



FDA Approval Decisions Report December-February 2007

Overview

For investors in pharmaceutical and biotech companies, rigorous monitoring of drug pipelines is essential. No milestone is more influential than the FDA approval decision date, frequently called the PDUFA date (from Prescription Drug User Fee Act).

This Revere Report features **companies with expected FDA approval decision dates in the next three months**. To provide further insights into **each drug candidate's likelihood of approval and competitive landscape**, the FDA Approval Decisions Report includes **key data based on Revere's patented classification system and proprietary pipeline database** - specifically, whether each drug candidate:

- utilizes a mechanism of action already approved by the FDA in other drugs
- faces two or fewer alternative drugs with the same mechanism of action for the same indication
- would be the first or second FDA approved drug for the company

Contents

- Recent Approval Results/Updates
- Expected PDUFA Dates in the Next Three Months
- Price and Financial Info

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Notes:

1. Some expected PDUFA (Prescription Drug User Fee Act) dates are Revere estimates based on NDA (New Drug Approval) submission dates. Companies are not obligated to disclose NDA submission dates or PDUFA dates, and the FDA may change its approval decision date without prior notice.
2. Drugs developed by private firms or by companies not traded publicly in the U.S. are excluded from this analysis.

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Recent Approval Results/Updates

Company (Symbol) / Drug Candidate			
Indications	Primary mode of action (PMOA)	Previous Expected PDUFA Date	Approval results/update
Novadel Pharma Inc (NVD) / NitroMist (Nitroglycerin Lingual Aerosol)			
Acute Relief Or Acute Prophylaxis Of Angina Pectoris	Vasodilatory Agents	11/03/2006	Approved 11/03/2006
Par Pharmaceutical Companies, Inc (PRX) / NitroMist (Nitroglycerin Lingual Aerosol)			
Acute Relief Or Acute Prophylaxis Of Angina Pectoris	Vasodilatory Agents	11/03/2006	Approved 11/03/2006
Altana AG (ADR) (AAA) / Omnaris (Nasal Spray Ciclesonide)			
Nasal Symptoms Associated With Seasonal And Perennial Allergic Rhinitis	Steroidal Anti-Inflammatory Drugs (SAID)	11/07/2006	Approved 10/23/2006
GlaxoSmithKline plc (ADR) (GSK) / Entereg (Alvimopan)			
Post-Operative Ileus (POI)	Opioid Receptor Antagonists	<u>11/09/2006</u>	Approvable Letter Received 11/06/2006
Adolor Corporation (ADLR) / Entereg (Alvimopan)			
Post-Operative Ileus (POI)	Opioid Receptor Antagonists	<u>11/09/2006</u>	Approvable Letter Received 11/06/2006
Roche Holding Ltd. (ADR) (RHHBY) / Herceptin (Trastuzumab)			
Adjuvant Treatment Of HER2-Positive Node-Positive Breast Cancer	Monoclonal Antibodies	<u>11/17/2006</u>	Approved 11/16/2006
Genentech, Inc. (DNA) / Herceptin (Trastuzumab)			
Adjuvant Treatment Of HER2-Positive Node-Positive Breast Cancer	Monoclonal Antibodies	<u>11/17/2006</u>	Approved 11/16/2006
Genentech, Inc. (DNA) / Avastin (Bevacizumab)			
First-Line Treatment Of Locally Recurrent Or Metastatic Breast Cancer In Combination With Chemotherapies	Monoclonal Antibodies	<u>11/22/2006</u>	Approvable Letter Received 09/11/2006
Roche Holding Ltd. (ADR) (RHHBY) / Avastin (Bevacizumab)			
First-Line Treatment Of Locally Recurrent Or Metastatic Breast Cancer In Combination With Chemotherapies	Monoclonal Antibodies	<u>11/22/2006</u>	Approvable Letter Received 09/11/2006
Novartis AG (ADR) (NVS) / Galvus (Vildagliptin)			
Non-Insulin Dependent Diabetes Mellitus (NIDDM)/Type 2 Diabetes	Dipeptidyl Peptidase (DPP) Inhibitors	11/30/2006	Rescheduled to 02/28/2007

Expected PDUFA Dates are Revere estimates based on NDA (New Drug Approval) submission dates. Underlined dates indicate that Revere has confirmed directly with the company or indirectly through company filings and press releases.

Expected PDUFA Dates in the Next Three Months

December Drug Candidates

Companies

BioSante Pharmaceuticals, Inc. (BPA)
Cephalon, Inc. (CEPH)
Johnson & Johnson (JNJ)
Millennium Pharmaceuticals, Inc. (MLNM)
Nabi Biopharmaceuticals (NABI)
Novartis AG (ADR) (NVS) [2]
Oscient Pharmaceuticals Corporation (OSCID)

Sectors

- I** Biopharmaceuticals
 - Cardiovascular System
 - Endocrinology/Metabolism
 - Infectious Diseases
 - Neurology
 - Oncology

Notes:

1. Some drug candidates are filed jointly by two companies.
2. Companies with multiple drug candidates in the same month are shown in **bold type** with the number of drug candidates in brackets [].

Company (Symbol) / Drug Candidate	Indications	Primary mode of action (PMOA)	Expected PDUFA Date	Proven PMOA?	Two or Fewer Alternatives?	1 st /2 nd Drug?
Nabi Biopharmaceuticals (NABI) / Nabi-HB (Hepatitis B Immune Globulin)						
	Prevention Of Hepatitis B Virus Re-infection Of Transplanted Livers In Patients With Hepatitis B	Immunoglobulins	December 2006	Yes	Yes Chiron Pulminiq (Aerosolized Cyclosporine) / (NVS)	No
Millennium Pharmaceuticals, Inc. (MLNM) / Velcade (Bortezomib)						
	Relapsed Or Refractory Mantle Cell Lymphoma	Proteasome Inhibitors	<u>12/08/2006</u>	Yes	Yes Only Candidate with This PMOA for This Indication	No
Oscient Pharmaceuticals Corporation (OSCID) / FACTIVE (Gemifloxacin Mesylate)						
	5 Day Therapy For Acute Bacterial Sinusitis	Quinolones/Fluoroquinolones	<u>12/15/2006</u>	Yes	Yes Cipro Tablets/Cipro Oral Suspension/Cipro XR (Ciprofloxacin) / (BAY) Ketek (Telithromycin) / (SNY)	No
BioSante Pharmaceuticals, Inc. (BPA) / Bio-E-Gel (Estradiol Gel)						
	Moderate-To-Severe Hot Flashes In Menopausal Women	Estrogens	12/15/2006	Yes	No Multiple Drugs	Yes
Johnson & Johnson (JNJ) / Invega (Paliperidone ER OROS)						
	Schizophrenia	Serotonin/Dopamine Receptor Blocking Agents	<u>12/20/2006</u>	Yes	Yes Iloperidone / (VNDA) Geodon (Ziprasidone Mesylate) / (PFE)	No
Novartis AG (ADR) (NVS) / Tekturna (Aliskiren)/Formerly Rasilez						
	Hypertension	Renin Inhibitors	12/20/2006	No	Yes Only Candidate with This PMOA for This Indication	No
Novartis AG (ADR) (NVS) / Exforge (Valsartan/Amlodipine)						
	Hypertension	Angiotensin Converting Enzyme Inhibitors (ACE Inhibitors)/Calcium Channel Blockers	12/27/2006	Yes	No Multiple Drugs	No
Cephalon, Inc. (CEPH) / Nuvigil (Armodafinil)						
	Excessive Sleepiness Associated With Narcolepsy, Shift Work Sleep Disorder, And Obstructive Sleep Apnea/Hypopnea Syndrome	Alpha Adrenergic Receptor Agonists	12/29/2006	Yes	Yes Only Candidate with This PMOA for This Indication	No

Expected PDUFA Dates are Revere estimates based on NDA (New Drug Approval) submission dates. Underlined dates indicate that Revere has confirmed directly with the company or indirectly through company filings and press releases. **Two or Fewer Alternatives** -- If Approved, Drug Will Likely Face Two or Fewer Alternatives in Same Drug Class for Same Indication? **1st/2nd Drug** -- 1st or 2nd FDA Approved Drug of the Company?

January Drug Candidates

Companies

Amylin Pharmaceuticals, Inc. (AMLN)
Connetics Corporation (CNCT) [2]
 Eli Lilly & Co. (LLY)
 Enzon Pharmaceuticals, Inc. (ENZN)
 Genta Incorporated (GNTA)
 GlaxoSmithKline plc (ADR) (GSK)
 KOS Pharmaceuticals, Inc. (KOSP)
 Nektar Therapeutics (NKTR)
 Pfizer Inc. (PFE)
 Schwarz Pharma, Inc. (SWTZY)
 Shire plc (ADR) (SHPGY)
 Wyeth (WYE)

Sectors

- I Biopharmaceuticals
 - Cardiovascular System
 - Dermatology
 - Digestive System
 - Endocrinology/Metabolism
 - Hematology
 - Immunology
 - Neurology
 - Oncology
 - Urology

Notes:

1. Some drug candidates are filed jointly by two companies.
2. Companies with multiple drug candidates in the same month are shown in **bold type** with the number of drug candidates in brackets [].

Company (Symbol) / Drug Candidate	Indications	Primary mode of action (PMOA)	Expected PDUFA Date	Proven PMOA?	Two or Fewer Alternatives?	1 st /2 nd Drug?
Amylin Pharmaceuticals, Inc. (AMLN) / Byetta (Exenatide)						
	Add-On Therapy To Thiazolidinediones (TZDs) In People With Non-Insulin Dependent Diabetes Mellitus (NIDDM)/Type 2 Diabetes Who Are Not Achieving Acceptable Blood Sugar Control	Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 Receptor Agonists)	01/02/2007	Yes	Yes Liraglutide (NN 2211) / (NVO)	No
Eli Lilly & Co. (LLY) / Byetta (Exenatide)						
	Add-On Therapy To Thiazolidinediones (TZDs) In People With Type 2 Diabetes Who Are Not Achieving Acceptable Blood Sugar Control	Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 Receptor Agonists)	01/02/2007	Yes	Yes Liraglutide (NN 2211) / (NVO)	No
Enzon Pharmaceuticals, Inc. (ENZN) / Cimzia (Certolizumab Pegol)						
	Crohn's Disease	Tumor Necrosis Factor-Alpha Antagonists (TNF-Alpha Antagonists)	01/02/2007	Yes	Yes Humira (Adalimumab) / (ABT) Centocor Remicade (Infliximab) / (JNJ)	No
Nektar Therapeutics (NKTR) / Cimzia (Certolizumab Pegol)						
	Crohn's Disease	Tumor Necrosis Factor-Alpha Antagonists (TNF-Alpha Antagonists)	01/02/2007	Yes	Yes Humira (Adalimumab) / (ABT) Centocor Remicade (Infliximab) / (JNJ)	No
Pfizer Inc. (PFE) / Fesoterodine						
	Overactive Bladder/Urinary Incontinence	Muscarinic Receptor Antagonists	January 2007	Yes	No Multiple Drugs	No
Schwarz Pharma, Inc. (SWTZY) / Fesoterodine						
	Overactive Bladder/Urinary Incontinence	Muscarinic Receptor Antagonists	January 2007	Yes	No Multiple Drugs	No
KOS Pharmaceuticals, Inc. (KOSP) / Niaspan CF (Niacin)						
	Hypercholesterolemia	Free Fatty Acid Inhibitors	01/12/2007	Yes	Yes Only Candidate with This PMOA for This Indication	No
Connetics Corporation (CNCT) / Primolux (Clobetasol Propionat)						

Company (Symbol) / Drug Candidate	Indications	Primary mode of action (PMOA)	Expected PDUFA Date	Proven PMOA?	Two or Fewer Alternatives?	1 st /2 nd Drug?
Company (Symbol) / Drug Candidate						
	Atopic Dermatitis (Eczema)	Steroidal Anti-Inflammatory Drugs (SAID)	<u>01/17/2007</u>	Yes	Yes Synalar (Fluocinolone Acetonide) / (MRX) Dermik Laboratories Psorcon E (Diflorasone Diacetate) / (SNY)	No
Connetics Corporation (CNCT) / Primolux (Clobetasol Propionat)						
	Psoriasis	Steroidal Anti-Inflammatory Drugs (SAID)	<u>01/17/2007</u>	Yes	Yes Synalar (Fluocinolone Acetonide) / (MRX) Dermik Laboratories Psorcon E (Diflorasone Diacetate) / (SNY)	No
Shire plc (ADR) (SHPGY) / Mesavance/SPD 476 (Mesalamine)						
	Mild-To-Moderate Ulcerative Colitis	Cyclooxygenase Inhibitors (COX Inhibitors)/Lipoxygenase Inhibitors	<u>01/19/2007</u>	Yes	No Multiple Drugs	No
Wyeth (WYE) / Desvenlafaxine Succinate/DVS-233						
	Major Depressive Disorder	Selective Norepinephrine Reuptake Inhibitors (SNRI)	<u>01/22/2007</u>	Yes	Yes Only Candidate with This PMOA for This Indication	No
Genta Incorporated (GNTA) / Genasense (Oblimersen Sodium)						
	Chronic Lymphocytic Leukemia (CLL) In Combination With Fludarabine and Cyclophosphamide	Antisense Agents	<u>01/29/2007</u>	Yes	Yes Only Candidate with This PMOA for This Indication	No
GlaxoSmithKline plc (ADR) (GSK) / Arixtra (Fondaparinux Sodium)						
	Acute Coronary Syndrome (ACS)	Thrombin Inhibitors	<u>01/31/2007</u>	Yes	Yes Angiomax (Bivalirudin) / (MDCO)	No






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February Drug Candidates

Companies

Acambis plc (ADR) (ACAM)
 MedImmune, Inc. (MEDI)
 Merck & Co., Inc. (MRK)
 Nektar Therapeutics (NKTR)
 Novartis AG (ADR) (NVS)
 Roche Holding Ltd. (ADR) (RHHBY)
 Serono S.A. (ADR) (SRA)
 Watson Pharmaceuticals, Inc. (WPI)

Sectors

I Biopharmaceuticals
 Digestive System
 Endocrinology/Metabolism
 Hematology
 Immunology
 Infectious Diseases

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Company (Symbol) / Drug Candidate	Indications	Primary mode of action (PMOA)	Expected PDUFA Date	Proven PMOA?	Two or Fewer Alternatives?	1 st /2 nd Drug?
Merck & Co., Inc. (MRK) / MK-0517 (Intravenous Aprepitant)						
	Chemotherapy-Induced Nausea And Vomiting (CINV)	Neurokinin-1 (NK-1) Receptor Antagonists	February 2007	Yes	Yes Only Candidate with This PMOA for This Indication	No
Serono S.A. (ADR) (SRA) / Rebif (Recombinant Interferon Beta-1a)						
	New Formulation For The Treatment Of Relapsing-Remitting Multiple Sclerosis (MS)	Interferons	02/05/2007	Yes	Yes AVONEX (Interferon beta-1a) / (BIIB)	No
Watson Pharmaceuticals, Inc. (WPI) / AndrX Laboratories ACTOplus met XR (Pioglitazone/Metformin Extended Release)						
	Non-Insulin Dependent Diabetes Mellitus (NIDDM)/Type 2 Diabetes Who Are Not Controlled Adequately With Metformin Only	Biguanides/Peroxisome Proliferator-Activated Receptor Agonists (PPAR Agonists)	02/05/2007	Yes	Yes Avandamet (Rosiglitazone Maleate/Metformin) / (GSK)	No
Acambis plc (ADR) (ACAM) / Smallpox-ACAM2000						
	Smallpox Vaccine	Variola (Smallpox)	<u>02/14/2007</u>	No	Yes Only Candidate with This PMOA for This Indication	Yes
MedImmune, Inc. (MEDI) / Cold Adapted Influenza Vaccine-Trivalent (CAIV-T)						
	Influenza Vaccine (Flu Vaccine) In Healthy Individuals 5 To 49 Years Of Age	Influenza (Flu)	02/14/2007	Yes	No Multiple Drugs	No
Nektar Therapeutics (NKTR) / Mircera/CERA (Continuous Erythropoiesis Receptor Activator)						
	Anemia Associated With Renal Disease	Recombinant Human Erythropoietins	02/20/2007	No	No Multiple Drugs	No
Roche Holding Ltd. (ADR) (RHHBY) / Mircera/CERA (Continuous Erythropoietin Receptor Activator)						
	Anemia Associated With Renal Disease	Recombinant Human Erythropoietins	02/20/2007	No	No Multiple Drugs	No
Novartis AG (ADR) (NVS) / Galvus (Vildagliptin)						
	Non-Insulin Dependent Diabetes Mellitus (NIDDM)/Type 2 Diabetes	Dipeptidyl Peptidase (DPP) Inhibitors	02/28/2007	Yes	Yes Januvia (Sitagliptin Phosphate) / (MRK)	No

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Price and Financial Info

December 2006

Data as of 11/30/2006

Name	Ticker	Last Price	Market Cap.	30d Avg. Volume	Price To Tang. Book Value	Total Debt to Equity %	Cash & Equiv.+ ST Inv.	1 Year Return %	Rel. Perf. vs. ^BPHRM
BioSante Pharmaceuticals, Inc.	BPA	2.55	58.583	269,871	22.73	0	4.5	-42.83%	-53.02%
Cephalon, Inc.	CEPH	74.75	4,557.173	2,148,915	n/a	173.55	668.0	47.06%	36.87%
Johnson & Johnson	JNJ	65.91	191,096.488	9,705,776	7.01	5.84	14,692.0	6.74%	-3.45%
Millennium Pharmaceuticals, Inc.	MLNM	11.23	3,548.986	4,139,368	6.35	8.33	635.6	6.85%	-3.34%
Nabi Biopharmaceuticals	NABI	7.06	426.801	569,817	3.83	96.94	64.9	119.94%	109.75%
Novartis AG (ADR)	NVS	58.41	137,187.557	1,710,928	3.56	23.89	8,530.0	11.47%	1.28%
Oscient Pharmaceuticals Corporation	OSCID	5.90	79.945	101,193	n/a	1,657.69	42.8	-62.18%	-72.37%

Definitions: Market Cap. - Market Capitalization, Price To Tang. Book Value - Price to Tangible Book Value, Cash & Equiv.+ ST Inv. - Cash and Equivalents + Short-Term Investments, Rel. Perf. vs. ^BPHRM - Relative Performance vs. Revere Biopharm Index,

January 2007

Data as of 11/30/2006

Name	Ticker	Last Price	Market Cap.	30d Avg. Volume	Price To Tang. Book Value	Total Debt to Equity %	Cash & Equiv.+ ST Inv.	1 Year Return %	Rel. Perf. vs. ^BPHRM
Amylin Pharmaceuticals, Inc.	AMLN	40.00	5,209.680	1,605,651	7.76	29.65	832.5	6.95%	-3.24%
Connetics Corporation	CNCT	17.35	599.020	713,288	n/a	370.89	229.5	30.84%	20.65%
Eli Lilly & Co.	LLY	53.59	60,641.853	5,337,920	4.65	37.44	3,618.5	6.12%	-4.07%
Enzon Pharmaceuticals, Inc.	ENZN	8.33	365.670	802,487	n/a	0	170.0	22.68%	12.49%
Genta Incorporated	GNTA	0.80	122.980	2,749,971	3.93	0.38	40.1	-34.43%	-44.62%
GlaxoSmithKline plc (ADR)	GSK	53.13	153,088.360	1,616,257	14.86	60.09	6,595.8	7.18%	-3.01%
KOS Pharmaceuticals, Inc.	KOSP	77.73	3,702.346	1,587,135	6.40	3.83	543.7	16.75%	6.56%
Nektar Therapeutics	NKTR	16.50	1,489.878	1,443,814	9.12	174.06	481.6	-2.19%	-12.38%
Pfizer Inc.	PFE	27.49	198,215.123	41,348,940	8.49	11.57	13,291.0	29.67%	19.48%
Schwarz Pharma, Inc.	SWTZY	120.80	n/a	n/a	n/a	n/a	n/a	121.25%	111.06%
Shire plc (ADR)	SHPGY	60.60	10,197.385	953,977	11.86	0	955.2	65.85%	55.66%
Wyeth	WYE	48.28	65,018.626	7,986,816	6.19	62.4	8,166.9	16.17%	5.98%

Definitions: Market Cap. - Market Capitalization, Price To Tang. Book Value - Price to Tangible Book Value, Cash & Equiv.+ ST Inv. - Cash and Equivalents + Short-Term Investments, Rel. Perf. vs. ^BPHRM - Relative Performance vs. Revere Biopharm Index,

February 2007

Data as of 11/30/2006

Name	Ticker	Last Price	Market Cap.	30d Avg. Volume	Price To Tang. Book Value	Total Debt to Equity %	Cash & Equiv.+ ST Inv.	1 Year Return %	Rel. Perf. vs. ^BPHRM
Acambis plc (ADR)	ACAM	4.03	216.347	55,480	2.27	14.49	87.3	-45.24%	-55.43%
MedImmune, Inc.	MEDI	32.69	7,819.689	2,242,920	7.77	91.3	722.8	-8.97%	-19.16%
Merck & Co., Inc.	MRK	44.51	96,631.333	12,980,476	5.50	31.04	9,087.0	51.39%	41.20%
Nektar Therapeutics	NKTR	16.50	1,489.878	1,443,814	9.12	174.06	481.6	-2.19%	-12.38%
Novartis AG (ADR)	NVS	58.41	137,187.557	1,710,928	3.56	23.89	8,530.0	11.47%	1.28%
Roche Holding Ltd. (ADR)	RHHBY	91.05	157,072.638	n/a	8.62	24.11	16,040.6	20.60%	10.41%
Serono S.A. (ADR)	SRA	22.60	13,828.497	68,310	5.72	27.87	1,759.5	23.30%	13.10%
Watson Pharmaceuticals, Inc.	WPI	25.67	2,630.354	1,034,896	2.33	26.93	906.8	-23.05%	-33.24%

Definitions: Market Cap. - Market Capitalization, Price To Tang. Book Value - Price to Tangible Book Value, Cash & Equiv.+ ST Inv. - Cash and Equivalents + Short-Term Investments, Rel. Perf. vs. ^BPHRM - Relative Performance vs. Revere Biopharm Index,