharma/Biotech M&A Deals in H1 2014 and 2013

Year	Rank	Acquiring company	Target company or business unit	M&A deal status	Deal value ($bn)
H1 2014	1	Actavis	Forest Laboratories	Closed	25.0
	2	Novartis	Oncology business unit of GlaxoSmithKline	Open	16.0
	3	GlaxoSmithKline	Vaccines (excluding flu) business unit of Novartis	Open	7.1
	4	Mallinckrodt	Questcor Pharmaceuticals	Open	5.6
	5	Merck & Co	Idenix Pharmaceuticals	Open	3.9
2013	1	Amgen	Onyx Pharmaceuticals	Closed	10.4
	2	Valeant Pharmaceuticals	Bausch + Lomb	Closed	8.7
	3	Perrigo Company	Elan	Closed	8.6
	4	Actavis	Warner Chilcott	Closed	8.5
	5	AstraZeneca	Diabetes business of Bristol-Myers Squibb	Closed	4.3

The mid-year milestone sparked a number of other inversion transactions besides AbbVie-Shire, and of course Pfizer's abortive megamerger with AstraZeneca for the UK tax home could easily resurrect itself before the end of 2014 once the six-month waiting period expires – or earlier if Astra agrees to talk.

What 2014 has seen less of is big deals to acquire single products or pipelines in drug development companies. The same bullish public equity markets that have rewarded biotech investors so handsomely have also made them prohibitively expensive as potential acquisition targets. Look no further than a company like one-product Intercept Pharmaceuticals' rocket ride into the midcap stratosphere on the strength of a phase II readout as a sign of what the trading frenzy has wrought.

The biggest single-product deal so far this year is a risky-looking one: Merck & Co's takeout of Idenix Pharmaceuticals for the hep C asset IDX21437. This is a sensible ploy strategically as the bigger company needed something like Idenix's nucleotide inhibitor to plug into an antiviral cocktail, but at a price tag of close to $4bn there can be no denying that it is a gamble.

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APPROVALS ON RECORD PACE, BUT VALUE FALLS BACK

Biggest Five Approved Drugs to Date (to July 31)

Rank	Product	Pharmacology class	Company	Approval date	US sales 2019 ($m)
1	Otezla	Phosphodiesterase IV inhibitor	Celgene	21/03/2014	1,056
2	Cyramza	Anti-VEGF-2 MAb	Eli Lilly	21/04/2014	732
3	Entyvio	Anti-a4b7 integrin MAb	Takeda	19/05/2014	626
4	Farxiga	SGLT2 inhibitor	AstraZeneca	08/01/2014	602
5	Zydelig	PI3K inhibitor	Gilead Sciences	23/07/2014	550

Given the record run of the past two years, the rate at which new drugs have been approved this year might be seen as disappointing. So far, just a single asset expected to hit blockbuster US sales numbers in its first five years has been approved: Celgene's Otezla, which will just clear the bar at $1.1bn in 2019, according to EvaluatePharma's consensus data.

By June 30, 22 products were approved, and another five have been given the nod since the end of the second quarter, bringing the total to 27 novel agents with a forecast $7bn in US sales five years out. Besides Otezla, an antirheumatic, these include Eli Lilly's cancer drug Cyramza, AstraZeneca's diabetes pill Farxiga and GlaxoSmithKline's COPD treatment Incruse Ellipta. Gilead's first oncology entry Zydelig got an early approval in July, a product that should crack the half-billion US sales benchmark in 2019.

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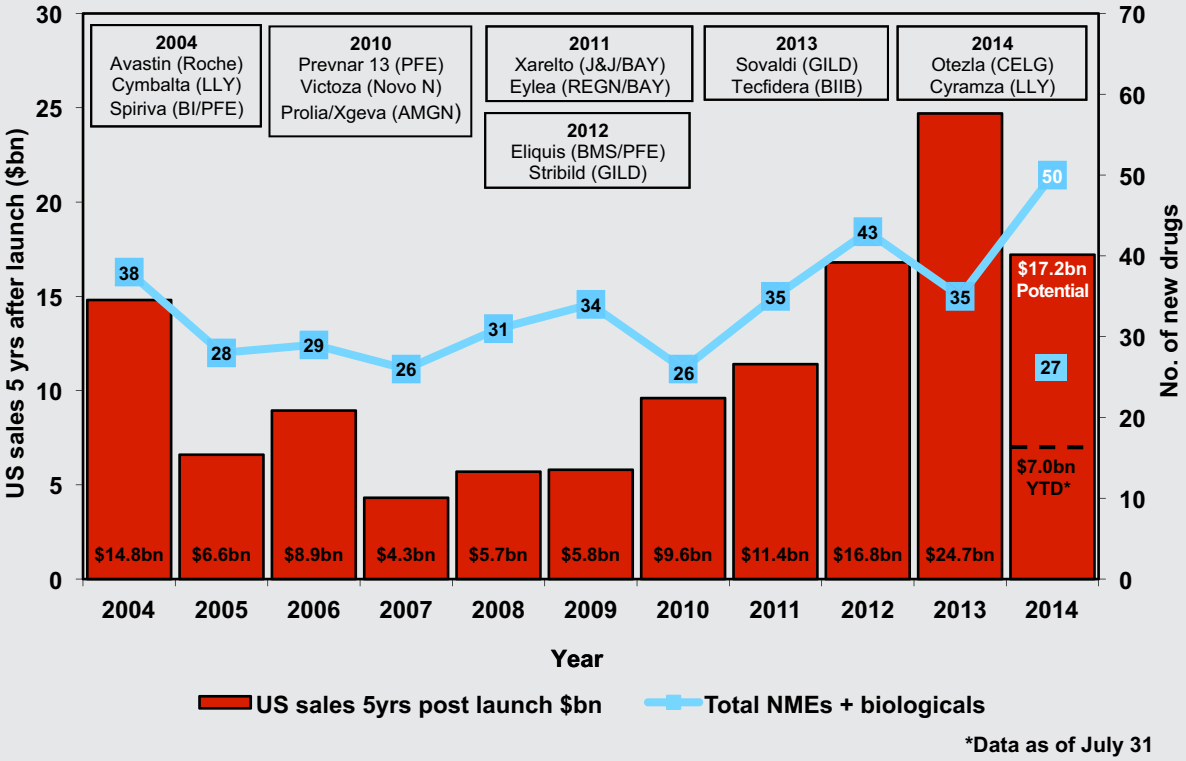
FDA Approval Count vs. Total USA Product Sales 5 Years After Launch



The year could turn out to be a heavily backend-loaded one. A total of 50 new molecular entities could be approved by year-end with some $17.2bn in total US sales in 2019. This would be one of the biggest years ever in terms of approvals, although the five-year sales numbers will still be behind the impressive $24.7bn of 2013; that year is heavily skewed by the premiere of Sovaldi, on track to become the biggest drug launch in history.

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Top Five Potential Approvals of 2014

Rank	Product	Biological?	Pharmacology class	Company	Approval date	US sales 2019 ($m)
1	Pembrolizumab	Yes	Anti-PD-1 MAb	Merck & Co	28/10/2014	1,915
2	Ledipasvir/Sofosbuvir	No	NS5A & NS5B polymerase inhibitor	Gilead Sciences	10/10/2014	1,615
3	ABT-267/ABT-333/ABT-450	No	NS5A inhibitor, non-nucleoside NS5B polymerase inhibitor, NS3/4A protease inhibitor	AbbVie	Q4 2014	1,296
4	Esbriet	No	TNFa inhibitor	InterMune	Q4 2014	730
5	Plegridy	Yes	Interferon beta	Biogen Idec	21/08/2014	653

See appendices for full table

Hepatitis C and immuno-oncology are clearly the themes of the second half of the year. In hep C, 2014 will see decisions for Gilead's pill combining Sovaldi with ledipasvir and AbbVie's three-molecule combination, and in immuno-oncology the programmed death-1 pathway will come alive with a possible decision on Merck & Co's pembrolizumab.

These will comprise the top three projects thought to be up for approval in the second half of the year. Moreover, of the 24 that could get an FDA first approval by the year's end, five are in oncology or hepatitis C, the result of the industry's healthy investment and even healthier return in these two categories.

Report author: Jonathan Gardner

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APPENDICES

Potential Approvals of 2014

Rank	Product	Biological?	Pharmacology class	Company	PDUFA date	US sales 2019 ($m)
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2	Ledipasvir/Sofosbuvir	No	NS5A & NS5B polymerase inhibitor	Gilead Sciences	10/10/2014	1,615
3	ABT-267/ABT-333/ABT-450	No	NS5A inhibitor, non-nucleoside NS5B polymerase inhibitor, NS3/4A protease inhibitor	AbbVie	Q4 2014	1,296
4	Esbriet	No	TNFa inhibitor	InterMune	Q4 2014	730
5	Plegridy	Yes	Interferon beta	Biogen Idec	21/08/2014	653
6	Jardiance	No	SGLT2 inhibitor	Boehringer Ingelheim	Q3 2014	549
7	Trulicity	Yes	GLP-1 agonist	Eli Lilly	Q4 2014	540
8	Secukinumab	Yes	IL-17A MAb	Novartis	January 2015	489
9	V503	Yes	HPV vaccine	Merck & Co	Q4 2014	393
10	Natpara	Yes	Parathyroid hormone	NPS Pharmaceuticals	24/10/2014	353
11	Orbactiv	No	Glycopeptide	The Medicines Company	06/08/2014	295
12	Lynparza	No	PARP inhibitor	AstraZeneca	03/01/2015	287
13	Cerdelga	No	Glucosylceramide synthase inhibitor	Sanofi	Q3 2014	268
14	Suvorexant	No	Orexin 1 & 2 receptor antagonist	Merck & Co	Q1 2015	240
15	Farydak	No	Pan-deacetylase inhibitor	Novartis	Q4 2014	203
16	Movantik	No	Peripheral mu opioid antagonist	AstraZeneca	16/09/2014	135
17	Elonva	Yes	Follicle stimulating hormone	Merck & Co	Q3 2014	87
18	Vitekta	No	HIV integrase inhibitor	Gilead Sciences	04/10/2014	80
19	Tybost	No	CYP3A inhibitor	Gilead Sciences	03/10/2014	54
20	OBI-1	Yes	Factor VIII	Baxter International	Q3 2014	21
21	Macrilen	No	Growth hormone secretagogue/ghrelin receptor agonist	Æterna Zentaris	05/11/2014	20
22	Onexton	No	Anti-acne agent	Valeant Pharmaceuticals International	30/11/2014	9
23	Rapiacta	No	Neuraminidase inhibitor	Biocryst Pharmaceuticals	23/12/2014	8
					Total	***10,240***

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