

Shifting Strategies

The Game of Risk: Mitigation, Funding, World Domination

By Trista Morrison
Editor

The object of the military-themed board game might be total world domination, but in the biotech game of risk, just surviving can be tricky enough.

A decade ago, the biggest risk factor on biotech's table was technical risk: Was the mechanism of action valid? Risk was considered somewhat mitigated once a company hit proof-of-concept, spawning a brief surge in so-called "derisked" specialty pharma business models based on known mechanisms of action.

But today, "everybody is more worried about regulatory and commercial risk than technical risk," said Bryan Roberts, general partner at venture capital firm Venrock. And the problem is that no one – not VCs, not the public markets and not potential partners – wants to take on the heightened risk.

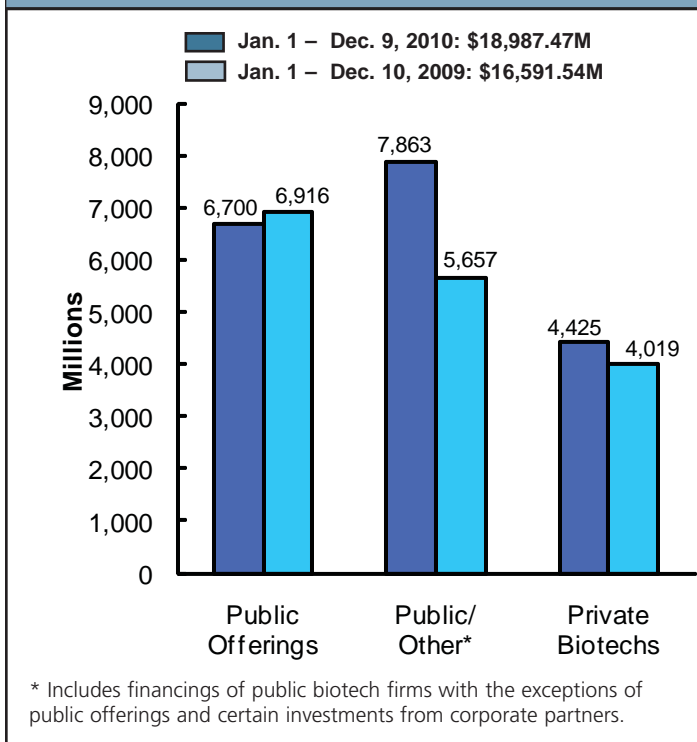
Risk Avoidance

On the venture side, Roberts said investors are moving away from the specialty pharma model, which is no longer seen as the derisked Promised Land it was once thought to be.

"Investors are always desperately seeking a model that can produce returns, but there is an imbalance between when you see new model and the time it takes to build a company," Roberts explained. While VCs were backing specialty pharma business models, regulatory risk was increasing, and pharma partners started to balk at paying for products they had technically derisked and then spun out to biotech, but which still had regulatory and commercial risk.

These days, investors would rather "take technical risk and hope they can sell before they have to take commercial and regulatory risk," Roberts said.

**Money Raised By Biotech
In 2010 Vs. 2009**



But the public markets have not been keen on funding regulatory and commercial risk either, as evidenced by the underwhelming valuations assigned to biotechs recently completing initial public offerings, many of which were far past proof-of-concept and well into Phase III trials. Even companies that have long been public are feeling it: Cadence Pharmaceuticals Inc. saw its stock fall after winning FDA approval of pain reliever Ofirmev (acetaminophen) as

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Under the ASH Radar

MMRC ASH Data Validate Better-Faster-Cheaper Trials

By Arlene Weintraub

BioWorld Insight Contributing Writer

Streamlining the clinical trial process is a top priority for all drug developers, and the Multiple Myeloma Research Consortium (MMRC) seems to have hit upon a strategy that works, if data presented at last week's American Society of Hematology (ASH) annual meeting are any indication.

With hundreds of clinical trials reporting data at ASH, MMRC's presentation didn't get much attention. But the nonprofit's findings should be of interest to industry.

According to data presented, clinical trials conducted within the MMRC opened 60 percent faster than the average oncology trial. Those trials also completed enrollment two months earlier than expected and recruited 25 percent more patients than originally planned.

"Because we opened faster, it allowed our sites to be involved in the study longer, which means we actually accrued more patients than the other sites," says Kathy Giusti, a myeloma patient and CEO of the MMRC.

The MMRC is a sister organization to the Multiple Myeloma Research Foundation, which Giusti and her twin sister started in 1998 shortly after her diagnosis. Giusti, a Harvard University educated pharma executive, believed clinical trials would be more efficient if research sites worked together instead of independently. So she founded MMRC in 2004 with the goal of bringing rival cancer-research groups together to accelerate research. (See *BioWorld Insight*, May 19, 2003.)

Giusti's strategy for clinical trial success is three-pronged. First she recruited 13 of the best-known cancer centers in the country, including the Mayo Clinic, City of Hope National Medical Center, and the Dana Farber Cancer Institute. Researchers from those sites work with MMRC's internal investigators to select the best drug candidates to take forward.

The second part of the process is central contracting.

Rather than the drug company having to establish a separate contract with each research site – an often time-consuming process – MMRC formulates one agreement for all the centers to sign. "We move the central contracting through fairly quickly," Giusti said.

Then MMRC places project managers at each research site. "Those project managers work with us to facilitate IRB [institutional review board], to monitor accruals, and to make sure the data is input in a timely manner," Giusti said.

MMRC's streamlined approach has been vital to companies such as Onyx Pharmaceuticals Inc., of Emeryville, Calif. In a recent trial of Onyx's multiple myeloma drug carfilzomib, MMRC represented only a third of the trial sites, but the consortium ended up recruiting more than 65 percent of the patients who participated.

Carfilzomib, a next-generation proteasome inhibitor that Onyx acquired from Proteolix Inc., showed particular promise in patients refractive to Velcade (bortezomib, Millennium/Takeda), according to detailed Phase IIb data presented at ASH. Onyx plans to file for accelerated approval next year, and the company cited MMRC as critical in arranging clinical and coordinator advisory boards, linking the company with principal investigators, providing access to centralized contracts and providing guidance on site selection, protocol design, and registration pathways. (See *BioWorld Today*, Dec. 8, 2010.)

"Because we opened faster, it allowed our sites to be involved in the study longer, which means we actually accrued more patients than the other sites."

—Kathy Giusti, CEO, Multiple Myeloma Research Consortium

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Revlimid Under Fire

Cancer Drug Causes Cancer: Catastrophe or Minor Blip?

By **Brian Orelli**

BioWorld Insight Contributing Writer

Investors were stunned by data at last week's American Society of Hematology (ASH) annual meeting showing multiple myeloma patients taking Celgene Corp.'s Revlimid (lenalidomide) experienced an increase in secondary malignancies across three Phase III trials. (See *BioWorld Today*, Dec. 7, 2010.)

But the investor reaction may have been a bit overdone. This isn't the first cancer drug to show an increase in the rate of secondary cancers, after all.

"Many drugs can cause therapy-related acute myeloid leukemia," Michelle LeBeau, professor at the University of Chicago, pointed out.

For example, leukemia is a common secondary malignancy associated with the use of alkylating agents and topoisomerase II inhibitors. These drugs treat cancer by damaging the DNA of tumor cells, but they can also damage the DNA of normal tissues such as immature blood cells, causing leukemia.

Additionally, stem cell transplants, which are used to treat multiple myeloma, have been shown to increase the rate of secondary malignancies.

For Revlimid, there are two key issues, as ISI Group analyst Mark Schoenebaum sees it: Is the effect even real? And if it is a bona fide side effect, does it really matter?

As to the first question, the rates of secondary malignancies in patients taking Revlimid were three times higher than the rates for placebo-treated patients, but the actual difference amounted to just a few patients. Additionally, in some of the trials, patients taking placebo were not followed as long, and the shorter observation period could have reduced the apparent rate of secondary malignancies.

The mechanism by which Revlimid might cause secondary malignancies isn't clear either. The drug is known to stimulate B-cells and there was an increase in B-cell derived malignancies in two of the trials. But there was also an increase in solid tumors that weren't clustered into any one tumor type, suggesting there wasn't one mechanism causing them.

Management at Celgene isn't convinced Revlimid is causing the secondary malignancies. "We believe second cancers in myeloma to be a disease, rather than a therapeutic effect," Mohamad Hussein, vice president of medical affairs for hematology, told *BioWorld Insight*.

Even if Revlimid is causing the secondary malignancies, there's the question of whether or not it matters.

While cancer-causing chemotherapy drugs typically just treat a primary tumor, Celgene is positioning Revlimid to be used as a maintenance drug to delay remission.

"There is absolutely no question that giving long durations of Revlimid therapy clearly prolongs the time that

patients stay in myeloma remission versus not giving long durations of Revlimid therapy," Schoenebaum said in a post-ASH conference call.

But he cautioned that the jury is still out on whether delaying a myeloma relapse is better than just treating it when it happens. The side effects have to be taken into account.

The gold standard for answering this question is overall survival. "If

you could prove that people are living longer by prolonging the remission, that would clearly answer the question," said Schoenebaum. "If the patients are living longer, who cares" about the secondary malignancies, he added.

Unfortunately for Celgene, none of the three trials was designed to look at overall survival, and the crossover of patients from the placebo group to the Revlimid group after relapse confounds the analysis.

Until the questions of cause/effect and significance can be answered, the data from ASH are likely to hang over Revlimid's head and Celgene's shares. ■

"If you could prove that people are living longer by prolonging the remission, that would clearly answer the question. If the patients are living longer, who cares [about the secondary malignancies]."

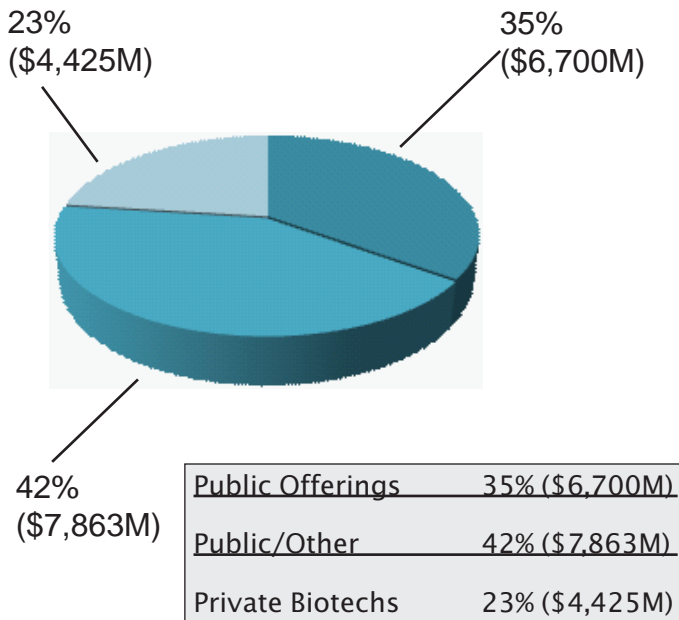
– Mark Schoenebaum, analyst, ISI Group

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Money Raised By Biotech in 2010: Jan. 1 - Dec. 9, 2010



Risk

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investors worried about commercial risks. (See *BioWorld Today*, Nov. 4, 2010.)

Big pharma partners, too, are treading carefully around regulatory and commercial risk. Obesity drugs from Arena Pharmaceuticals Inc. and Orexigen Therapeutics Inc. didn't snag big pharma partnerships until their FDA reviews were well underway. Even drugs that gain FDA approval aren't assured a deal: Savient Pharmaceuticals Inc.'s stock plummeted more than 44 percent after the company failed to find a buyer, despite the fact that its gout drug Krystexxa (pegloticase) is FDA approved, and reimbursement risk appeared to affect Somaxon Pharmaceuticals Inc.'s partnering prospects earlier this year for approved insomnia drug Silenor (doxepin), which eventually landed in the hands of Proctor & Gamble Co. (See *BioWorld Insight*, Nov. 8, 2010.)

While regulatory and commercial risks are significant, Bob More, general partner with Frazier Healthcare Ventures, said the primary risk he hears CEOs and board members fretting over these days is financing risk.

"Financing risk is a reflection of all the other risks," More noted, but it has increased over the last few years to the point that biotechs can face bankruptcy even if they meet their milestones.

Risk Mitigation

So what's a biotech to do?

One classic risk mitigation strategy in many industries is

diversification, but More doesn't think that translates well to biotech. "I don't think increasing the size of your product portfolio decreases risk," he said, adding that it's difficult for biotechs to focus on multiple programs, and if the lead program fails, the company will take a hit regardless of what else it has.

Indeed, biotech's rallying cry seems to have shifted from "multiple-shots-on-goal" to "one-trick-pony" over the past few years, thanks to a shortage of cash and limited exit strategies. Exelixis Inc. is the most recent example: after years of serving as the multiple-shots-on-goal poster child, the biotech announced a plan to sell off its pipeline and focus on cancer drug XL184. (See *BioWorld Insight*, June 15, 2009, and *BioWorld Today*, Dec. 6, 2010.)

More said the secret to getting pharma to shoulder a product's regulatory and commercial risk is to build companies that pharma wants. That's easier said than done, of course, because pharma doesn't always know what it wants and has a tendency to shift priorities. But more than one venture capitalist has suggested that rather than building companies to sell to the highest bidder, the industry should custom build for its only reliable customer: pharma. (See *BioWorld Insight*, Aug. 24, 2009.)

Roberts suggested that biotechs may be able to overcome funding risk by returning to their roots of addressing technical risk. He noted that if a company lowers technical risk by proving a novel approach in an area of high unmet need, the regulatory and commercial risk will also be lower, because the FDA, insurers and patients are more likely to support the product. All of which means pharma will pay for it, Roberts added.

As an example, he pointed to Reata Pharmaceuticals Inc.'s recent \$450 million upfront payment from Abbott for ex-U.S. rights to chronic kidney disease drug bardoxolone. Bardoxolone is an inflammation modulator that targets the Nrf2 transcription factor. Reata proved its mechanism with good Phase II data in the large chronic kidney disease market, which was enough to catch Abbott's eye. (See *BioWorld Today*, Sept. 24, 2010.)

Addressing technical risk can make companies appealing to investors, too, Roberts noted. "Biotech investing is really a picking game," he said. "You can't invest in the basket and hope to do well. You've got to pick well. And I think the core of the picking game is innovation."

Of course the private markets, public markets and marketing partnerships are not the only ways to fund risk. Some biotechs are leveraging their platform technologies in a service provider model to bring in extra funding, while some have focused on government contracts.

Earlier this year, Achaogen Inc. won a first of its kind Biomedical Advanced Research and Development Authority contract to investigate broad-spectrum antibiotic ACHN-490 for both bioterrorism and community infections.

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WEEK IN REVIEW

Financings

Catabasis Pharmaceuticals Inc. received a \$14.5 million second tranche to its series A financing.

Geron Corp. is raising \$100 million in a public stock offering.

Medivir AB raised \$40.6 million in a private placement of stock.

Momenta Pharmaceuticals Inc. raised \$57.4 million in a public stock offering.

Sagent Pharmaceuticals Inc. filed to raise up to \$100 million in an initial public offering.

Thrombogenics Inc. raised \$75 million in its previously announced private placement of stock.

XenoPort Inc. raised \$28.6 million in a public stock offering.

Deals

Dicerna Therapeutics Inc. and **Kyowa Hakko Kirin Co. Ltd.** expanded their \$1.4 billion DsiRNA deal.

Geron Corp. signed a \$37 million deal with **Angiochem Inc.** for a Phase I cancer drug.

Mesoblast Ltd. inked a potential \$1.7 billion stem cell deal with **Cephalon Inc.**

Theratechnologies Inc. partnered Egrifta (tesamorelin) with **Sanofi-Aventis Group SA** for emerging markets.

... And More

BioWorld Today has coverage of the American Society of Hematology annual meeting.

Cell Therapeutics Inc. is appealing the FDA's request for another trial of pixantrone for NHL.

Exelixis Inc. is cutting 65 percent of its staff and focusing on cancer drug XL184.

Human Genome Sciences Inc.'s FDA decision date for Benlysta (belimumab) got bumped to March 10, 2011.

Orexigen Therapeutics Inc.'s Contrave (naltrexone/bupropion) got a shocking thumbs-up from an FDA panel.

WORD ON THE STREET

"The world needs more drugs, but I'm not convinced the world needs more drug companies."

– *Bob More, general partner with Frazier Healthcare Ventures*

"Investors have been skeptical about biosimilar [antibodies], but we believe they will pay more attention to the threat as discussions heat up in 2011."

– *Robyn Karnauskas, analyst with Deutsche Bank Equity Research*

"Pyrrhic victory, if a victory at all."

– *Elemer Piros, analyst with Rodman and Renshaw, on the difficulties that may follow Orexigen Therapeutics Inc.'s positive FDA panel vote on obesity drug Contrave (naltrexone/bupropion)*

WEEK IN WASHINGTON

A survey from PricewaterhouseCoopers and BIOCOM showed most life science executives think FDA relations with industry have improved, but 58 percent said politics has had too much influence on the approval process.

Risk

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Roberts said there will have to be more programs like this to help "defray the huge cost of bringing a product to market." (See *BioWorld Today*, Aug. 31, 2010.)

For all biotechs, More cited credibility as a key to risk mitigation. He advised companies to set reasonable expectations and achieve them, thus building credibility.

"This business does come down to people," More said. "When we lose credibility, everything's out the window." ■

FDA Approvals In November

Company	Drug	Indication
Acrux Ltd.	Axiron	Testosterone deficiency
Amgen Inc.	Xgeva	To prevent skeletal-related events in patients with bone metastases from solid tumors
Avanir Pharmaceuticals Inc.	Nuedexta	Pseudobulbar affect
Cadence Pharmaceuticals Inc.	Ofirmev	To manage mild to moderate pain, moderate to severe pain with adjunctive opioid analgesics and reduction of fever
Cerexa Inc.	Teflaro	Community-acquired bacterial pneumonia
CNS Therapeutics Inc.	Gablofen	Severe spasticity
Eisai Inc.	Halaven	Metastatic breast cancer patients who have received at least two prior chemotherapy regimens for late-stage disease
Novartis AG	Afinitor	Subependymal giant cell astrocytoma
Shire plc	Vyvanse	For attention deficit hyperactivity disorder in adolescents ages 13 to 17
Theratechnologies Inc.	Egrifta	HIV-associated lipodystrophy

Phase I Clinical Trials Update: November 2010

Company (Country)	Product	Description	Indication	Status (Date)#
AUTOIMMUNE				
Neovacs SA (France)	IFNa-Kinoid	Immunotherapy	Lupus	A drug safety monitoring board said it should proceed to a higher dose in an ongoing Phase I/II trial (II/16)
CANCER				
Affimed Therapeutics AG (Germany)	AFM13	TandAb antibody	Hodgkin's lymphoma	First patients have been treated in a Phase I study (II/16)
Alnylam Pharmaceuticals Inc.	ALN-VSP	A systemically delivered RNAi therapeutic	Advanced solid tumors with liver involvement	Phase I data showed it is generally well tolerated, and the study has not yet reached a maximum tolerated dose (II/12)
Astex Therapeutics (UK)	AT7519	Cell-cycle inhibitor that targets cyclin-dependent kinases	Cancer	Clinical data showed it was safe and well tolerated in nine out of 29 patients at four dose levels over 2.5 to 11.1 months and will progress to Phase II studies (II/12)
AVEO Pharmaceuticals Inc.	Tivozanib	An inhibitor of VEGF receptors 1, 2 and 3	Metastatic breast and colorectal cancers	Started patient enrollment in a Phase Ib trial (II/17)
BioAlliance Pharma SA (France)	AMEP biotherapy	Designed to target integrins	Metastatic melanoma	Phase I data showed satisfactory safety and a well-accepted electrotransfer technology (II/24)

Company (Country)	Product	Description	Indication	Status (Date)#
BioCancell Therapeutics Inc. (Israel)	BC-819	A plasmid comprised of the HI9 gene regulatory sequence that drives the expression of Diphtheria Toxin A	Pancreatic cancer	It hit its endpoints in a Phase I/IIa trial and demonstrated excellent safety with no side effects (II/2)
Infinity Pharmaceuticals Inc.	IPI-926	An oral molecule that inhibits a component of the Hedgehog pathway	Metastatic pancreatic cancer	Company is enrolling patients for a Phase Ib/II trial (II/16)
Myrexis Inc.	Azixa	A microtubule destabilizing agent	Glioblastoma	Azixa was well tolerated and showed antitumor activity, with one patient experiencing tumor regression and four having stable disease (II/22)
Oncolytics Biotech Inc. (Canada)	Reolysin	Oncolytic virus product	Solid tumors	Is starting a Phase I trial of Reolysin in combination with cyclophosphamide in pediatric patients (II/19); Phase I data showed it was safe and well tolerated, and one of 16 patients achieved a complete response; the disease control rate was 88% (II/30)
Oncothyreon Inc.	PX-866	A small-molecule PI3K inhibitor	Advanced cancers	Enrolled the first patient in a Phase I/II trial of PX-866 in combination with docetaxel (II/4)
S*Bio Pte Ltd. (Singapore)	SB1317	TG02	Advanced/refractory hematologic malignancies	Entered a Phase I trial (II/23)
SuperGen Inc.	SGI-1776	An orally administered inhibitor of Pim kinases	Solid tumors	Discontinued development due to a failure to identify a safe dose in a Phase I trial (II/12)
Threshold Pharmaceuticals Inc.	TH-302	Hypoxia-activated prodrug	Soft tissue sarcoma	When used with doxorubicin, TH-302 had a 33% response rate in patients who have not received doxorubicin previously in the Phase I/II trial (II/16)
CARDIOVASCULAR				
ChemoCentryx Inc.	CCX168	Oral, small-molecule antagonist designed to target complement 5a	Renal vasculitis	Phase I data showed an excellent safety profile; it produced greater than 90 percent receptor blockage of inflammatory cells in the blood throughout the day (II/11)
Endotis Pharma (France)	Avidin	Antidote for the anticoagulant EP217609	For use in cardiac surgery	Completed a Phase I study showing EP217609 and avidin were well tolerated in the 36 healthy subjects enrolled (II/16)

Company (Country)	Product	Description	Indication	Status (Date)#
Regado Biosciences Inc.	RB006	Pegnivacogin; inhibits Factor IXa	Venous thrombosis	Phase I data demonstrated that a single subcutaneous injection resulted in dose-dependent inhibition of Factor IXa, with effects that persisted longer than one week after injection (II/4)
Renova Therapeutics	AC6	Gene therapy	Congestive heart failure	Started a Phase I trial (II/12)
ReNeuron Group plc (UK)	ReN001	Neural fetal stem cell therapy	Ischemic stroke	The first patient has been treated and discharged in the Phase I trial, and will be monitored for two years (II/17)
CENTRAL NERVOUS SYSTEM				
7TM Pharma A/S (Denmark)	TM38837	CB1 receptor antagonist	Obesity	Completed a Phase I trial (II/12)
CeNeRx BioPharma Inc.	TriRima	A reversible and selective inhibitor of monoamine oxidase A	Treatment-resistant depression	Showed excellent safety in a Phase I study (II/3)
DIABETES				
Arena Pharmaceuticals Inc.	APD597	GPR119 agonist	Type II diabetes	Phase I data showed the drug was well tolerated, had dose-proportional pharmacokinetics, and provided evidence for incretin stimulation (II/8)
DARA BioSciences Inc.	DB959	An oral PPAR delta/gamma agonist	Type II diabetes	Completed a Phase I study showing the safety was comparable to placebo with no reports of moderate, severe or serious adverse events in any subjects (II/5)
INFECTION				
Inhibitex Inc.	INX-189	A nucleotide polymerase inhibitor	Hepatitis C virus	Started a Phase Ib ascending dose trial (II/2)
Inovio Pharmaceuticals Inc.	Pennvax-B	A DNA vaccine	To prevent HIV infection	Achieved high vaccine-induced response rates and strong magnitude of immune responses in a Phase I study (II/18)
Pevion Biotech Ltd. (Switzerland)	PEV7	Vaccine	Vulvovaginal candidiasis	Showed positive preliminary results in a Phase I study that will enroll 48 healthy women (II/12)
MISCELLANEOUS				
Advanced Cell Technology Inc.	hESC therapy	Human embryonic stem cell program	Stargardt's macular dystrophy	FDA lifted the clinical hold and the company will start a Phase I/II trial in the first quarter of next year (II/23)
Biodel Inc.	Linjeta	Human insulin (rDNA origin)	Type I diabetes	Phase I data showed two modified formulations of Linjeta were associated with improved toleration profiles and lower maximal insulin concentrations compared to once-daily Linjeta injection (II/12)
NephRx Corp.	NX001	Kidney growth factor peptide	To prevent delayed renal graft function	Began Phase I trials (II/12)

Company (Country)	Product	Description	Indication	Status (Date)#
Soligenix Inc.	RiVax	A ricin subunit vaccine	Ricin toxin allergies	Completed enrollment in its Phase Ib trial in healthy volunteers (II/3)
Sylentis SA (Spain)	SYL040012	RNAi therapeutic	Glaucoma	Completed a Phase Ia trial (II/23)
XOMA Ltd.	XOMA 052	An antibody to interleukin-1 beta	Uveitis of Behcet's disease	Each of the five patients re-treated with XOMA 052 responded again to treatment and maintained their response for several months (II/II)
YM BioSciences Inc. (Canada)	CYT387	JAK1/JAK2 inhibitor	To reduce spleen size	Data from the initial portion of the Phase I/II trial demonstrated substantial activity in reducing spleen size and controlling constitutional symptoms, while also improving anemia (II/9); Phase I/II trial was expanded to five sites (II/19)

Notes:

Public biotech company stock symbols can be found in the stock report located on the last two pages of this issue.

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Phase II Clinical Trials Update: November 2010

Company (Country)	Product	Description	Indication	Status (Date)#
AUTOIMMUNE				
Anthera Pharmaceuticals Inc.	A-623	An inhibitor of B-cell activating factor	Systemic lupus erythematosus	Company placed a voluntary hold on its Phase IIb study due to cracking in a number of clinical product vials (II/17)
Ardea Biosciences Inc.	RDEA594	A selective URAT1 transporter inhibitor	Gout	Completed enrollment in a Phase IIb trial and showed it reduced uric acid levels to a greater degree than either of the marketed drugs alone when it was used with febuxostat or allopurinol (II/10)
Incyte Corp.	INCB28050	Oral JAK inhibitor	Active rheumatoid arthritis	Final six-month data from its Phase IIa trial showed that all three doses improved on the primary endpoint (II/12)
CANCER				
Access Pharmaceuticals Inc.	ProLindac	Second-generation DACH-platinum cancer drug	Platinum-sensitive ovarian cancer patients	Started a Phase II combination trial that will give ProLindac intravenously with paclitaxel (II/4)
Algeta ASA (Norway)	Alpharadin	Radium-223 chloride	Bone metastases resulting from castration-resistant prostate cancer	Phase I and II data showed it is safe, easy to use and requires no specialized equipment (II/4)
Antisense Pharma GmbH (Germany)	AP 12009	A phosphorothioate oligodeoxynucleotide	Anaplastic astrocytoma and glioblastoma multiforme	Phase IIb data showed it was effective, with long-term survival rates three times higher than those of patients who received standard chemotherapy (II/3)
Celldex Therapeutics Inc.	CDX-110	Rindopepimut	Glioblastoma	Phase II data showed that 66% of patients were progression-free at 8.5 months from a diagnosis of 5.5 months from start of vaccination (II/23)
Cell Therapeutics Inc.	PPX	Paclitaxel poliglumex	High-grade gliomas	Phase II data of PPX combined with temozolomide and radiotherapy showed a high rate of complete and partial response (II/23)
CytRx Corp.	Bafetinib	A dual bcr-abl and lyn kinase inhibitor	Brain tumors	Began a Phase II trial in six to eight patients (II/11)
Genta Inc.	Tesetaxel	An oral, small-molecule taxane	Metastatic breast cancer	Started Phase IIb trials in HER2-negative breast cancer patients with progressive disease (II/9)
Innate Pharma SA (France)	IPH 2101	An anti-KIR monoclonal antibody	Smoldering myeloma	Started patient inclusion in a Phase II trial (II/24)
Plexikon Inc. and Roche AG (Switzerland)	PLX4032	Targets patients with BRAF V600E mutations	Melanoma	Phase II data showed a 52% response rate (II/8)
Provectus Pharmaceuticals Inc.	PV-10	Injectable formulation of Rose Bengal	Metastatic melanoma	Enrolled more than 40 patients in a compassionate-use program, including 10 expanded access patients from the Phase II trial (II/24)

Company (Country)	Product	Description	Indication	Status (Date)#
Sunesis Pharmaceuticals Inc.	Vosaroxin	Replication-dependent DNA-damaging agent	Acute myeloid leukemia	Phase II data showed preliminary leukemia-free survival of 14.4 months and median overall survival of 7.1 months when used in combination with cytarabine (11/11)
CARDIOVASCULAR				
Alexion Pharmaceuticals Inc.	Soliris	Eculizumab	Atypical hemolytic uremic syndrome	Phase II data showed patients who are resistant to plasma therapy met primary and key secondary endpoints (11/23)
BioInvent International AB (Sweden)	BI-204	Monoclonal antibody therapy	Atherosclerotic cardiovascular disease	Ready to begin Phase II studies (11/11)
Cardio3 BioSciences (Belgium)	C-Cure	A stem cell product that derives cells from the patient's own bone marrow and guides them to cardiac lineage cells	Cardiovascular disease	Six-month Phase II data demonstrated significant improvements in a number of measures of patient heart function, with an 18.1% increase in left ventricular ejection fraction over baseline, compared with 3.6% in the control group (11/18)
Inspiration Biopharmaceuticals Inc.	OBI-1	Intravenous recombinant porcine factor VIII product	Hemophilia	Started a Phase II/III study of OBI-1 for hemophilia (11/22)
Resverlogix Corp. (Canada)	RVX-208	Oral small-molecule drug	Cardiovascular disease	Phase II data showed it boosted levels of apolipoprotein A-1, but not at statistically significant levels; the trial did find statistically significant increases in HDL cholesterol, including alpha particles or functional HDL, and statistically significant increases in large HDL particles (11/18)
CENTRAL NERVOUS SYSTEM				
Catalyst Pharmaceutical Partners Inc.	CPP-109	A version of vigabatrin	Cocaine addiction	Started a Phase IIb trial (11/19)
Cytos Biotechnology Ltd. (Switzerland)	NIC002	Nicotine vaccine	Smoking cessation	Phase II trials will commence and include 65 smokers to assess how vaccination against nicotine affects the pharmacokinetics of nicotine during smoking (11/8)
Lithera Inc.	LIPO-102	An injectable combination of salmeterol xinafoate and fluticasone propionate	Fat reduction	Phase IIb data showed it appeared to be well tolerated and produced substantial reductions in abdominal fat (11/4)
NeurAxon Inc.	NXN-188	A dual-action neuronal nitric oxide synthase and 5-HT _{1B} /ID activator	Migraine	Phase II data showed a statistically significant response from four hours through 24 hours, though the trial did not reach the primary endpoint of pain relief at two hours (11/2)

Company (Country)	Product	Description	Indication	Status (Date)#
NeuroDerm Ltd. (Israel)	ND0801	A dermal patch based on a combination with nicotinic actions	Attention deficit disorders/attention deficit hyperactivity disorder	Started a Phase IIa trial in adults (II/10)
Nile Therapeutics Inc.	CD-NP	A chimeric peptide	Acute decompensated heart failure and renal insufficiency	Phase II data showed that multiple doses were well tolerated with favorable drug activity (II/3)
Regado Biosciences Inc.	RB006	Factor IXa inhibitor; peganivacogin	Acute coronary syndrome	Phase IIb data showed it resulted in consistent and near complete inhibition of Factor IX in patients with stable anticoagulation throughout catheterization (II/17)
Sangamo BioSciences Inc.	SB-509	A zinc finger protein transcriptional activator of the VEGF-A gene	Amyotrophic lateral sclerosis	Phase II data demonstrated it was well tolerated and 40% of patients had delayed deterioration of toe and ankle muscle strength, compared to 23% of control patients (II/19)
Synta Pharmaceuticals Corp.	Elesclomol	An oxidative stress inducer	Ovarian, fallopian tube or primary peritoneal cancer	Is starting a Phase II trial of elesclomol in combination with paclitaxel (II/2)
DIABETES				
Halozyme Therapeutics Inc.	Insulin-PH20	Recombinant human insulin with rHuPH20	Type I diabetes	Phase II data showed it achieved its non-inferiority endpoint compared to lispro (II/16)
Oramed Pharmaceuticals Inc. (Israel)	ORMD-0801	Oral insulin formulation	Diabetes	Phase IIb data showed it was safe and tolerable and decreased insulin and C reactive protein levels compared to placebo (II/16)
INFECTION				
Argos Therapeutics Inc.	ARS-004	Arcelis HIV program	HIV	Phase IIa data demonstrated a significant reduction in viral load and a delay in viral rebound kinetics during a 12-week antiretroviral treatment interruption when compared to pre-ART viral loads (II/10)
Bionor Pharma ASA (Norway)	Vacc-4x	HIV vaccine	HIV	Phase IIb data showed a statistically significant reduction in viral load of HIV virus (II/19)
Biotron Ltd. (Australia)	Virion	Targets the Vpu protein	HIV	A study demonstrating that Vpu protein of HIV makes the virus able to avoid the body's immune defenses supports Biotron's drug candidate, which has completed a Phase Ib/IIa efficacy trial (II/30)
Furiex Pharmaceuticals Inc.	JNJ-Q2	Antibacterial drug	Acute bacterial skin and skin structure infections	Phase II data showed positive results for both clinical cure and early response rates (II/12)
Immunitor USA Inc.	V5	Vaccine	Tuberculosis	Completed enrollment for its Phase IIb trial (II/16)

Company (Country)	Product	Description	Indication	Status (Date)#
Intercell AG (Austria)	V710	A vaccine designed to prevent Staphylococcus aureus infections	Staphylococcus aureus infections	Phase II data showed it can elicit a sustained immune response in a relatively immunocompromised patient population (II/19)
Medivir AB (Sweden)	TMC435	A hepatitis C protease inhibitor	Hepatitis C virus	Phase IIb data showed patients treated with TMC435 and standard of care demonstrated high response rates and antiviral efficacy in all patient groups up to and including week four, 12 and 24 (II/19)
Thallion Pharmaceuticals Inc. (Canada) and LFB Biotechnologies SA (France)	Shigamabs	A dual monoclonal antibody targeted to the Stx1 and Stx2 toxins secreted by STEC	Shigatoxin-producing E. coli infections	Started a Phase II trial (II/30)
Vertex Pharmaceuticals Inc.	Telaprevir	Protease inhibitor	Hepatitis C virus	Added an extra treatment arm to the Phase II trial of telaprevir with VX-222 (II/II)
MISCELLANEOUS				
Aastrom Biosciences Inc.	Autologous cell therapy	Therapy that takes bone marrow stem cells from a patient's hip, expanding the cells and reinjecting it back into the patient	Critical limb ischemia	Phase IIb data showed it hit the primary endpoint, but failed to show statistical significance in a key secondary endpoint of amputation-free survival (II/19)
Action Pharma A/S (Denmark)	AP214	Designed to target the melanocortin receptors	Kidney injury in patient undergoing cardiac surgery	Started Phase IIb trials (II/9)
Cephalon Inc.	Reslizumab	An interleukin-5 antibody	Eosinophilic-predominant asthma	Phase II data showed a trend toward improvement in asthma control associated with a significant improvement in lung function and a decrease in airway eosinophilia (II/18)
Circassia Ltd. (UK)	ToleroMune	T-cell vaccine	Dust mite allergies	Phase II data showed it met safety and efficacy endpoints (II/19)
Cytochroma Inc. (Canada)	CTAPI01	A capsule designed to treat vitamin D insufficiency	Vitamin D insufficiency	Phase I/II data showed it achieved gradual increases of 25D3 to target, but also reduced intact parathyroid hormone at 24 hours by a mean of 19% from baseline (II/19)
Mimetogen Pharmaceuticals Inc. (Canada)	MIM-D3	Nerve growth factor mimetic	Dry eye disease	Started a Phase II trial (II/23)
Neurocrine Biosciences Inc.	Elagolix	A nonpeptide gonadotropin-releasing hormone receptor agonist	Endometriosis	Phase II data confirmed improvements in pain, with 86% of subjects reporting it was much improved or very much improved (II/23)

Company (Country)	Product	Description	Indication	Status (Date)#
NeurogesX Inc.	NGX-1998	A liquid formulation of high-concentration capsaicin	Postherpetic neuralgia	Dosed the first patient in a Phase II study (II/3)
NicOx SA (France) and Bausch & Lomb	BOL-303259-X	A nitric oxide-donating prostaglandin F2-alpha analogue	Glaucoma and ocular hypertension	Started a Phase IIb study (II/16)
Raptor Pharmaceutical Corp.	DR Cysteamine	Enteric-coated, microbead formulation of cysteamine bitartrate in gelatin capsules	Huntington's disease	First patient has been dosed in its Phase II trial (II/9)
Reata Pharmaceuticals Inc. and Abbott	Bardoxolone methyl	An antioxidant inflammation modulator	Chronic kidney disease	Phase IIb data suggested it may reduce the stage of CKD and improve estimated glomerular filtration rate and other measures of kidney function in the majority of patients (II/23)
Verona Pharma plc (UK)	RPL554	A long-acting phosphodiesterase-3/4 inhibitor	Asthma	Started a higher-dose Phase II trial (II/30)
Vertex Pharmaceuticals Inc.	VX-770	A CFGR potentiator	Cystic fibrosis	Phase II data showed improvement in lung function and markers of disease (II/19)

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- *And much more!*

Phase III Clinical Trials Update: November 2010

Company (Country)	Product	Description	Indication	Status (Date)#
AUTOIMMUNE				
Acorda Therapeutics Inc.	Ampyra	Dalfampridine	Multiple sclerosis	Phase III data from the second of two pivotal trials demonstrated that a significantly greater proportion of MS patients taking dalfampridine extended-release tablets had a consistent improvement in walking speed compared to those receiving placebo (II/18)
Cipher Pharmaceuticals Inc. (Canada)	CIP-Isotretinoin	Formulation of isotretinoin	Severe, nodular acne	Completed patient enrollment in its Phase III safety study (II/1)
CANCER				
Amgen Inc.	Prolia	Denosumab	Breast cancer with bone metastases	Phase III data showed it was superior to Zometa in preventing skeletal-related events (II/10)
Antismona plc (UK)	ASA404	Tumor vascular disrupting agent	Lung cancer	Interim analysis indicated the Phase III trial should be halted as the drug was unlikely to provide benefit (II/12)
CARDIOVASCULAR				
Amarin Corp. plc	AMR101	Prescription grade omega-3 fatty acid drug; ethyl icosapentate	High triglycerides	Pivotal Phase III trial showed it lowered triglycerides and did not increase low-density lipoprotein cholesterol (II/30)
Amgen Inc.	Nplate	Romiplostim	Chronic immune thrombocytopenia	Results from the first open-label study comparing it to standard of care showed that both the incidence of treatment failure and the need for splenectomy were reduced among Nplate-treated patients (II/12)
Bristol-Myers Squibb Co.	Apixaban	Factor Xa inhibitor	Acute coronary syndrome	Discontinued its Phase III trial due to a clinically important increase in bleeding among patients taking apixaban (II/22)
Omthera Pharmaceuticals Inc.	Epanova	Omega-3 compound	High triglycerides	Omthera submitted an SPA to the FDA for a Phase III study (II/23)
United Therapeutics Corp.	Adcirca	Tadalafil	Pulmonary arterial hypertension	Phase III data showed that 38% of patients achieved a >40 meter improvement in six-minute walk distance from baseline at week 16; the improvement milestone was maintained at 52 weeks in 79% of patients (II/4)
CENTRAL NERVOUS SYSTEM				
Clinical Data Inc.	Vilazodone	A dual-acting serotonergic antidepressant	Major depressive disorder	Phase III data showed the drug's impact on overall sexual function at 40 mg/day was similar to that of placebo (II/23)
Hemispherx Biopharma Inc.	Ampligen	Toll-like receptor 3 modulator	Chronic fatigue syndrome	Phase III data showed a reduced incidence of prolonged QT interval (II/23)

Company (Country)	Product	Description	Indication	Status (Date)#
Intellect Neurosciences Inc. and Johnson & Johnson	Bapineuzumab	A monoclonal antibody based on Intellect's Antiselinin platform technology	Alzheimer's disease	Completed enrollment in Phase III trials (II/23)
MAP Pharmaceuticals Inc.	Levadex	Orally inhaled migraine therapy	Migraine	Phase III data showed it demonstrated low recurrence rates at both 24 hours and 48 hours (II/1)
Nabi Biopharmaceuticals Inc.	NicVAX	A nicotine conjugate vaccine	Nicotine addiction	Completed enrollment of a second Phase III trial (II/10)
Titan Pharmaceuticals Inc.	Probuphine	A subcutaneous implant formulation that uses ProNeura technology to deliver a steady dose of buprenorphine	Opioid addiction	Phase III data showed it had significantly less illicit opioid use and patients experienced fewer symptoms of withdrawal and craving (II/18)
DIABETES				
Arena Pharmaceuticals Inc.	Lorcress	Lorcaserin	Obesity in diabetic patients	Phase III data from two trials showed 47.5% and 47.2% of lorcaserin patients lost more than 5% of their weight, approximately double the 20.3% and 25% for placebo patients (II/10)
Diamyd Medical AB (Sweden)	Diamyd	Antigen-based therapy	Type I diabetes	Enrolled 310 people in a Phase III study (II/11)
INFECTION				
Merck & Co. Inc.	Isentress	Raltegravir; integrase inhibitor	HIV	Phase III data showed it enabled 83.2% of HIV patients to achieve viral suppression when dosed once daily (II/30)
Napo Pharmaceuticals Inc.	CRO-ID	Crofelemer	Chronic diarrhea in HIV/AIDS patients	Phase III data showed that 125 mg twice daily exhibited a statistically significant improvement in terms of reducing watery stools (II/5)
Optimer Pharmaceuticals Inc.	Prugel	Prulifloxacin; an investigational fluoroquinolone prodrug	Infectious diarrhea	Company terminated a research study due to a higher than expected incidence of cutaneous rash during the course of a study on the possible interaction between Prugel and antacids (II/12)
The Medicines Co.	Oritavancin	Antibiotic	Acute bacterial skin and skin structure infection	Reached agreement with the FDA on an SPA for a Phase III program (II/30)
MISCELLANEOUS				
Hyperion Therapeutics Inc.	HPN-100	Glycerol phenylbutyrate	Urea cycle disorders	Met its primary endpoint in a Phase III trial (II/3)
Ironwood Pharmaceuticals Inc.	Linaclotide	Agonist of the guanylate cyclase type-C receptor located on the luminal surface of the intestine	Irritable bowel syndrome with constipation	It met all primary and secondary endpoints, showing a statistically significant improvement compared to placebo in the 26-week Phase III trial (II/3)

Company (Country)	Product	Description	Indication	Status (Date)#
Merck & Co. Inc.	Vytorin	Ezetimibe/simvastatin	Chronic kidney disease	SHARP study results demonstrated that it reduced the incidence of first major vascular events, defined as nonfatal heart attacks or cardiac death, stroke or any revascularization procedure by a statistically significant 16.1% compared to placebo (II/23)
Protalix BioTherapeutics Inc.	Uplyso	Taliglucerase alfa	Gaucher disease	Preliminary Phase III data from the first 15 patients showed they can be safely switched from Cerezyme with maintenance of efficacy achieved over a nine-month period (II/3)
Regeneron Pharmaceuticals Inc.	VEGF Trap-Eye	Aflibercept	Neovascular form of age-related macular degeneration	Phase III data showed it met the primary endpoint compared to the current standard of care, Lucentis (II/23)

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American Association for the Study of Liver Diseases

(The 61st annual meeting was held Oct. 29 - Nov. 2 in Boston.)

Company (Country)	Product	Description	Indication	Status (Date)#
Anadys Pharmaceuticals Inc.	ANA598	Direct-acting antiviral	Hepatitis C virus	Phase II data showed it accelerated the rate of patients achieving undetectable levels of virus compared to placebo (II/2)
Biolex Therapeutics Inc.	Locteron	A controlled-release version of interferon alfa 2b	Flu-like adverse events	Phase IIb data showed a statistically significant reduction in the frequency and severity of flu-like adverse events and reduced use of concomitant medications compared to the Pegintron control (II/2)
Gilead Sciences Inc.	Viread	Tenofovir disoproxil fumarate	Chronic hepatitis B virus infection	Phase III data showed no resistance to Viread emerging over 192 weeks of treatment (II/2)
GlobelImmune Inc.	GI-5005	Therapeutic vaccine	Chronic hepatitis C virus infection	Phase IIb data showed it improved sustained virologic response by 12% in patients with genotype 1 infection who had failed prior treatment with standard of care (II/2)
Idera Pharmaceuticals Inc.	IMO-2125	An immune modulator	Hepatitis C virus	Phase I data showed it was well tolerated at all five dose levels, and induced a broad immune response with dose-dependent increases in serum concentrations of antiviral proteins and activation of cellular immune responses (II/2)
Merck & Co. Inc.	Boceprevir	Protease inhibitor	Hepatitis C virus	Phase III data showed a 66% cure rate when used with standard of care (II/2)
Novartis AG (Switzerland)	Tyzeka	Telbivudine	Hepatitis B virus	Data showed that pregnant women treated in their second to third trimesters benefited from treatment and no transmission of HBV to newborns was detected at 28 weeks post-birth (II/2)
Vertex Pharmaceuticals Inc.	Telaprevir	Protease inhibitor	Hepatitis C virus	Phase III data showed 75% and 72% cure rates when used with standard of care (II/2)

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American College of Rheumatology

(The 74th annual meeting was held Nov. 7 - 11 in Atlanta.)

Company (Country)	Product	Description	Indication	Status (Date)#
Alder Biopharmaceuticals Inc. and Bristol-Myers Squibb Co.	ALD518	Anti-IL6 antibody	Rheumatoid arthritis	Phase IIa data showed it reduced disease activity, induced remission and improved quality of life (II/9)
Bristol-Myers Squibb Co.	Orencia	Abatacept	Rheumatoid arthritis	Phase III data showed similar improvements in RA disease activity with its monthly intravenous drug and a new formulation given in weekly subcutaneous injections, following a single intravenous loading dose (II/9)
ChemoCentryx Inc.	CCX354	Oral, small molecule designed to target the chemokine receptor CXCR1	Rheumatoid arthritis	Phase I data showed an excellent safety profile and that once-daily doses produced greater than 90% receptor coverage on blood leukocytes throughout the day (II/10)
Horizon Pharma Inc.	HZT-501	A single-tablet formulation of ibuprofen and high-dose famotidine	Pain	A long-term safety study showed it was comparable to ibuprofen alone and had a two-fold reduction in the incidence of dyspepsia (II/10)
Horizon Pharma Inc.	Lodotra	A modified-release formulation of prednisone	Rheumatoid arthritis	Pivotal data showed a statistically significant and clinically relevant higher response rate evaluated by ACR response criteria in patients treated with 5 mg of Lodotra compared to placebo, in addition to standard RA therapy, after 12 weeks of treatment (II/10)
Pfizer Inc.	Tasocitinib	Oral JAK inhibitor; CP-690,550	Rheumatoid arthritis	Phase III data showed that 59.8% (low dose) and 65.7% (high dose) of patients achieved ACR20, compared to 26.7% for control (II/9)
Roche AG (Switzerland)	Actemra	Tocilizumab	Rheumatoid arthritis	Phase III data showed that it helped patients with systemic juvenile idiopathic arthritis; 85% on drug and 24% on placebo achieved a 30% improvement (II/9)
UCB SA (Belgium) and Immunomedics Inc.	Epratuzumab	A monoclonal antibody targeting CD22	Active systemic lupus erythematosus	Phase IIb data showed that certain doses were associated with a meaningful and statistically significant reduction in disease activity in adult patients (II/10)
UCB SA (Belgium)	Cimzia	Certolizumab pegol	Rheumatoid arthritis	Phase IIIb data showed it met its primary endpoint with 51.1% of patients achieving ACR20 score vs. 25.9% in the control group (II/10)

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American Heart Association

(The AHA's Scientific Sessions were held Nov. 13-17 in Chicago.)

Company (Country)	Product	Description	Indication	Status (Date)#
Amylin Pharmaceuticals Inc. and Eli Lilly and Co.	Byetta	Exenatide	Type II diabetes	Data from a retrospective study of nearly 375,000 Type II diabetes patients showed higher baseline lipid levels, blood pressure, obesity and evidence of prior cardiovascular disease in Byetta-treated patients than in patients treated with most other therapies (II/18)
Bayer HealthCare AG (Germany) and Johnson & Johnson Pharmaceutical Research & Development LLC	Rivaroxaban	Factor Xa inhibitor	Stroke and embolism	Phase III data showed it was superior in reducing the risk of stroke and non-central nervous system systemic embolism, with a 21% relative risk reduction, when given once daily (II/16)
Celladon Corp. and Targeted Genetics Corp.	Mydicar	Genetically targeted enzyme replacement therapy	Advanced heart failure	Phase II data demonstrated significant improvements in clinical outcomes and key disease markers (II/16)
Cytori Therapeutics Inc.	ADRCs	Adipose tissue-derived regenerative cells	Chronic myocardial ischemia	Demonstrated a statistically significant improvement in cardiac functional capacity at 18 months (II/16)
Diffusion Pharmaceuticals LLC	TSC	Trans Sodium Crocetinate	Peripheral artery disease	Phase I/II data demonstrated that it improved walking ability, delayed onset of leg pain and enhanced overall quality of life (II/16)
Pfizer Inc.	Inspra	Eplerenone	Chronic heart failure	Clinical data showed a 37% statistically significant reduction in risk of cardiovascular death or heart failure hospitalization (II/16)
PolyMedix Inc.	PMX-60056	A synthetic small-molecule designed to reverse heparin and low molecular weight heparin anti-coagulants	For use as an anti-coagulant	Phase Ib/II data showed it restored blood-clotting times to the normal range even before administration of the 10-minute infusion was completed (II/16)
Pozen Inc.	PA32540	A coordinated-delivery tablet of enteric-coated aspirin 325 mg and immediate-release omeprazole 40 mg	Cardiovascular disease	Phase I data showed no ex vivo drug-drug interaction with clopidogrel when administered 10 hours apart in healthy patients (II/16)
Regado Biosciences Inc.	RB006	A selective Factor IXa inhibitor	Cardiovascular disease	Data examining its effects in 28 healthy volunteers who received a single dose of 0.5 mg/kg, 1 mg/kg or 3 mg/kg demonstrated potent, dose-dependent inhibition of thrombin generation vs. placebo (II/16)

Company (Country)	Product	Description	Indication	Status (Date)#
Scios Inc.	Natrecor	Nesiritide	Heart failure	Results of a 7,141-patient study demonstrated no statistically significant difference in dyspnea between Natrecor and placebo (11/16)

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MMRC

Continued from page 2

One of the reasons MMRC is able to accrue so many patients for trials so quickly is that the foundation has amassed a vibrant online community. Although multiple myeloma is a rare cancer – affecting only about 46,000 Americans – they have embraced Giusti’s foundation as a go-to resource for information and support. “We really encourage all the patients to be online with us,” Giusti said. “So at any one time we can

reach out to them to let them know when trials are opening.”

The MMRC is currently running 27 trials with 16 investigational agents. Giusti isn’t aware of many other research partnerships that operate like her group – yet. But the Cystic Fibrosis Foundation has a similar effort underway, she said, and she expects the collaborative approach to eventually catch fire throughout the research community, benefitting both drug developers and patients who want to see new products reach the market faster. ■



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European Organisation for Research and Treatment of Cancer

(The EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics was held Nov. 16-19 in Berlin.)

Company (Country)	Product	Description	Indication	Status (Date)#
Acceleron Pharma Inc.	ACE-041	Angiogenesis inhibitor	End-stage cancer	Phase I data showed clinical efficacy (II/22)
Aeterna Zentaris Inc.	AEZS-108	A targeted cytotoxic drug in which doxorubicin is linked to D-Lys(6)-luteinizing hormone releasing hormone	Endometrial cancer	Phase II data showed two complete responses, 10 partial responses and 17 cases of stable disease; the drug was well tolerated (II/19)
AVEO Pharmaceuticals Inc.	Tivozanib	An inhibitor of VEGF receptors 1, 2 and 3	Advanced gastrointestinal cancers	A Phase Ib trial of tivozanib in combination with FOLFOX6 showed partial responses in six of 17 patients, and stable disease in another eight patients (II/19)
Cerulean Pharma Inc.	CRLX101	First-in-class nanoparticle	Cancer	Phase I data showed that five advanced cancer patients who had previously relapsed and progressed on multiple therapies were stable for more than six months (II/19)
Curis Inc.	CUDC-101	A multitargeted inhibitor of HDAC, EGFR and HER2	Advanced cancer	Phase I data showed it was well tolerated and showed evidence of biological activity (II/19)
Exelixis Inc.	XL184	An inhibitor of tumor growth, metastasis and angiogenesis that targets MET and VEGFR2	Metastatic castration-resistant prostate cancer	Interim data showed 19 of 20 patients achieved complete or partial resolution of metastatic lesions on bone scan at 12 weeks (II/19)
ImmunoGen Inc.	IMGN388	Targeted anticancer compound	Solid tumors	Data from the first trial showed it was well tolerated at doses up to and including 130 mg/m ² (II/22)
MethylGene Inc. (Canada)	MGCD265	An oral multi-targeted receptor tyrosine kinase inhibitor	Solid tumor	When it was used with docetaxel, four non-small-cell lung cancer patients experienced stable disease for eight to 13 months; in the erlotinib arm, one gastric cancer patients was stable for at least 11 cycles (II/19)
Oncothyreon Inc.	PX-866	An irreversible small-molecule phosphatidylinositol-3-kinase inhibitor	Advanced solid tumors	Phase I data showed that eight of 19 evaluable patients stabilized as their best response; the compound was well tolerated (II/19)
Oxigene Inc.	Zybrestat	Fosbretabulin tromethamine, or CA4P	Cancer	Phase II data showed that the median time to progression for patients receiving zybrestat plus bevacizumab and chemotherapy was 9.5 months (II/22)

Company (Country)	Product	Description	Indication	Status (Date)#
Pfizer Inc.	PF-02341066	Oral anaplastic lymphoma kinase inhibitor	ALK-positive advanced non-small-cell lung cancer	Phase I data indicated that most patients respond to treatment by 12 weeks (II/19)

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Non-U.S. Clinical Trials & Regulatory Actions: Nov. 2010

Company (Country)	Product	Description	Indication	Status (Date)#
CANCER				
Astex Therapeutics (UK)	AT9283	Oncogenic kinase inhibitor	Multiple myeloma	Started Phase II trials in Canada (II/5)
Cell Therapeutics Inc.	Pixuvri	Pixantrone dimaleate	Non-Hodgkin's lymphoma	Submitted a marketing authorization application to the EMA for Pixuvri (II/2); MAA was validated and accepted for review by the EMA (II/19)
Celsion Corp.	ThermoDox	A heat-activated liposomal encapsulation of doxorubicin	Hepatocellular carcinoma	Received a positive opinion from the EMA's Committee for Orphan Medicinal Products regarding orphan drug designation (II/12)
Incuron LLC (joint venture between Cleveland BioLabs Inc. and Bioprocess Capital Ventures)	CBLC102	Quinacrine	Liver tumors	Dosed the first patient in a Phase Ib trial in the Russian Federation (II/2)
Progenics Pharmaceuticals Inc. and Ono Pharmaceutical Co. Ltd. (Japan)	ONO-3849	Subcutaneous methylnaltrexone; Relistor in the U.S.	Opioid-induced constipation in cancer patients	Started Phase II testing in Japan (II/17)
PharmaMar SA (subsidiary of Grupo Zeltia SA; Spain)	PMO1183	Marine-derived compound	Solid tumors	Phase I data showed it was safe and well tolerated, and exhibited antitumor activity in different tumor types, and determined a recommended dose for Phase II trials (II/29)
Roche AG (Switzerland)	MabThera	Rituximab	Follicular lymphoma	European Commission approved its use as a maintenance treatment for people who have responded to initial induction therapy (II/1)
CARDIOVASCULAR				
Ligand Pharmaceuticals Inc. and GlaxoSmithKline plc (UK)	Revolade	Eltrombopag; TPO receptor agonist	Chronic idiopathic thrombocytopenic purpura	Granted approval in Japan (II/3)
Pharming Group NV (the Netherlands) and Swedish Orphan Biovitrum AB (Sweden)	Ruconest	A recombinant C1 inhibitor	Hereditary angioedema	European Commission granted approval (II/3)

Company (Country)	Product	Description	Indication	Status (Date)#
INFECTION				
Medicago Inc.	Vaccine	H5N1 avian influenza vaccine based on its virus-like particle technology	Influenza	Received clearance from Health Canada to start a Phase II study (II/2)
MISCELLANEOUS				
Apricus Biosciences Inc.	Vitaro	Topically applied treatment that incorporates alprostadil	Erectile dysfunction	Health Canada granted marketing approval for Vitara as a first-line therapy (II/16)
Nuvo Research Inc. (Canada)	WF10	Designed to work by targeting the macrophage to regulate normal immune function	Allergic rhinitis	Met its primary endpoint in a Phase II trial carried out in Leipzig, Germany (II/10)
Protalix BioTherapeutics Inc. (Israel) and Pfizer Inc.	Taliglucerase alfa	A plant-cell expressed form of glucocerebrosidase	Gaucher's disease	Submitted an MAA to the EMA (II/30)
PTC Therapeutics Inc.	Ataluren	An oral small molecule	Nonsense mutation cystic fibrosis	Phase IIa data from a trial in Belgium and France showed it improved production and function of cystic fibrosis transmembrane conductance regulator, and it was safe and well tolerated (II/16)
Santarus Inc.	Budesonide	MMX 9 mg	Ulcerative colitis	An eight-week European study showed the 9 mg arm was superior to placebo (II/9)
Synageva BioPharma Corp.	SBC-102	Recombinant human lysosomal acid lipase; an enzyme replacement therapy	Lysosomal acid lipase deficiency	Received orphan product designation from the EMA (II/10)
Talecris Biotherapeutics Holdings Corp.	Prolastin-C; AIPi	Alphal-proteinase inhibitor	Emphysema	It reduced lung tissue loss in a three-year Danish-Dutch study of 56 patients and a 24-30-month study of 77 patients (II/16)
Notes:				
CHMP = Committee for Medicinal Products for Human Use; EMA = European Medicines Agency; MAA = Marketing authorization application; MRP = Mutual Recognition Procedure.				
Public biotech company stock symbols can be found in the stock report located on the last two pages of this issue.				
# The date indicated refers to the <i>BioWorld Today</i> issue in which the news item can be found.				


FDA Submissions, Approvals & Other Actions: Nov. 2010

Company (Country)	Product	Description	Indication	Status (Date)#
AUTOIMMUNE				
Human Genome Sciences Inc.	Benlysta	Belimumab	Systemic lupus erythematosus	FDA panel voted in favor of approval (11/17)
CANCER				
Adventrx Pharmaceuticals Inc.	Exelbine	Vinorelbine injectable meulsion; ANX-530	Non-small-cell lung cancer	Submitted an NDA (11/4)
Amgen Inc.	Xgeva	A RANK ligand inhibitor; denosumab	To prevent skeletal-related events in patients with bone metastases from solid tumors	The FDA approved denosumab 120 mg as a therapy to prevent skeletal-related events (11/22)
Eisai Inc. (part of Eisai Co. Ltd.; Japan)	Halaven	Eribulin mesylate	Metastatic breast cancer	FDA approved it for patients who have received at least two prior chemotherapy regimens for late-stage disease (11/16)
EUSA Pharma Inc. (UK)	Erwinase	L-asparaginase derived from Erwinia chrysanthem	Acute lymphoblastic leukemia	Submitted a BLA for use in ALL patients with hypersensitivity to E. coli-derived asparaginase (11/10)
Neogenix Oncology Inc.	NPC-1C	Ensituximab	Pancreatic cancer	FDA granted orphan drug status (11/2)
Semafore Pharmaceuticals Inc.	SF1126	A peptidic prodrug of the PI3K and mTOR inhibitor LY294002	B-cell chronic lymphocytic leukemia	Received orphan drug designation from the FDA (11/10)
Spectrum Pharmaceuticals	Fusilev	Levolumin for injection	Advanced metastatic colorectal cancer	Submitted a complete response to the FDA's complete response letter issued in October 2009 (11/2); FDA accepted it for filing and review (11/30)
CARDIOVASCULAR				
Clinical Data Inc.	PRX-8066	Selective serotonin 2B receptor antagonist	Pulmonary arterial hypertension	FDA granted orphan drug designation (11/2)
Sangart Inc.	MP4CO	Therapy based on the MP4 molecule designed to enhance the perfusion of oxygen-deprived tissues and provide targeted oxygen delivery in the capillaries	Sickle cell disease	Was granted orphan drug designation by the FDA in treating acute painful sickling crises (11/16)
CENTRAL NERVOUS SYSTEM				
Avanir Pharmaceuticals Inc.	Nuedexta	Dextromethorphan hydrobromide and quinidine sulfate	Pseudobulbar affect	FDA granted approval (11/2)

Company (Country)	Product	Description	Indication	Status (Date)#
Cadence Pharmaceuticals Inc.	Ofirmev	Formerly Acetavance; an intravenous formulation of acetaminophen	Pain and fever	FDA approved it to manage mild to moderate pain, moderate to severe pain with adjunctive opioid analgesics and reduction of fever (11/4)
CNS Therapeutics Inc.	Gablofen	Baclofen injection	Severe spasticity	FDA approved Gablofen (11/24)
NuPathe Inc.	Zelrix	A single-use, transdermal sumatriptan patch	Migraine	Submitted an NDA for Zelrix (11/2)
Shire plc (Ireland)	Vyvanse	Lisdexamfetamine dimesylate	Attention deficit hyperactivity disorder	FDA approved Vyvanse for attention deficit hyperactivity disorder in adolescents ages 13 to 17 (11/16)
Vivus Inc.	Qnexa	Phentermine/topiramate	Obesity	FDA issued a complete response letter, requesting a detailed assessment of the teratogenic potential and evidence that it does not increase risk for major adverse cardiovascular events (11/1)
Xanodyne Pharmaceuticals Inc.	Darvon, Darvon-N and Darvocet	Propoxyphene, propoxyphene napsylate and propoxyphene and acetaminophen	Pain	Company voluntarily withdrew from the market the opioid painkillers due to cardiovascular safety concerns, following concerns raised by the FDA last year (11/22)
INFECTION				
Cerexa Inc. and parent company Forest Laboratories Inc.	Teflaro	Ceftaroline fosamil; a broad-spectrum bactericidal cephalosporin	Community-acquired bacterial pneumonia	FDA approved Teflaro (11/2)
Emergent BioSolutions Inc.	AVP-21D9	Monoclonal antibody	Anthrax	Was granted orphan drug designation by the FDA (11/5)
Gilead Sciences Inc.	Truvada	Emtricitabine and tenofovir disoproxil fumarate	HIV	Submitted an NDA to market a single combination pill of Truvada plus Tibotec Pharmaceuticals Ltd.'s TMC278, after Phase III data showed it cut the risk of infection by 44% (11/24)
Theratechnologies Inc.	Egrifta	Tesamorelin	HIV-associated lipodystrophy	FDA approved Egrifta (11/12)
Vertex Pharmaceuticals Inc.	Telaprevir	Protease inhibitor	Hepatitis C virus	Vertex completed its rolling NDA submission (11/24)
MISCELLANEOUS				
Acrux Ltd. (Australia) and Eli Lilly and Co.	Axiron	Testosterone topical solution CIII	Testosterone deficiency	FDA approved Axiron (11/29)
Discovery Laboratories Inc.	KL4	KL4 surfactant	Cystic fibrosis	FDA granted orphan drug designation (11/2)
Novartis AG (Switzerland)	Afinitor	Everolimus tablets	Subependymal giant cell astrocytoma	Received FDA approval (11/2)

Company (Country)	Product	Description	Indication	Status (Date)#
XenoPort Inc. and GlaxoSmithKline plc (UK)	Horizant	Gabapentin enacarbil	Restless legs syndrome	FDA accepted for review GSK's response to the February complete response letter (11/9)
<p>Notes: BLA = Biologics license application; CMA = Continuous marketing application; FDA = Food and Drug Administration; IND = Investigational new drug application; NDA = New drug application; PDUFA = Prescription Drug User Fee Act; SPA = Special protocol assessment. Public biotech company stock symbols can be found in the stock report located on the last two pages of this issue. # The date indicated refers to the <i>BioWorld Today</i> issue in which the news item can be found.</p>				

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The Week's Biggest Gainers and Losers

10 BIGGEST U.S. WINNERS FOR THE WEEK

(By Percent)		(By Dollars)	
EpiCept	162.16	ONYX Pharma	3.88
Orexigen Therap	74.84	Orexigen Therap	3.60
Vivus	36.68	Genomic Health	2.81
Cytokinetics	34.40	Vivus	2.52
Lexicon Pharma	26.52	Targacept	2.13
Cypress Biosciences	21.13	Pharmasset	1.67
Alexza Pharma	21.02	Emergent BioSol	1.26
GTC Biotherap	20.23	Osiris Therap	1.25
Cardiome Pharma	19.65	MannKind	1.17
Osiris Therapeutics	18.68	Myriad Genetics	1.16

10 BIGGEST U.S. LOSERS FOR THE WEEK

(By Percent)		(By Dollars)	
Molecular Insite	-67.66	Celgene	-3.13
EntreMed	-22.17	Cephalon	-2.69
Accentia Biopharma	-20.45	Alimera Sci	-1.62
AVAX Technologies	-20.00	Human Gen Sci	-1.59
Geron	-18.97	EntreMed	-1.55
Aastrom Biosci	-17.71	Dendreon	-1.28
Advanced Life Sci	-16.00	Geron	-1.14
Pharmos	-14.55	Genzyme	-1.09
Alimera Sciences	-13.60	Momenta Pharma	-1.02
Access Pharma	-13.10	Biogen Idec	-0.70

BioWorld Stock Report For Public Biotechnology Companies

Company	Symbol	Close 12/3	Close 12/10	%Change		Vol (000)
				WK	YTD	
3S Bio	SSRX	15.02	15.3	1.86	11.76	955
Aastrom Biosci	ASTM	2.88	2.37	-17.71	670.73	17845
Acadia Pharma	ACAD	0.74	0.7001	-5.39	-46.96	891
Accentia Biopharma	ABPI	0.88	0.7	-20.45	133.33	822
Access Pharma	ACCP	2.9	2.52	-13.10	-23.40	719
Achillion	ACHN	2.75	2.87	4.36	-7.72	573
Acorda Therap	ACOR	26.4	27.38	3.71	8.65	2496
Acusphere	ACUS	0.073	0.07	-4.11	-6.67	370
Adamis	ADMP	0.225	0.225	0.00	-29.69	457
Adolor	ADLR	1.19	1.18	-0.84	-19.18	704
Advanced Life Sci	ADLS	0.025	0.021	-16.00	-87.65	8873
AEterna Zentaris	AEZS	1.54	1.56	1.30	93.33	14717
Affymax	AFFY	6.22	6.06	-2.57	-75.51	3847
Affymetrix	AFFX	4.36	4.42	1.38	-24.32	1995
Albany Molecular	AMRI	5.05	5.58	10.50	-38.55	476
Alexion Pharma	ALXN	76	76.24	0.32	56.17	4688
Alexza Pharma	ALXA	0.9007	1.09	21.02	-54.58	7179
Alimera Sciences	ALIM	11.91	10.29	-13.60	-6.45	354
Alkermes	ALKS	10.61	11.27	6.22	19.77	5277
Allos Therapeutics	ALTH	3.925	3.98	1.40	-39.51	4252
Alnylam Pharma	ALNY	9.24	9.47	2.49	-46.25	2167
Alseres	ALSE	0.2	0.2	0.00	0.00	4
AMAG Pharma	AMAG	16.23	16.54	1.91	-56.51	1686
Amarin	AMRN	5.54	5.5775	0.68	290.03	13779
Amgen	AMGN	53.73	53.89	0.30	-4.74	25781
Amicus	FOLD	4.03	4.05	0.50	2.02	81
Amylin Pharma	AMLN	13.12	13.79	5.11	-2.82	12226
Anthera Pharma	ANTH	5.25	4.84	-7.81	-30.96	182
Antigenics	AGEN	0.89	0.9127	2.55	42.61	1126
Ardea Biosciences	RDEA	22.31	22.35	0.18	59.64	340
Arena Pharma	ARNA	1.42	1.53	7.75	-56.90	38225
Ariad Pharma	ARIA	4.1	4.43	8.05	94.30	10147
ArQule	ARQL	5.58	5.92	6.09	60.43	985
Array BioPharma	ARRY	3.2	3.28	2.50	16.73	1663
Aryx	ARYX	0.342	0.32	-6.43	-90.03	713
Auxilium Pharma	AUXL	19.8	20.07	1.36	-33.06	2331
Avanir	AVNR	3.97	3.99	0.50	110.00	21292
Avax Tech	AVXT	0.045	0.036	-20.00	-78.82	212
AVEO Pharma	AVEO	15.01	14.86	-1.00	65.29	443
AVI BioPharma	AVII	1.81	1.85	2.21	26.71	4817
Bellus Health	BLUS	0.051	0.054	5.88	-66.25	80
BioCryst Pharma	BCRX	4.82	4.94	2.49	-23.53	806
Biodel	BIOD	1.8	1.68	-6.67	-61.29	2503
Biodelivery Sci	BDSI	2.68	2.78	3.73	-29.26	428
Biogen Idec	BIIB	67	66.3	-1.04	23.93	8957
BioMarin Pharma	BMRN	27.4	27.26	-0.51	44.92	3107
Biomimetic Therap	BMTI	11.42	11.7	2.45	-1.93	362
Bio-path Holdings	BPTH	0.41	0.395	-3.66	-8.14	32
BioSante Pharma	BPAX	1.45	1.49	2.76	2.76	1366
Cadence Pharma	CADX	7.65	7.89	3.14	-18.41	2161
Cardiome	CRME	5.115	6.12	19.65	37.53	4554
Cardiovascular Bio	CVBT	0.335	0.345	2.99	72.50	2200
Catalyst Pharma	CPRX	1.01	0.98	-2.97	55.56	165
Celera Genomics	CRA	5.905	6.17	4.49	-10.58	2049
Celgene	CELG	60.59	57.46	-5.17	3.20	46622
Cell Therapeutics	CTIC	0.38	0.3735	-1.71	-67.24	10350

Company	Symbol	Close 12/3	Close 12/10	%Change		Vol (000)
				WK	YTD	
CellDex Therap	CLDX	4.12	4.23	2.67	-9.42	922
CEL-SCI	CVM	0.78	0.9	15.38	0.00	12349
Cephalon	CEPH	65.915	63.23	-4.07	1.30	5586
Cerus	CERS	2.4	2.18	-9.17	9.55	2922
Chelsea Therap	CHTP	5.42	5.36	-1.11	98.52	1320
Cleveland Biolabs	CBLI	7.04	7.01	-0.43	111.78	698
Columbia Labs	CBRX	1.51	1.76	16.56	62.96	17415
CombiMatrix	CBMX	1.93	1.7501	-9.32	-72.65	162
Compugen	CGEN	3.96	4.03	1.77	-16.91	287
Corcept	CORT	4.09	4.24	3.67	52.52	1872
CorMedix	CRMD	1.23	1.42	15.45	-52.67	65
Cornerstone Therap	CRTX	5.76	5.96	3.47	-2.30	163
Cortex Pharma	CORX	0.18	0.1802	0.11	80.20	232
Crucell	CRXL	31.83	31.51	-1.01	56.14	391
Cubist Pharma	CBST	21.54	21.69	0.70	14.34	3518
Curis	CRIS	1.68	1.89	12.50	-41.85	2021
Cypress Biosci	CYPB	4.07	4.93	21.13	-14.56	5471
Cytokinetics	CYTK	2.18	2.93	34.40	0.69	4594
CytRx	CYTR	1.05	1.05	0.00	-6.25	1955
Dara Biosciences	DARA	2.41	2.15	-10.79	-69.55	179
Dendreon	DNDN	38.93	37.65	-3.29	43.26	7280
DepoMed	DEPO	5.47	5.52	0.91	64.78	2364
DiaDexus	DDXS	0.25	0.27	8.00	-44.90	769
Discovery Labs	DSCO	0.1768	0.171	-3.28	-72.79	9493
DURECT	DRRX	2.91	3.17	8.93	28.34	1737
Dusa Pharma	DUSA	2.45	2.49	1.63	60.65	120
Dyax	DYAX	2.19	2.18	-0.46	-35.69	1508
Dynavax	DVAX	1.99	2.3	15.58	61.97	6639
Emergent BioSol	EBS	18.49	19.75	6.81	45.33	772
Emisphere Tech	EMIS	2.15	2.15	0.00	102.83	224
Entremed	ENMD	6.99	5.44	-22.17	-38.18	889
Enzo Biochem	ENZ	4.7	4.84	2.98	-10.04	631
Enzon Pharma	ENZN	11.27	11.44	1.51	8.64	970
EpiCept	EPCT	0.37	0.97	162.16	-44.25	5345
Exelixis	EXEL	5.9	6.64	12.54	-9.91	10483
Flamel Tech	FLML	7.01	6.85	-2.28	-7.43	175
Forest Labs	FRX	32.31	32.68	1.15	1.78	6684
Generex Biotech	GNBT	0.293	0.306	4.44	-42.26	5492
Genomic Health	GHDX	19.95	22.76	14.09	16.36	1307
Genoptix	GDXD	17.09	18.2	6.50	-48.78	1114
Gen-Probe	GPRO	53.75	54.72	1.80	27.49	1127
GenVec	GNVC	0.4625	0.4602	-0.50	-61.65	2797
Genzyme	GENZ	70.91	69.82	-1.54	42.46	16938
Geron	GERN	6.01	4.87	-18.97	-12.25	38005
Gilead Sciences	GILD	37.25	37.61	0.97	-13.08	38806
GTC Biotherap	GTCB	0.2911	0.35	20.23	-53.33	55
GTx	GTXI	2.82	2.64	-6.38	-37.14	428
Harbor Biosci	HRBR	0.14	0.136	-2.86	-73.33	494
Harvard Bio	HBIO	4.05	3.92	-3.21	9.80	123
Human Genome	HGSI	25.6	24.01	-6.21	-21.48	18382
Idenix Pharma	IDIX	4.04	4.7	16.34	118.60	835
Idera Pharma	IDRA	2.52	2.44	-3.17	-52.80	228
Immucor	BLUD	18.47	19.52	5.68	-3.56	2057
ImmunoGen	IMGN	8.34	8.7	4.32	10.69	2453
Immunomedics	IMMU	3.35	3.48	3.88	8.41	2359
Incyte	INCY	15.65	15.51	-0.89	70.25	7742

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Company	Symbol	Close 12/3	Close 12/10	%Change WK	%Change YTD	Vol (000)
Infinity Pharma	INFI	6.27	5.88	-6.22	-4.85	232
Inhibitex	INHX	2.75	3	9.09	226.09	2440
Insmad	INSM	0.645	0.5949	-7.77	-22.74	4344
Inspire Pharma	ISPH	6.99	7.1	1.57	28.62	1691
InterMune	ITMN	12.74	13.82	8.48	5.98	2828
Ironwood Pharma	IRWD	10.88	10.84	-0.37	-6.95	1001
ISIS Pharma	ISIS	9.52	9.63	1.16	-13.32	2356
ISTA Pharma	ISTA	4.41	4.47	1.36	-1.97	382
Keryx Biopharma	KERX	4.96	4.89	-1.41	95.60	9419
La Jolla Pharma	LJPC	0.026	0.0263	1.15	-84.25	1108
Labopharm	DDSS	0.9695	0.94	-3.04	-54.81	1154
Lexicon	LXRX	1.32	1.67	26.52	-1.76	7997
Ligand Pharma	LGND	8.5	8.45	-0.59	289.40	445
MannKind	MNKD	6.34	7.51	18.45	-14.27	12009
Map Pharma	MAPP	14.5	14.53	0.21	52.47	241
MDRINA	MRNA	1.668	1.589	-4.74	96.17	345
Maxygen	MAXY	6.77	6.8	0.44	11.66	1040
Metabolix Inc.	MBLX	10.88	11.52	5.88	4.25	1352
Micromet	MITI	7.53	7.65	1.59	14.86	2929
Molecular Insight	MIPI	0.773	0.25	-67.66	-88.89	4863
Momenta Pharma	MNTA	15.72	14.7	-6.49	16.67	6231
Myrexia	MYRX	3.76	3.84	2.13	-23.66	318
Myriad Genetics	MYGN	21.66	22.82	5.36	-12.53	3906
Nabi Biopharma	NABI	5.24	5.72	9.16	16.73	1180
Nanogen	NGEN	0.01	0.0101	1.00	-57.02	617
Nektar Therap	NKTR	13.3	14.06	5.71	50.86	2160
NeoPharma	NEOL	0.26	0.255	-1.92	-12.07	75
Neurocrine Biosci	NBIX	7.91	7.94	0.38	191.91	1358
NeurogesX	NGSX	5.65	6.4	13.27	-16.99	217
Northwest Biothera	NWBO	0.71	0.68	-4.23	-13.92	597
NovaBay	NBY	1.77	1.839	3.90	-10.73	184
Novavax	NVAX	2.24	2.34	4.46	-12.03	2166
NPS Pharma	NPSX	6.325	7.07	11.78	107.94	1677
Omeros	OMER	8.18	8	-2.20	13.96	204
OncoGenex Pharma	OGXI	16.04	16.04	0.00	-28.01	152
Oncothyreon	ONTY	3.38	3.23	-4.44	-40.07	599
Onyx Pharma	ONXX	29.37	33.25	13.21	13.33	7422
Opko Health	OPK	3.11	3.58	15.11	95.63	2509
Optimer Pharma	OPTR	9.8	10.18	3.88	-9.67	1587
OraSure Tech	OSUR	5.3	5.22	-1.51	2.76	391
Ore Pharma	ORXE	0.349	0.339	-2.87	-15.25	46
Orexigen	OREX	4.81	8.41	74.84	13.04	47293
Osiris Thera	OSIR	6.69	7.94	18.68	11.20	568
Osteotech	OSTE	6.5	6.5	0.00	103.13	161
OxIGENE	OXGN	0.202	0.203	0.50	-82.19	5966
Oxis International	OXIS	0.16	0.165	3.13	-17.50	1146
Pain Therapeutics	PTIE	7.92	8.4	6.06	56.72	863
Palatin Tech	PTN	1.05	1.01	-3.81	173.34	632
Panacos Pharma	PANC	0.006	0.006	0.00	-70.00	502
Protein Design	PDLI	5.87	6.04	2.90	-11.95	14381
Peregrine Pharma	PPHM	1.59	1.58	-0.63	-46.62	1526
Pharma Prdt Dev	PPDI	25.88	26.14	1.00	11.52	2572
Pharmacyclics	PCYC	5.78	5.85	1.21	86.31	4048
Pharmasset	VRUS	47.2	48.87	3.54	136.09	1341
Pharmos	PARS	0.11	0.094	-14.55	44.62	115
Poniard Pharma	PARD	0.3702	0.42	13.45	-77.05	1602
Pozen	POZN	6.71	7.12	6.11	19.06	643
Progenics Pharma	PGNX	4.93	4.95	0.41	11.49	490
Qiagen	QGEN	19.08	19.6	2.73	-12.23	5284
QLT Inc.	QLTI	6.31	6.69	6.02	34.88	895
Regeneron Pharma	REGN	29.98	30.2	0.73	24.90	2438
Repligen	RGEN	3.96	3.93	-0.76	-4.38	280
Response Genetics	RGDX	2.32	2.31	-0.43	83.33	34
Rexahn Pharma	RNN	1.08	1.13	4.63	66.18	1855
Rigel Pharma	RIGL	8.26	8.1	-1.94	-14.83	1174
Rosetta Genomics	ROSG	1.03	1.05	1.94	-40.00	267
Rxi Pharma	RXII	3.48	3.7	6.32	-19.21	1253
Sangamo Biosci	SGMO	5.22	5.72	9.58	-3.38	2492
Santarus	SNTS	2.88	3.1	7.64	-32.90	1462
Savient Pharma	SVNT	12.005	11.9	-0.87	-12.56	6615
SciClone Pharma	SCLN	3.79	4.05	6.86	73.82	1526
Seattle Genetics	SGEN	15.87	15.18	-4.35	49.41	4724
Sequenom	SQNM	6.46	6.47	0.15	56.28	9166
SIGA Tech	SIGA	12.7	12.72	0.16	119.31	1088
Somaxon Pharma	SOMX	2.76	2.84	2.90	162.96	6177
Spectrum Pharma	SPPI	4.95	5.6	13.13	26.13	7496
StemCells	STEM	1.11	1.1	-0.90	-12.70	10556
Sucampo Pharma	SCMP	3.6	3.76	4.44	-6.93	142
Sunesis Pharma	SNSS	0.39	0.387	-0.77	-63.83	15565
SuperGen	SUPG	2.66	2.81	5.64	7.25	1697
Synta Pharma	SNTA	4.88	5.39	10.45	6.52	1568
Targacept	TRGT	21.92	24.05	9.72	15.07	419
Targeted Genetics	TGEN	0.39	0.4	2.56	150.00	104

Company	Symbol	Close 12/3	Close 12/10	%Change WK	%Change YTD	Vol (000)
Telik	TELK	0.6899	0.7195	4.29	-8.26	1009
Tengion	TNGN	2.3699	2.35	-0.84	-89.45	154
Theravance	THRX	26.5	27.1	2.26	107.35	1564
Titan Pharma	TTNP	1.2	1.21	0.83	-47.62	222
Transcept Pharma	TSPT	6.57	7.05	7.31	3.68	106
Transgenomic	TBIO	0.61	0.61	0.00	-11.59	420
Trimeris	TRMS	2.46	2.4	-2.44	-8.40	326
Trinity Biotech	TRIB	7.71	8.44	9.47	108.91	477
Trius Therap	TSRX	3.23	3.355	3.87	-29.07	254
Trubion Pharma	TRBN	4.3303	4.3303	0.00	12.48	59
Unigene	UGNE	0.48	0.48	0.00	-33.33	372
United Therap	UTHR	62.47	63.25	1.25	20.13	3102
Vanda Pharma	VNDA	8.18	8.29	1.34	-26.31	730
Vermillion	VRML	5.16	5.57	7.95	-49.23	638
Vertex Pharma	VRTX	33.49	34.13	1.91	-20.35	11011
Vical	VICL	1.81	1.85	2.21	-43.77	2092
ViroPharma	VPHM	15.96	16.89	5.83	101.31	2873
Vivus	VVUS	6.87	9.39	36.68	2.07	39501
XenoPort	XNPT	7.72	7.58	-1.81	-59.14	2354
Zaliscus Inc	ZLCS	1.27	1.34	5.51	0.00	3434
ZymoGenetics	ZGEN	9.76	9.76	0.00	52.74	1270

LONDON STOCK EXCHANGE

Company	Symbol	12/3	12/10	%WK	%YTD	Volume
Antisoma	ASM	6.22	6.35	2.09	-80.76	2867
Ark Therapeutics	AKT	4.5	3.99	-11.33	-71.60	3834
Asterand	ATD	11.76	14.92	26.87	-19.78	1195
Oxford Biomedica	OXB	9.41	8	-14.98	-28.89	2161
Phytopharm	PYM	7.37	7.32	-0.68	-32.47	300
Puricore	PURI	51.05	51.4	0.69	283.58	71
Renovo Group	RNVO	46.29	45	-2.79	55.71	1672
SkyePharma	SKP	33.4	32.97	-1.29	-61.64	42
Vernalis plc	VER	31.75	32.5	2.36	-62.64	129

Note: Prices are denoted in pence.

TORONTO STOCK EXCHANGE

Company	Symbol	12/3	12/10	%WK	%YTD	Volume
Adherex Technol	AHX	0.035	0.03	-14.29	-33.33	220
Allon Therap	NPC	0.38	0.36	-5.26	12.50	406
BELLUS Health	BLU	0.055	0.05	-9.09	-72.22	1290
Bioniche Life Sci	BNC	1.4	1.48	5.71	164.29	966
Cangene	CNJ	3.05	3.1	1.64	-39.22	118
Isotechnika	ISA	0.23	0.24	4.35	45.45	496
Lorus Therap	LOR	1.08	1.08	0.00	1561.54	61
Medicago	MDG	0.43	0.415	-3.49	-38.06	933
MethylGene	MYG	0.175	0.15	-14.29	-46.43	387
Oncolytics Biotech	ONC	5.09	6.41	25.93	133.09	1107
Protox Therap	PRX	0.48	0.54	12.50	-36.47	577
Resverlogix	RVX	2.85	2.51	-11.93	3.72	1033
SemBioSys Gene	SBS	0.08	0.09	12.50	-55.00	1770
Tekmira Pharma	TKM	4.74	4.69	-1.05	404.30	30
Thallion Pharma	TLN	0.12	0.125	4.17	13.64	80
Theratechnologies	TH	5.68	5.46	-3.87	23.25	1182
Wex Pharma	WXI	0.105	0.11	4.76	-33.33	26
YM BioSciences	YM	2	1.84	-8.00	26.90	767

Note: Prices are denoted in Canadian dollars.

NOTES:

Trading volumes for Nasdaq, Amex and NYSE are recorded as the total number of shares traded (in thousands) on a weekly basis (cumulative Monday through Friday); the weekly and YTD % changes are from IPO completion, where applicable.

Average Percent Change Week: +2.97%

Range: -67.66% to +162.16%; Number Of Companies: 216 (does not include LSE or TSX; not market weighted)

Average Percent Change YTD: +13.34%

Range: -90.03% to +670.73%; Number Of Companies: 216 (does not include LSE or TSX; not market weighted)