Boston Area Chapter
ENGINEERING
PHARMACEUTICAL
INNOVATION

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# NEWSLETTER

April 2006, Volume XVI, No. 1

## IN THIS ISSUE



## ISPE Boston Area Chapter Ski Outing Slides to Success

***by Jim Grunwald***

The Chapter Social Program Committee hosted its annual ski outing to Loon Mountain on Friday, 3 March. The participants were treated to a trip which included bus transportation, ski tickets, along with good food and beverages at the après ski function held in the Paul Bunyon Lounge. Due to a late season blast of cold and snow our skiers and snowboarders experienced excellent conditions with no lines. The group of more than 40 attendees had lots of energy on and off the slope, as evidenced by the great turns, funny jokes and even a few bumps and bruises to take home.

Special thanks to the Social Programs Committee for planning this event: Doyle Johnson, Chair, Gene Dennen and Chris Opolski. The Chapter also would like to thank the event sponsors; Automatech, Ultrafiltronics, RDK Engineers and SPEC Process Engineering & Construction who underwrote the bus transportation.

*Concludes on page 11.*

## 2006 Calendar of Events

**ISPE Boston Area Educational Program**
***"Water, water everywhere but nary a drop to drink"***
23 May, Royal Sonesta, Cambridge, MA

**ISPE Boston Area Chapter Annual Golf Tournament**
17 August, Granite Links Golf Club, Quincy, MA

**2006 ISPE Boston Classroom Training and GAMP Americas Forum**
11 - 15 September, Hyatt Regency Cambridge, Cambridge, MA

**ISPE Boston Area Chapter Product Show**
18 October, Gillette Stadium Clubhouse, Foxboro, MA

# President's Message

Dear Boston Area Chapter Members,

How time flies... as I sit here pondering what to write and reflecting on the first half of my term as President, I realize how much more I had intended to do; initiate this, make that better, try some of this, maybe see if there is interest in doing that...

But wait, sitting at the helm of an organization is not about me personally doing things and being involved with every detail of the Chapter's operations, it's about leading the Chapter and insuring its future. Volunteer organizations only exist through effective leadership, and the many efforts that are initiated and developed by its Members. The Boston Area Chapter has a very strong committee structure to deliver products; including educational programs, socials, newsletter, product show, Student Chapters, and relations with our region's life science institutions. Without strong succession planning and volunteers, the Chapter cannot maintain its reputation as an outstanding ISPE Chapter. Please consider joining one of our committees and help perpetuate the great products the Boston Area Chapter delivers to its membership, even if simply an ancillary basis. It's your Chapter, come help make it happen!

Speaking of delivered products, on 30 January, the Educational Program Committee (EPC) held a novel seminar on "Real-Time Quality in Manufacturing and Just-in-Time Validation". It addressed the industry wide challenges of meeting quality requirements while minimizing drag to supply chain operations. With 100 people in attendance it was great success. On 9 March, the EPC hosted a very unique seminar on Nanotechnology entitled: "Size Does Matter" The program addressed future application of nano particles in biotech and pharmaceutical therapies. The future seems to be arriving faster than we can prepare for it.

Stay tuned for up coming educational programs, including: start-up of high purity water systems, project leadership, and emerging bioreactor technologies.

Despite the low accumulations of snow pack this year, the Chapter's Annual Ski Trip to Loon Mountain in New Hampshire was graded with two thumbs up; great day of skiing and fun was had by all. Big thanks to both the Educational Program Committee and the Social Committee for their efforts in producing these programs.

I also am pleased to announce dates for both our Annual Golf Tournament and Product Show. This year's Tournament will be held on Thursday, 17 August 2006, again, at the very popular Granite Links in Quincy, Massachusetts. Our Product Show Team has been hard at work selecting a new venue for 2006. While the Newton Marriott has served us very well, we simply out grew its capacity. The new location, for 2006 only, will be Gillette Stadium Clubhouse in Foxboro, Massachusetts! Save the date for Wednesday, 18 October 2006. New event elements and features will be rolled out over the next few months, check the Web site for our new Product Show Web page.

Gee, I guess we have done quite a bit these past six months….

That's it from the helm.

**Niall Johnson**
President, ISPE Boston Area Chapter

# Consider C/M Partnering Agreements to Improve Value, Quality

***by Kevin Brettmann***

*This article is reprinted from the January 2005 issue of the ISPE Pacific Northwest Chapter Newsletter.*

Seeking greater efficiency, value, and quality in their construction programs, pharmaceutical and biotech companies are increasingly developing strategic alliances with construction managers and translating these into formal written agreements called master agreements.

A master agreement is a contract with a qualified construction manager (CM), which agrees to provide the client with construction management services at one or more sites. In developing this type of construction contract, a CM and client negotiate as much as 90 percent of the general terms and conditions in advance of a specific construction project. Typically a client prequalifies, and develops master services agreements with, several CMs.

When a project arises, the client seeks proposals from this short list. Selection is based on the firm's track record and experience with a given project type, the quality of the proposed team, and experience in the geographic area in question. After selecting one of these companies for the project, the client and CM need only fill in the remaining details regarding the project specifications, and the project will be off and running.

Clients are motivated to develop master agreements by a number of key factors. These include:

- The desire to reduce the number of service providers to a select few who can handle multiple project types in a greater number of locations, enhancing performance consistency.
- Increased risk sharing.
- Shorter project delivery cycles.
- Improved selection process.
- More favorable commercial terms.

## Streamlining and More

A streamlined bid process is the most obvious benefit to the client of a master agreement. A short list of service providers decreases the time the client needs to select a CM for a project and to generate supporting documentation. There are other potential benefits, as well:

- Enhanced commitment at the senior management level. Developed and signed at the executive level of both the client's and CM's organizations, the master agreement formalizes a long-term strategic alliance between the two organizations. A commitment to the mutual benefit of both organizations is driven from the top down.

*Concludes on page 6.*

# Industry News in Brief

***by Janet Tice***

***Industry News in Brief,*** *a regular feature of the Boston Area Chapter Newsletter, presents news items concerning companies in the pharma, biotech, medical device and related fields with an emphasis on companies with a local presence and topics of special interest to our readers.*

## Bristol-Myers Squibb Weighs Devens Site for Biologics Plant

The previously unnamed pharmaceutical firm that is scouting an 85-acre parcel at Devens in central Massachusetts for a $1.1 billion manufacturing plant turns out to be Bristol-Myers Squibb, company spokesman Jeff MacDonald confirmed recently. Based on its discussions with MassDevelopment, the quasi-state agency that is redeveloping the former army base, the company would build a 750,000 square foot facility employing 550 people with an average annual salary of $60K.

The reason for the secrecy surrounding the negotiations between Bristol-Myers and MassDevelopment is that the company also is looking at properties in Rhode Island, New York and Raleigh, North Carolina. According to MacDonald, the company is still considering all its options and has not finalized a timeline for selecting a site but is committed to expanding its biologics business, now centered in Syracuse, New York.

Luring Bristol-Myers to Devens would provide a needed economic engine for the region and the state but, even more importantly, would signal a comeback for manufacturing in Massachusetts, according to business leaders. If Devens wins out, the $1.1 billion investment in the project would be exceeded, in the suburbs, only by the $2 billion Intel poured into the former Digital Equipment manufacturing facility in Hudson over the last eight years.

*(Source: Davis Bushnell, The Boston Globe, 5 February 2006).*

## Idenix, Novartis Seek Approval for Chronic Hepatitis B Treatment

Idenix Pharmaceuticals Inc. and Novartis Pharmaceuticals Corp. have applied to the FDA for approval of a treatment for chronic hepatitis B. The agency has up to 60 days to review the application and decide whether to accept it for further review. The filing marks an important step in the quest to develop treatments for hepatitis, a steady killer especially in developing countries. It also is the latest US advance for Novartis, a unit of Switzerland's Novartis AG, which has been investing heavily in the US biotech industry.

Since 2003, Novartis has put roughly $700 million into Idenix, which specializes in treatments for infectious diseases. Telbivudine, Idenix's daily pill to treat the hepatitis B virus, is closer to FDA approval than any of the firm's other drugs and appears to offer advantages over the standard therapy based on the results of ongoing clinical trials. The hepatitis B virus is one of the prime causes of hepatitis, an inflammation of the liver that affects as many as 1.25 million Americans and can lead to life-threatening conditions such as liver failure, cirrhosis and cancer.

In a related development, Idenix has reported positive results after only four weeks of a 48-week clinical trial of valopicitabine, an experimental drug targeting the hepatitis C virus. The company plans to release more data in the spring and begin a late-stage clinical trial in the second half of the year

*(Source: Ross Kerber, The Boston Globe, 4 January 2006 and Mass High Tech, 16-22 January 2006).*

## UMass Beats MIT and Harvard in Tech Transfer Dollars

UMass made $26.3 million in fiscal year 2004 through licensing agreements. That places it among the top 11 US colleges for technology licensing revenues, according to a recent report by the Association of University Technology Managers. UMass beat MIT, which raised $25.8 million, and the $16.7 million raised by Harvard.

Technology transfer offices patent, market and manage the inventions of academic researchers so that institutions can generate funds for more research. About $19 million of the UMass licensing revenue stemmed from technologies developed at the Massachusetts Biological Laboratory, the Boston-based arm of the university that focuses on public health and develops and manufactures vaccines, while another $4 million came from RNA interference technology, a potential new tool for medical therapies. The University of Massachusetts is seeking $120 million from the state legislature to finance laboratories and other facilities for four of its campuses.

*(Source: The Worcester Business Journal, 12 December 2005).*

## FDA Action Mars Boston Scientific Successful Bid for Guidant

The FDA has criticized Boston Scientific Corp. for "ongoing systemic violations" of quality-control standards and said it would not approve new products from the company until the deficiencies are corrected. The agency issued a warning letter citing the company for failing to report, or not reporting on time, dozens of possible device failures that had the potential for causing deaths or serious injuries. It also said the company had neglected to report two recalls of surgical products that carried short-circuit and fire dangers. The letter was unusually sweeping, addressing "potentially all manufacturing sites, all facilities of Boston Scientific" according to an FDA official.

According to the FDA, the problems cited in the letter involved three US plants that make four products, including the company's popular Taxus stent. It is unclear specifically which products in the Boston Scientific pipeline would be affected by the moratorium, which applies to Class III or major new devices, but could pose a danger to the company's plans to get US approval for its next-generation stent, the Taxus Liberte, which is a major prospect.

The FDA letter was dated January 25, the same day Boston Scientific won an epic takeover battle with Johnson & Johnson to buy Guidant

## Industry News in Brief

*Continued.*

Corp. for $27 billion. Both Boston Scientific and Guidant said that the FDA action would have no effect on the takeover agreement. Guidant, which also is under FDA scrutiny for malfunctioning heart devices, said it was aware of the issues involved in the letter before agreeing to the takeover.

In a follow-up meeting with the FDA on 3 February, Boston Scientific officials committed to "working closely" with the FDA and set an "aggressive timeline" for resolving its quality control problems.
*(Source: William H. Bulkeley and Anna Wilde Mathews, The Wall Street Journal, 27 January 2006 and The Wall Street Journal, 2-4 February 2006).*

### Epix to Cut Staff after FDA Calls for New Trials

Epix Pharmaceuticals Inc. has reported it plans to "reduce substantially" its number of employees because the FDA has provided the company with an "approvable" letter related to the company's novel blood-pool contrast agent, Vasovist. This is the second approvable letter received by the Cambridge company since it filed its New Drug Application for Vasovist in December 2003. The "approvable" designation means the FDA wants the company to provide more convincing data – in this case a re-read of images from previous studies and a new clinical study – before it grants approval for the drug.

The number of job cuts has not yet been disclosed but layoffs and a reduction in research efforts on certain products are expected to begin during first quarter, according to chief executive Michael Astrue. The company currently employs 90.
*(Source: Mass High Tech, 12-18 December 2005).*

### Alnylam Will Take Shot at Flu using RNAi Technology

Alnylam Pharmaceuticals has said it will start development on a treatment for pandemic flu, funded in part by a grant from the US Department of Defense. Alnylam is one of several companies searching for new ways to fight influenza, which is estimated to kill more than 30,000 Americans annually. The flu has become a new focus of interest because bird-borne influenzas currently plaguing Asia could turn into a virulent human form with the potential to create a global pandemic.

The treatment being developed by Alnylam would use the RNA interference (RNAi) technique in which short strands of genetic material are custom-built to shut down flu virus genes. Chief executive John Maraganore said Alnylam's approach marks a significant improvement over current antivirals because the new drug targets a segment of the flu DNA that has been "conserved" or unchanged over generations, enabling it to shut down genes that appear in any new virus that may develop.

According to the Centers for Disease Control, RNAi is a promising approach but administering the drug will be challenging because strands

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## Consider C/M Partnering Agreements to Improve Value, Quality

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- Working with industry leaders. Ideally, master agreements are struck with a select number of highly qualified CMs.

- Selection based on team and approach. Because the master agreement has already outlined most of the terms and conditions of the construction contract, greater emphasis is placed on selection based on the proposed project team—the "A" team—and their approach to the particular project, and less emphasis is placed on the price.

- Single points of contact with partners. The master agreement includes complementary organization charts that match the client's and CM's organizations, identifying the point of contact at each level and location.

In addition to the individual benefits of each of these features, collectively these have the potential to drive higher project performance.

### Avoiding the Pitfalls

To reap all the benefits of a master agreement, a client needs to recognize and avoid the potential pitfalls:

- Assuming the best-qualified team will be assigned to a particular project. One of the key benefits of a master agreement is the assurance that the client will be assigned the "A" team for a particular project. But there are two potential pitfalls in this assumption: the specific expertise of the team, in which individuals listed as team members may not be adequately experienced for the project; or unintentional team scheduling conflicts. The client should guard against these pitfalls by specifying the desired team expertise level in the project RFP.

- Assuming higher performance standards will be met. The master agreement has great potential to drive higher project performance. Nevertheless, general performance criteria, standard industry metrics, and appropriate incentives for quality, safety, cost savings, and schedule should be written into the master agreement and further detailed for each project.

- Failure to incorporate criteria to eliminate poor performer. Similarly, clients should protect themselves by ensuring that the master agreement spells out the nonperformance criteria that will trigger termination of the contract.

### Don't Sign it and Shelve it

Finally, recognize that the alliance requires much more than a written agreement to achieve the intended results. A master agreement is only the beginning of a long-term relationship between the client and CM—so don't sign it and shelve it. Remember that the CM and client share similar goals in developing a master project agreement, including cost effective services, larger project share with the client for the CM, consistent competition with qualified peers, and better alignment with its respective clients' capital plans. Therefore, it is to the client's benefit to maintain the focus on overall performance, provide ongoing feedback, and create effective incentives for superior outcomes.

It is also to the client's long-term benefit to communicate future business goals and capital expense plans. Indeed, the alliance can be much more than a construction contract—it is an opportunity for the client to engage the CM in strategic planning to support the cost effective growth of its capital assets.

### About the Author

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## Industry News in Brief

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of RNA can be fragile. No RNAi drug has yet been approved for any disease and only three are in human tests, including a drug to treat respiratory syncytial virus also being developed by Alnylam.
*(Source: Stephen Heuser, The Boston Globe, 15 December 2005).*

### Cubist Cranks up Staff Levels

Lexington-based Cubist Pharmaceuticals plans to hire 36 more salespeople in response to robust sales and anticipation that the FDA will grant approval for expanded use of Cubicin to treat heart and blood infections. Cubicin is an intravenous antibiotic already approved for treatment of skin infections. The FDA has granted the company's application "priority" status and is scheduled to rule by 24 March. Sales of Cubicin, introduced to the market in late 2004, reached $100 million in June 2005. The company, founded in 1992, will employ approximately 400 when this latest hiring increase is complete.
*(Source: Dyke Hendrickson, Mass High Tech, 28 November - 4 December 2005).*

### Withdrawn Biogen Idec Drug Tysabri to get FDA Review in March

Biogen Idec Inc. and its partner Elan Corp. have announced that a FDA advisory committee is scheduled to review their multiple sclerosis drug Tysabri on March 7. The drug, which was given "fast track" approval in November 2004, was withdrawn from the market just three months later following reports of two cases of progressive multifocal leukoencephalopathy (PML) among patients using the drug. FDA advisors will focus in their meeting on whether neurologists can adequately monitor PML.

In January, Biogen Idec chief executive James Mullen said the company expects to reintroduce the product in the US by midyear. According to recent forecasts by analysts, Tysabri may generate annual sales of $1 billion by 2010. Original estimates, before the safety concerns arose, had been for annual sales of up to $3 billion.
*(Source: The Boston Globe, 24 January 2006).*

### Wyeth Signs Pacts to Expand Biotech Line

Looking to bolster its growing biotech business, Wyeth has reached a pact with Trubion Pharmaceuticals of Seattle to develop and market antibody-like drugs. The arrangement, valued at up to $800 million if certain research milestones are met, gives Wyeth access to leads for drugs to treat cancer and immune-system disorders, while Triburon expects to benefit from Wyeth's capabilities in manufacturing, clinical trials and marketing.

Triburon's drugs are based on proteins that are much smaller than antibodies and include an experimental treatment for rheumatoid arthritis that depletes immune-system cells involved in inflammation. Biotech

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# Regulatory and Legislative Highlights

***by Janet Tice***

*__Regulatory and Legislative Highlights,__ a regular feature of the Boston Area Chapter Newsletter, reviews recent actions by the FDA and other regulatory agencies and governmental bodies, both federal and regional, with the potential to impact the pharma, biotech, and device industries, and related fields.*

## FDA Finds Drugs from "Canadian" Online Pharmacies Not Canadian

The FDA has found that the majority of prescription drugs ordered from web sites believed to be Canadian pharmacies originate from outside Canada based on an inspection of packages ordered by US consumers. The agency looked at packages suspected of containing pharmaceuticals sent from India, Israel, Costa Rica and Vanuatu – four countries the FDA said appeared to be sources of drugs that were ordered from pharmacies alleged to be Canadian in origin.

Out of nearly 4000 parcels examined, almost 1700, or 43 percent, had been ordered from "Canadian" Internet pharmacies and were represented as being of Canadian origin. Of these, 85 percent of the drugs were not manufactured in Canada and, in fact, came from 27 different countries. In addition to having been falsely promoted as being of Canadian origin, many of the drugs were not adequately labeled in English. The agency also sampled some of the drugs and found that 32 of those tested were counterfeit.

The FDA has long warned consumers not to order drugs via the Internet from Canada or other foreign countries but many consumers continue to do so because drugs obtained in this fashion usually cost less than those sold in the US. According to FDA Acting Commissioner Andrew von Eschenbach, "This operation suggests that drugs ordered from so-called Canadian Internet sites are not drugs of known safety and efficacy."

*(Source: Jennifer Corbett Dooren, The Wall Street Journal, 20 December 2005).*

## New FDA Rule May Aid Drug Firms in Liability Suits

A new rule recently issued by the FDA to make drug labels easier to read also preempts state laws that conflict with the agency's stance on drug warnings, potentially aiding manufacturers in some liability lawsuits. FDA officials said the aim of the new rule is to simplify labels that have become complex legal disclaimers cluttered with information not pertinent to the patient or physician.

However, they also included language in the preamble preempting certain state laws, stating that an FDA-approved label "whether … in the old or new format, preempts conflicting or contrary state law, regulations or decisions of a court of law for purposes of product liability litigation." Print advertising that reprints warning information from the drug labels is also protected. The new rule takes effect June 30 and represents the FDA's first overhaul of the onionskin label that accompanies prescription drugs in 25 years.

Some lawmakers and representatives of trial lawyers criticized the new rule as a protection from liability for the drug industry and an attempt on the part of the FDA to confer upon itself authority it does not have. On the other hand, Victor Schwartz of the American Tort Reform Association said the change is less sweeping than opponents fear, simply immunizing companies from claims alleging they failed in their "duty to warn." He said it will not reduce the thousands of Vioxx lawsuits, for example, already filed against Merck; nor will it stop juries from awarding millions in punitive damages to injured Americans since these awards require proof of conscious, flagrant actions by the manufacturer and indifference to patient safety.

*(Source: Diedtra Henderson, The Boston Globe, 19 January 2006).*

## Biosafety Lab in South End Gets Final OK

The federal government gave final approval in early February to Boston University's plan to build a high-security research laboratory in the South End. The long-expected decision from the NIH assures that BU Medical Center will receive $128 million in federal money to help pay for the 195,000-square-foot facility to be built on Albany Street. The building will house a Biosafety Level 4 lab, the target of longstanding opposition, as well as lower-security research facilities. Construction is expected to begin almost immediately with completion slated for 2008.

The lab has drawn opposition from groups of scientists, environmentalists and community activists since it was first proposed three years ago. They have advanced worst-case scenarios in which, through accident or terrorism, an infectious agent would be released, causing an epidemic of illness and even death in surrounding communities. On the other hand, federal records show that over a 30-year period there is no evidence that any virus or bacterium has ever escaped from a Level 4 facility.

The lab has received wide support from top Massachusetts lawmakers Mayor Tom Menino, Governor Mitt Romney and Senator Edward Kennedy. In a statement following the approval announcement, Mayor Menino described the lab, which is expected to produce 1300 construction jobs, 660 permanent positions and generate over $1 billion in research grants over the next 20 years, as a "critical component of Boston's life sciences infrastructure" and promised that the city's health board will "ensure that the new lab adheres to the strictest safety regulations in the country."

*(Source: Stephen Smith, The Boston Globe, 3 February 2006).*

## FDA Says Asthma Drug Labels May Need Changes

The FDA has said it wants stronger warnings and new physician recommendations on three drugs used for long term maintenance of asthma symptoms. The warnings would apply to GlaxoSmithKline PLC's Serevent and Advair and Novartis AG's Foradil and would more clearly state that the drugs might cause severe and sometimes fatal asthma attacks in some patients. Foradil is marketed in the US by Schering-Plough Corp.

## Regulatory and Legislative Highlights

*Continued.*

In response, GlaxoSmithKline said it disagreed with the FDA's request, while Schering-Plough said it would send out a letter to health care professionals describing any changes once the new label is finalized. Since the FDA must negotiate drug-labeling changes with manufacturers, and given Glaxo's opposition, it is unclear when the proposed changes would be made.
*(Source: The Wall Street Journal, 21 November 2005).*

### EU Grants Tentative Approval for Biogeneric Drug

Moving closer to opening its market to generic copies of biotech drugs, Europe recently gave tentative approval to Omnitrope, Novartis AG's bid to duplicate Pfizer's drug, Genotropin. Genotropin, with 2005 sales of $808 million worldwide, is a growth hormone treatment used in children who fail to grow sufficiently and in adults with growth hormone deficiency.

The European Medicines Agency, Europe's equivalent of the FDA, recommended approval of the new drug, stating that Novartis's studies have shown Omnitrope has "comparable quality, safety and efficacy" to Genotropin. If given final OK by the European Commission, the drug could be on the market in Europe later this year.

In the US, Congress and the FDA have not yet decided whether to allow drug companies to market copies of biotech drugs. With traditional "small molecule" drugs which are created using chemical processes considered relatively easy to duplicate, there are clear regulatory rules covering the manufacture of generic copies. These rules do not yet exist for biotech drugs whose makers argue that their products are more complicated to copy because they are large, complex molecules created using living systems.

With several lucrative biotech drugs off-patent and biotech drugs with current annual sales of $18 billion losing patent protection over the next five years, generic drug makers are lining up to produce biogenerics. Sandoz, Novartis's generics unit, says it has several in its pipeline in addition to Omnitrope and other giants, including Barr Laboratories of New York have been pushing for FDA action.
*(Source: Jeanne Whalen, The Wall Street Journal, 28 January 2006 and Stephen Heuser, The Boston Globe, 13 February 2006).*

### Momenta Poised to Enter Market for Biogenerics

Instead of fighting the arrival of biogenerics, at least one local biotech company is welcoming it. Momenta Pharmaceuticals of Cambridge became one of the hottest small biotech stocks in the US last year because of a new technology that analyzes the structure of sugar molecules. The technique could allow the company to create exact copies of an off-patent drug and prove to the FDA that they are identical to the original.

Last August, Momenta filed an application for a generic version of

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## Regulatory and Legislative Highlights

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Lovenox, a blood thinner with annual sales of $2.4 billion. Although Lovenox is a sugar rather than a protein or antibody, it is more complex than anything the FDA has evaluated as a generic, according to Momenta CEO Alan Crane. The company is still waiting to hear from regulators, but Crane said that if the company is successful, it could turn its attention to more complex biogenerics, such as proteins, many of which have never been fully described.
*(Source: Stephen Heuser, The Boston Globe, 13 February 2006).*

## Quick Takes

***by Janet Tice***

Life sciences companies with a local presence have been busy over the last few months in the area of new product development and/or approval. A few of the highlights include:

| Product | Application | Activity |
|---|---|---|
| **AstraZeneca** | | |
| Galida | diabetes | all in late-stage human trials |
| NXY-059 | stroke | |
| Zactima | lung cancer | |
| AZD6140 | arterial thrombosis | |
| AGI-1067 | atherosclerosis | |
| AZD7121 | lung and colorectal cancer | |
| **Bristol-Myers Squibb** | | |
| Orencia | rheumatoid arthritis | FDA approved |
| **Merck** | | |
| RotaTeq | Rotavirus vaccine | FDA approval |
| **Novartis** | | |
| Femara | breast cancer | FDA approved for expanded use |
| Rasilez (SPP100) | hypertension | filing for FDA approval in early 2006 |
| Galvus (LAF237) | diabetes | filing for FDA approval in early 2006 |
| **Vertex** | | |
| VX-950 | hepatitis C | FDA fast track status granted |
| VX-409 | nerve pain | development partnership with GlaxoSmithKline |

### Clinical Trial Registry Data Growing

Drug companies are making more information public regarding clinical trials they are conducting. However some still withhold key details, such as the name of the drug being studied or the main outcome being measured. In a new analysis of a federal registry recently published in the New England Journal of Medicine, Merck & Co. received somewhat better marks than it received in an earlier analysis. In contrast, Pfizer Inc., GlaxoSmithKline PLC, and Novartis AG are lagging.

The registry, www.clinicaltrials.gov, run by the National Library of Medicine, was created in 2004 as part of an overhaul of FDA monitoring. It requires certain types of studies to be listed, such as late-stage trials involving life-threatening illnesses, but did not get wide participation from the drug industry until September 2004, when editors of medical journals said they would no longer publish results of any studies that were not first listed in a public registry.

The idea behind the registry is to make it easier for scientists, regulators, and the public to cross-check what studies are being done on a drug and to get an overview of risks and benefits. The registry includes studies by universities, government and industry, but concerns about openness center on industry. The analysis covers the period from 20 May through 11 October, during which time entries rose to 22,714 from 13,153, spiking around 13 September when the medical journals' new policy took effect.
*(Source: The Boston Globe, 29 December 2005).*

### FDA Panel Backs OTC Sale of Diet Pill

GlaxoSmithKline recently won the support of a US advisory panel to sell its Xenical diet pill without a doctor's prescription. The FDA advisors voted 11 to 3 in favor of allowing over-the-counter access to the drug, known chemically as orlistat, for use by overweight adults for up to six months. Xenical generated $497 million in worldwide sales for Glaxo in 2004.

If the agency ultimately approves the drug, it would be the first prescription weight-loss drug to be approved for sale over the counter at a time when two-thirds of Americans are overweight or obese. In reaching its decision, the advisors overcame FDA staff concerns that patients might misuse the drug, which has been available by prescription in the US since 1999. If approved, the drug would be marketed by Glaxo under the name Alli at half of the current 120-milligram dosage.

Xenical works by blocking about one-third of the fat in food from being digested. The drug also can reduce the absorption of some fat-soluble vitamins and has been linked to kidney stones, gallstone, and hepatitis, according to the FDA. According to an FDA medical expert, "The challenge here is to … make a reasonable risk-benefit assessment of a drug that, if available over the counter, will be used by at least some people for cosmetic weight loss." Although the FDA usually follows the recommendations of its advisory panels, it is not obligated to do so.
*(Source: Shannon Pettypiece and Catherine Larkin, The Boston Globe, 24 January 2006).*

## Ski Outing...

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A big thank you to Superior Controls for sponsoring the trip photography and our après ski function. The Social Programs Committee is planning its next major event, the annual Golf Outing to be held in August 2006.

Should you be interested in volunteering on any ISPE Boston Area Chapter Committee please contact: ispe@camihq.com.

## Industry News in Brief

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giant Genentech and partner Biogen Idec have applied for FDA approval for Rituxan for the same use. Rituxan is an antibody drug that affects the same cells and is already approved for cancer treatment.

In addition, Wyeth recently signed two other biotech deals. One, with Exelixis Inc. of South San Francisco, CA, covers metabolic and liver-disease treatments; another, with Progenics Pharmaceuticals Inc. of Tarrytown, NY, gives Wyeth rights to an experimental drug designed to counteract the side effects of opiate pain killers.
*(Source: Scott Hensley, The Wall Street Journal, 3 January 2006).*

### Alkermes Alcoholism Drug Wins Tentative OK from FDA

A much-anticipated alcoholism drug from Alkermes won conditional approval in the form of an "approvable letter" in December, paving the way for its introduction to the market later this year. The drug, Vivitrol (formerly called Vivitrex), is an injectable form of an oral medication, naltrexone, long prescribed to treat alcoholism. Vivitrol is designed to be administered monthly, by a physician, and treatment is to be accompanied by counseling. Alkermes says the chance for successful therapy is increased using Vivitrol because alcoholics will not be tempted to stop taking their pills.

Vivitrol is delivered through Alkermes' polymer technology. As the spherical polymer dissolves, it releases the medicine contained inside. According to the company, the FDA wants data proving the slow-release version of naltrexone contained in the injectable works similarly to the version delivered in the pills. The company also needs to finalize the drug's label. Oral naltrexone includes a warning for possible liver damage, which may reduce the number of prescriptions doctors write. The company has not said whether the warning was an issue in negotiations over the label.

Alkermes has focused its efforts on finding novel ways to deliver drugs to increase patient compliance. Besides Vivitrol, Alkermes has formed partnerships to create drugs to treat schizophrenia and is working on an insuln inhaler. If approved, Vivitrol would be the first drug that Alkermes has developed on its own to reach the market.
*(Source: Stephen Heuser, The Boston Globe, 29 December 2005 and Suzanne Sataline, The Wall Street Journal, 30 December 2005).*

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## New Members

**Holly J. Battaglia,** Validation Engineer II, Genzyme Corp.
**Richard B. Battaglia,** Validation Engineer II, Genzyme Corp.
**David E. Berardinelli,** Mechanical Operations Manager, A/Z Corporation
**David S. Bricker,** Senior Director, Aseptic Mfg., AstraZeneca
**Peter Canisius, Jr.,** Engineer II, AMEC
**Daniel C. Cole,** Senior Project Manager, Parsons
**Alice Day,** Lonza Biologics Inc.
**Christopher J. Desmarais,** Validation Engineer, Avant Immunotherapeutics Inc.
**Jonathan M. Eisenberg,** Senior Consulting Engineer, Rolf Jensen & Associates
**George M. Ferencik,** Director, Healthcare Div., Columbia Construction Co.
**Thomas B. Fraser,** Project Engineer, Astrazeneca
**Kimberly Groff,** Environmental Engineer, AMEC Biopharmaceuticals
**Abhishek Gupta,** Senior Assoc. QA Validation, Biogen Idec MA Inc.
**Chad B. Harrington,** Project Engineer, Stryker Biotech
**Brian D. Lapietra,** Account Manager, New England Controls
**Milan N. Madani,** Senior Systems Engineer, Wyeth BioPharma
**Gopinath Madhavachari,** Supervisor Controls Valid, Abbott Bioresearch Center
**William T. Mallonee,** Technical Sales, Terracon Corp.
**Dermot A. Murray,** Regional Director - Northeast, Paladiem Technologies, Inc.
**Brendan R. Odonnell,** Process Engineer, Mylan Technologies Inc.
**Won S. Park,** President, GRN Boston North
**Wayne K. Pearson,** President, Castle Hill Technologies
**Brian Seed, Professor,** Massachusetts General Hospital
**Joseph Sheehan,** Engineer, AstraZeneca
**Arthur J. Smith, Jr.,** Process Engineer, Genzyme Corp.
**Adam Sokolnicki,** Process Dev. Engineer, Altus Pharmaceuticals
**Rodman Stull,** Executive Director and General Manager, AstraZeneca
**Foss Tighe,** Systems Dev. Manager, New England Research Institutes