

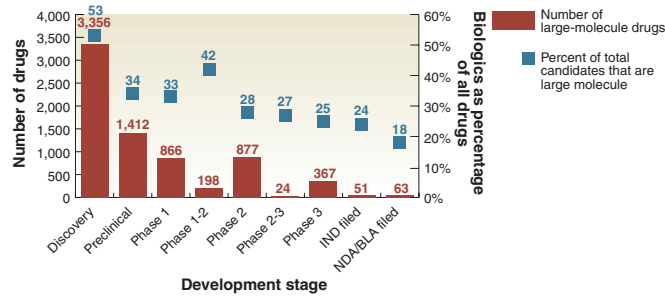
# Biotech blockbusters consolidate markets

Stacy Lawrence

Biologics are an increasingly significant part of the research pipeline, accounting for more than half of discovery-stage candidates and almost one-fifth of new applications for US Food and Drug Administration (FDA) approval. Although newly approved HIV treatment Atripla (efavirenz, emtricitabine, tenofovir), and human papilloma virus vaccine Gardasil are expected to garner >\$1.5 billion in sales in 2007, almost all the major \$1-billion-plus projections are for supplemental indications for mainstays like Avastin (bevacizumab) and Herceptin (trastuzumab).

## Biotech drug candidates by phase

Large-molecules now comprise >50% of discovery-stage candidates and almost 20% of applications for approval.



Source: BioPharm Insight

## Pending BLA filings

Company	Product	PDUFA date (BLA)	Projected revenue 2007 (\$ millions)
Abbott Pharmaceuticals	Humira (adalimumab; anti-tumor necrosis factor alpha)	3/7/07 (sBLA)	4,031
Acambis/Baxter	ACAM2000 smallpox vaccine (clone of Dryvax vaccinia virus derived in human diploid cell line)	2/18/07	NA
Alexion Pharmaceuticals	Soliris (eculizumab; anti-C5)	Filed 9/20/06	325
Cangene	Accretropin (generic human growth hormone)	5/17/07	NA
Dendreon Pharmaceuticals	Provenge (fusion of prostatic acid phosphatase to granulocyte-macrophage colony-stimulating factor)	2007	NA
Enzon Pharmaceuticals	Onscapar (PEG-L-asparaginase)	Filed 11/05 (sBLA)	29
Genentech	Avastin (bevacizumab; anti-vascular endothelial growth factor)	Filed 5/25/06 and 10/11/06 (sBLA)	4,775
Genentech	Herceptin (trastuzumab; anti-HER2)	11/16/06 (sBLA)	1,700
GlaxoSmithKline/ID Biomedical	FluLaval (egg-derived, split virion influenza vaccine)	1/23/07	862
MedImmune	FluMist (live trivalent influenza virus)	Refiled (sBLA)	350
Roche Mircera	CERA (continuous erythropoietin receptor activator)	2/20/07	700
Sanofi-Aventis	Pentacel (Hemophilus influenzae type b-diphtheria, tetanus, acellular pertussis and inactivated poliovirus vaccine)	5/25/06	NA
Schering AG	Betaseron (interferon beta-1b)	12/06 (sBLA)	1,230
Serono	Rebif (interferon beta-1a)	2/4/07 (sBLA)	1,975
UCB/Nektar Therapeutics	Cimzia (certolizumab-pegol (Fab' fragment); anti-tumor necrosis factor alpha)	2/07	300

BLA, biologic license application; sBLA, supplemental BLA; NA, not available; PDUFA, Prescription Drug User Fee Act. Source: Cowen and Company

## Blockbuster biotech approvals

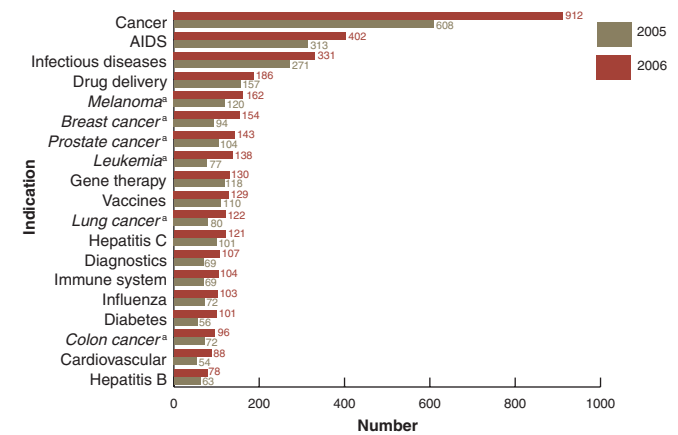
Company/partner	Product	Indication	Status	PDUFA/approval date	Peak potential (\$ billions)
Gilead/Bristol	Atripla (efavirenz, emtricitabine, tenofovir disoproxil fumarate)	HIV	Approved	Approved 7/13/06*	2.0-2.5
MedImmune/Merck	Gardasil (quadrivalent human papillomavirus types 6, 11, 16, 18)	HPV vaccine	Approved	Approved 6/8/06*	1.50
Genentech/Roche	Avastin (bevacizumab)	Breast cancer	Decision pending (sBLA)	Approvable 9/11/06	1.0-1.5
Genentech/Roche	Avastin (bevacizumab)	Non-small cell lung cancer	Approved (sBLA)	Approved 10/16/06	1.0-1.5
Biogen-Idec/Genentech	Rituxan (rituximab)	Intermediate or aggressive frontline NHL	Approved (sBLA)	Approved 2/10/06*	0.5-1.0
Biogen-Idec/Elan	Tysabri (natalizumab)	Relapsing multiple sclerosis	Approved (sBLA)	Approved 6/5/06**	0.5-1.0
Pozen/GlaxoSmithKline	Trexima (sumatriptan succinate and naproxen sodium)	Migraine	Decision pending	Approvable 6/8/06	0.5-1.0
Genentech/Novartis	Lucentis (ranibizumab)	Wet age-related macular degeneration	Approved	Approved 6/30/06*	0.5-1.0
Celgene	Revlimid (lenalidomide)	Multiple myeloma	Approved (sNDA)	Approved 6/30/06*	0.5-1.0
Amgen	Vectibix (panitumumab)	Refractory colorectal cancer	Approved	Approved 9/27/06	0.5-1.0

\*FDA priority review. \*\*Extended PDUFA date. sBLA, supplemental Biologic License Application; sNDA, supplemental New Drug Application; NHL, non-Hodgkins lymphoma; PDUFA, Prescription Drug User Fee Act. Source: Cowen and Company

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## Investigational biotech drugs by indication

The number of biologic candidates has increased across every major indication, by an average of >40%



<sup>a</sup>Cancer subtype broken out from total cancer Source: BioPharm Insight

## Top ten biotech drugs by global sales

Product/company	Type	2005 sales (\$ millions)	1H2006 Sales (\$ millions)
Enbrel (etanercept)/Amgen/Wyeth	Recombinant fusion protein; soluble TNF receptor linked to IgG1	3,657	2,087
Remicade (infliximab)/Centocor	Chimeric mAb; anti-TNF-alpha	3,477	2,042
Aranesp (darbepoetin alfa)/Amgen	Recombinant erythropoietin with two additional N-glycosylation sites	3,273	1,948
Rituxan (rituximab)/Biogen-Idec/Genentech	Chimeric mAb; anti-CD20	3,154	1,917
Procrit (erythropoietin)/Amgen	Recombinant erythropoietin	3,324	1,594
Herceptin (trastuzumab)/Genentech	Humanized mAb; anti-HER-2	1,629	1,480
Neulasta (PEG-filgrastim)/Amgen/Dompeic Biotech	Recombinant methionyl human granulocyte colony stimulating factor (Filgrastim) conjugated to monomethoxypolyethylene glycol	2,288	1,309
Epogen (erythropoietin)/Amgen	Recombinant erythropoietin	2,455	1,217
Avastin (bevacizumab)/Genentech	Humanized mAb; anti-vascular endothelial growth factor	1,264	1,134
Epogin/NeoRecormon (Roche)	Recombinant erythropoietin	1,710	898

mAb, monoclonal antibody; TNF, tumor necrosis factor. Source: Signals, Recombinant Capital

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