



# FDA Approval Decisions Report April-June 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
<b>New River Pharmaceuticals, Inc. (NRPH) / Vyvanse (Lisdexamfetamine Dimesylate)/Formerly NRP104</b>				
	Attention Deficit Hyperactivity Disorder (ADHD) In Pediatric Patients 6-12 Years Of Age	Sympathomimetic Agents	March 2007	<b>Approved</b> 02/23/2007
<b>Shire plc (ADR) (SHPGY) / Vyvanse (Lisdexamfetamine Dimesylate)/Formerly NRP104</b>				
	Attention Deficit Hyperactivity Disorder (ADHD) In Pediatric Patients 6-12 Years Of Age	Sympathomimetic Agents	March 2007	<b>Approved</b> 02/23/2007
<b>Merck Serono S.A. (ADR) (SRA) / Serostim (Somatropin)</b>				
	HIV-Associated Adipose Redistribution Syndrome (HARS)/ Lipodystrophy	Growth Hormones	March 2007	Result Pending
<b>AstraZeneca plc (ADR) (AZN) / Humira (Adalimumab)</b>				
	Moderate-To-Severe Crohn's Disease	Tumor Necrosis Factor-Alpha Antagonists (TNF-Alpha Antagonists)	<u>03/07/2007</u>	<b>Approved</b> 02/27/2007
<b>Abbott Laboratories (ABT) / Humira (Adalimumab)</b>				
	Moderate-To-Severe Crohn's Disease	Tumor Necrosis Factor-Alpha Antagonists (TNF-Alpha Antagonists)	<u>03/07/2007</u>	<b>Approved</b> 02/27/2007
<b>Eli Lilly &amp; Co. (LLY) / Cymbalta (Duloxetine Hydrochloride)</b>				
	Generalized Anxiety Disorder (GAD)	Serotonin/Norepinephrine Reuptake Inhibitors	03/09/2007	<b>Approved</b> 02/26/2007
<b>GlaxoSmithKline plc (ADR) (GSK) / Tykerb (Lapatinib Ditosylate)</b>				
	Advanced Or Metastatic HER2 Positive Breast Cancer In Combination With Xeloda (Capecitabine) In Women Who Have Received Prior Therapy	Tyrosine Kinase Inhibitors	<u>03/13/2007</u>	<b>Approved</b> 03/13/2007
<b>Novartis AG (ADR) (NVS) / Tekturna (Aliskiren)</b>				
	Hypertension	Renin Inhibitors	03/20/2007	<b>Approved</b> 03/06/2007
<b>Alexion Pharmaceuticals, Inc. (ALXN) / Soliris (Eculizumab)</b>				
	Paroxysmal Nocturnal Hemoglobinuria (PNH)	Monoclonal Antibodies	03/20/2007	<b>Approved</b> 03/16/2007
<b>Merck &amp; Co., Inc. (MRK) / JANUMET (Sitagliptin phosphate/Metformin)/Formerly MK-0431A</b>				
	Non-Insulin Dependent Diabetes Mellitus (NIDDM)/Type 2 Diabetes	Biguanides/Dipeptidyl Peptidase (DPP) Inhibitors	03/31/2007	Result Pending

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

### April Drug Candidates

#### Companies

GlaxoSmithKline plc (ADR) (GSK)  
 Insite Vision Inc. (ISV)  
 Inspire Pharmaceuticals, Inc. (ISPH)  
 Ligand Pharmaceuticals Inc. (LGND)  
 Neurochem Inc. (USA) (NRMX)  
 Questcor Pharmaceuticals (QSC)  
**Wyeth (WYE) [3]**

#### Sectors

**I** Biopharmaceuticals  
 Allergies  
 Endocrinology/Metabolism  
 Immunology  
 Infectious Diseases  
 Musculoskeletal System  
 Neurology  
 Oncology

#### 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 <sup>st</sup> /2 <sup>nd</sup> Drug?
<b>Wyeth (WYE) / Torisel (Temsirolimus)</b>						
	Advanced Renal Cell Carcinoma (Kidney Cancer)	Mammalian Target Of Rapamycin (mTOR) Inhibitors	04/06/2007	No	<b>Yes</b> Only Candidate with This PMOA for This Indication	No
<b>Neurochem Inc. (USA) (NRMX) / Kiacta (Eprodinate)/Formerly Fibrillex</b>						
	Amyloid A Amyloidosis (AA Amyloidosis)	Glycosaminoglycan (GAG) Mimetic Agents	<u>04/16/2007</u>	No	<b>Yes</b> Only Candidate with This PMOA for This Indication	Yes
<b>Ligand Pharmaceuticals Inc. (LGND) / Viviant (Bazedoxifene)</b>						
	Prevention Of Postmenopausal Osteoporosis	Selective Estrogen Receptor Modulators (SERM)	04/23/2007	Yes	<b>Yes</b> Only Candidate with This PMOA for This Indication	Yes
<b>Wyeth (WYE) / Viviant (Bazedoxifene)</b>						
	Prevention Of Postmenopausal Osteoporosis	Selective Estrogen Receptor Modulators (SERM)	04/23/2007	Yes	<b>No</b> Multiple Drugs	No
<b>Questcor Pharmaceuticals (QSC) / HP Acthar Gel (Corticotropin)</b>						
	Infantile Spasms (West Syndrome)	Corticotropins	04/23/2007	Yes	<b>Yes</b> Only Candidate with This PMOA for This Indication	No
<b>Wyeth (WYE) / Pristiq (Desvenlafaxine Succinate)/Formerly DVS-233</b>						
	Relief Of Vasomotor Symptoms Associated With Menopause	Selective Norepinephrine Reuptake Inhibitors (SNRI)	04/26/2007	Yes	<b>Yes</b> Only Candidate with This PMOA for This Indication	No
<b>Insite Vision Inc. (ISV) / AzaSite (Azithromycin)</b>						
	Acute Bacterial Conjunctivitis	Macrolides	04/27/2007	Yes	<b>Yes</b> Erythromycin / (BOL)	Yes
<b>Inspire Pharmaceuticals, Inc. (ISPH) / AzaSite (Azithromycin)</b>						
	Acute Bacterial Conjunctivitis	Macrolides	04/27/2007	Yes	<b>Yes</b> Erythromycin / (BOL)	No
<b>GlaxoSmithKline plc (ADR) (GSK) / Allermist (Intranasal Fluticasone Furoate)s</b>						
	Seasonal Allergic Rhinitis, Perennial Allergic Rhinitis	Steroidal Anti-Inflammatory Drugs (SAID)	04/27/2007	Yes	<b>No</b> Multiple Drugs	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? **1<sup>st</sup>/2<sup>nd</sup> Drug** -- 1st or 2nd FDA Approved Drug of the Company?

## May Drug Candidates

### Companies

AstraZeneca plc (ADR) (AZN)  
 Critical Therapeutics, Inc. (CRTX)  
 Dendreon Corporation (DNDN)  
 GlaxoSmithKline plc (ADR) (GSK)  
 ISTA Pharmaceuticals, Inc. (ISTA)  
 MedImmune, Inc. (MEDI)  
 Merck & Co., Inc. (MRK)  
 Nektar Therapeutics (NKTR)  
 Oscient Pharmaceuticals Corporation (OSCI)  
 Roche Holding Ltd. (ADR) (RHHBY)  
 Shire plc (ADR) (SHPGY)  
 SkyePharma PLC (ADR) (SKYE)  
 Valera Pharmaceuticals, Inc. (VLRX)  
 sanofi-aventis (ADR) (SNY)

### Sectors

**I** Biopharmaceuticals  

 Dermatology  
 Endocrinology/Metabolism  
 Hematology  
 Infectious Diseases  
 Musculoskeletal System  
 Neurology  
 Oncology  
 Ophthalmology  
 Respiratory System

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Company (Symbol) / Drug Candidate	Indications	Primary mode of action (PMOA)	Expected PDUFA Date	Proven PMOA?	Two or Fewer Alternatives?	1 <sup>st</sup> /2 <sup>nd</sup> Drug?
<b>GlaxoSmithKline plc (ADR) (GSK) / Altabax (Retapamulin)</b>						
	Impetigo	Pleuromutilins	May 2007	No	<b>Yes</b> Only Candidate with This PMOA for This Indication	No
<b>Oscient Pharmaceuticals Corporation (OSCI) / FACTIVE (Gemifloxacin Mesylate)</b>						
	5 Day Therapy For Mild To Moderate Community-Acquired Pneumonia	Quinolones/Fluoroquinolones	<u>05/01/2007</u>	Yes	<b>Yes</b> Levaquin/Levaquin-Oral (Levofloxacin) / (JNJ)	No
<b>Valera Pharmaceuticals, Inc. (VLRX) / Supprelin (Histrelin)</b>						
	Central Precocious Puberty (CPP)/Early Onset Of Puberty In Children	Gonadotropin Releasing Hormone (GnRH) Agonists	<u>05/03/2007</u>	Yes	<b>Yes</b> Lupron/Lupron Depot Series (Leuprolide Acetate) / (ABT)	No
<b>ISTA Pharmaceuticals, Inc. (ISTA) / T-Pred (Tobramycin/Prednisolone Acetate)</b>						
	Steroid-Responsive Inflammatory Ocular Conditions	Antibacterial Agents/Steroidal Anti-Inflammatory Drugs (SAID)	05/04/2007	Yes	<b>No</b> Multiple Drugs	No
<b>Merck &amp; Co., Inc. (MRK) / Arcoxia (Etoricoxib/MK-663)</b>						
	Osteoarthritis	Cyclooxygenase 2 Inhibitors (COX-2 Inhibitors), Cyclooxygenase-2 Inhibitors (COX-2 Inhibitors)	05/10/2007	Yes	<b>Yes</b> Prexige (Lumiracoxib) / (NVS) Celebrex (Celecoxib) / (PFE)	No
<b>Dendreon Corporation (DNDN) / Provenge (Recombinant Prostatic Acid Phosphatase Antigen)</b>						
	Metastatic, Androgen Independent Prostate Cancer	Vaccines	<u>05/15/2007</u>	No	<b>Yes</b> GVAX Prostate Cancer / (CEGE)	Yes
<b>AstraZeneca plc (ADR) (AZN) / Seroquel SR (Quetiapine Fumarate Sustained Release)</b>						
	Schizophrenia	Monoaminergic Antagonists	<u>05/17/2007</u>	Yes	<b>No</b> Multiple Drugs	No
<b>Nektar Therapeutics (NKTR) / Mircera/CERA (Continuous Erythropoiesis Receptor Activator)</b>						
	Anemia Associated With Renal Disease	Recombinant Human Erythropoietins	05/18/2007	No	<b>No</b> Multiple Drugs	No
<b>Roche Holding Ltd. (ADR) (RHHBY) / Mircera/CERA (Continuous Erythropoietin Receptor Activator)</b>						
	Anemia Associated With Renal Disease	Recombinant Human Erythropoietins	05/18/2007	No	<b>No</b> Multiple Drugs	No

Company (Symbol) / Drug Candidate	Indications	Primary mode of action (PMOA)	Expected PDUFA Date	Proven PMOA?	Two or Fewer Alternatives?	1 <sup>st</sup> /2 <sup>nd</sup> Drug?
<b>Shire plc (ADR) (SHPGY) / SPD465 (Dextroamphetamine/Amphetamine)</b>						
	Attention Deficit Hyperactivity Disorder (ADHD) In Adults	Sympathomimetic Agents	<u>05/21/2007</u>	Yes	<b>Yes</b> Dexedrine (Dextroamphetamine Sulfate) / (GSK)	No
<b>sanofi-aventis (ADR) (SNY) / Xyzal (Levocetirizine Dihydrochloride)</b>						
	Seasonal Allergic Rhinitis, Perennial Allergic Rhinitis, Chronic Idiopathic Urticaria	Antihistamines	05/28/2007	Yes	<b>No</b> Multiple Drugs	No
<b>MedImmune, Inc. (MEDI) / FluMist Refrigerated Formualtion (Influenza Vaccine Live, Intranasal)</b>						
	Influenza Vaccine (Flu Vaccine) In Children 12 Months To 59 Months Of Age Who Do Not Have A History Of Wheezing Or Asthma	Influenza (Flu)	<u>05/28/2007</u>	Yes	<b>Yes</b> Fluzone (Influenza Virus Vaccine) / (SNY)	No
<b>SkyePharma PLC (ADR) (SKYE) / Zileuton CR</b>						
	Prophylaxis And Chronic Treatment Of Asthma In Adults And Children 12 Years Of Age And Older	5-Lipoxygenase Inhibitors	<u>05/31/2007</u>	Yes	<b>Yes</b> Only Candidate with This PMOA for This Indication	No
<b>Critical Therapeutics, Inc. (CRTX) / Zileuton CR</b>						
	Prophylaxis And Chronic Treatment Of Asthma In Adults And Children 12 Years Of Age And Older	5-Lipoxygenase Inhibitors	<u>05/31/2007</u>	Yes	<b>Yes</b> Only Candidate with This PMOA for This Indication	Yes

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## June Drug Candidates

### Companies

Encysive Pharmaceuticals, Inc. (ENCY)  
 Gilead Sciences, Inc. (GILD)  
 Labopharm Inc. (DDSS)  
 Pfizer Inc. (PFE)  
 Shire plc (ADR) (SHPGY)  
 sanofi-aventis (ADR) (SNY)

### Sectors

- I Biopharmaceuticals
  - Cardiovascular System
  - Infectious Diseases
  - 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 <sup>st</sup> /2 <sup>nd</sup> Drug?	
<b>Pfizer Inc. (PFE) / Maraviroc/UK-427,857</b>						
Human Immunodeficiency Virus (HIV)	CCR-5 Inhibitors	June 2007	No	<b>Yes</b> Only Candidate with This PMOA for This Indication	No	
<b>sanofi-aventis (ADR) (SNY) / Lovenox (Enoxaparin Sodium)</b>						
Acute ST-Segment Elevation Myocardial Infarction (Acute Heart Attack)	Thrombin Inhibitors	06/06/2007	Yes	<b>Yes</b> Angiomax (Bivalirudin) / (MDCO)	No	
<b>Encysive Pharmaceuticals, Inc. (ENCY) / Thelin (Sitaxsentan)</b>						
Pulmonary Arterial Hypertension (PAH)	Endothelin Receptor Antagonists	<u>06/15/2007</u>	No	<b>Yes</b> Ambrisentan / (GILD)	Yes	
<b>Gilead Sciences, Inc. (GILD) / Ambrisentan</b>						
Pulmonary Arterial Hypertension (PAH)	Endothelin Receptor Antagonists	<u>06/18/2007</u>	No	<b>Yes</b> Thelin (Sitaxsentan) / (ENCY)	No	
<b>Labopharm Inc. (DDSS) / Tramadol Once-Daily</b>						
Moderate To Severe Pain	Opioids	<u>06/19/2007</u>	Yes	<b>No</b> Multiple Drugs	Yes	
<b>Shire plc (ADR) (SHPGY) / Connexyn (Guanfacine Extended Release)/Formerly SPD 503</b>						
Attention Deficit Hyperactivity Disorder (ADHD) In Children Aged 6 To 17 Years	Alpha Adrenergic Receptor Agonists	<u>06/22/2007</u>	Yes	<b>Yes</b> Only Candidate with This PMOA for This Indication	No	

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## Price and Financial Info

### April 2007

Data as of 03/30/2007

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
GlaxoSmithKline plc (ADR)	GSK	55.07	157,833.642	1,531,239	15.07	58.49	5,967.3	4.64%	6.28%
Insite Vision Inc.	ISV	1.45	134.463	211,577	n/a	0	1.0	-22.04%	-20.41%
Inspire Pharmaceuticals, Inc.	ISPH	5.60	236.535	206,488	3.02	27.25	95.6	8.53%	10.16%
Ligand Pharmaceuticals Inc.	LGND	10.02	1,012.103	2,183,524	n/a	105.99	171.8	-22.63%	-20.99%
Neurochem Inc. (USA)	NRMX	15.35	594.383	1,240,769	n/a	0	49.1	2.88%	4.52%
Questcor Pharmaceuticals	QSC	1.03	70.803	380,023	4.19	0	18.4	-37.58%	-35.94%
Wyeth	WYE	49.95	67,066.966	6,481,064	6.47	62.93	8,727.2	2.65%	4.28%

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,

### May 2007

Data as of 03/30/2007

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
AstraZeneca plc (ADR)	AZN	53.59	82,116.870	1,376,658	7.40	7.99	7,760.0	5.39%	7.02%
Critical Therapeutics, Inc.	CRTX	2.20	94.385	267,108	1.89	2.87	49.0	-57.69%	-56.06%
Dendreon Corporation	DNDN	13.50	1,112.867	5,800,358	8.85	18.89	106.5	176.07%	177.71%
GlaxoSmithKline plc (ADR)	GSK	55.07	157,833.642	1,531,239	15.07	58.49	5,967.3	4.64%	6.28%
ISTA Pharmaceuticals, Inc.	ISTA	8.45	219.396	123,840	n/a	n/a	n/a	36.29%	37.92%
MedImmune, Inc.	MEDI	36.39	8,651.628	5,757,072	7.47	84.55	827.4	-1.70%	-0.07%
Merck & Co., Inc.	MRK	43.79	95,023.423	10,937,712	6.26	38.93	8,713.0	22.97%	24.60%
Nektar Therapeutics	NKTR	13.07	1,194.562	2,275,996	8.24	192.95	458.6	-35.99%	-34.36%
Oscient Pharmaceuticals Corporation	OSCI	5.33	72.221	133,543	n/a	n/a	n/a	-66.18%	-64.55%
Roche Holding Ltd. (ADR)	RHHBY	88.95	153,449.857	48,500	6.81	20.9	19,532.8	17.97%	19.60%
sanofi-aventis (ADR)	SNY	43.41	117,241.635	1,439,264	n/a	15.23	1,537.2	-8.67%	-7.03%
Shire plc (ADR)	SHPGY	61.91	10,510.678	651,924	11.15	0	1,126.9	31.86%	33.50%
SkyePharma PLC (ADR)	SKYE	5.64	425.123	22,450	n/a	1,434.57	45.5	-15.32%	-13.68%
Valera Pharmaceuticals, Inc.	VLRX	8.28	123.680	5,865	4.91	0.09	14.1	-17.61%	-15.98%

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,

### June 2007

Data as of 03/30/2007

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
Encysive Pharmaceuticals, Inc.	ENCY	2.71	169.295	1,658,355	n/a	0	43.8	-45.72%	-44.09%
Gilead Sciences, Inc.	GILD	76.30	35,493.188	4,597,320	19.55	72.63	936.9	23.72%	25.36%
Labopharm Inc.	DDSS	5.72	324.598	102,293	4.86	16.75	84.8	n/a	
Pfizer Inc.	PFE	25.19	178,265.309	36,735,600	6.82	11.18	28,227.0	-0.04%	1.59%
sanofi-aventis (ADR)	SNY	43.41	117,241.635	1,439,264	n/a	15.23	1,537.2	-8.67%	-7.03%
Shire plc (ADR)	SHPGY	61.91	10,510.678	651,924	11.15	0	1,126.9	31.86%	33.50%

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,