

Pipelines turn to biotech

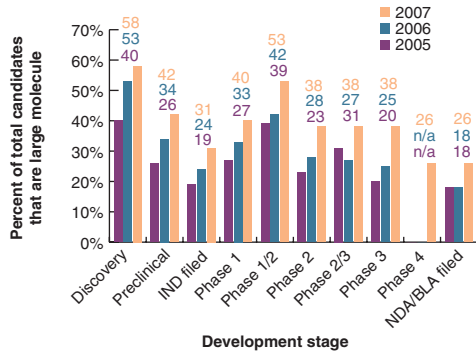
Stacy Lawrence

Biologics have established a high profile along the whole research pipeline, accounting for four out of ten preclinical candidates and one in four submissions for US marketing approval. Cancer candidates predominate, with those in infectious diseases and the central nervous system not far behind. Only one new biologic was

approved in 2006: paroxysmal nocturnal hemoglobinuria treatment Soliris (eculizumab). The rest were all based around existing products—either new versions or new uses in supplemental indications. Last year, Enbrel was the first biotech drug to break \$4 billion in sales.

Biotechnology candidates by phase

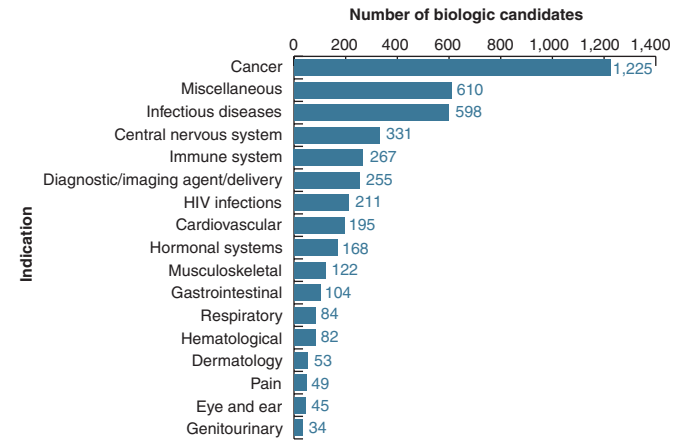
More than one-quarter of FDA submissions for marketing approval and 42% of products in preclinical testing are large molecules.



Source: BioPharm Insight. IND, investigational new drug application; NDA, new drug application; BLA, biologics license application.

Investigational biotech drugs by indication

Cancer still accounts for twice as many candidates in development as any other indication.



Source: BioPharm Insight.

Pending BLA submissions

Company	Product	PDUFA date	Type
Abbott	Humira	2/8/07	sBLA
Amgen	Romiplostim	Submitted	BLA
Amgen, Wyeth	Enbrel	Submitted	sBLA
Biogen Idec, Genentech, Roche	Rituxan	1/26/08	sBLA
Bristol-Myers	Orencia	Accepted	BLA
Cangene	Accretropin	5/17/07	BLA
Dendreon	Provenge	5/15/07	BLA
Genentech, Roche	Avastin	2/23/08	sBLA
Genentech, Roche	Herceptin	4/28/08	sBLA
Gen-Probe, Novartis	Ultrio NAT	Jul-Dec 2008	sBLA
GlaxoSmithKline,	Cervarix	12/4/07	BLA
MedImmune			
Lev	Cinryze	1/30/08	BLA
Omrix, Johnson & Johnson	Evicil	1/8/08	sBLA
Regeneron	Rilonacept	11/7/07	BLA
Roche	Mircera (CERA)	11/14/07	BLA
UCB, Nektar	Cimzia	Filed 2/06	BLA
ZymoGenetics, Bayer	rhThrombin	1/18/08	BLA

Source: BioCentury, Cowen and Company. BLA, biologics license application; sBLA, supplemental BLA; PDUFA, Prescription Drug User Fee Act.

Top-selling biologics

Product	Companies	2006 sales (\$ billion)	First half 2007 sales (\$ billion)	Projected 2007 sales (\$ billion)	Percent change
Enbrel	Amgen, Wyeth, Takeda	4.47	2.56	5.12	15%
Remicade	Johnson & Johnson, Schering-Plough, Tanabe	3.77	2.46	4.92	31%
Rituxan/MabThera	Biogen Idec, Genentech, Roche	3.86	2.20	4.40	14%
Aranesp	Amgen	4.12	1.97	3.94	-4%
Herceptin	Genentech, Roche	3.13	1.94	3.88	24%
Procrit/Epex	Johnson & Johnson	3.18	1.58	3.16	-1%
Avastin	Genentech, Roche	2.36	1.56	3.12	32%
Neulasta	Amgen	2.71	1.54	3.08	14%
Epogen	Amgen, Kirin	2.85	1.40	2.80	-2%
Lantus	Sanofi-Aventis	2.20	1.28	2.56	16%

Source: BioCentury.

Blockbuster biotech approvals

Company	Product	Indication	2007 approval	Status	Peak sales potential (\$ billions)
Cephalon	Nuvigil (amordafinil)	Daytime sleepiness	Approved	Approved 18-Jun	\$1-2
Onyx/Bayer	Nexavar (sorafenib)	Hepatocellular carcinoma	Likely	PDUFA 28-Dec	\$1+
ImClone	Erbix (cetuximab)	Refractory colorectal cancer (survival claim)	Approved	Approved 2-Oct	\$1
Genzyme	Renvela (sevelamer carbonate)	Serum phosphorus control in dialysis patients with chronic kidney disease	Approved	Approved 21-Oct	\$1
Alexion	Soliris (eculizumab)	Paroxysmal nocturnal hemoglobinuria	Approved	Approved 19-Mar	\$0.5-1+
Speedel/Novartis	Tekturna	Hypertension	Approved	Approved 6-Mar	\$0.5-1

Includes small molecule candidates. Source: Cowen and Company. PDUFA, Prescription Drug User Fee Act.

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