



# FDA Approval Decisions Report January-March 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>Nabi Biopharmaceuticals (NABI) / Nabi-HB (Hepatitis B Immune Globulin)</b>			
Prevention Of Hepatitis B Virus Re-infection Of Transplanted Livers In Patients With Hepatitis B	Immunoglobulins	December 2006	Result Pending
<b>Millennium Pharmaceuticals, Inc. (MLNM) / Velcade (Bortezomib)</b>			
Relapsed Or Refractory Mantle Cell Lymphoma	Proteasome Inhibitors	<u>12/08/2006</u>	<b>Approved</b> 12/08/2006
<b>BioSante Pharmaceuticals, Inc. (BPA) / Elestrin (Estradiol Gel)</b>			
Moderate-To-Severe Hot Flashes In Menopausal Women	Estrogens	12/15/2006	<b>Approved</b> 12/18/2006
<b>Oscient Pharmaceuticals Corporation (OSCI) / FACTIVE (Gemifloxacin Mesylate)</b>			
5 Day Therapy For Acute Bacterial Sinusitis	Quinolones/Fluoroquinolones	<u>12/15/2006</u>	Result Pending
<b>Bradley Pharmaceuticals, Inc. (BDY) / Elestrin (Estradiol Gel)</b>			
Moderate-To-Severe Hot Flashes In Menopausal Women	Estrogens	12/15/2006	<b>Approved</b> 12/18/2006
<b>Novartis AG (ADR) (NVS) / Tekturna (Aliskiren)/Formerly Rasilez</b>			
Hypertension	Renin Inhibitors	12/20/2006	<b>Rescheduled to</b> 03/20/2007
<b>Johnson &amp; Johnson (JNJ) / Invega (Paliperidone ER Tablets)</b>			
Schizophrenia	Serotonin/Dopamine Receptor Blocking Agents	<u>12/20/2006</u>	<b>Approved</b> 12/20/2006
<b>Novartis AG (ADR) (NVS) / Exforge (Valsartan/Amlodipine)</b>			
Hypertension	Angiotensin Converting Enzyme Inhibitors (ACE Inhibitors)/Calcium Channel Blockers	12/27/2006	<b>Approved</b> 12/22/2006
<b>Cephalon, Inc. (CEPH) / Nuvigil (Armodafinil)</b>			
Excessive Sleepiness Associated With Narcolepsy, Shift Work Sleep Disorder, And Obstructive Sleep Apnea/Hypopnea Syndrome	Alpha Adrenergic Receptor Agonists	12/29/2006	Result Pending
<b>Eli Lilly &amp; Co. (LLY) / Byetta (Exenatide)</b>			
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	<b>Approved</b> 12/22/2006
<b>Amylin Pharmaceuticals, Inc. (AMLN) / Byetta (Exenatide)</b>			
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	<b>Approved</b> 12/22/2006
<b>Genta Incorporated (GNTA) / Genasense (Oblimersen Sodium)</b>			
Chronic Lymphocytic Leukemia (CLL) In Combination With Fludarabine and Cyclophosphamide	Antisense Agents	<u>01/29/2007</u>	<b>Non-Approvable Letter Received</b> 12/15/2006
<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>Approvable Letter Received</b> 12/21/2006

**Company (Symbol) / Drug Candidate****Shire plc (ADR) (SHPGY) / Vyvanse (Lisdexamfetamine Dimesylate)/Formerly NRP104**

Attention Deficit Hyperactivity Disorder (ADHD) In Pediatric Patients 6-12 Years Of Age	Sympathomimetic Agents	March 2007	<b>Approvable Letter Received</b> 12/21/2006
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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

Abbott Laboratories (ABT)  
**Connetics Corporation (CNCT) [2]**  
 Enzon Pharmaceuticals, Inc. (ENZN)  
 GlaxoSmithKline plc (ADR) (GSK)  
 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  
 Immunology  
 Neurology  
 Urology

#### 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>Enzon Pharmaceuticals, Inc. (ENZN) / Cimzia (Certolizumab Pegol)</b>						
	Crohn's Disease	Tumor Necrosis Factor-Alpha Antagonists (TNF-Alpha Antagonists)	01/02/2007	Yes	<b>Yes</b> Centocor Remicade (Infliximab) / (JNJ) Humira (Adalimumab) / (ABT)	No
<b>Nektar Therapeutics (NKTR) / Cimzia (Certolizumab Pegol)</b>						
	Crohn's Disease	Tumor Necrosis Factor-Alpha Antagonists (TNF-Alpha Antagonists)	01/02/2007	Yes	<b>Yes</b> Centocor Remicade (Infliximab) / (JNJ) Humira (Adalimumab) / (ABT)	No
<b>Pfizer Inc. (PFE) / Fesoterodine</b>						
	Overactive Bladder/Urinary Incontinence	Muscarinic Receptor Antagonists	January 2007	Yes	<b>No</b> Multiple Drugs	No
<b>Schwarz Pharma, Inc. (SWTZY) / Fesoterodine</b>						
	Overactive Bladder/Urinary Incontinence	Muscarinic Receptor Antagonists	January 2007	Yes	<b>No</b> Multiple Drugs	No
<b>Abbott Laboratories (ABT) / KOS Pharmaceuticals Niaspan CF (Niacin)</b>						
	Hypercholesterolemia	Free Fatty Acid Inhibitors	01/12/2007	Yes	<b>Yes</b> Only Candidate with This PMOA for This Indication	No
<b>Connetics Corporation (CNCT) / Primolux (Clobetasol Propionat)</b>						
	Psoriasis	Steroidal Anti-Inflammatory Drugs (SAID)	<u>01/17/2007</u>	Yes	<b>Yes</b> Synalar (Fluocinolone Acetonide) / (MRX) Dermik Laboratories Psorcon E (Diflorasone Diacetate) / (SNY)	No
<b>Connetics Corporation (CNCT) / Primolux (Clobetasol Propionat)</b>						
	Atopic Dermatitis (Eczema)	Steroidal Anti-Inflammatory Drugs (SAID)	<u>01/17/2007</u>	Yes	<b>Yes</b> Synalar (Fluocinolone Acetonide) / (MRX) Dermik Laboratories Psorcon E (Diflorasone Diacetate) / (SNY)	No
<b>Shire plc (ADR) (SHPGY) / Mesavance/SPD 476 (Mesalamine)</b>						
	Mild-To-Moderate Ulcerative Colitis	Cyclooxygenase Inhibitors (COX Inhibitors)/Lipoxygenase Inhibitors	<u>01/19/2007</u>	Yes	<b>No</b> Multiple Drugs	No
<b>Wyeth (WYE) / Pristiq (Desvenlafaxine Succinate)/Formerly DVS-233</b>						
	Major Depressive Disorder	Selective Norepinephrine Reuptake Inhibitors (SNRI)	<u>01/22/2007</u>	Yes	<b>Yes</b> Only Candidate with This PMOA for This Indication	No

Company (Symbol) / Drug Candidate		Primary mode of action (PMOA)	Expected PDUFA Date	Proven PMOA?	Two or Fewer Alternatives?	1 <sup>st</sup> /2 <sup>nd</sup> Drug?
Indications						
<b>GlaxoSmithKline plc (ADR) (GSK) / Arixtra (Fondaparinux Sodium)</b>						
Acute Coronary Syndrome (ACS)	Thrombin Inhibitors	<u>01/31/2007</u>	Yes	<b>Yes</b>	No Angiomax (Bivalirudin) / (MDCO)	





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?

## February Drug Candidates

### Companies

Acambis plc (ADR) (ACAMY)  
 MedImmune, Inc. (MEDI)  
 Merck & Co., Inc. (MRK)  
 Novartis AG (ADR) (NVS)  
 Serono S.A. (ADR) (SRA)  
 Watson Pharmaceuticals, Inc. (WPI)

### Sectors

**I** Biopharmaceuticals  
 Digestive System  
 Endocrinology/Metabolism  
 Immunology  
 Infectious Diseases

#### Notes:

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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>Merck &amp; Co., Inc. (MRK) / MK-0517 (Intravenous Aprepitant)</b>						
Chemotherapy-Induced Nausea And Vomiting (CINV)	Neurokinin-1 (NK-1) Receptor Antagonists	February 2007	Yes	<b>Yes</b> Only Candidate with This PMOA for This Indication	No	
<b>Serono S.A. (ADR) (SRA) / Rebif (Recombinant Interferon Beta-1a)</b>						
New Formulation For The Treatment Of Relapsing-Remitting Multiple Sclerosis (MS)	Interferons	02/05/2007	Yes	<b>Yes</b> AVONEX (Interferon beta-1a) / (BIIB)	No	
<b>Watson Pharmaceuticals, Inc. (WPI) / AndrX Laboratories ACTOplus met XR (Pioglitazone/Metformin Extended Release)</b>						
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	<b>Yes</b> Avandamet (Rosiglitazone Maleate/Metformin) / (GSK)	No	
<b>Acambis plc (ADR) (ACAMY) / Smallpox-ACAM2000</b>						
Smallpox Vaccine	Variola (Smallpox)	<u>02/14/2007</u>	No	<b>Yes</b> Only Candidate with This PMOA for This Indication	Yes	
<b>MedImmune, Inc. (MEDI) / Cold Adapted Influenza Vaccine-Trivalent (CAIV-T)</b>						
Influenza Vaccine (Flu Vaccine) In Healthy Individuals 5 To 49 Years Of Age	Influenza (Flu)	02/14/2007	Yes	<b>No</b> Multiple Drugs	No	
<b>Novartis AG (ADR) (NVS) / Galvus (Vildagliptin)</b>						
Non-Insulin Dependent Diabetes Mellitus (NIDDM)/Type 2 Diabetes	Dipeptidyl Peptidase (DPP) Inhibitors	02/28/2007	Yes	<b>Yes</b> Januvia (Sitagliptin Phosphate) / (MRK)	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?

## March Drug Candidates

### Companies

Abbott Laboratories (ABT)  
 Alexion Pharmaceuticals, Inc. (ALXN)  
 AstraZeneca plc (ADR) (AZN)  
 Eli Lilly & Co. (LLY)  
 GlaxoSmithKline plc (ADR) (GSK)  
 Merck & Co., Inc. (MRK)  
 New River Pharmaceuticals, Inc. (NRPH)  
 Novartis AG (ADR) (NVS)  
 Serono S.A. (ADR) (SRA)  
 Shire plc (ADR) (SHPGY)

### Sectors

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

#### Notes:

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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>New River Pharmaceuticals, Inc. (NRPH) / Vyvance (Lisdexamfetamine Dimesylate)/Formerly NRP104</b>						
	Attention Deficit Hyperactivity Disorder (ADHD) In Pediatric Patients 6-12 Years Of Age	Sympathomimetic Agents	March 2007	Yes	<b>Yes</b> Dexedrine (Dextroamphetamine Sulfate) / (GSK)	Yes
<b>Serono S.A. (ADR) (SRA) / Serostim (Somatropin)</b>						
	HIV-Associated Adipose Redistribution Syndrome (HARS)/ Lipodystrophy	Growth Hormones	March 2007	Yes	<b>Yes</b> Only Candidate with This PMOA for This Indication	No
<b>Shire plc (ADR) (SHPGY) / Vyvance (Lisdexamfetamine Dimesylate)/Formerly NRP104</b>						
	Attention Deficit Hyperactivity Disorder (ADHD) In Pediatric Patients 6-12 Years Of Age	Sympathomimetic Agents	March 2007	Yes	<b>Yes</b> Dexedrine (Dextroamphetamine Sulfate) / (GSK)	No
<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>	Yes	<b>Yes</b> Cimzia (Certolizumab Pegol) / (ENZN)	No
<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>	Yes	<b>Yes</b> Cimzia (Certolizumab Pegol) / (ENZN)	No
<b>Eli Lilly &amp; Co. (LLY) / Cymbalta (Duloxetine Hydrochloride)</b>						
	Generalized Anxiety Disorder (GAD)	Serotonin/Norepinephrine Reuptake Inhibitors	03/09/2007	Yes	<b>Yes</b> Only Candidate with This PMOA for This Indication	No
<b>GlaxoSmithKline plc (ADR) (GSK) / Tykerb (Lapatinib Ditosylate)</b>						
	Advanced Or Metastatic HER2 Positive Breast Cancer In Women Who Have Received Prior Therapy	Tyrosine Kinase Inhibitors	03/16/2007	Yes	<b>Yes</b> Only Candidate with This PMOA for This Indication	No
<b>Novartis AG (ADR) (NVS) / Tekturna (Aliskiren)/Formerly Rasilez</b>						
	Hypertension	Renin Inhibitors	03/20/2007	No	<b>Yes</b> Only Candidate with This PMOA for This Indication	No
<b>Alexion Pharmaceuticals, Inc. (ALXN) / Soliris (Eculizumab)</b>						
	Paroxysmal Nocturnal Hemoglobinuria (PNH)	Monoclonal Antibodies	03/20/2007	Yes	<b>Yes</b> Only Candidate with This PMOA for This Indication	Yes
<b>Merck &amp; Co., Inc. (MRK) / JANUMET (Sitagliptin phosphate/Metformin)/Formerly MK-0431A</b>						

Company (Symbol) / Drug Candidate	Primary mode of action (PMOA)	Expected PDUFA Date	Proven PMOA?	Two or Fewer Alternatives?	1 <sup>st</sup> /2 <sup>nd</sup> Drug?
Indications Non-Insulin Dependent Diabetes Mellitus (NIDDM)/Type 2 Diabetes	Biguanides/Dipeptidyl Peptidase (DPP) Inhibitors	03/31/2007	No	<b>Yes</b> 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? **1<sup>st</sup>/2<sup>nd</sup> Drug** -- 1st or 2nd FDA Approved Drug of the Company?

## Price and Financial Info

### January 2007

Data as of 12/28/2006

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
Abbott Laboratories	ABT	48.93	75,100.897	4,390,260	29.98	60.42	1,051.1	21.26%	13.70%
Connetics Corporation	CNCT	17.47	603.167	505,264	n/a	370.89	229.5	20.32%	12.75%
Enzon Pharmaceuticals, Inc.	ENZN	8.37	367.426	545,831	n/a	0	170.0	13.41%	5.85%
GlaxoSmithKline plc (ADR)	GSK	52.54	151,205.069	1,202,000	14.57	60.09	6,644.8	3.22%	-4.35%
Nektar Therapeutics	NKTR	15.44	1,394.165	1,433,272	8.53	174.06	481.6	-4.40%	-11.96%
Pfizer Inc.	PFE	26.07	187,976.286	57,360,252	8.05	11.57	13,291.0	10.47%	2.90%
Schwarz Pharma, Inc.	SWTZY	124.50	n/a	507	n/a	n/a	n/a	94.68%	87.12%
Shire plc (ADR)	SHPGY	62.15	10,458.210	603,253	12.16	0	955.2	60.39%	52.82%
Wyeth	WYE	51.42	69,247.263	4,993,904	6.59	62.4	8,166.9	9.08%	1.51%

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 12/28/2006

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)	ACAMY	3.70	198.631	19,280	2.01	14.49	90.5	-48.75%	-56.32%
MedImmune, Inc.	MEDI	32.39	7,747.927	2,339,616	7.70	91.3	722.8	-10.20%	-17.77%
Merck & Co., Inc.	MRK	43.55	94,547.173	10,579,466	5.38	31.04	9,087.0	36.48%	28.91%
Novartis AG (ADR)	NVS	57.73	135,590.445	1,397,866	3.51	23.89	8,530.0	10.76%	3.20%
Serono S.A. (ADR)	SRA	22.30	13,644.932	91,862	5.64	27.87	1,759.5	12.74%	5.17%
Watson Pharmaceuticals, Inc.	WPI	26.05	2,669.291	881,538	2.36	26.93	906.8	-20.96%	-28.53%

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,

### March 2007

Data as of 12/28/2006

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
Abbott Laboratories	ABT	48.93	75,100.897	4,390,260	29.98	60.42	1,051.1	21.26%	13.70%
Alexion Pharmaceuticals, Inc.	ALXN	40.40	1,400.542	539,788	n/a	1,746.41	110.7	102.00%	94.43%
AstraZeneca plc (ADR)	AZN	53.80	83,434.275	1,720,782	8.37	8.19	6,169.0	10.13%	2.57%
Eli Lilly & Co.	LLY	52.01	56,773.542	5,882,796	4.35	37.44	3,618.5	-9.94%	-17.51%
GlaxoSmithKline plc (ADR)	GSK	52.54	151,205.069	1,202,000	14.57	60.09	6,644.8	3.22%	-4.35%
Merck & Co., Inc.	MRK	43.55	94,547.173	10,579,466	5.38	31.04	9,087.0	36.48%	28.91%
New River Pharmaceuticals, Inc.	NRPH	54.24	1,991.625	645,518	n/a	0	162.8	104.87%	97.31%
Novartis AG (ADR)	NVS	57.73	135,590.445	1,397,866	3.51	23.89	8,530.0	10.76%	3.20%
Serono S.A. (ADR)	SRA	22.30	13,644.932	91,862	5.64	27.87	1,759.5	12.74%	5.17%
Shire plc (ADR)	SHPGY	62.15	10,458.210	603,253	12.16	0	955.2	60.39%	52.82%

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,