



FDA Approval Decisions Report January-March 2008

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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
Neurocrine Biosciences, Inc. (NBIX) / Indiplon Immediate Release Capsule			
Primary (Chronic) And Transient Insomnia	Gamma-Aminobutyric Acid (GABA) Receptor Agonists	<u>12/12/2007</u>	Approvable Letter Received 12/12/2007
DOV Pharmaceutical, Inc. (DOVP) / Indiplon Immediate Release Capsule			
Primary (Chronic) And Transient Insomnia	Gamma-Aminobutyric Acid (GABA) Receptor Agonists	<u>12/12/2007</u>	Approvable Letter Received 12/12/2007
Jazz Pharmaceuticals, Inc. (JAZZ) / Luvox CR (Fluvoxamine Controlled Release)			
Obsessive Compulsive Disorder (OCD) And Social Anxiety Disorder (SAD)	Selective Serotonin Reuptake Inhibitors (SSRI)	<u>12/21/2007</u>	Approvable Letter Received 12/21/2007
Solvay S.A. (ADR) (SVYSY) / Solvay Pharmaceuticals Luvox CR (Fluvoxamine Controlled Release)			
Obsessive Compulsive Disorder (OCD) And Social Anxiety Disorder (SAD)	Selective Serotonin Reuptake Inhibitors (SSRI)	<u>12/21/2007</u>	Approvable Letter Received 12/21/2007
Pharmacyclics, Inc. (PCYC) / XCYTRIN (Motexafin Gadolinium)			
Non-Small Cell Lung Cancer (NSCLC) With Brain Metastases	Chemo/Radiation Sensitizer	<u>12/31/2007</u>	Non-Approvable Letter Received 12/21/2007
GlaxoSmithKline plc (ADR) (GSK) / Cervarix (HPV16/HPV18 Vaccine)			
Human Papillomavirus (HPV) Vaccine, Cervical Cancer Vaccine	Papillomavirus, Papillomavirus Vaccines	01/29/2008	Approvable Letter Received 12/17/2007

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

January Drug Candidates

Companies

Biogen Idec Inc. (BIIB)
 Cardiome Pharma Corp.(USA) (CRME)
 Elan Corporation, plc (ADR) (ELN)
 Johnson & Johnson (JNJ)
 MiddleBrook Pharmaceuticals, Inc. (MBRK)
 Omrix Biopharmaceuticals, Inc. (OMRI)
 Progenics Pharmaceuticals, Inc. (PGNX)
 Roche Holding Ltd. (ADR) (RHHBY)
 Sciele Pharma Inc. (SCRX)
 SkyePharma PLC (ADR) (SKYEY)
 Solvay S.A. (ADR) (SVYSY)
 Spectrum Pharmaceuticals, Inc. (SPPI)
 Wyeth (WYE)
 ZymoGenetics, Inc. (ZGEN)

Sectors

- I Biopharmaceuticals
 - Cardiovascular System
 - Digestive System
 - Infectious Diseases
 - Oncology
 - Surgery
- I Medical Devices
 - General Surgery

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?
Sciele Pharma Inc. (SCRX) / Controlled Release Sular (Nisoldipine)						
	Hypertension	Calcium Channel Blocking Agents	<u>01/02/2008</u>	Yes	No Multiple Drugs	No
SkyePharma PLC (ADR) (SKYEY) / Controlled Release Sular (Nisoldipine)						
	Hypertension	Calcium Channel Blocking Agents	<u>01/02/2008</u>	Yes	No Multiple Drugs	No
Omrix Biopharmaceuticals, Inc. (OMRI) / Evicel (Liquid Fibrin Sealant)						
	Fibrin Sealant For Hemostasis (Bleeding Control) During Kidney Surgery And General Surgical Procedures	Topical	<u>01/08/2008</u>	Yes	No Multiple Drugs	No
Elan Corporation, plc (ADR) (ELN) / Tysabri (Natalizumab)						
	Moderately To Severely Active Crohn's Disease	Alpha 4 Integrin Inhibitors	<u>01/11/2008</u>	Yes	Yes Only Candidate with This PMOA for This Indication	No
Biogen Idec Inc. (BIIB) / Tysabri (Natalizumab)						
	Moderately To Severely Active Crohn's Disease	Alpha 4 Integrin Inhibitors	<u>01/11/2008</u>	Yes	Yes Only Candidate with This PMOA for This Indication	No
Spectrum Pharmaceuticals, Inc. (SPPI) / ISO-vorin (Levofolinic Acid)						
	Osteosarcoma (Bone Cancer)	Folic Acid Derivatives	<u>01/11/2008</u>	Yes	Yes Only Candidate with This PMOA for This Indication	Yes
ZymoGenetics, Inc. (ZGEN) / rThrombin						
	Reduce Bleeding During Surgery/Critical Care (Hemostasis)	Coagulating Agents (Coagulants)	<u>01/17/2008</u>	Yes	Yes Thrombin JMI / (KG) Evithrom (Human Thrombin) / (OMRI)	Yes
Cardiome Pharma Corp.(USA) (CRME) / Kynapid (Vernakalant)/Formerly RSD1235 I.V.						
	Acute Conversion Of Atrial Fibrillation	Sodium Channel Blocking Agents/Potassium Channel Blocking Agents	<u>01/18/2008</u>	Yes	Yes Lanoxin (Digoxin) / (GSK)	Yes
Solvay S.A. (ADR) (SVYSY) / Solvay Pharmaceuticals Pulzium (Tedisamil)						

Company (Symbol) / Drug Candidate	Indications	Primary mode of action (PMOA)	Expected PDUFA Date	Proven PMOA?	Two or Fewer Alternatives?	1 st /2 nd Drug?
	Atrial Fibrillation, Atrial Flutter	Potassium Channel Blocking Agents	<u>01/18/2008</u>	Yes	Yes Azimilide / (PG) Tikosyn (Dofetilide) / (PFE)	No
Johnson & Johnson (JNJ) / Tibotec TMC125 (Etravirine)						
	Treatment Of HIV-1 Infection In Combination With Other Antiretroviral Agents	Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI)	<u>01/18/2008</u>	No	Yes Rescriptor (Delavirdine Mesylate) / (PFE) Sustiva (Efavirenz) / (BMJ)	No
MiddleBrook Pharmaceuticals, Inc. (MBRK) / Amoxicillin PULSYS						
	Acute Pharyngitis/Tonsillitis (Strep Throat) In Adults And Adolescents Due To Group A Streptococcal Infections	Penicillin Derivatives	<u>01/23/2008</u>	Yes	Yes Amoxil (Amoxicillin) / (GSK)	No
Roche Holding Ltd. (ADR) (RHHBY) / Xeloda (Capecitabine)						
	First-Line Or Second-Line Treatment Of Metastatic Colorectal Cancer (Colon Cancer) In Combination With Eloxatin (Oxaliplatin) And With Or Without Avastin (Bevacizumab)	Pyrimidine Analogs	01/25/2008	Yes	Yes Only Candidate with This PMOA for This Indication	No
Progenics Pharmaceuticals, Inc. (PGNX) / MNTX (Subcutaneous Methylnaltrexone)						
	Opioid-Induced Constipation (OIC) In Patients Receiving Palliative Care	Opioid Receptor Antagonists	<u>01/30/2008</u>	No	Yes Entereg (Alvimopan) / (ADLR)	Yes
Wyeth (WYE) / MNTX (Subcutaneous Methylnaltrexone)						
	Opioid-Induced Constipation (OIC) In Patients Receiving Palliative Care	Opioid Receptor Antagonists	<u>01/30/2008</u>	No	Yes Entereg (Alvimopan) / (ADLR)	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?

February Drug Candidates

Companies

Abbott Laboratories (ABT) [2]

Adolor Corporation (ADLR)
 AstraZeneca plc (ADR) (AZN)
 Axcan Pharma Inc. (USA) (AXCA)
 Genentech, Inc. (DNA)

GlaxoSmithKline plc (ADR) (GSK) [2]

Merck & Co., Inc. (MRK)
 Regeneron Pharmaceuticals, Inc. (REGN)
 Roche Holding Ltd. (ADR) (RHHBY)
 sanofi-aventis (ADR) (SNY)

Sectors

- I Biopharmaceuticals
- Dermatology
- Digestive System
- Hematology
- Immunology
- Infectious Diseases
- Oncology
- Surgery

Notes:

- Some drug candidates are filed jointly by two companies.
- 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?
Abbott Laboratories (ABT) / Humira (Adalimumab)						
	Moderate To Severe Chronic Plaque Psoriasis	Tumor Necrosis Factor-Alpha Antagonists (TNF-Alpha Antagonists)	02/01/2008	Yes	Yes Enbrel/Enbrel Once-Weekly (Etanercept) / (AMGN) Centocor Remicade (Infliximab) / (JNJ)	No
AstraZeneca plc (ADR) (AZN) / Humira (Adalimumab)						
	Moderate To Severe Chronic Plaque Psoriasis	Tumor Necrosis Factor-Alpha Antagonists (TNF-Alpha Antagonists)	02/01/2008	Yes	Yes Enbrel/Enbrel Once-Weekly (Etanercept) / (AMGN) Centocor Remicade (Infliximab) / (JNJ)	No
GlaxoSmithKline plc (ADR) (GSK) / Kinrix (Diphtheria, Tetanus, Acellular Pertussis-Inactivated Polio Virus Vaccine (DTaP-IPV))						
	Diphtheria, Tetanus, Acellular Pertussis And Polio Vaccine	Diphtheria/Tetanus/Acellular Pertussis (DTaP)	February 2008	Yes	Yes Only Candidate with This PMOA for This Indication	No
Axcan Pharma Inc. (USA) (AXCA) / Ultrase (Pancrelipase)/Ultrase MT (Pancrelipase)						
	Chronic Pancreatitis, Exocrine Pancreatic Insufficiency, Pancreatic Deficiency Related To Cystic Fibrosis (CF)	Enzyme Replacement Therapy	02/01/2008	Yes	No Multiple Drugs	No
Adolor Corporation (ADLR) / Entereg (Alvimopan)						
	Post-Operative Ileus (POI)	Opioid Receptor Antagonists	<u>02/08/2008</u>	No	Yes MNTX (Subcutaneous Methylnaltrexone) / (PGNX)	Yes
GlaxoSmithKline plc (ADR) (GSK) / Entereg (Alvimopan)						
	Post-Operative Ileus (POI)	Opioid Receptor Antagonists	<u>02/08/2008</u>	No	Yes MNTX (Subcutaneous Methylnaltrexone) / (PGNX)	No
sanofi-aventis (ADR) (SNY) / Gardasil (Quadrivalent Human Papillomavirus Recombinant Vaccine)						
	Vaginal And Vulvar Cancer Vaccine	Papillomavirus, Papillomavirus Vaccines	02/15/2008	Yes	Yes Only Candidate with This PMOA for This Indication	No
Merck & Co., Inc. (MRK) / Gardasil (Quadrivalent Human Papillomavirus Recombinant Vaccine)						
	Vaginal And Vulvar Cancer Vaccine	Papillomavirus, Papillomavirus Vaccines	02/15/2008	Yes	Yes Only Candidate with This PMOA for This Indication	No
Abbott Laboratories (ABT) / KOS Pharmaceuticals Simcor (Niacin/Simvastatin)						

Company (Symbol) / Drug Candidate	Indications	Primary mode of action (PMOA)	Expected PDUFA Date	Proven PMOA?	Two or Fewer Alternatives?	1 st /2 nd Drug?
	Hypercholesterolemia, Dyslipidemia	Free Fatty Acid Inhibitors/HMG CoA Reductase Inhibitors (Statins)	02/20/2008	Yes	Yes Only Candidate with This PMOA for This Indication	No
Roche Holding Ltd. (ADR) (RHHBY) / Avastin (Bevacizumab)						
	First-Line Treatment Of Locally Recurrent Or Metastatic Breast Cancer In Combination With Chemotherapies	Monoclonal Antibodies	<u>02/22/2008</u>	Yes	Yes Only Candidate with This PMOA for This Indication	No
Genentech, Inc. (DNA) / Avastin (Bevacizumab)						
	First-Line Treatment Of Locally Recurrent Or Metastatic Breast Cancer In Combination With Chemotherapies	Monoclonal Antibodies	<u>02/22/2008</u>	Yes	Yes Only Candidate with This PMOA for This Indication	No
Regeneron Pharmaceuticals, Inc. (REGN) / Riloncept (Interleukin-1 Cytokine Trap)						
	CIAS1-Associated Periodic Syndrome (CAPS)	Interleukin-1 Receptor Antagonists (IL-1 Antagonists)	<u>02/29/2008</u>	Yes	Yes Only Candidate with This PMOA for This Indication	Yes

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March Drug Candidates

Companies

Bristol Myers Squibb Co. (BMY)
CV Therapeutics, Inc. (CVTX)
Cephalon, Inc. (CEPH)
Johnson & Johnson (JNJ)
MGI Pharma, Inc. (MOGN)
QLT Inc. (USA) (QLTI)

Sectors

- I Biopharmaceuticals
 - Dermatology
 - Digestive System
 - Infectious Diseases
 - Neurology
 - Oncology
- I Medical Devices
 - Cardiology

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?
MGI Pharma, Inc. (MOGN) / Aloxi (Palonosetron)						
	Postoperative Nausea And Vomiting	Serotonin Receptor Antagonists	<u>03/04/2008</u>	Yes	No Multiple Drugs	No
Bristol Myers Squibb Co. (BMY) / Abilify (Aripiprazole)/Abilify Discmelt (Aripiprazole Orally Disintegrating Tablet)						
	Bipolar I Disorder, Manic Or Mixed Episode With Or Without Psychotic Features In Pediatric Patients Aged 10-17	Serotonin/Dopamine Receptor Partial Agonists	03/14/2008	Yes	Yes Only Candidate with This PMOA for This Indication	No
CV Therapeutics, Inc. (CVTX) / Regadenoson						
	Diagnostic Cardiac Stress Test Used To Increase Blood Flow In Patients Undergoing Cardiac Perfusion Imaging Studies	Stress/Exercise Test	03/14/2008	No	Yes Binodenoson / (KG)	Yes
Johnson & Johnson (JNJ) / Ceftobiprole						
	Complicated Skin And Skin Structure Infections (cSSSI), Including Those Caused By Methicillin-Resistant Staphylococcus aureus (MRSA)	Cephalosporin Derivatives	03/18/2008	Yes	Yes Only Candidate with This PMOA for This Indication	No
Cephalon, Inc. (CEPH) / Treanda (Bendamustine Hydrochloride)						
	Chronic Lymphocytic Leukemia (CLL)	Nitrogen Mustard Type	03/21/2008	Yes	Yes Cytosan/Lyophilized Cytosan (Cyclophosphamide) / (BMY)	No
QLT Inc. (USA) (QLTI) / ACZONE Gel (Dapsone Topical Gel)						
	Treatment Of Moderate To Severe Acne Vulgaris Without Prior Blood Monitoring And Screening Of G6PD	Sulfonamides	03/28/2008	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?

Price and Financial Info

January 2008

Data as of 12/31/2007

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
Biogen Idec Inc.	BIIB	56.92	16,698.581	5,592,774	12.91	31.25	671.3	15.71%	20.94%
Cardiome Pharma Corp.(USA)	CRME	8.92	568.405	1,506,014	6.79	0	85.9	-20.00%	-14.78%
Elan Corporation, plc (ADR)	ELN	21.98	10,275.333	2,798,960	n/a	0	805.9	49.02%	54.24%
Johnson & Johnson	JNJ	66.70	190,878.728	10,268,904	13.57	18.12	8,320.0	1.03%	6.25%
MiddleBrook Pharmaceuticals, Inc.	MBRK	1.20	56.074	63,188	n/a	153.16	5.9	-69.31%	-64.09%
Omxix Biopharmaceuticals, Inc.	OMRI	34.74	588.821	185,035	5.17	0.55	85.4	14.81%	20.03%
Progenics Pharmaceuticals, Inc.	PGNX	18.07	536.841	366,674	3.41	0	145.7	-29.80%	-24.57%
Roche Holding Ltd. (ADR)	RHHBY	85.40	147,325.682	169,048	5.47	17.99	20,828.3	-4.53%	0.70%
Sciele Pharma Inc.	SCRX	20.45	729.012	625,013	583.21	76.59	204.2	-14.79%	-9.57%
SkyePharma PLC (ADR)	SKYEY	2.40	195.597	10,004	n/a	1,434.57	46.9	-53.49%	-48.27%
Solvay S.A. (ADR)	SVYSY	141.30	11,968.269	794	3.36	43.96	613.3	-6.42%	-1.20%
Spectrum Pharmaceuticals, Inc.	SPPI	2.72	84.920	160,951	1.43	0	65.8	-50.81%	-45.59%
Wyeth	WYE	44.19	59,176.595	6,047,128	4.73	69.12	12,919.1	-13.22%	-7.99%
ZymoGenetics, Inc.	ZGEN	11.67	799.430	461,951	5.45	45.75	198.5	-25.05%	-19.82%

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 2008

Data as of 12/31/2007

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
Abbott Laboratories	ABT	56.15	86,764.552	5,412,392	1,016.05	78.44	2,549.0	15.27%	20.49%
Adolor Corporation	ADLR	4.60	211.690	1,445,159	1.75	0	147.5	-38.83%	-33.61%
AstraZeneca plc (ADR)	AZN	42.82	62,490.739	958,365	n/a	98.52	3,530.0	-20.04%	-14.81%
Axcan Pharma Inc. (USA)	AXCA	23.00	1,273.615	1,033,077	4.31	0.09	309.6	61.52%	66.74%
Genentech, Inc.	DNA	67.07	70,630.810	6,010,312	7.98	20.17	2,920.0	-17.33%	-12.11%
GlaxoSmithKline plc (ADR)	GSK	50.39	138,769.826	1,719,320	13.53	69.63	6,215.2	-4.49%	0.73%
Merck & Co., Inc.	MRK	58.11	126,480.310	11,782,218	6.83	28.22	7,391.5	33.28%	38.50%
Regeneron Pharmaceuticals, Inc.	REGN	24.15	1,597.516	681,335	10.55	132.1	397.0	20.33%	25.55%
Roche Holding Ltd. (ADR)	RHHBY	85.40	147,325.682	169,048	5.47	17.99	20,828.3	-4.53%	0.70%
sanofi-aventis (ADR)	SNY	45.53	123,790.107	1,034,302	n/a	n/a	n/a	-1.39%	3.84%

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,

March 2008

Data as of 12/31/2007

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
Bristol Myers Squibb Co.	BMY	26.52	52,470.112	11,139,788	11.19	54.94	3,582.0	0.76%	5.98%
Cephalon, Inc.	CEPH	71.76	4,811.616	1,099,530	n/a	101.29	731.1	1.92%	7.14%
CV Therapeutics, Inc.	CVTX	9.05	539.978	772,099	n/a	0	194.8	-35.17%	-29.95%
Johnson & Johnson	JNJ	66.70	190,878.728	10,268,904	13.57	18.12	8,320.0	1.03%	6.25%

MGi Pharma, Inc.	MOGN	40.53	3,267.240	5,878,596	171.91	179.7	164.3	120.15%	125.38%
QLT Inc. (USA)	QLTI	4.42	329.822	781,958	1.92	65	172.2	-47.75%	-42.53%

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,