Evaluate Vantage

June 23, 2016

Valuable late-stage pipeline sets 2017 up for some big events

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A look at the value of the industry's R&D pipeline seems to support the assumption that productivity remains buoyant. Assets worth $77.5bn are awaiting regulatory judgement while the phase III pipeline is worth $362bn, *EvaluatePharma's* NPV data show.

Not all will make it to market but, combined with an uptick in the number and value of novel molecules coming to market in the past couple of years, an argument can be made for a sustained improvement in output. A successful launch of the three most valuable research assets – all of which are valued by sellside analysts at more than $10bn each – could boost confidence in pipelines further (see tables below).

These assets are Roche's multiple sclerosis antibody Ocrevus, Sanofi's dermatitis antibody dupilumab and Lilly's breast cancer pill abemaciclib. All are in phase III, and their developers have pledged to have them filed by the end of the year, setting up 2017 for some huge approval decisions.

The value of assets by stage	
	Today's NPV ($bn)
Filed	77.49
Phase III	362.31
Phase II	90.80
Phase I	18.47
Pre-clinical	2.80
Research project	3.55
Total	555.42

The table above reveals the phase III bulge, and a logical distribution of valuations. Still, the huge weight attached to the pivotal stage of testing shows that there are many substantial assets currently awaiting late-stage clinical validation – 2017 will also return some big clinical news.

A string of high-profile successes or failures can have a big influence on the overall investor sentiment towards the pharma sector. So, with equity markets decidedly jittery amid ongoing macroeconomic concerns and global instability, the industry cannot take its collective eye off driving further productivity improvements – and positive pipeline news.

Most valuable filed assets				
Project	**Company**	**Drug type and lead indication**	**Today's NPV ($bn)**	**Events**
ABP 501	Amgen	Anti-TNFa MAb; RA, psoriasis	6.20	FDA panel July 12; PDUFA Sept 23, 2016
Austedo	Teva	VMAT2 inhibitor; Huntington's	4.02	Received CRL May 2016
Parsabiv	Amgen	CaSR agonist; hyperparathyroidism	3.68	PDUFA Aug 24, 2016
Baricitinib	Eli Lilly	JAK-1/2 inhibitor; RA	3.64	PDUFA Jan 19, 2017
Crisaborole	Anacor	PDE4 inhibitor; eczema/dermatitis	3.44	PDUFA Jan 6, 2017

Most valuable, if ...

The most valuable project awaiting approval is Amgen's Humira biosimilar and, while this certainly has value, when it will actually reach the market is another question (*Can Humira still dominate in 2022?, April 21, 2016*). Lilly's JAK inhibitor baricitinib represents another threat to Humira.

Teva has said it will respond before the end of the third quarter to the complete response letter for the Huntington's disease therapy Austedo, which it gained via the $3.5bn acquisition of Auspex. With an NPV of $4bn based on current sales forecasts, Teva will need to meet these hopes to justify the price tag, although there are questions about its commercial value (*Neurocrine's success sets up showdown of the me-toos, October 9, 2015*).

Parsabiv is Amgen's Sensipar follow-on, formerly known as AMG 416, a treatment for dialysis patients suffering the complication of end-stage renal disease *(Sensipar follow-on will test Amgen's powers of persuasion, August 19, 2014*).

Finally crisaborole, now dubbed Eucrysa, is a topical eczema treatment that Pfizer bought via the $5.2bn acquisition of Anacor last year. It is worth noting that this valuation is based on sellside analysts tracking Anacor rather than Pfizer, which has yet to complete the takeover.

Most valuable phase III assets				
Project	**Company**	**Drug type and lead indication**	**Today's NPV ($bn)**	**Event**
Ocrevus	Roche	Anti-CD20 MAb; RMS, PPMS	20.49	Filings expected H1 2016
Dupilumab	Sanofi	IL-4 & IL-13 MAb; atopic dermatitis	12.87	Rolling BLA to complete this year
Abemaciclib	Eli Lilly	CDK 4 & 6 inhibitor; breast cancer	10.00	Filing due Q3 2016
Durvalumab	AstraZeneca	Anti-PD-L1 MAb; lung, head & neck cancers	8.19	PIII data due H1 2017
Lampalizumab	Roche	Anti-complement factor D MAb; dry AMD	7.67	PIII data due late 2017

Rocketing Ocrevus

Leading the charge among phase III candidates is Roche's MS hopeful Ocrevus (ocrelizumab), which has seen its valuation more than triple since phase III data were released last October.

Sanofi has also said it intends to complete the rolling submission of dupilumab by the end of the year. This would be the first systemic drug to treat atopic dermatitis, and is leading the pack in a promising new class (*Dupilumab grabs atopic dermatitis head start, April 01, 2016*).

Lilly's abemaciclib should be filed on the basis of phase II data from the Monarch-1 trial in the third quarter – the project has breakthrough therapy designation so approval could come relatively quickly (*Watch out Ibrance*

– here comes abemaciclib, February 11, 2016).

AstraZeneca's durvalumab is already highly valued despite having no phase III data – Arctic (NCT02352948) and Pacific (NCT02125461) both report next year.

Finally Roche's lampalizumab makes it into the top five despite pivotal data being even further away. This asset represents a rare promising product for dry AMD.

Most valuable phase II assets			
Project	**Company**	**Drug type and lead indication**	**Today's NPV ($bn)**
CTL019	Novartis	Anti-CD19 CAR-T; leukaemia	4.31
LentiGlobin BB305	bluebird bio	Haemoglobin gene therapy	2.47
Vosoritide	BioMarin Pharmaceutical	Natriuretic peptide; Achondroplasia	1.99
Axalimogene Filolisbac	Advaxis	HPV vaccine; cervical, head & neck	1.75
PF-06290510	Pfizer	*S aureus* vaccine	1.74

Cell and gene therapy top phase II

A look at the top phase II assets reveals some of the industry's riskier bets, albeit ones that promise to be game-changing should they succeed.

Novartis's CAR-T therapy leads the pack by some margin – the asset ranks as the industry's 17th most valuable pipeline project. This is perhaps a surprising valuation given that its close competitor Kite has said it plans to launch its CAR-T product next year, while the decidedly more reticent Novartis does not expect to file until 2017.

Bluebird's sickle cell gene therapy remains some way away from the market, with data at ASH in December a big event on the horizon. Meanwhile, news is awaited on a move into phase III for BioMarin's vosoritide, a treatment for achondroplasia, the most common cause of dwarfism.

Advaxis's therapeutic cancer vaccine looks the most generously valued in this group, considering the struggles that this field has had to establish convincing efficacy.

And finally Pfizer's *Staphylococcus aureus* vaccine should yield data next year from a huge phase IIb trial recruiting 2,600 subjects undergoing elective spinal fusion surgery, to see if it can reduce the rate of surgical site infections.

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