



FDA Approval Decisions Report September-November 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
Johnson & Johnson (JNJ) / Doribax (Doripenem)				
	Nosocomial Pneumonia, Including Ventilator-Associated Pneumonia	Carbapenems	08/04/2008	Complete Response Letter Received 08/21/2008
Gilead Sciences, Inc. (GILD) / Viread (Tenofovir Disoproxil Fumarate)				
	Chronic Hepatitis B Virus (HBV)	Nucleoside Reverse Transcriptase Inhibitors (NRTI), Reverse Transcriptase Inhibitors (Nucleoside Analogs)	<u>08/11/2008</u>	Approved 08/11/2008
Eisai Co., Ltd (ADR) (ESALY) / MGi Pharma Oral Aloxi (Palonosetron)				
	Chemotherapy Induced Nausea And Vomiting	Serotonin Receptor Antagonists	<u>08/22/2008</u>	Approved 08/23/2008
BioDelivery Sciences International, Inc. (BDSI) / Onsolis (Fentanyl Buccal Soluble Film)/Formerly BEMA Fentanyl				
	Breakthrough Cancer Pain In Opioid Tolerant Patients	Opioids	08/29/2008	Complete Response Letter Received 08/28/2008
Novartis AG (ADR) (NVS) / Chiron Procleix Ultrio Assay				
	Detection Of Donated Blood For Hepatitis B Virus (HBV)	Hepatitis C Virus, Human Immunodeficiency Virus (HIV), Hepatitis B Virus	12/19/2008	Approved 08/13/2008
Gen-Probe Incorporated (GPRO) / Procleix Ultrio Assay				
	Detection Of Donated Blood For Hepatitis B Virus (HBV)	Hepatitis C Virus, Human Immunodeficiency Virus (HIV), Hepatitis B Virus	12/19/2008	Approved 08/13/2008

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

September Drug Candidates

Companies

Abbott Laboratories (ABT)
 Cephalon, Inc. (CEPH)
 Eli Lilly & Co. (LLY)
 Genentech, Inc. (DNA)
 General Electric Company (GE)
 Gilead Sciences, Inc. (GILD)
 GlaxoSmithKline plc (ADR) (GSK)
 Ligand Pharmaceuticals Inc. (LGND)
 Novadel Pharma Inc (NVD)
 OSI Pharmaceuticals, Inc. (OSIP)
Roche Holding Ltd. (ADR) (RHHBY) [2]

Sectors

 Biopharmaceuticals
 Cardiovascular System
 Hematology
 Immunology
 Musculoskeletal System
 Neurology
 Oncology
 Pain Management
 Respiratory System
 Medical Devices
 Radiology

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) / Vicodin CR (Controlled Release Acetaminophen/Hydrocodone)						
	Moderate To Moderately Severe Pain	Analgesics/Opioids	Sep 2008	Yes	No Multiple Drugs	No
Roche Holding Ltd. (ADR) (RHHBY) / Tarceva (Erlotinib)						
	New Maximum Tolerated Dose (MTD) For Smokers With Non-Small Cell Lung Cancer (NSCLC)	Epidermal Growth Factor Receptor Tyrosine Kinase (EGFR-TK) Inhibitors	Sep 2008	Yes	Yes Only Candidate with This PMOA for This Indication	No
OSI Pharmaceuticals, Inc. (OSIP) / Tarceva (Erlotinib)						
	New Maximum Tolerated Dose (MTD) For Smokers With Non-Small Cell Lung Cancer (NSCLC)	Epidermal Growth Factor Receptor Tyrosine Kinase (EGFR-TK) Inhibitors	Sep 2008	Yes	Yes Only Candidate with This PMOA for This Indication	No
Genentech, Inc. (DNA) / Tarceva (Erlotinib)						
	New Maximum Tolerated Dose (MTD) For Smokers With Non-Small Cell Lung Cancer (NSCLC)	Epidermal Growth Factor Receptor Tyrosine Kinase (EGFR-TK) Inhibitors	Sep 2008	Yes	Yes Only Candidate with This PMOA for This Indication	No
Cephalon, Inc. (CEPH) / Fentora (Fentanyl Buccal Tablet)						
	Management Of Breakthrough Pain In Opioid Tolerant Patients With Chronic Pain Conditions	Opioids	<u>09/12/2008</u>	Yes	Yes ALZA Duragesic (Fentanyl) / (JNJ) Embeda (Abuse Resistant Morphine Sulphate/Naltrexone) / (ALO)	No
Gilead Sciences, Inc. (GILD) / Inhaled Aztreonam Lysine						
	Pulmonary Infection Related To Cystic Fibrosis (CF)	Monobactams	<u>09/16/2008</u>	Yes	Yes Only Candidate with This PMOA for This Indication	No
Roche Holding Ltd. (ADR) (RHHBY) / Actemra (Tocilizumab)						
	Rheumatoid Arthritis (RA)	Monoclonal Antibodies	09/19/2008	Yes	Yes Ocrelizumab/R1594 (Humanized Anti-CD20 Monoclonal Antibody) / (DNA) Golimumab / (SGP)	No
Ligand Pharmaceuticals Inc. (LGND) / Promacta (Eltrombopag)						
	Idiopathic Thrombocytopenia Purpura (ITP)/Thrombocytopenia	Thrombopoietin Agonists	<u>09/19/2008</u>	No	Yes Only Candidate with This PMOA for This Indication	Yes
GlaxoSmithKline plc (ADR) (GSK) / Promacta (Eltrombopag)						

Company (Symbol) / Drug Candidate	Indications	Primary mode of action (PMOA)	Expected PDUFA Date	Proven PMOA?	Two or Fewer Alternatives?	1 st /2 nd Drug?
Idiopathic Thrombocytopenia Purpura (ITP)/Thrombocytopenia						
		Thrombopoietin Agonists	<u>09/19/2008</u>	No	Yes Only Candidate with This PMOA for This Indication	No
General Electric Company (GE) / GE Healthcare AdreView (Iobenguane I 123 Injection)						
	Detection Of Neuroendocrine Cancer In Pediatric And Adult Patients	Injectable	<u>09/19/2008</u>	Yes	Yes Only Candidate with This PMOA for This Indication	No
Novadel Pharma Inc (NVD) / ZolpiMist (Zolpidem Tartrate Oral Spray)						
	Short-Term Treatment Of Insomnia	Gamma-Aminobutyric Acid (GABA) Receptor Agonists	09/23/2008	Yes	No Multiple Drugs	Yes
Eli Lilly & Co. (LLY) / Prasugrel						
	Acute Coronary Syndrome (ACS) In Patients Undergoing Percutaneous Coronary Intervention	Adenosine Diphosphate (ADP) Inhibitors	<u>09/26/2008</u>	Yes	Yes AZD6140 (ADP Antagonist) / (AZN) Plavix (Clopidogrel Bisulfate) / (BMY)	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?

October Drug Candidates

Companies

Abbott Laboratories (ABT)
 AMAG Pharmaceuticals, Inc. (AMAG)
 Barr Pharmaceuticals, Inc. (BRL)
 Cephalon, Inc. (CEPH)
 Cipher Pharmaceuticals Inc (DND:CA)
 Cypress Bioscience, Inc. (CYPB)
 Enzon Pharmaceuticals, Inc. (ENZN)
 Forest Laboratories, Inc. (FRX)
 Johnson & Johnson (JNJ)
 K-V Pharmaceutical Company (KV/A)
 Nektar Therapeutics (NKTR)
 Salix Pharmaceuticals, Ltd. (SLXP)
 Watson Pharmaceuticals, Inc. (WPI)

Sectors

- Biopharmaceuticals
 - ◆ Digestive System
 - ◆ Endocrinology/Metabolism
 - ◆ Hematology
 - ◆ Immunology
 - ◆ Infectious Diseases
 - ◆ Musculoskeletal System
 - ◆ Obstetrics/Gynecology
 - ◆ Oncology
 - ◆ Pain Management
 - ◆ Urology

Notes:

- Some drug candidates are filed jointly by two companies.
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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?
Abbott Laboratories (ABT) / TriLipix (Next Generation Fenofibrate)						
	Hypertriglyceridemia, Hypercholesterolemia	Plasma Triglyceride Reducing Agents (Fibrate Compounds)	Oct 2008	Yes	Yes ANTARA (Fenofibrate) / (OSCI) Lipofen (Fenofibrate Lidose Delivery) / (DND:CA)	No
Nektar Therapeutics (NKTR) / Cimzia (Certolizumab Pegol)						
	Rheumatoid Arthritis (RA)	Tumor Necrosis Factor-Alpha Antagonists (TNF-Alpha Antagonists)	10/06/2008	Yes	No Multiple Drugs	No
Enzon Pharmaceuticals, Inc. (ENZN) / Cimzia (Certolizumab Pegol)						
	Rheumatoid Arthritis (RA)	Tumor Necrosis Factor-Alpha Antagonists (TNF-Alpha Antagonists)	10/06/2008	Yes	No Multiple Drugs	No
Watson Pharmaceuticals, Inc. (WPI) / Silodosin						
	Benign Prostate Hyperplasia (BPH)	Alpha Adrenergic Receptor Blocking Agents (Alpha Blockers)	10/10/2008	Yes	No Multiple Drugs	No
Cipher Pharmaceuticals Inc (DND:CA) / CIP-Tramadol Hydrochloride Extended Release						
	Moderate To Moderately Severe Pain	Opioids	10/13/2008	Yes	No Multiple Drugs	Yes
AMAG Pharmaceuticals, Inc. (AMAG) / Ferumoxytol						
	Iron Deficiency Anemia In Patients With Chronic Kidney Disease (CKD)	Iron Supplements, Oral	10/17/2008	Yes	Yes Only Candidate with This PMOA for This Indication	No
Johnson & Johnson (JNJ) / Prezista (Darunavir)						
	Human Immunodeficiency Virus (HIV)-1-Infected, Treatment-naive Adults	Protease Inhibitors	10/21/2008	Yes	No Multiple Drugs	No
K-V Pharmaceutical Company (KV/A) / Gestiva						
	Preterm Birth Prevention In Women With A History Of Preterm Delivery	Progestins	<u>10/24/2008</u>	Yes	Yes Only Candidate with This PMOA for This Indication	No
Barr Pharmaceuticals, Inc. (BRL) / Lo Seasonique (Levonorgestrel/Ethinyl Estradiol)						
	Pregnancy Prevention/Contraception	Estrogens/Progestins	<u>10/24/2008</u>	Yes	No Multiple Drugs	No

Company (Symbol) / Drug Candidate	Indications	Primary mode of action (PMOA)	Expected PDUFA Date	Proven PMOA?	Two or Fewer Alternatives?	1 st /2 nd Drug?
Cypress Bioscience, Inc. (CYPB) / Milnacipran						
	Fibromyalgia Syndrome (FMS)	Serotonin/Norepinephrine Reuptake Inhibitors	10/31/2008	Yes	Yes Only Candidate with This PMOA for This Indication	Yes
Forest Laboratories, Inc. (FRX) / Milnacipran						
	Fibromyalgia Syndrome (FMS)	Serotonin/Norepinephrine Reuptake Inhibitors	10/31/2008	Yes	Yes Only Candidate with This PMOA for This Indication	No
Cephalon, Inc. (CEPH) / Treanda (Bendamustine Hydrochloride)						
	Indolent Non-Hodgkin's Lymphoma (NHL) Refractory To Rituxumab	Nitrogen Mustard Type	10/31/2008	Yes	Yes Only Candidate with This PMOA for This Indication	No
Salix Pharmaceuticals, Ltd. (SLXP) / Granulated Mesalamine						
	Ulcerative Colitis Remission Maintenance	Cyclooxygenase Inhibitors (COX Inhibitors)/Lipoxygenase Inhibitors	<u>10/31/2008</u>	Yes	Yes Pentasa (Mesalamine) / (SHPGY) Asacol (Mesalamine) / (PG)	No

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November Drug Candidates

Companies

AstraZeneca plc (ADR) (AZN) [3]
 Johnson & Johnson (JNJ)
 Ligand Pharmaceuticals Inc. (LGND)
 Pfizer Inc. (PFE)
 Pharmaceutical Product Development, Inc. (PPDI)
 Takeda Pharmaceutical Company Limited (TKPHF)

Sectors

- Biopharmaceuticals
 - ◆ Endocrinology/Metabolism
 - ◆ Infectious Diseases
 - ◆ Musculoskeletal System
 - ◆ Neurology
 - ◆ Pain Management

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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?
AstraZeneca plc (ADR) (AZN) / Seroquel XR (Quetiapine Fumarate Sustained Release)						
	Manic Episodes Associated With Bipolar Disorder	Monoaminergic Antagonists	11/03/2008	Yes	Yes Risperdal (Risperidone) / (JNJ) Zyprexa (Olanzapine) / (LLY)	No
AstraZeneca plc (ADR) (AZN) / Seroquel XR (Quetiapine Fumarate Sustained Release)						
	Depressive Episodes Associated With Bipolar Disorder	Monoaminergic Antagonists	11/03/2008	Yes	Yes Zyprexa (Olanzapine) / (LLY) Risperdal (Risperidone) / (JNJ)	No
Takeda Pharmaceutical Company Limited (TKPHF) / Alogliptin (Dipeptidyl Peptidase IV (DPP IV) Inhibitor)						
	Non-Insulin Dependent Diabetes Mellitus (NIDDM)/Type 2 Diabetes	Dipeptidyl Peptidase (DPP) Inhibitors	11/04/2008	Yes	No Multiple Drugs	No
Pharmaceutical Product Development, Inc. (PPDI) / Takeda Alogliptin (Dipeptidyl Peptidase IV (DPP IV) Inhibitor)						
	Non-Insulin Dependent Diabetes Mellitus (NIDDM)/Type 2 Diabetes	Dipeptidyl Peptidase (DPP) Inhibitors	11/04/2008	Yes	No Multiple Drugs	Yes
Pfizer Inc. (PFE) / Fablyn (Lasofoxifene)/Formerly Oporia						
	Treatment Of Osteoporosis In Postmenopausal Women	Selective Estrogen Receptor Modulators (SERM)	11/14/2008	Yes	Yes Evista (Raloxifene Hydrochloride) / (LLY) Viviant (Bazedoxifene) / (WYE)	No
Ligand Pharmaceuticals Inc. (LGND) / Fablyn (Lasofoxifene)/Formerly Oporia						
	Treatment Of Osteoporosis In Postmenopausal Women	Selective Estrogen Receptor Modulators (SERM)	11/14/2008	Yes	Yes Evista (Raloxifene Hydrochloride) / (LLY) Viviant (Bazedoxifene) / (WYE)	Yes
Johnson & Johnson (JNJ) / Tapentadol Hydrochloride Immediate Release						
	Relief Of Moderate To Severe Acute Pain	Opioid Receptor Antagonists/Norepinephrine Reuptake Inhibitors	11/21/2008	No	Yes Only Candidate with This PMOA for This Indication	No
AstraZeneca plc (ADR) (AZN) / MedImmune Motavizumab/Formerly Numax						
	Respiratory Syncytial Virus (RSV) In High-Risk Infants	Monoclonal Antibodies	11/28/2008	Yes	Yes Only Candidate with This PMOA for This Indication	No

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Price and Financial Info

September 2008

Data as of 09/02/2008

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	58.87	90,750.870	5,068,912	42.06	73.24	5,178.3	13.41%	16.51%
Cephalon, Inc.	CEPH	76.04	5,169.297	1,146,760	28.43	70.32	673.4	1.32%	4.42%
Eli Lilly & Co.	LLY	46.74	53,141.041	4,802,940	4.29	31.31	5,170.0	-18.50%	-15.40%
Genentech, Inc.	DNA	98.01	103,464.255	3,781,520	9.74	23.14	4,505.0	31.01%	34.12%
General Electric Company	GE	28.85	287,000.592	40,504,500	15.93	469.74	18,989.0	-25.78%	-22.67%
Gilead Sciences, Inc.	GILD	50.40	46,368.317	6,623,776	12.29	34.56	1,347.7	38.59%	41.69%
GlaxoSmithKline plc (ADR)	GSK	47.07	123,178.099	1,074,641	58.93	184.5	10,270.5	-9.86%	-6.76%
Ligand Pharmaceuticals Inc.	LGND	3.32	315.369	519,795	10.05	3.97	85.0	-47.01%	-43.91%
Novadel Pharma Inc	NVD	0.18	10.925	57,837	17.45	111.34	4.8	-76.00%	-72.90%
OSI Pharmaceuticals, Inc.	OSIP	50.37	2,898.211	834,874	32.16	293.62	430.1	47.67%	50.77%
Roche Holding Ltd. (ADR)	RHHBY	83.80	144,565.469	83,988	5.67	13.43	15,123.5	-2.27%	0.83%

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,

October 2008

Data as of 09/02/2008

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	58.87	90,750.870	5,068,912	42.06	73.24	5,178.3	13.41%	16.51%
AMAG Pharmaceuticals, Inc.	AMAG	39.60	673.257	552,426	2.57	0	202.2	-27.54%	-24.43%
Barr Pharmaceuticals, Inc.	BRL	67.24	7,317.702	1,682,259	19.62	92.86	547.0	32.15%	35.26%
Cephalon, Inc.	CEPH	76.04	5,169.297	1,146,760	28.43	70.32	673.4	1.32%	4.42%
Cipher Pharmaceuticals Inc	DND:CA	1.10	26.460	3,619	2.11	0	9.4	-43.59%	-40.49%
Cypress Bioscience, Inc.	CYPB	6.65	251.922	437,557	1.79	0	153.4	-49.85%	-46.75%
Enzon Pharmaceuticals, Inc.	ENZN	9.00	403.886	609,614	6.91	704.26	119.3	10.97%	14.08%
Forest Laboratories, Inc.	FRX	36.33	11,075.767	2,191,312	3.44	0	1,832.8	-3.45%	-0.35%
Johnson & Johnson	JNJ	71.78	200,588.919	10,545,460	11.64	29.99	13,058.0	16.17%	19.27%
K-V Pharmaceutical Company	KV/A	22.46	1,121.818	293,018	4.17	57.83	135.1	-17.82%	-14.72%
Nektar Therapeutics	NKTR	3.83	353.486	1,002,198	5.61	235.11	373.9	-53.69%	-50.59%
Salix Pharmaceuticals, Ltd.	SLXP	6.97	334.836	522,738	4.34	6.3	90.9	-39.50%	-36.39%
Watson Pharmaceuticals, Inc.	WPI	30.72	3,209.165	1,152,338	6.05	42	278.2	3.02%	6.12%

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,

November 2008

Data as of 09/02/2008

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
AstraZeneca plc (ADR)	AZN	49.06	71,210.492	1,767,447	n/a	93.11	4,514.0	-0.28%	2.82%
Johnson & Johnson	JNJ	71.78	200,588.919	10,545,460	11.64	29.99	13,058.0	16.17%	19.27%
Ligand Pharmaceuticals Inc.	LGND	3.32	315.369	519,795	10.05	3.97	85.0	-47.01%	-43.91%
Pfizer Inc.	PFE	19.33	130,303.410	36,452,316	5.21	25.08	27,220.0	-22.18%	-19.08%
Pharmaceutical Product Development, Inc.	PPDI	41.61	4,955.984	870,104	4.94	0	496.1	18.78%	21.89%
Takeda Pharmaceutical Company Limited	TKPHF	52.30	n/a	248	n/a	n/a	n/a	-21.71%	-18.60%

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,