

BioCentury

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Finance

PDUFAs produce yawns

By Stephen Hansen
Senior Writer

There are more than twice as many PDUFA dates this year than last — at least 40 vs. 17 — but only a handful of potential approvals are drumming up interest among buysiders. Investors are focusing on areas such as HCV, which is almost unanimously seen as maintaining its momentum into 2012, while oral autoimmune therapies and selected cancer products are also attracting attention.

According to buysiders, the large number of compounds under review at **FDA** does not equate to a large amount of excitement. Kurt von Emster of venBio described the PDUFA dates for 2012 as having “marginal impact.” OrbiMed’s Sven Borho echoed this, saying it is “not the greatest year” for approvals.

A few potential approvals are attracting attention. Eric Roberts of Caxton Advantage and Deka Investment’s Kai Bruening like the chances of ridaforolimus from **Ariad Pharmaceuticals Inc.** and partner **Merck & Co. Inc.** to treat metastatic soft tissue or bone sarcomas. The compound has a June 5 PDUFA date.

Buysiders Joep Muijers of LSP and International Biotechnology Trust’s David Pinniger also like **Ironwood Pharmaceuticals Inc.’s** linaclotide, which is under review to treat chronic constipation and irritable bowel syndrome with constipation (IBS-C). The PDUFA date is expected in June. Ironwood will co-commercialize linaclotide in the U.S. with **Forest Laboratories Inc.**

Roberts also named Ironwood as fitting the profile of a potential takeover target — having a Phase III or marketed product while retaining a significant part of the economics of the asset. However, such a deal won’t be straightforward, as the company created two classes of shares in its 2010 IPO (see *BioCentury*, Feb. 1, 2010).

Amarin Corp. plc is another mid-cap with an upcoming FDA action that Muijers and Roberts tip as a potential takeover target, given the good Phase III data for its AMR101 in hypertriglyceridemia. The compound has a July 26 PDUFA date (see *BioCentury*, Dec. 6, 2010).

HCV big again

Buysiders expect HCV to continue to be the hot area in 2012, following the 2011 launches of protease inhibitors Incivek telaprevir from **Vertex Pharmaceuticals Inc.** and Victrelis boceprevir from Merck, as well as **Gilead Sciences Inc.’s** proposed acquisition of **Pharmasset Inc.** for about \$11 billion.

This year could see the fast rise of second-generation products. In particular, Harald Schwarz of Medical Strategy named TMC435, a once-daily protease inhibitor from **Medivir AB** and **Johnson & Johnson**. “Most participants in the market expect that if the second-generation products are approved, Incivek will lose market share at once,” he said.

Data are expected this year from three Phase III trials of TMC435 in HCV genotype 1.

Investors also are looking for data in 2012 to elucidate whether protease inhibitors will remain a key component in oral HCV cocktails. These include Phase II trials of TMC435 plus Pharmasset’s PSI-7977; Vertex’s VX-222, a non-nucleoside HCV NS5B polymerase inhibitor plus Incivek; and **Bristol-Myers Squibb Co.’s** daclatasvir, an HCV NS5A protein inhibitor, plus PSI-7977.

Beyond the data, investors are expecting further consolidation in the space. Almost all cited three HCV plays as likely to enter partnerships or be acquired in 2012: **Idenix Pharmaceuticals Inc.**, **Achillion Pharmaceuticals Inc.** and **Inhibitex Inc.**

As BB Biotech’s Daniel Koller noted: “I think in HCV we are far from over. It’s still

more a question of will it be partnerships or straightforward acquisitions.”

Late on Saturday, Inhibitex announced it has opted for the latter, having reached a definitive agreement to be acquired by Bristol-Myers for \$26 per share in cash, or \$2.5 billion. Shareholders owning 17% of the biotech have already agreed to tender their shares.

Inhibitex’s lead program is nucleotide polymerase inhibitor INX-189, which is in Phase II testing. The other two HCV picks have multiple unpartnered HCV assets, with Idenix being the most advanced. Its nucleotide polymerase inhibitor IDX184 is in Phase IIb testing. Achillion’s lead is ACH-1625, an HCV NS3

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Harald Schwarz, Medical Strategy

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protease inhibitor in Phase II (see *BioCentury*, Oct. 31, 2011).

Before the Inhibitex announcement, Pinniger said his money was on Achillion to be the next HCV takeout.

Autoimmune goes oral

Investors are also eyeing the oral autoimmune space for 2012, in particular oral therapies in multiple sclerosis (MS) and Janus kinase (JAK) inhibitors in rheumatoid arthritis (RA).

Roberts said “autoimmune is certainly the biggest story for 2012.”

With impressive data last year, Pinniger said **Biogen Idec Inc.**'s BG-12 is already “transitioning to a commercial positioning story, and I think everyone is now beginning to have to think about the implications of success for BG-12 on the rest of Biogen's business.”

Biogen plans to submit an NDA for BG-12 in 1H12.

Muijers will be looking at whether **Novartis AG**'s Gilenya fingolimod can pick up market share before BG-12 enters the market. The sphingosine 1-phosphate (S1P) receptor agonist had 3Q11 sales of \$153 million, up from \$4 million in 3Q10. The drug was approved in the U.S. and Russia in September 2010.

In RA, buysiders such as Schwarz, Muijers and Miller Tabak's Les Funtleyder said they are looking at how quickly the market will accept oral JAK inhibitors. **Pfizer Inc.**'s tofacitinib is leading the way with a PDUFA date in August. It is also under review in the EU.

The next most advanced JAK inhibitors for RA are in Phase II development and include GLPG0634 from **Galapagos N.V.**, LY3009104 from **Incyte Corp.** and partner **Eli Lilly and Co.**, and VX-509 from Vertex.

Finally, Koller is also looking forward to data for apremilast, **Celgene Corp.**'s oral phosphodiesterase-4 (PDE-4) inhibitor. The company expects to have Phase III results in psoriasis and psoriatic arthritis in mid-2012 and Phase IIb data in RA in 1H12.

The question is will apremilast “be the BG-12 for Celgene or not?” he said. “That's one of the biggies we are going to prepare for in terms of what the potential outcomes could mean and how the Street will view that.”

More in cancer

While JAK inhibitors are starting to make waves in RA, they've already made a splash in myelofibrosis with the approval of Incyte's Jakafi ruxolitinib. Five investors polled by BioCentury named Incyte as a pick for 2012, based on their expectations for a good launch.

The excitement around Jakafi also triggered von Emster and Pinniger to name **YM BioSciences Inc.** as one of their picks. The company's CYT387, a JAK-1 and JAK-2 inhibitor, is expected to start Phase III testing for myelofibrosis in mid-2012.

Borho and Pinniger also like **Pharmacyclics Inc.** in 2012. The company's lead product is PCI-32765, a Bruton's tyrosine kinase (Btk) inhibitor partnered with J&J. The partners plan to start Phase III testing for chronic lymphocytic leukemia (CLL) in 1H12.

The success of J&J's Zytiga abiraterone, coupled with good data last year for Alpharadin radium-223 from **Algeta ASA** and **Bayer AG** and MDV3100 from **Medivation Inc.** and **Astellas Pharma Inc.** have buysiders including Muijers, Borho and Schwarz expecting prostate cancer to remain interesting through 2012.

Algeta and Bayer expect to submit an NDA for Alpharadin by mid-2012. Medivation and Astellas plan a pre-NDA meeting with FDA in early 2012, with regulatory timelines to be provided after the meeting.

Although it wasn't picked by buysiders, the space also includes Xgeva denosumab from **Amgen Inc.** An sBLA to treat men with castration-resistant prostate cancer (CRPC) at risk of developing bone metastases will be reviewed by FDA's Onco-

logic Drugs Advisory Committee on Feb. 8. The PDUFA date is April 26.

Andrew Bogan of Bogan Associates said he is excited about antibody-drug conjugate (ADC) companies, with other buysiders naming two of these companies — **Seattle Genetics Inc.** and **ImmunoGen Inc.** — as picks for 2012.

This year, ImmunoGen and partner **Genentech Inc.** are expecting data from the Phase III EMILIA trial of T-DMI trastuzumab emtansine in second-line metastatic breast cancer, with worldwide regulatory submissions expected by year end.

Schwarz named ImmunoGen, along with Medivation, as potential takeouts by their partners.

Seattle Genetics is being watched following its recent launch of lymphoma drug Adcetris brentuximab. Tom Brakel of Feder-

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“I think in HCV we are far from over. It's still more a question of will it be partnerships or straightforward acquisitions.”

Daniel Koller, BB Biotech

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ated Investors said the launch has gone better than expected, with 3Q11 sales of \$10 million, well above the Street's consensus estimate of \$2.1 million.

Selena Chaisson of Bailard picked **Endocyte Inc.** as an ADC-like concept, citing its targeted ovarian cancer therapy. Koller, who also likes the company, noted Endocyte's platform is like ADCs, but for small molecules.

Endocyte is expecting to submit two MAAs in 1Q12: one for EC145, a combination of a folate vitamin analog with a microtubule destabilizing anticancer agent for advanced ovarian cancer, and one for EC20, an imaging agent to detect the presence of folate receptor to select patients for folate-targeted therapy.

Borho thinks carfilzomib from **Onyx Pharmaceuticals Inc.** could be interesting, although he noted it could be "tricky to get approved," as the NDA is based on Phase II data. The selective proteasome inhibitor is under FDA review to treat relapsed and refractory multiple myeloma (MM) with a July 27 PDUFA date.

Split on obesity

Vivus Inc.'s Qnexa, which has a Feb. 22 review by the Endocrinologic and Metabolic Drugs Advisory Committee meeting and an April 17 PDUFA date, is a binary pick. Investors either said the outcome is very important, or something not to be touched with a 10-foot pole.

Borho is one who is picking Vivus and said if Qnexa is approved it could be the most interesting story of the year.

Roberts is also putting a bet on Vivus for 2012. He said a new obesity agent could be "the most exciting development for the pharma industry since statins."

Others buysiders were not keen on any obesity companies, given FDA's high safety hurdles.

Big caps

Among the big biotechs, multiple European buysiders picked **Actelion Ltd.** for 2012. The company plans to announce data in 1H12 from the Phase III SERAPHIN trial of macitentan in pulmonary arterial hypertension (PAH). Koller said the data are very important, since the biotech has positioned the data as a binary event for the stock.

With Actelion's blockbuster PAH drug Tacleer bosentan beginning to go off patent in 2015, Bruening said the company needs macitentan to work, "or else the company probably gets sold."

Koller said one of his picks is Vertex because of its cystic fibrosis pipeline. The company's Kalydeco ivacaftor has an April 18 PDUFA date.

Koller also is looking forward to hemophilia data from Biogen Idec and **Swedish Orphan Biovitrum AB.** The partners are expecting a pair of Phase III data readouts in 2H12 for FIXFc, a long-acting Factor IX replacement for hemophilia B, and rFVIII Fc, a long-acting Factor VIII for hemophilia A.

Among big caps, Schwarz and Bruening said **BioMarin Pharmaceutical Inc.** is a potential acquisition target given pharma's continued interest in Orphan drugs.

Mid-, small caps

In the mid-cap space, both Bruening and Koller said they like **Halozyme Therapeutics Inc.** because its platform provides near- and mid-term milestone potential.

The biotech is partnered with **Baxter International Inc.** to develop HyQ. The subcutaneous treatment combines plasma-based IV Gammagard and rHuPH20, a recombinant human PH20 hyaluronidase enzyme. A BLA and MAA are under review to treat primary immunodeficiencies. The partners expect a decision on the BLA in 2Q12 and MAA this year.

Halozyme and **Roche** are also developing a subcutaneous formulation of Herceptin trastuzumab that last October met the co-primary endpoints in a Phase III trial in HER2-positive early breast cancer. The companies plan an MAA submission this year.

Muijrs said he is waiting to see the data in the chronic obstructive pulmonary disease space. By year end, **Theravance Inc.** plans to announce Phase III data for Relovair fluticasone furoate/vilanterol, a corticosteroid/long-acting adrenergic receptor beta 2 agonist (LABA) combination.

If the data are good, Theravance and partner **GlaxoSmithKline plc** may have an opportunity to catch up with competitor Novartis and its partners

Vectura Group plc and **Sosei Group Corp.** Novartis said in October it was delaying U.S. regulatory submissions for its COPD products NVA237 and QVA149.

Muijrs also said **MorphoSys AG** would be one mid-stage company he'd be interested in buying, as it has a solid antibody platform and stable balance sheet. This year the company will have its first Phase II data from an in-house program, MOR103, a human HuCAL antibody against granulocyte macrophage-colony stimulating factor (GM-CSF) for RA.

Although none of the buysiders picked **Optimer Pharmaceuticals Inc.**, it is another mid-cap with a drug launch under scrutiny by investors. In July, the company launched Dificid fidaxomicin to treat *Clostridium difficile*-associated diarrhea and reported 3Q11 sales of \$10.6 million. Koller said "people are still divided over Optimer. Is it just an M&A speculation or is it reality in terms of long-term value creation through this antibiotic they sell?"

Among the small caps, von Emster picked **Raptor Pharmaceutical Corp.** This quarter the company plans to submit an NDA for DR Cysteamine, a delayed-release formulation of a degradation product of the amino acid cysteine to treat nephropathic cystinosis.

One of Schwarz's small cap picks is **ALK-Abello A/S**, as he's expecting Phase III data for "a group of their oral allergy products, against grass pollen and ragweed allergy."

Roberts has two small cap picks: **Anthera Pharmaceuticals Inc.** and **Curis Inc.** He expects Phase III data this year for Anthera's varespladib, a secretory phospholipase A2 (PLA2G2A; sPLA2) inhibitor for acute coronary syndrome (ACS).

Curis is a regulatory play. Last year, partner Genentech submitted an MAA and NDA for vismodegib, a small molecule hedgehog pathway inhibitor for advanced basal cell carcinoma (BCC). The PDUFA date is March 8.

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"Autoimmune is certainly the biggest story for 2012."

Eric Roberts, Caxton Advantage

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COMPANIES AND INSTITUTIONS MENTIONED

Achillion Pharmaceuticals Inc. (NASDAQ:ACHN), New Haven, Conn.
Actelion Ltd. (SIX:ATLN), Allschwil, Switzerland
Algeta ASA (OSE:ALGETA), Oslo, Norway
ALK-Abello A/S (CSE:ALK-B), Horsholm, Denmark
Amarin Corp. plc (NASDAQ:AMRN), Dublin, Ireland
Amgen Inc. (NASDAQ:AMGN), Thousand Oaks, Calif.
Anthera Pharmaceuticals Inc. (NASDAQ:ANTH), Hayward, Calif.
Ariad Pharmaceuticals Inc. (NASDAQ:ARIA), Cambridge, Mass.
Astellas Pharma Inc. (Tokyo:4503), Tokyo, Japan
Baxter International Inc. (NYSE:BAX), Deerfield, Ill.
Bayer AG (Xetra:BAY), Leverkusen, Germany
Biogen Idec Inc. (NASDAQ:BIIB), Weston, Mass.
BioMarin Pharmaceutical Inc. (NASDAQ:BMRN), Novato, Calif.
Bristol-Myers Squibb Co. (NYSE:BMJ), New York, N.Y.
Celgene Corp. (NASDAQ:CELG), Summit, N.J.
Curis Inc. (NASDAQ:CRIS), Lexington, Mass.
Eli Lilly and Co. (NYSE:LLY), Indianapolis, Ind.
Endocyte Inc. (NASDAQ:ECYT), West Lafayette, Ind.
Forest Laboratories Inc. (NYSE:FRX), New York, N.Y.
Galapagos N.V. (Euronext:GLPG; Pink:GLPYY), Mechelen, Belgium
Genentech Inc., South San Francisco, Calif.
Gilead Sciences Inc. (NASDAQ:GILD), Foster City, Calif.
GlaxoSmithKline plc (LSE:GSK; NYSE:GSK), London, U.K.
Halozyne Therapeutics Inc. (NASDAQ:HALO), San Diego, Calif.
Idenix Pharmaceuticals Inc. (NASDAQ:IDIX), Cambridge, Mass.
ImmunoGen Inc. (NASDAQ:IMGN), Waltham, Mass.
Incyte Corp. (NASDAQ:INCY), Wilmington, Del.
Inhibitex Inc. (NASDAQ:INHX), Alpharetta, Ga.
Ironwood Pharmaceuticals Inc. (NASDAQ:IRWD), Cambridge, Mass.
Johnson & Johnson (NYSE:JNJ), New Brunswick, N.J.
Medivation Inc. (NASDAQ:MDVN), San Francisco, Calif.
Medivir AB (SSE:MVIR B), Huddinge, Sweden
Merck & Co. Inc. (NYSE:MRK), Whitehouse Station, N.J.
MorphoSys AG (Xetra:MOR), Martinsried, Germany
Novartis AG (NYSE:NVS; SIX:NOVN), Basel, Switzerland
Onyx Pharmaceuticals Inc. (NASDAQ:ONXX), South San Francisco, Calif.
Optimer Pharmaceuticals Inc. (NASDAQ:OPTR), San Diego, Calif.
Pfizer Inc. (NYSE:PFE), New York, N.Y.
Pharmacyclics Inc. (NASDAQ:PCYC), Sunnyvale, Calif.
Pharmasset Inc. (NASDAQ:VRUS), Princeton, N.J.
Raptor Pharmaceutical Corp. (NASDAQ:RPTP), Novato, Calif.
Roche (SIX:ROG; OTCQX:RHHBY), Basel, Switzerland
Seattle Genetics Inc. (NASDAQ:SGEN), Bothell, Wash.
Sosei Group Corp. (Tokyo:4565), Tokyo, Japan
Swedish Orphan Biovitrum AB (SSE:SOBI), Stockholm, Sweden
Theravance Inc. (NASDAQ:THRX), South San Francisco, Calif.
U.S. Food and Drug Administration (FDA), Silver Spring, Md.
Vectura Group plc (LSE:VEC), Chippenham, U.K.
Vertex Pharmaceuticals Inc. (NASDAQ:VRTX), Cambridge, Mass.
Vivus Inc. (NASDAQ:VVUS), Mountain View, Calif.
YM BioSciences Inc. (TSX:YM; NYSE-A:YMI), Mississauga, Ontario

Top biotech products

At least 34 drugs developed and marketed by biotech companies are anticipated to have more than \$500 million in sales in 2011. Of those, 20 are expected to bring in more than \$1 billion in annual sales. However, 10 of the top drugs could post lower year-on-year numbers, in some cases because of exchange rates. In 2010, 29 drugs were projected to fall in the \$500 million-plus group, and five were projected to show declines over 2009 sales. Product sales as reported by companies listed. (A) Global in-market sales; (B) 2011 sales projected from 1H11 figures; (C) Sales of Synagis are seasonal, extrapolation assumes 4Q11 sales at least match 4Q10 sales; (D) Incivek approved by FDA in May 2011, extrapolation assumes 4Q11 sales at least match 3Q11; Figures in foreign currencies are converted to U.S. dollars based on exchange rates at the end of each financial period. \$M

Company	Product	2010 sales	2011 9-mo sales	2011 run rate	Proj chg
Amgen Inc. (NASDAQ:AMGN)/ Pfizer Inc. (NYSE:PFE)/ Takeda Pharmaceutical Co. Ltd. (Tokyo:4502)	Enbrel etanercept	\$7,263.8	\$5,883.1	\$7,844.1	8%
Biogen Idec Inc. (NASDAQ:BIIB)/ Genentech Inc./Roche (SIX:ROG; OTCQX:RHHBY)	Rituxan rituximab (MabThera)	\$6,783.1	\$4,900.7	\$6,534.3	-4%
Genentech Inc./Roche (SIX:ROG; OTCQX:RHHBY)	Avastin bevacizumab	\$6,895.2	\$4,373.7	\$5,831.6	-15%
Genentech Inc./Roche (SIX:ROG; OTCQX:RHHBY)	Herceptin trastuzumab	\$5,793.8	\$4,332.6	\$5,776.8	0%
Amgen Inc. (NASDAQ:AMGN)	Neulasta pegfilgrastim	\$3,558.0	\$2,954.0	\$3,938.7	11%
Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA) (A)	Copaxone glatiramer acetate	\$3,316.0	\$2,885.0	\$3,846.7	16%
Genentech Inc./Roche (SIX:ROG; OTCQX:RHHBY)/ Novartis AG (NYSE:NVS; SIX:NOVN)	Lucentis ranibizumab	\$3,089.0	\$2,751.5	\$3,668.7	19%
Gilead Sciences Inc. (NASDAQ:GILD)	Atripla efavirenz/emtricitabine/tenofovir	\$2,926.6	\$2,361.2	\$3,148.3	8%
Celgene Corp. (NASDAQ:CELG)	Revlimid lenalidomide	\$2,469.2	\$2,353.3	\$3,137.7	27%
Gilead Sciences Inc. (NASDAQ:GILD)	Truvada emtricitabine/tenofovir	\$2,649.9	\$2,129.1	\$2,838.8	7%
Biogen Idec Inc. (NASDAQ:BIIB)	Avonex interferon beta-1a	\$2,518.4	\$1,983.4	\$2,644.5	5%
Amgen Inc. (NASDAQ:AMGN)	Aranesp darbepoetin alfa	\$2,486.0	\$1,765.0	\$2,353.3	-5%
Amgen Inc. (NASDAQ:AMGN)	Epogen epoetin alfa	\$2,524.0	\$1,554.0	\$2,072.0	-18%
Actelion Ltd. (SIX:ATLN)	Tracleer bosentan	\$1,746.1	\$1,270.6	\$1,694.1	-3%
UCB Group (Euronext:UCB) (B)	Keppra levetiracetam	\$1,256.5	\$736.3 (1H11)	\$1,472.6	17%
OSI Pharmaceuticals Inc./Astellas Pharma Inc. (Tokyo:4503)/ Roche (SIX:ROG; OTCQX:RHHBY)	Tarceva erlotinib	\$1,414.0	\$1,021.9	\$1,362.5	-4%
Amgen Inc. (NASDAQ:AMGN)	Neupogen filgrastim	\$1,286.0	\$939.0	\$1,252.0	-3%
Genentech Inc./Roche (SIX:ROG; OTCQX:RHHBY)/ Novartis AG (NYSE:NVS; SIX:NOVN)	Xolair omalizumab	\$1,053.1	\$842.8	\$1,123.7	7%
Biogen Idec Inc. (NASDAQ:BIIB)/ Elan Corp. plc (NYSE:ELN) (A)	Tysabri natalizumab	\$1,230.0	\$1,130.0	\$1,506.7	22%
Cephalon Inc./Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA) (B)	Provigil modafinil	\$1,124.5	\$512.6 (1H11)	\$1,025.2	-9%
Onyx Pharmaceuticals Inc. (NASDAQ:ONXX)/ Bayer AG (Xetra:BAY)	Nexavar sorafenib	\$934.0	\$731.5	\$975.3	4%
Genzyme Corp./Sanofi (Euronext:SAN; NYSE:SNY)	Cerezyme imiglucerase	\$719.6	\$599.3	\$799.1	11%
Endo Pharmaceuticals Holdings Inc. (NASDAQ:ENDP)	Lidoderm lidocaine	\$782.6	\$592.9	\$790.5	1%
Amgen Inc. (NASDAQ:AMGN)	Sensipar cinacalcet (Mimpara)	\$714.0	\$592.0	\$789.3	11%
Shire plc (LSE:SHP; NASDAQ:SHPGY)	Vvyanse lisdexamfetamine	\$634.2	\$587.9	\$783.9	24%
Medimmune LLC/AstraZeneca plc (LSE:AZN; AZN) (C)	Synagis palivizumab	\$1,038.0	\$564.0	\$961.0	-7%
Alexion Pharmaceuticals Inc. (NASDAQ:ALXN)	Soliris eculizumab	\$541.0	\$555.9	\$741.2	37%
Genzyme Corp./Sanofi (Euronext:SAN; NYSE:SNY)	Renagel/Renvela sevelamer	\$697.7	\$555.5	\$740.7	6%

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Post-launch report

While Provenge sipuleucel-T from **Dendreon Corp.** (NASDAQ:DNDN) disappointed investors in 2011, two new drugs — Prolia/Xgeva denosumab and Incivek telaprevir — are likely to come close to or exceed \$500 million in annual sales within the first year or two post-launch, and generic enoxaparin from **Momenta Pharmaceuticals Inc.** (NASDAQ:MNTA) will likely top \$1 billion in 2011 sales. Denosumab, from **Amgen Inc.** (NASDAQ:AMGN) had sales of \$339 million for the first nine months of 2011. It is approved as Prolia to treat osteoporosis and as Xgeva to prevent skeletal related events in adults with bone metastases. **Vertex Pharmaceuticals Inc.** (NASDAQ:VRTX) launched Incivek for HCV in May 2011, and had already posted sales of \$494.1 million as of Sept. 30, 2011. Momenta's enoxaparin was launched in 2010 by Sandoz, the generics unit of **Novartis AG** (NYSE:NVS; SIX:NOVN), and raked in \$790 million in sales during the first nine months of 2011.

Dendreon's shares ended 2011 down 78%. Last August, the company withdrew its full-year revenue guidance of \$350-\$400 million on lower-than-expected uptake of the prostate cancer immunotherapy (see *BioCentury*, Aug. 8, 2011). The stock was up 63% last week after the company announced that 4Q11 sales grew 25% to \$82 million from 3Q11 and beat the Street's estimate of about \$69 million. Dendreon's shares remain down 66% from August, however. Sales figures below for selected drugs approved in 2010 or 2011, and for which sales figures are disclosed. (A) Approval in 2010 unless otherwise noted; \$M

Company	Product	Indication	2010 approval (A)	2011 sales through 9/30
Acorda Therapeutics Inc. (NASDAQ:ACOR)	Ampyra dalfampridine	Improve walking ability in patients with multiple sclerosis (MS)	U.S.	\$153.3
Amgen Inc. (NASDAQ:AMGN)	Prolia denosumab	Osteoporosis; bone loss associated with hormone ablation in men with prostate cancer	U.S./EU (osteoporosis); EU (prostate cancer)	\$122.0
Amgen Inc. (NASDAQ:AMGN)	Xgeva denosumab	Skeletal-related events in patients with bone metastases from solid tumors	U.S.	\$217.0
AstraZeneca plc (LSE:AZN; NYSE:AZN)	Brilique ticagrelor	Atherothrombotic events in acute coronary syndrome (ACS)	EU	\$16.0
AstraZeneca plc (LSE:AZN; NYSE:AZN)/ Bristol-Myers Squibb Co. (NYSE:BMJ)	Kombiglyze XR saxagliptin/metformin	Type II diabetes	U.S.	\$320 (incl sales of Onglyza saxagliptin)
Auxilium Pharmaceuticals Inc. (NASDAQ:AUXL)	Xiaflex collagenase clostridium histolyticum	Dupuytren's contracture	U.S.	\$40.7
Avanir Pharmaceuticals Inc. (NASDAQ:AVNR)	Nuedexta dextromethorphan/quinidine	Pseudobulbar affect (PBA)	U.S.	\$7.0 (FY ended 9/30/11)
BioMarin Pharmaceutical Inc. (NASDAQ:BMRN)	Amifampridine 3,4-diaminopyridine (Firdapse)	Lambert Eaton Myasthenic Syndrome (LEMS)	EU	\$9.8
Cadence Pharmaceuticals Inc. (NASDAQ:CADX)/ Bristol-Myers Squibb Co. (NYSE:BMJ)	Ofirmev IV acetaminophen	Pain and fever	U.S.	\$5.6
Dainippon Sumitomo Pharma Co. Ltd. (Tokyo:4506; Osaka:4506)	Latuda lurasidone	Schizophrenia	U.S. (launched Feb 2011)	\$41 (U.S. sales Feb-Jun 2011) <i>See next page</i>

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Company	Product	2010 sales	2011 9-mo sales	2011 run rate	Proj chg
Gilead Sciences Inc. (NASDAQ:GILD)	Viread tenofovir	\$732.2	\$547.0	\$729.3	0%
Cubist Pharmaceuticals Inc. (NASDAQ:CBST)	Cubicin daptomycin	\$624.9	\$534.5	\$712.7	14%
Celgene Corp. (NASDAQ:CELG)/ Nippon Shinyaku Co. Ltd. (Tokyo:4516; Osaka:4516)	Vidaza azacitidine	\$534.3	\$544.0	\$725.3	36%
Vertex Pharmaceuticals Inc. (NASDAQ:VRTX) (D)	Incivek telaprevir	NA	\$494.1	\$913.7	NA
Shire plc (LSE:SHP; NASDAQ:SHPGY)	Adderal XR	\$360.8	\$408.0	\$544.0	51%
Amylin Pharmaceuticals Inc. (NASDAQ:AMLN)	Byetta exenatide	\$559.3	\$385.1	\$513.5	-8%

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Company	Product	Indication	2010 approval (A)	2011 sales through 9/30
Dendreon Corp. (NASDAQ:DNDN)	Provenge sipuleucel-T	Metastatic castration-resistant prostate cancer (CRPC)	U.S.	\$228 (gross sales for FY ended 12/31/11)
Eisai Co. Ltd. (Tokyo:4523; Osaka:4523)	Halaven eribulin	Previously treated metastatic breast cancer	U.S.	¥6,200 (\$80.6) (6 mos ended 9/30/11)
Endo Pharmaceuticals Holdings Inc. (NASDAQ:ENDP)	Fortesta testosterone gel	Male hypogonadism	U.S.	\$9.5 (U.S. sales)
Forest Laboratories Inc. (NYSE:FRX)	Teflaro ceftaroline	Community acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI)	U.S.	\$8.0 (6 mos ended 9/30/11; launched Mar 2011)
Forest Laboratories Inc. (NYSE:FRX)	Vibryd vilazodone	Major depressive disorder (MDD)	U.S. (1/21/11)	\$12.6 (U.S. sales 6 mos ended 9/30/11)
Forest Laboratories Inc. (NYSE:FRX)/ Takeda Pharmaceutical Co. Ltd. (Tokyo:4502)	Daliresp roflumilast (Daxas - EU)	Severe chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis	EU (2010)/ U.S. (2/28/11)	\$9.7 (U.S. sales 6 mos ended 9/30/11)
Genmab A/S (CSE:GEN)/GlaxoSmithKline plc (LSE:GSK; NYSE:GSK)	Arzerra ofatumumab	Chronic lymphocytic leukemia (CLL)	EU	£32 (\$50)
Genzyme Corp./Sanofi (Euronext:SAN; NYSE:SNY)	Lumizyme alglucosidase alfa	Late onset Pompe's disease	U.S.	€200 (\$269) (6 mos ended 9/30/11; incl sales of Myozyme)
GlaxoSmithKline plc (LSE:GSK; NYSE:GSK)	Votrient pazopanib	Advanced renal cell carcinoma (RCC)	EU	£69 (\$107.8)
GW Pharmaceuticals plc (LSE:GWP)/ Bayer AG (Xetra:BAY)	Sativex sublingual cannabis spray	Spasticity due to MS	U.K./Spain	£4.4 (\$6.9M) (FY ended 9/30/11)
InterMune Inc. (NASDAQ:ITMN)	Esbriet pirfenidone	Idiopathic pulmonary fibrosis (IPF)	EU (3/3/11)	\$0.1
Ista Pharmaceuticals Inc. (NASDAQ:ISTA)	Bromday bromfenac	Ocular inflammation and pain following cataract surgery	U.S.	\$61.4 (incl sales of twice-daily version Xibrom bromfenac)
Ligand Pharmaceuticals Inc. (NASDAQ:LGND)/GlaxoSmithKline plc (LSE:GSK; NYSE:GSK)	Revolade eltrombopag (Promacta - U.S.)	Chronic idiopathic thrombocytopenic purpura (ITP)	EU	£51 (\$79.7)
Merck & Co. Inc. (NYSE:MRK)	Dulera mometasone/formoterol inhalation aerosol	Asthma	U.S.	\$59.0
Merck & Co. Inc. (NYSE:MRK)	Victralis boceprevir	HCV	U.S. (5/13/11)/ EU (7/18/11)	\$53.0
Momenta Pharmaceuticals Inc. (NASDAQ:MNTA)/Novartis AG (NYSE:NVS; SIX:NOVN)	Generic enoxaparin	Anticoagulant	U.S.	\$789.7
Novartis AG (NYSE:NVS; SIX:NOVN)	Gilenya fingolimod	Relapsing forms of MS	U.S.	\$291
Optimer Pharmaceuticals Inc. (NASDAQ:OPTR)	Dificid fidaxomicin	<i>Clostridium difficile</i> -associated diarrhea (CDAD)	U.S. (5/27/11)	\$10.6
Pozen Inc. (NASDAQ:POZN)/AstraZeneca plc (LSE:AZN; NYSE:AZN)	Vimovo naproxen/esomeprazole	Osteoarthritis (OA), rheumatoid arthritis (RA) and ankylosing spondylitis; gastric ulcers in patients at risk for NSAID-associated gastric ulcers	U.S./U.K.	\$19.8

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New products to watch

Selected drugs that received regulatory approval in 2011. *Source: BCIQ: BioCentury Online Intelligence*

Company	Product	Indication	2011 approval
Amgen Inc. (NASDAQ:AMGN)	Xgeva denosumab	Skeletal-related events in adults with bone metastases from solid tumors	EU
Amylin Pharmaceuticals Inc. (NASDAQ:AMLN)/Alkermes Inc. (NASDAQ:ALKS)	Bydureon exenatide once weekly using Alkermes' drug delivery technology	Type II diabetes	EU
AstraZeneca plc (LSE:AZN; NYSE:AZN)	Brilinta ticagrelor	Reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome (ACS)	U.S.
AstraZeneca plc (LSE:AZN; NYSE:AZN)	Caprelsa vandetanib	Unresectable, locally advanced or metastatic medullary thyroid cancer	U.S.
AstraZeneca plc (LSE:AZN; NYSE:AZN)/Bristol-Myers Squibb Co. (NYSE:BMJ)	Komboglyze saxagliptin/metformin	Type II diabetes	EU
Bayer AG (Xetra:BAY)	Gadavist gadobutrol injection	Diagnostic MRI to detect and visualize areas with disrupted blood-brain barrier and/or abnormal CNS vascularity	U.S.
Bayer AG (Xetra:BAY)/Johnson & Johnson (NYSE:JNJ)	Xarelto rivaroxaban	Prevent deep vein thrombosis (DVT) and pulmonary embolism (PE) in patients undergoing knee or hip replacement surgery and prevent stroke and systemic embolism in patients with non-valvular atrial fibrillation (AF)	U.S.
Biofrontera AG (Xetra:B8F)	Ameluz (BF-200 ALA)	Actinic keratosis	EU
BioSpecifics Technologies Corp. (NASDAQ:BSTC)/Auxilium Pharmaceuticals Inc. (NASDAQ:AUXL)/Pfizer Inc. (NYSE:PFE)	Xiapex collagenase clostridium histolyticum	Dupuytren's contracture in adult patients with a palpable cord	EU
Boehringer Ingelheim GmbH/Eli Lilly and Co. (NYSE:LLY)	Tradjenta linagliptin (Trajenta - EU)	Type II diabetes	U.S./EU
Bristol-Myers Squibb Co. (NYSE:BMJ)	Yervoy ipilimumab	Unresectable or metastatic melanoma	U.S./EU
Bristol-Myers Squibb Co. (NYSE:BMJ)	Nulojix belatacept	Prevent organ rejection in adult patients receiving a kidney transplant who are Epstein-Barr virus (EBV) seropositive	U.S./EU
Bristol-Myers Squibb Co. (NYSE:BMJ)	Orencia abatacept subcutaneous formulation	Moderate to severe rheumatoid arthritis (RA)	U.S.

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Company	Product	Indication	2010 approval (A)	2011 sales through 9/30
Roche (SIX:ROG; OTCQX:RHHBY)	Actemra tocilizumab (RoActemra - EU)	Moderate to severe RA	U.S. (approved in EU in 2009)	CHF433 (\$478.6)
Salix Pharmaceuticals Ltd. (NASDAQ:SLXP)	Xifaxan rifaximin 550 mg tablets	Hepatic encephalopathy recurrence in advanced liver disease	U.S.	\$264.4
Sanofi (Euronext:SAN; NYSE:SNY)	Jevtana cabazitaxel	Metastatic hormone-refractory prostate cancer	U.S.	€141 (\$189.6)
Savient Pharmaceuticals Inc. (NASDAQ:SVNT)	Krystexxa pegloticase	Chronic gout	U.S.	\$3.2
Shire plc (LSE:SHIP; NASDAQ:SHPGY)	Vpriv velaglucerase alfa	Type I Gaucher's disease	U.S./EU	\$186.9
Somaxon Pharmaceuticals Inc. (NASDAQ:SOMX)	Silenor doxepin	Insomnia	U.S.	\$16.5 (gross sales)
Vertex Pharmaceuticals Inc. (NASDAQ:VRTX)/Johnson & Johnson (NYSE:JNJ)	Incivek telaprevir (Incivo - EU)	HCV	U.S. (5/23/11)/EU (9/19/11)	\$494.1 (May 2011 to 9/30/11)

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Company	Product	Indication	2011 approval
Bristol-Myers Squibb Co. (NYSE:BMJ)/ Pfizer Inc. (NYSE:PFE)	Eliquis apixaban	Prevent venous thromboembolism (VTE) in adults who have undergone elective hip or knee replacement surgery	EU
BTG plc (LSE:BGJ)/ Johnson & Johnson (NYSE:JNJ)	Zytiga abiraterone acetate	Metastatic castration-resistant prostate cancer (CRPC) in combination with prednisone in patients whose disease has progressed on or after a docetaxel-based chemotherapy regimen	U.S./EU
Chugai Pharmaceutical Co. Ltd. (Tokyo:4519)/ Roche (SIX:ROG; OTCQX:RHHBY)	Mircera methoxy polyethylene glycol-epoetin beta	Renal anemia	Japan
CSL Ltd. (ASX:CSL)	Corifact human coagulation factor XIII concentrate	Prevent bleeding in people with congenital Factor XIII deficiency	U.S.
Daiichi Sankyo Co. Ltd. (Tokyo:4568; Osaka:4568)	Lixiana edoxaban	Prevent VTE after major orthopedic surgery	Japan
Daiichi Sankyo Co. Ltd. (Tokyo:4568; Osaka:4568)/ Roche (SIX:ROG; OTCQX:RHHBY)	Zelboraf vemurafenib and companion BRAF V600 Mutation Test	Unresectable or metastatic melanoma in patients with BRAF V600E mutations as determined by an FDA-approved test	U.S.
Depomed Inc. (NASDAQ:DEPO) (DM-1796)	Gralise gabapentin	Post-herpetic neuralgia (PHN)	U.S.
Eisai Co. Ltd. (Tokyo:4523; Osaka:4523)	Halaven eribulin	Locally advanced or metastatic breast cancer	EU/Switzerland/ Japan
Elan Corp plc (NYSE:ELN)/ Acorda Therapeutics Inc. (NASDAQ:ACOR)/ Biogen Idec Inc. (NASDAQ:BIIB)	Fampyra fampridine	Improve walking ability in patients with multiple sclerosis (MS) who have walking disability	EU
Endo Pharmaceuticals Holdings Inc. (NASDAQ:ENDP)/ Gruenthal Group	Crush-resistant formulation of Opana ER oxymorphone	Moderate to severe pain in patients requiring continuous opioid treatment	U.S.
Fibrocell Science Inc. (OTCBB:FCSC)	laViv azficel-T	Improve the appearance of moderate to severe nasolabial fold wrinkles	U.S.
Forest Laboratories Inc. (NYSE:FRX)	Viiibryd vilazodone	Major depressive disorder (MDD)	U.S.
Gilead Sciences Inc. (NASDAQ:GILD)/ Johnson & Johnson (NYSE:JNJ)	Complera emtricitabine/rilpivirine/tenofovir (Eviplera - EU)	HIV-1 infection in treatment-naive patients	U.S./EU
Hologic Inc. (NASDAQ:HOLX)/ KV Pharmaceuticals Co. (NYSE:KVA)	Makena hydroxyprogesterone caproate injection	Reduce the risk of preterm delivery before 37 weeks of pregnancy in women with a history of at least one spontaneous preterm birth	U.S.
HRA Pharma S.A./Sosei Group Corp. (Tokyo:4565)	NorLevo levonorgestrel	Emergency contraceptive	Japan
Human Genome Sciences Inc. (NASDAQ:HGSI)/ GlaxoSmithKline plc (LSE:GSK; NYSE:GSK)	Benlysta belimumab	Active, autoantibody-positive systemic lupus erythematosus (SLE)	U.S./EU
Incyte Corp. (NASDAQ:INCY)	Jakafi ruxolitinib	Myelofibrosis	U.S.
InterMune Inc. (NASDAQ:ITMN)	Esbriet pirfenidone	Mild to moderate idiopathic pulmonary fibrosis (IPF)	EU
Johnson & Johnson (NYSE:JNJ)	Edurant rilpivirine	HIV infection in combination with other antiretrovirals in treatment-naive patients	U.S.
Johnson & Johnson (NYSE:JNJ)/ Elan Corp. plc (NYSE:ELN)	Xeplion paliperidone palmitate	Maintenance treatment of schizophrenia in adult patients stabilized with paliperidone or risperidone	EU
Kyowa Hakko Kirin Co. Ltd (Tokyo:4151)	Rectiv nitroglycerin 0.4% ointment	Moderate to severe pain associated with chronic anal fissures	U.S.

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Company	Product	Indication	2011 approval
Meda AB (SSE:MEDAA)/ Valeant Pharmaceuticals International Inc. (NYSE:VRX; TSX:VRX)/ GlaxoSmithKline plc (LSE:GSK; NYSE:GSK)	Potiga ezogabine (Trobalt retigabine - EU)	Adjunctive therapy for partial onset seizures	U.S./EU
Merck & Co. Inc. (NYSE:MRK)	Juvisync sitagliptin/simvastatin	Type II diabetes and high cholesterol	U.S
Merck & Co. Inc. (NYSE:MRK)	Victrelis boceprevir	Chronic HCV genotype 1 infection in combination with standard of care	U.S./EU
Mitsubishi Tanabe Pharma Corp. (Tokyo:4508; Osaka:4508)/ Novartis AG (NYSE:NVS; SIX:NOVN)	Gilenya fingolimod (Imusera - Japan)	Relapsing-remitting multiple sclerosis (RRMS)	EU/Switzerland/Canada/Australia/Japan
Novartis AG (NYSE:NVS; SIX:NOVN)/ Eisai Co. Ltd. (Tokyo:4523; Osaka:4523)	Arcapta Neohaler indacaterol (Onbrez Inhalation Capsules - Japan)	Chronic obstructive pulmonary disease (COPD)	U.S./Japan
Optimer Pharmaceuticals Inc. (NASDAQ:OPTR)/ Cubist Pharmaceuticals Inc. (NASDAQ:CBST)/ Astellas Pharma Inc. (Tokyo:4503)	Dificid fidaxomicin (Dificlir - EU)	<i>Clostridium difficile</i> -associated diarrhea (CDAD)	U.S./EU
Orexo AB (SSE:ORX)/ Paladin Labs Inc. (TSX:PLB)/ Kyowa Hakko Kirin Co. Ltd. (Tokyo:4151)	Abstral fentanyl	Breakthrough cancer pain	U.S./Canada
Pacira Pharmaceuticals Inc. (NASDAQ:PCRX)	Exparel bupivacaine	Post-operative pain	U.S.
Pfizer Inc. (NYSE:PFE)	Vyndaqel tafamidis	Transthyretin (TTR) familial amyloid polyneuropathy (FAP)	EU
Pfizer Inc. (NYSE:PFE)/ Abbott Laboratories (NYSE:ABT)	Xalkori crizotinib from Pfizer and companion anaplastic lymphoma kinase (ALK) FISH test from Abbott	Non-small cell lung cancer (NSCLC)	U.S.
Pharmaxis Ltd. (ASX:PXS; Pink:PXSLY)	Bronchitol mannitol	Cystic fibrosis (CF)	Australia
Regeneron Pharmaceuticals Inc. (NASDAQ:REGN)/ Bayer AG (Xetra:BAY)	Eylea aflibercept ophthalmic solution	Wet age-related macular degeneration (AMD)	U.S.
Roche (SIX:ROG; OTCQX:RHHBY)	cobas 4800 HPV test	Identify women at highest risk for cervical cancer	U.S.
Sanofi (Euronext:SAN; NYSE:SNY)	Jevtana cabazitaxel	Second-line metastatic hormone-refractory prostate cancer (HRPC)	EU
Sanofi (Euronext:SAN; NYSE:SNY)/ Shire plc (LSE:SHP; NASDAQ:SHPGY)	Firazyr icatibant	Acute attacks of hereditary angioedema (HAE)	U.S.
Seattle Genetics Inc. (NASDAQ:SGEN)/ Takeda Pharmaceutical Co. Ltd. (Tokyo:4502)	Adcetris brentuximab vedotin	Hodgkin's lymphoma and anaplastic large cell lymphoma (ALCL)	U.S.
Simcere Pharmaceutical Group (NYSE:SCR)	Iremod iguratimod	RA	China
Takeda Pharmaceutical Co. Ltd. (Tokyo:4502)	Edarbi azilsartan medoxomil	Hypertension	U.S./EU
Takeda Pharmaceutical Co. Ltd. (Tokyo:4502)	Edarbyclor azilsartan/chlorthalidone	Hypertension	U.S.
Takeda Pharmaceutical Co. Ltd. (Tokyo:4502)	Liovel alogliptin/pioglitazone	Type II diabetes	Japan
Theravance Inc. (NASDAQ:THRX)	Vibativ telavancin	Nosocomial pneumonia, including ventilator-associated pneumonia (VAP) known or suspected to be caused by MRSA	EU

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Approval watch

Selected products up for approval in 2012. *Source: BCIQ: BioCentury Online Intelligence*

Company	Product	Indication	Event	Milestone
Access Pharmaceuticals Inc. (OTCBB:ACCP)/ RHEI Pharmaceuticals Inc.	MuGard mucoadhesive oral rinse	Treat and prevent oral mucositis	Regulatory action in China	1H12
Aeterna Zentaris Inc. (TSX:AEZ; NASDAQ:AEZS)/Keryx Biopharmaceuticals Inc. (NASDAQ:KERX)	Perifosine	Refractory metastatic colorectal cancer (mCRC)	FDA action	4Q12
Affymax Inc. (NASDAQ:AFFY)/Takeda Pharmaceutical Co. Ltd. (Tokyo:4502)	Peginesatide (formerly Hematide)	Anemia in chronic kidney disease (CKD) patients	PDUFA date	3/27/12
Alexza Pharmaceuticals Inc. (NASDAQ:ALXA)	Adasuve loxapine with schizophrenia or bipolar disorder	Acute agitation in patients	PDUFA date	2/4/12
Amarin Corp. plc (NASDAQ:AMRN)	AMR101 (formerly Miraxion)	Hypertriglyceridemia	PDUFA date	7/26/12
Amgen Inc. (NASDAQ:AMGN)/Daiichi Sankyo Co. Ltd. (Tokyo:4568; Osaka:4568)	Xgeva denosumab	Prevent bone metastasis in men with castration-resistant prostate cancer (CRPC)	FDA panel; PDUFA date	2/8/12; 4/26/12
Amylin Pharmaceuticals Inc. (NASDAQ:AMLN)/Alkermes plc (NASDAQ:ALKS)	Bydureon exenatide once weekly using Alkermes drug delivery technology	Type II diabetes	PDUFA date	1/28/12
Arena Pharmaceuticals Inc. (NASDAQ:ARNA)/Eisai Co. Ltd. (Tokyo:4523; Osaka:4523)	Lorcaserin	Obesity	FDA action	2012 (submitted complete response to FDA in January)
Ariad Pharmaceuticals Inc. (NASDAQ:ARIA)/ Merck & Co. Inc. (NYSE:MRK)	Ridaforolimus	Metastatic soft tissue or bone sarcomas	PDUFA date	6/5/12
Astellas Pharma Inc. (Tokyo:4503)	Mirabegron	Overactive bladder (OAB)	PDUFA date	6/29/12
Astex Pharmaceuticals Inc. (NASDAQ:ASTX)/ Eisai Co. Ltd. (Tokyo:4523; Osaka:4523)/ Johnson & Johnson (NYSE:JNJ)	Dacogen decitabine	Acute myelogenous leukemia (AML)	FDA panel; PDUFA date	2/9/12; 3/06/12
Bavarian Nordic A/S (CSE:BAVA)	Imvamune vaccine	Prevent smallpox infection	Regulatory action in Canada	2012
BioSante Pharmaceuticals Inc. (NASDAQ:BPAX)/Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA)	Bio-T-Gel transdermal testosterone	Hypogonadism in men	PDUFA date	2/14/12
Bristol-Myers Squibb Co. (NYSE:BMJ)/ AstraZeneca plc (LSE:AZN; NYSE:AZN)	Dapagliflozin	Type II diabetes	PDUFA date	1/28/12

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Company	Product	Indication	2011 approval
Transcept Pharmaceuticals Inc. (NASDAQ:TSPT)/Purdue Pharma L.P.	Intermezzo zolpidem	Insomnia when middle of the night awakening is followed by difficulty returning to sleep	U.S.
Vertex Pharmaceuticals Inc. (NASDAQ:VRTX)/Johnson & Johnson (NYSE:JNJ)/Mitsubishi Tanabe Pharma Corp. (Tokyo:4508; Osaka:4508)	Incivek telaprevir (Incivo - EU; Telavic - Japan)	Chronic HCV genotype 1 infection in combination with standard of care	U.S./EU /Japan
ViroPharma Inc. (NASDAQ:VPHM)	Cinryze C1 esterase inhibitor	Treat and prevent angioedema attacks in patients with HAE	EU
XenoPort Inc. (NASDAQ:XPNT)/ GlaxoSmithKline plc (LSE:GSK; NYSE:GSK)	Horizant gabapentin enacarbil extended-release tablets	Moderate to severe primary restless legs syndrome (RLS)	U.S.

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Company	Product	Indication	Event	Milestone
Bristol-Myers Squibb Co. (NYSE:BMJ)/ Pfizer Inc. (NYSE:PFE)	Eliquis apixaban	Prevent stroke and systemic embolism in patients with atrial fibrillation (AF)	PDUFA date	3/28/12
Celgene Corp. (NASDAQ:CELG)	Revlimid lenalidomide	Front-line multiple myeloma (MM)	MAA action	Mid-2012
Celgene Corp. (NASDAQ:CELG)	Abraxane nab-paclitaxel	Non-small cell lung cancer (NSCLC)	FDA action	YE12
Cell Therapeutics Inc. (NASDAQ:CTIC; Milan:CTIC)	Pixuvri pixantrone	Relapsed or refractory aggressive NHL	FDA panel; MAA action; PDUFA date	2/9/12; 1Q12; 4/24/12
Chelsea Therapeutics International Ltd. (NASDAQ:CHTP)/Dainippon Sumitomo Pharma Co. Ltd. (Tokyo:4506; Osaka:4506)	Northera droxidopa	Symptomatic neurogenic orthostatic hypotension (NOH)	FDA panel; PDUFA date	2/23/12; 3/28/12
Columbia Laboratories Inc. (NASDAQ:CBRX)/ Watson Pharmaceuticals Inc. (NYSE:WPI)	Prochieve vaginal progesterone gel	Prevent preterm birth	FDA panel; PDUFA date	1/20/12; 2/26/12
Corcept Therapeutics Inc. (NASDAQ:CORT)	Korlym mifepristone (formerly Corlux)	Cushing's syndrome	PDUFA date	2/17/12
Curis Inc. (NASDAQ:CRIS)/Genentech Inc./ Roche (SIX:ROG; OTCQX:RHHBY)	Vismodegib	Advanced basal cell carcinoma (BCC) in adults for whom surgery is considered inappropriate	PDUFA date	3/8/12
Epigenomics AG (Xetra:ECX)	Epi proColon 2.0	Detect colon cancer	FDA panel	2012
Galenica Ltd. (SIX:GALN)/Daiichi Sankyo Co. Ltd. (Tokyo:4568; Osaka:4568)	Injectafer ferric carboxymaltose	Iron deficiency anemia	PDUFA date	8/3/12
Gilead Sciences Inc. (NASDAQ:GILD)/ Japan Tobacco Inc. (Tokyo:2914; Osaka:2914)	Fixed-dose Quad elvitegravir/cobicistat/emtricitabine/tenofovir	HIV-1 infection in adults	PDUFA date	8/27/12
Horizon Pharma Inc. (NASDAQ:HZNP)/ SkyePharma plc (LSE:SKP)	Lodotra prednisone using SkyePharma's Geoclock delivery technology	Rheumatoid arthritis (RA)	PDUFA date	7/26/12
Incyte Corp. (NASDAQ:INCY)/Novartis AG (NYSE:NVS; SIX:NOVN)	Jakafi ruxolitinib	Myelofibrosis	MAA action	2012
Ironwood Pharmaceuticals Inc. (NASDAQ:IRWD)/Forest Laboratories Inc. (NYSE:FRX)	Linaclotide	Irritable bowel syndrome with constipation (IBS-C)	PDUFA date	June
Map Pharmaceuticals Inc. (NASDAQ:MAPP)/ Allergan Inc. (NYSE:AGN)/Nektar Therapeutics (NASDAQ:NKTR)	Levadex dihydroergotamine mesylate using Map's Tempo Inhaler	Acute migraine	PDUFA date	3/26/12
Meda AB (SSE:MEDAA)	Dymista azelastine/fluticasone	Seasonal allergic rhinitis in patients ages ≥12 years	PDUFA date	Early May
MedImmune LLC/AstraZeneca plc (LSE:AZN; NYSE:AZN)	MEDI-3250 vaccine	Prevent seasonal influenza	PDUFA date	2/29/12
NeurogesX Inc./Astellas Pharma Inc. (Tokyo:4503)	Qutenza capsaicin	Pain associated with HIV-distal sensory polyneuropathy	PDUFA date	3/7/12
Onyx Pharmaceuticals Inc. (NASDAQ:ONXX)	Carfilzomib	Relapsed and refractory MM	PDUFA date	7/27/12
Pfizer Inc. (NYSE:PFE)	Tofacitinib	Moderate to severe active RA	PDUFA date	August
Progenics Pharmaceuticals Inc. (NASDAQ:PGNX)/Salix Pharmaceuticals Ltd. (NASDAQ:SLXP)	Subcutaneous Relistor methylnaltrexone	Opioid-induced constipation (OIC) in patients with non-cancer pain	PDUFA date	4/27/12
Protalix Biotherapeutics Inc. (NYSE-A:PLX; Tel Aviv:PLX)	Taliglucerase alfa	Gaucher's disease	PDUFA date	5/1/12

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2012 milestones

Selected products with Phase III or regulatory milestones expected in 2012. *Source: BCIQ: BioCentury Online Intelligence*

Company	Product	Indication	Event	Milestone
Abbott Laboratories (NYSE:ABT) carbidopa	Duodopa levodopa/	Advanced Parkinson's disease (PD) in patients with severe motor fluctuations	Final Ph III data	YE12
AcelRx Pharmaceuticals Inc. (NASDAQ:ACRX)	Sufentanil NanoTab PCA System	Post-operative pain in patients undergoing major abdominal surgery	Ph III data	2012
Actelion Ltd. (SIX:ATLN)/Nippon Shinyaku Co. Ltd. (Tokyo:4516; Osaka:4516)	Macitentan (formerly Actelion-1, ACT-064992)	Pulmonary arterial hypertension (PAH)	Ph III data	1H12
Active Biotech AB (SSE:ACTI)	Anyara	Renal cell carcinoma (RCC)	Ph II/III data	2012
Aegerion Pharmaceuticals Inc. (NASDAQ:AEGR)	Lomitapide	Homozygous familial hypercholesterolemia (hoFH)	Submit NDA and MAA	1Q12
Aeterna Zentaris Inc. (TSX:AEZ; NASDAQ:AEZS)	Solorel macimorelin	Diagnose adult growth hormone deficiency (AGHD)	Submit NDA	Early 2012
Aeterna Zentaris Inc. (TSX:AEZ; NASDAQ:AEZS)/Keryx Biopharmaceuticals Inc. (NASDAQ:KERX)	Perifosine	Refractory metastatic colorectal cancer (mCRC)	Ph III data; submit NDA	1Q12; 2Q12
Agennix AG (Xetra:AGX)	Talactoferrin oral	Refractory non-small cell lung cancer (NSCLC)	Ph III data	1H12
Algeta ASA (OSE:ALGETA)/Bayer AG (Xetra:BAY)	Alpharadin radium-223	Bone metastases in patients with castration-resistant prostate cancer (CRPC)	Submit regulatory applications	Mid-2012
Almirall S.A. (Madrid:ALM)/Forest Laboratories Inc. (NYSE:FRX)	Aclidinium bromide/formoterol	Chronic obstructive pulmonary disease (COPD)	Ph III data	1H12

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Company	Product	Indication	Event	Milestone
Qiagen N.V. (Xetra:QIA; NASDAQ:QGEN)	Therascreen K-RAS	Identify K-Ras mutation status to predict response to anti-EGFR therapies	PMA approval	Mid-2012
QRxPharma Ltd. (ASX:QRX; OTCQX:QRXPY)	MoxDuo IR morphine/oxycodone	Moderate to severe acute pain	PDUFA date	6/25/12
Regeneron Pharmaceuticals Inc. (NASDAQ:REGN)	Arcalyst rilonacept	Prevent gout flares in patients initiating uric acid-lowering therapy	PDUFA date	7/30/12
Talon Therapeutics Inc. (OTCBB:TALON)/Tekmira Pharmaceuticals Corp. (TSX:TKM; NASDAQ:TKMR)	Marqibo vincristine	Acute lymphoblastic leukemia (ALL)	PDUFA date	5/13/12
Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA)	Beclomethasone dipropionate nasal aerosol	Seasonal and perennial allergic rhinitis	PDUFA date	3/24/12
Vertex Pharmaceuticals Inc. (NASDAQ:VRTX)	Kalydeco ivacaftor	Cystic fibrosis (CF)	PDUFA date	4/18/12
Vivus Inc. (NASDAQ:VVUS)	Qnexa phentermine/topiramate	Obesity	MAA action; FDA panel; PDUFA date	1Q12; 2/22/12; 4/17/12
Vivus Inc. (NASDAQ:VVUS)/Mitsubishi Tanabe Pharma Corp. (Tokyo:4508; Osaka:4508)	Avanafil	Erectile dysfunction (ED)	PDUFA date	4/29/12
XenoPort Inc. (NASDAQ:XPNT)/GlaxoSmithKline plc (LSE:GSK; NYSE:GSK)	Horizant gabapentin enacarbil	Manage postherpetic neuralgia (PHN)	FDA action	June (assumes 10-mo standard review)

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Amicus Therapeutics Inc. (NASDAQ:FOLD)/ GlaxoSmithKline plc (LSE:GSK; NYSE:GSK)	Amigal migalastat	Fabry's disease	Ph III data	3Q12
Anacor Pharmaceuticals Inc. (NASDAQ:ANAC)	Tavaborole	Onychomycosis	Ph III data	YE12
Anthera Pharmaceuticals Inc. (NASDAQ:ANTH)/Eli Lilly and Co. (NYSE:LLY)/Shionogi & Co. Ltd. (Tokyo:4507; Osaka:4507)	Varespladib methyl	Acute coronary syndromes (ACS)	Topline Ph III data	2Q12
Arena Pharmaceuticals Inc. (NASDAQ:ARNA)/Eisai Co. Ltd. (Tokyo:4523; Osaka:4523)	Lorcaserin	Obesity	Submit MAA	1H12
Ariad Pharmaceuticals Inc. (NASDAQ:ARIA)	Ponatinib	Philadelphia chromosome- positive (Ph+) acute lymphoblastic leukemia (ALL) patients resistant or intolerant to dasatinib or nilotinib; chronic myelogenous leukemia (CML)	Submit NDA	Mid-2012
Auxilium Pharmaceuticals Inc. (NASDAQ:AUXL)/BioSpecifics Technologies Corp. (NASDAQ:BSTC)/Asahi Kasei Pharma Corp./Pfizer Inc. (NYSE:PFE)	Xiaflex collagenase clostridium histolyticum	Peyronie's disease	Ph III data	2Q12
Aveo Pharmaceuticals Inc. (NASDAQ:AVEO)/ Astellas Pharma Inc. (Tokyo:4503)	Tivozanib	Advanced RCC	Submit NDA and MAA	2012
Basilea Pharmaceutica AG (SIX:BSLN)	Ceftobiprole	Pneumonia	Submit MAA	2H12
Basilea Pharmaceutica AG (SIX:BSLN)	Toctino alitretinoin	Chronic refractory hand eczema	Topline Ph III HANDEL data	1Q12
Basilea Pharmaceutica AG (SIX:BSLN)/ Almirall S.A. (Madrid:ALM)	Toctino alitretinoin	Severe chronic hand eczema	Submit NDA	2H12
BioDelivery Sciences International Inc. (NASDAQ:BDSI)	BEMA Buprenorphine/ Naloxone	Opioid dependence	Pivotal trial data	March
Biogen Idec Inc. (NASDAQ:BIIB)	BG-12	Relapsing-remitting multiple sclerosis (RRMS)	Submit NDA	1H12
Biogen Idec Inc. (NASDAQ:BIIB)/Swedish Orphan Biovitrum AB (SSE:SOBI)	rFIXFc	Treat and prevent bleeding in patients with hemophilia B	Ph III data	2H12
Biogen Idec Inc. (NASDAQ:BIIB)/Swedish Orphan Biovitrum AB (SSE:SOBI)	rFVIIIc	Treat and prevent bleeding in patients with hemophilia A	Ph III data	2H12
BioMarin Pharmaceutical Inc. (NASDAQ:BMRN)	GALNS (BMN-110)	Mucopolysaccharidosis IVA (MPS-IVA, Morquio's syndrome)	Prelim Ph III data	2H12
Bristol-Myers Squibb Co. (NYSE:BMJ)	Brivanib (BMS-582664)	Colorectal cancer	Ph III data	2012
Bristol-Myers Squibb Co. (NYSE:BMJ)	Brivanib (BMS-582664)	Hepatocellular carcinoma (HCC)	Ph III data	2012
BTG plc (LSE:BGC)	Varisolve polidocanol microfoam	Varicose veins	Ph III data; submit NDA	1H12; YE12
Can-Fite BioPharma Ltd. (Tel Aviv:CFBI)	CF101	Psoriasis	Interim Ph II/III data	4Q12
Celgene Corp. (NASDAQ:CELG)	Apremilast	Psoriasis; psoriatic arthritis	Ph III data (psoriasis); Ph III data (psoriatic arthritis)	Mid-2012
Celgene Corp. (NASDAQ:CELG)	Pomalidomide	Multiple myeloma (MM) in salvage setting	Submit NDA and MAA	2H12

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Celgene Corp. (NASDAQ:CELG)	Revlimid lenalidomide	Myelodysplastic syndrome (MDS) in patients with 5q chromosomal deletion	Submit MAA	1Q12
Celgene Corp. (NASDAQ:CELG)/Otsuka Pharmaceutical Co. Ltd.	Abraxane nab-paclitaxel	Previously untreated metastatic melanoma; pancreatic cancer	Ph III data (melanoma); Ph III data (pancreatic)	Mid-2012; 2H12
Celsion Corp. (NASDAQ:CLSN)/Yakult Honsha Co. Ltd. (Tokyo:2267)	ThermoDox heat-activated liposome	Non-resectable HCC	Final Ph III data	YE12
Chugai Pharmaceutical Co. Ltd. (Tokyo:4519)/Taisho Pharmaceutical Co. Ltd. (Tokyo:4535)/Roche (SIX:ROG; OTCQX:RHHBY)	Injectable Boniva ibandronate	Osteoporosis	Submit regulatory application in Japan	2012
Clavis Pharma ASA (OSE:CLAVIS)	Elacytarabine	Early-stage acute myelogenous leukemia (AML); late-stage AML	Ph III data (early); Ph III data (late)	3Q12; 4Q12
Clinuvel Pharmaceuticals Ltd. (ASX:CUV; Xetra:UR9)	Scenesse afamelanotide	Prevent phototoxicity in patients with erythropoietic protoporphyria	Submit MAA	Early 2012
Dendreon Corp. (NASDAQ:DNDN)	Provenge sipuleucel-T	Asymptomatic or minimally symptomatic metastatic CRPC	Submit MAA	Early 2012
D-Pharm Ltd. (Tel Aviv:DPRM)	DP-b99	Acute ischemic stroke	Interim Ph III data	February
Direct Corp. (NASDAQ:DRRX)/Hospira Inc. (NYSE:HSP)/Takeda Pharmaceutical Co. Ltd. (Tokyo:4502)	Posidur saber-bupivacaine	Post-operative pain	Submit NDA	1H12
Elan Corp. plc (NYSE:ELN)/Zogenix Inc. (NASDAQ:ZGNX)	Zohydro hydrocodone bitartrate	Moderate to severe chronic pain	Submit NDA	2Q12
Endocyte Inc. (NASDAQ:ECYT)	EC145	Platinum-resistant ovarian cancer	Submit MAA	1Q12
Endocyte Inc. (NASDAQ:ECYT)	EC20 companion diagnostic for EC145	Detect and assess presence of folate receptor to select patients for folate-targeted therapy	Submit MAA	1Q12
Exact Sciences Corp. (NASDAQ:EXAS)	Cologuard stool-based DNA test	Detect colorectal cancer and precancerous adenomas	Submit PMA	2H12
Exelixis Inc. (NASDAQ:EXEL)	Cabozantinib	Medullary thyroid cancer (MTC)	Begin and complete rolling NDA	1H12
Forest Laboratories Inc. (NYSE:FRX)/Laboratoires Pierre Fabre S.A.	Levomilnacipran	Major depressive disorder (MDD)	Ph III data	1Q12; 2Q12
Gamida Cell Ltd./Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA)	StemEx cell therapy	Hematologic malignancies	Submit BLA	YE12
Genentech Inc./Roche (SIX:ROG; OTCQX:RHHBY)	Subcutaneous Herceptin trastuzumab	HER2-positive early breast cancer	Submit MAA	2012
Genentech Inc./Roche (SIX:ROG; OTCQX:RHHBY)/Novartis AG (NYSE:NVS; SIX:NOVN)	Lucentis ranibizumab	Diabetic macular edema (DME)	Additional Ph III data	1H12
Gilead Sciences Inc. (NASDAQ:GILD)	Cobicistat	HIV infection	Submit NDA	2Q12
GlaxoSmithKline plc (LSE:GSK; NYSE:GSK)	Tykerb lapatinib	Advanced gastric cancer; squamous cell cancer of the head and neck (SCCHN)	Ph III data (gastric); Ph III data (SCCHN)	YE12
H. Lundbeck A/S (CSE:LUN)	Ziconapine	Schizophrenia	Ph III data	2012
H. Lundbeck A/S (CSE:LUN)/Takeda Pharmaceutical Co. Ltd. (Tokyo:4502)	Lu AA21004	MDD	Ph III data	1H12
Hisamitsu Pharmaceutical Co. Inc. (Tokyo:4530; Osaka:4530)	LDMP (low-dose mesylate salt of paroxetine)	Vasomotor symptoms associated with menopause	Submit NDA	2012 <i>See next page</i>

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ImmunoGen Inc. (NASDAQ:IMGN)/ Genentech Inc./Roche (SIX:ROG; OTCQX:RHHBY)	Trastuzumab emtansine (T-DM1)	Second-line HER2-positive metastatic breast cancer	Ph III data; submit regulatory applications worldwide	1H12; 2012
Impax Laboratories Inc. (NASDAQ:IPXL)/ GlaxoSmithKline plc (LSE:GSK; NYSE:GSK)	IPX066 extended-release carbidopa/levodopa	PD	Submit MAA	2012
Isis Pharmaceuticals Inc. (NASDAQ:ISIS)/ Sanofi (Euronext:SAN; NYSE:SNY)	Kynamro mipomersen	hoFH	Submit NDA	1Q12
Japan Tobacco Inc. (Tokyo:2914; Osaka:2914)/ Gilead Sciences Inc. (NASDAQ:GILD)	Elvitegravir	HIV-1 infection	Submit NDA	2Q12
Johnson & Johnson (NYSE:JNJ)/ Global Alliance for TB Drug Development	TMC207	Multidrug resistant tuberculosis (MDR-TB)	Submit regulatory application	2012
Kael Co. Ltd. (KOSDAQ:082270)	GV1001	Non-resectable pancreatic cancer	Final Ph III data	YE12
Keryx Biopharmaceuticals Inc. (NASDAQ:KERX)/ Panion & BF Biotech Inc./Japan Tobacco Inc. (Tokyo:2914; Osaka:2914)	Zerenex ferric citrate	Hyperphosphatemia in patients with end-stage renal disease (ESRD)	Submit NDA	4Q12
Lannett Co. Inc. (NYSE-A:LCI)	C-Topical cocaine HCl topical solution	Anesthetic prior to a diagnostic procedure or surgery	Submit NDA	2012
Medivation Inc. (NASDAQ:MDVN)/ Pfizer Inc. (NYSE:PFE)	Dimebon latrepirdine	Mild to moderate Alzheimer's disease (AD)	Ph III data	1H12
Nanosphere Inc. (NASDAQ:NSPH)	Verigene Gram-Positive Blood Culture (BC-GP) assay	Detect Gram-positive bacterial infections	Submit 510(k)	1Q12
Novagali Pharma S.A. (Euronext:NOVA), being acquired by Santen Pharmaceutical Co. Ltd. (Tokyo:4536; Osaka:4536)	Cyclokot cyclosporine A	Severe dry eye disease	Submit MAA	4Q12
Novartis AG (NYSE:NVS; SIX:NOVN)/ Bristol-Myers Squibb Co. (NYSE:BMJ)	Ilaris canakinumab	Systemic juvenile idiopathic arthritis (SJIA)	Submit regulatory applications	2012
Novartis AG (NYSE:NVS; SIX:NOVN)/ Sosei Group Corp. (Tokyo:4565)/ Vectura Group plc (LSE:VEC)	QVA149 indacaterol/ glycopyrronium bromide	COPD	Ph III data; submit regulatory applications ex-U.S.	2012
Novo Nordisk A/S (CSE:NVO; NYSE:NVO)	DegludecPlus insulin degludec/insulin aspart	Type I and II diabetes	Submit NDA in Japan	1H12
NPS Pharmaceuticals Inc. (NASDAQ:NPSP)/ Takeda Pharmaceutical Co. Ltd. (Tokyo:4502)	Natpara (NPSP558)	Hypoparathyroidism	Submit NDA	2012
Omeros Corp. (NASDAQ:OMER)	OMS103HP ketoprofen/ amitriptyline/oxymetazoline	Reduce post-operative pain and improve post-operative joint function and motion following arthroscopic meniscectomy surgery	Ph III data	Mid-2012
Onyx Pharmaceuticals Inc. (NASDAQ:ONXX)/ Bayer AG (Xetra:BAY)	Nexavar sorafenib	Relapsed or refractory non- squamous NSCLC	Ph III data	Early 2012
Pharmaxis Ltd. (ASX:PXS; Pink:PXSLY)	Bronchitol mannitol	Cystic fibrosis (CF)	Submit NDA	1H12
Pozen Inc. (NASDAQ:POZN)	PA32540 aspirin/ omeprazole	Secondary prevention of cardio- and cerebrovascular events in patients at risk for developing aspirin-associated gastric ulcers	Ph III data; submit NDA	2Q12; 3Q12
Progenics Pharmaceuticals Inc. (NASDAQ:PGNX)/ Salix Pharmaceuticals Ltd. (NASDAQ:SLXP)	Oral methylnaltrexone	Opioid-induced constipation (OIC)	Submit NDA	Mid-2012
Prosensa B.V./GlaxoSmithKline plc (LSE:GSK; NYSE:GSK)	PRO051 antisense oligoribonucleotide	Duchenne muscular dystrophy (DMD)	Ph III data	YE12 <i>See next page</i>

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Raptor Pharmaceutical Corp. (NASDAQ:RPTP)	DR Cysteamine	Nephropathic cystinosis	Submit NDA and MAA	1Q12
Regeneron Pharmaceuticals Inc. (NASDAQ:REGN)/ Sanofi (Euronext:SAN; NYSE:SNY)	Zaltrap aflibercept (VEGF Trap)	First-line treatment of metastatic androgen-independent prostate cancer (AIPC)	Final Ph III data	1H12
Regeneron Pharmaceuticals Inc. (NASDAQ:REGN)/ Sanofi (Euronext:SAN; NYSE:SNY)	Zaltrap aflibercept (VEGF Trap)	mCRC	Resubmit BLA	Early 2012
S.L.A. Pharma AG/Ventrus Biosciences Inc. (NASDAQ:VTUS)	Diltiazem (VEN 307)	Anal fissures	Topline Ph III data	May
Sanofi (Euronext:SAN; NYSE:SNY)/ Bayer AG (Xetra:BAY)	Lemtrada alemtuzumab	Multiple sclerosis (MS)	Submit sBLA and MAA	1Q12
Sosei Group Corp. (Tokyo:4565)/ Novartis AG (NYSE:NVS; SIX:NOVN)/ Vectura Group plc (LSE:VEC)	Seebri Breezhaler glycopyrronium bromide	COPD	Additional Ph III data	1H12
Spectrum Pharmaceuticals Inc. (NASDAQ:SPPI)/ Allergan Inc. (NYSE:AGN)	Apaziqouone	Non-invasive bladder cancer	Submit NDA	2012
Stallergenes S.A. (Euronext:GENP)	Oralair sublingual immunotherapy	Grass pollen-induced allergic rhinoconjunctivitis	Submit BLA	2012
Sunesis Pharmaceuticals Inc. (NASDAQ:SNSS)/ Dainippon Sumitomo Pharma Co. Ltd. (Tokyo:4506; Osaka:4506)	Vosaroxin	Relapsed or refractory AML	Interim Ph III data	Mid-2012
Synta Pharmaceuticals Corp. (NASDAQ:SNTA)	Ganetespib	NSCLC	Interim Ph IIb/III data	2Q12
Targacept Inc. (NASDAQ:TRGT)/ AstraZeneca plc (LSE:AZN; NYSE:AZN)	TC-5214	Adjunct treatment for MDD in patients with an inadequate response to antidepressant therapy	Ph III data; submit MAA	1H12; 2H12
Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA)	Cinquin reslizumab	Eosinophilic asthma	Ph III data	4Q12
Theravance Inc. (NASDAQ:THRX)/ GlaxoSmithKline plc (LSE:GSK; NYSE:GSK)	Fluticasone furoate/vilanterol (Relovair)	COPD	Ph III data	January
Threshold Pharmaceuticals Inc. (NASDAQ:THLD)	TH-302	Metastatic and/or advanced soft tissue sarcoma	Interim Ph III data	YE12
TopoTarget A/S (CSE:TOPO)/ Spectrum Pharmaceuticals Inc. (NASDAQ:SPPI)	Belinostat	Relapsed or refractory peripheral T cell lymphoma (PTCL)	Submit NDA	2012
Tranzyme Inc. (NASDAQ:TZYM)/ Norgine B.V.	Ulimorelin	Postoperative ileus (POI)	Ph III ULISES 007 and ULISES 008 data	1H12
Trius Therapeutics Inc. (NASDAQ:TSRX)/ Dong-A Pharmaceutical Co. Ltd. (KSE:000640)/ Bayer AG (Xetra:BAY)	Tedizolid phosphate	Acute bacterial skin and skin structure infection (ABSSSI)	Ph III data	Early 2012
Veloxis Pharmaceuticals A/S (CSE:LCP)	LCP-Tacro tacrolimus	Prevent organ transplant rejection in stable renal transplant recipients	Submit MAA	Mid-2012
Vical Inc. (NASDAQ:VICL)/ AnGes MG Inc. (Tokyo:4563)/ Eczacibasi Group/Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA)	Allovecitin-7	Metastatic melanoma	Ph III data	Mid-2012
Vivus Inc. (NASDAQ:VVUS)	Qnexa phentermine/topiramate	Obesity	Final Ph III data	3Q12
Vivus Inc. (NASDAQ:VVUS)/ Mitsubishi Tanabe Pharma Corp. (Tokyo:4508; Osaka:4508)	Avanafil	Erectile dysfunction (ED)	Submit MAA	1Q12
Wilex AG (Xetra:WL6)	Rencorex girentuximab	Clear cell RCC	Ph III data	4Q12
Zealand Pharma A/S (CSE:ZEAL)/ Sanofi (Euronext:SAN; NYSE:SNY)	Lixisenatide	Type II diabetes	Submit NDA	2Q12
Ziopharm Oncology Inc. (NASDAQ:ZIOP)	Zymafos palifosfamide (ZIO-201)	First-line metastatic soft tissue sarcoma	Ph III PICASSO 3 data	2H12