Weekly
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Breaking News and Market Intelligence for the Clinical Trials Industry

Pfizer Warned by FDA for Inadequate Monitoring

Pfizer received a warning letter from the U.S. Food and Drug Administration (FDA) earlier this month, citing the pharmaceutical giant for inadequate clinical trial monitoring in the study of a pediatric drug—violations that led to the overdosing of at least 26 children.

The drug, unnamed in the FDA's letter, is reported to be Geodon, which is used to treat schizophrenia and bipolar disorder. Pfizer is seeking FDA approval for the drug to be used to treat children between the ages of 10 and 17 years.

Last week's warning was the latest in a string of FDA-Pfizer letters regarding violations in the Geodon study.

According to the FDA's letter, Pfizer failed to ensure proper monitoring at several clinical trial sites between 2005 and 2009, which resulted in overdosing of participants for several days—one for as long as 22 days.

Pfizer received its first letter related to the study in 2005, when an FDA investigation revealed "widespread overdosing of study subjects at multiple study sites." Despite efforts by Pfizer to improve the monitoring process, additional overdoses

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Aptium Oncology Launches Myeloma Research Network as IOM Calls for Improvements in Cancer Research

Aptium Oncology, a consulting and management company for cancer centers, is putting together a network of investigators specifically focused on myeloma and related cancers.

The Aptium Oncology Myeloma Consortium (AMyC) is modeled after Aptium's GI Cancer Consortium, a group launched in 2008 to focus on gastrointestinal cancers.

"What we did with the GI Consortium—AGICC—was to pull together a group of investigators who are opinion leaders in GI cancer treatment and who practice at institutions that have robust GI programs already in place and access to a large number of GI cancer patients. We gathered those investigators and institutions together, and we're supplying them with a grant, the purpose of which is to enhance their programs," said Marti McKinley, vice president of clinical research programs for both AGICC and AMyC.

The researchers, who hail from 11 of the country's largest cancer centers, will assist in the development and execution of phase Ib and phase II industry-sponsored trials. The institutions each receive $125,000 over two years to help them build their

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Industry Briefs

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CROs

- **Covance** is closing a testing site in Kalamazoo, Mich., as part of the CRO's ongoing efforts to cut back its preclinical services. The site will be closed by November, and, according to published reports, 63 workers will lose their jobs. Covance's early-stage division has struggled in recent months. Late last summer, the CRO delayed plans to build a $145-million preclinical toxicology testing facility in Virginia, a site that was purchased from Eli Lilly in 2007. In January, the company reported a 6% drop in year-end 2009 revenues for the early-development segment.

- **Almac Group**, an integrated drug development services company based in Craigavon, Northern Ireland, has formed a partnership with Queen's University Belfast aimed at breaking through two bottlenecks in discovery: target validation and identifying novel hits against those targets. They will concentrate their efforts in oncology. The program is being co-funded by Almac Group, Queens University Belfast and Invest Northern Ireland, a regional economic development agency that is part of the Department of Enterprise, Trade and Investment. Target validation work will be carried out at Queen's, and Almac Group will manage the project as well as own the intellectual property. The agreement between the two organizations allows Almac to commercialize output from the program, while Queen's will receive payments when certain milestones are reached based on the commercialization of drugs as they come through the pipeline. Through this agreement, Almac Group has access to the 350 scientists working at Queen's University Belfast's Centre for Cancer Research and Cell Biology.

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Industry Briefs (continued from page 2)

- **United BioSource Corporation** (UBC) partnered with Singapore-based **Clearstate**, a market intelligence firm focused on the healthcare and pharmaceutical industry. Through this partnership, UBC will offer market access, pricing and reimbursement strategies for drug and device manufacturers in the Asia-Pacific region. UBC opened its first office in Asia-Pacific in February. This office—based in Tokyo—will have a staff of 12 by the end of the year, according to UBC CEO Ethan Leder. Leder told CenterWatch earlier this year that the Asia-Pacific region has grown increasingly important to UBC as both regional and worldwide clients have requested increased services there.

- UK-based CRO **Chiltern International** is now a minority shareholder in San Francisco technology company endpoint Clinical, a company that provides integrated response technology (IRT) for clinical trials. The ownership stake comes as part of a strategic partnership the companies have formed to mutually expand each other's services. "The investment means Chiltern and our clients have access to expanded options in the mission critical IRT arena," said Chiltern CEO Glenn Kerkhof. "For endpoint, working closely with a globally recognized full service CRO adds value as they expand their market and continue to strategically grow their operation." Chiltern would not discuss the specific terms of the agreement with endpoint but it is not exclusive. Kerkhof said Chiltern has worked with other IRT providers over the years and will continue to do so.

- Preclinical CRO **Charles River Laboratories** received a Certificate of Good Laboratory Practice (GLP) compliance from the Organization for Economic Cooperation and Development (OECD) for Charles River's Shanghai, China, facility. According to the CRO, this is the first preclinical laboratory in China to receive GLP certification from an OECD member country. The certification designates that the site is in operating compliance with OECD principles of GLP for both toxicology and laboratory services.

- **PRA International** expanded its Asia-Pacific operations into New Zealand, hiring staff there and establishing a legal entity. The New Zealand staff will work closely with PRA's office in Sydney, Australia. New Zealand is a key research location for studies in skin cancer, multiple sclerosis, and asthma, the CRO said. The country is known for high recruitment rates, an efficient regulatory environment and counter-seasonality—which is advantageous to influenza and allergy studies.

Patient Recruitment

- Gay men and lesbians are being excluded from participation in some clinical trials based on their sexual orientation, according to a report in the **New England Journal of Medicine**. The authors of the study conducted exploratory searches on clinicaltrials.gov to find studies that required participants to be heterosexual. According to the report, published in March, studies that have sexual function as an endpoint are most likely to exclude people based on sexual orientation. Fifteen percent of the study listings that used the terms "erectile dysfunction," "couples" and "hypoactive" had exclusionary language. The report went on to say that studies that require participants to be in heterosexual relationships may also exclude non-married or single participants.

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Pfizer

and monitoring violations were uncovered in 2006 and 2007. These problems were identified and reported to the FDA by Pfizer itself, but the FDA noted that the 2006 discovery was made by a Pfizer data management unit, not a study monitor.

Pfizer took steps to remedy the problem by re-training staff and adding monitors, but a July 2009 FDA inspection prompted the latest warning letter when investigators discovered that Pfizer was still not following its own clinical trial safety guidelines.

The drugmaker responded with a letter to the FDA, ensuring that efforts would be made to protect participants in the future, but, in its latest warning, the FDA said Pfizer needs to provide a more specific outline for ensuring proper monitoring.

In a printed response on the company's web site, Pfizer was quick to point out that many of the violations had been discovered by the company itself.

"Many of the items cited by the FDA were first uncovered and reported to the FDA by Pfizer as far back as four years ago as part of our ongoing clinical trial monitoring and quality assurance processes. Since that time, Pfizer has instituted several new measures designed to improve monitoring and execution of clinical trials, including our oversight of clinical investigators," the statement said.

Pfizer has 15 days to respond to the FDA's letter, which was dated April 9. Pfizer said that it had communicated with the FDA and would spend the next two weeks creating a plan to ensure that similar errors do not occur in the future.

Aptium Oncology

programs. Aptium hopes this initial investment will result in a long-term business strategy.

"It's almost like another business line for the company," McKinley said. "What we have set out to do—and what we are doing with the GI consortium—is work with pharma companies to actually write the protocols with them and our investigators and to get the studies up and running. We take care of contractual arrangements—we have master agreements in place with each of the institutions. We'll do the data collection, provide for the data analysis and work with the companies to produce a clinical trial report and then, of course, publish."

The launch of the AMyc coincides with an Institute of Medicine report released last week saying that the government-funded Clinical Trials Cooperative Group Program, part of the National Cancer Institute (NCI), is "approaching a state of crisis" as late-stage clinical trials are being bogged down by waste and inefficiency. The Cooperative Group Program comprises more than 3,100 institutions and 14,000 investigators and enrolls about 25,000 patients a year. Despite these resources, according to the report, 40% of late-stage cancer trials end before completion.

The report, conducted at the request of NCI director John Niederhuber, recommended that the Cooperative Group Program improve the design and conduct of cancer trials to be more efficient and provide incentives to physicians and patients to increase participation.

McKinley said problems like those cited in the report are what led to the formation of Aptium's consortia.

"We see a big gap in the way that drugs are developed, with pharma companies kind of struggling to get trials up and running and recruited on time," McKinley said.

AMyC will be directed by Brian Durie, M.D., the co-founder and chair of the International Myeloma Foundation. Fifteen investigators applied to be a part of the consortium, and 11 were selected based on the strength of the investigators, their associated institutions and their perceived ability to quickly move studies through the clinical trial process.

Aptium is planning for the first two myeloma trials to begin soon. The company's GI Consortium has three trials ongoing for two different pharma companies.

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Profile: Independent Review Board

Pearl IRB, Indianapolis, Indiana

An interview with Diana Caldwell, president and co-founder

Year founded: 2010
Employees: 20
Tel: (317) 278-4100
Email: dcaldwell@pearlirb.com
Web site: www.pearlirb.com

How and why was Pearl IRB founded?

Pearl IRB was founded earlier this year, and we are the first and only commercial IRB in the state of Indiana and one of the few in the Midwest.

One of the reasons my co-founder Gretchen Bowker, chief operating officer, and I formed Pearl IRB was to meet a need that we saw in the clinical research industry for highly ethical, high value and efficient IRB reviews. Unfortunately, for many principal investigators [PIs], sponsors and CROs [contract research organizations], the IRB review process is perceived as a difficult, mysterious and often very frustrating process that they have to undergo before they can even get into the clinic.

Our first priority is protecting human subjects, but we believe we can do that while also balancing the needs of institutions, sponsors and SMOs [site management organizations] and CROs. The ultimate reason we founded Pearl IRB was to help patients. Our vision is to improve the clinical research process, which will lead to delivering therapeutics and diagnostics to patients sooner. Each of us has spent more than 15 years on the sponsor side; therefore, we understand the sponsor research process and we have experienced firsthand the inefficiencies that kept patients waiting.

I worked more than 15 years with Eli Lilly and Company in business roles, primarily in sales and marketing and also in operations and finance. Gretchen's background includes more than 25 years in regulatory affairs and device and drug development. For the last four years, she was director of services at a regulatory quality compliance consulting company called Safis Solutions. She and I met while working together there. Gretchen has been involved in the regulatory arena for 20 years.

To begin Pearl IRB, we first assessed the market and studied the needs of PIs, institutions, sponsors and CROs for independent and central IRB services. We formed the company to align ourselves to meet those needs. We built our quality system, created critical processes and assembled a powerhouse team with expertise and experience in clinical research, IRBs, regulatory and science that we think is needed to deliver top-quality service in this area.

What differentiates Pearl IRB from other IRBs?

High quality service and output. We engineered this company to deliver high quality service with uncompromising ethics. Ethics and patients are front and center, but also customer service and a high quality review process are really important to us. Our tagline and the three things we talk about are "Efficient. Ethical. Experienced."

We're also going to provide training to PIs, CRCs, clinical research associates, accreditation assistance and site monitoring and site remediation, so we can help with other ongoing site challenges they're facing.

Our board is very experienced. They possess a diversity of experience including members who have spent time with the FDA, members with PI experience, sponsor industry folks, people who have served on other IRBs and also those who have SMO and CRO backgrounds. Our board represents a 360-degree perspective of clinical research. We're also differentiated by the experience that spans across therapeutic categories in drugs, biologics, devices and diagnostics. Sometimes, you'll see IRBs that have more of a drug focus and some have more of a device/diagnostics focus. We have a good breadth of experience to cover all phases of research, the therapeutic categories and the type of research—either diagnostics or therapeutics.

Another differentiator is that we are a women-owned business. We offer the values and perspective that our combined 45 years in the industry brings to the table.

What challenges do you face?

Overall, for all of us, the complexity and the challenges of multicenter large clinical trials place more burden and complexity on all of us. FDA has clearly demonstrated through their increased number of warning letters that they will give increased scrutiny to both commercial and institutional IRBs. Part of this is the fallout from the 2008 sting operation by the GAO [Government Accounting Office] that caught Coast IRB. This created some bad press for commercial IRBs for a while. There have been more warning letters sent out to not only commercial IRBs but also to institutional IRBs.

We've also seen new draft guidance, which I think was very welcome, which was released by FDA earlier this year in the IRB continuing review process area, further articulating the IRB's role in the process. It really addresses this trend of complexity of multisite studies. It asks the IRB to take a more active role in looking across site data. A lot has changed since the days of one site, one PI studies.

How has the clinical research industry changed?

The industry, in general, faces increased scrutiny and an increased crunch in terms of funding. One of the things that sponsors are increasingly doing is continuing to outsource

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Profile: (continued from page 5)

all parts of the clinical research process. Sponsors are looking for increased efficiency, expertise and cost savings. This trend is in Pearl IRB's favor because outsourcing to an independent IRB does help with efficiencies and provides more focused expertise. Our board is professionally dedicated to their board services versus the internal institutional IRB folks who often have day jobs and other obligations that they need to meet. Time is money in clinical trials, and our IRB saves time.

In addition, I think a centralized IRB allows the sponsor and CRO to realize increased oversight and coordination, which ultimately offers better protection for subjects. A centralized IRB can help particularly with SAEs and site coordination to better understand what's going on with the data. A central IRB provides efficiencies but it is also ultimately better for clinical trial subjects.

We also see ongoing changes in the device industry and an increased need for clinical trials. We have extensive background in device and diagnostic development as well as small and large molecules. Device manufacturers also desire more efficiency, and the expertise we bring can help them as well. The trend and focus on personalized medicine is bringing about more drugs or biologics with companion diagnostics. We understand the complexity that trend brings to protocols.

Another challenge in the industry across all IRBs, but particularly institutional IRBs, is work overload. It is a common theme that there is more to review than capacity to do. This causes delays in studies and frustration for both parties. One of the answers to improved efficiency is a commercial IRB. Pearl IRB uses dedicated resources and business practices that allow the PI and the sponsor to clearly understand the laws and the oversight status and improves communication among all parties.

What are your plans for growth?

This is not a part-time venture. This is a company that we're committed to growing. We want to expand nationally and internationally—first to Canada in 2011.

We are in the process of obtaining state and national certification as a women-owned business right now. AAHRPP [Association for the Accreditation of Human Research Protection Programs] accreditation for IRBs is not required, but we will be seeking that accreditation. We have built our quality systems around AAHRPP's guidelines. We have employees on board who have successfully built systems for other accredited IRBs and have ensured that our systems were built to industry best practices.

One of the challenges for all of us is that there's some inertia in the marketplace to change from the traditional model using a PI's institution or hospital IRB. But the patients are waiting, and we all need to look at new and more efficient models to improve the research process. That may mean that an institution should outsource some or all of their reviews to a commercial IRB, that a sponsor will look to a centralized commercial IRB to provide increased efficiencies or a CRO partnering whenever they can.

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Drug & Device Pipeline News

Company	Drug/Device	Therapeutic Area	Status	Sponsor Info
Acorda Therapeutics	Glial Growth Factor 2 (GGF2)	heart failure	IND approved by the FDA; phase I trials planned	(914) 347-4300 www.acorda.com
Cornerstone Pharmaceuticals	CPI-613	cancer	Phase I trials planned in the U.S.	(609) 409-7050 www.cornerstonepharma.com
Genentech	GDC-0623	solid tumors	Phase I trials planned enrolling 62 subjects in the U.S.	(650) 225-1000 www.gene.com
Stemedica Cell Technologies	allogeneic stem cells	ischemic stroke	IND approved by the FDA; phase I/II trials planned in the U.S.	(858) 658-0910 www.stemedica.com
Transcept Pharmaceuticals	zolpidem tartrate	insomnia	Phase I trials planned enrolling 40 subjects in the Netherlands	(510) 215-3500 www.transcept.com
Emisphere Tech/ Novartis	oral PTH1-34	postmenopausal osteoporosis	Phase I trials initiated enrolling 120 subjects	(973) 532-8000 www.emisphere.com
Algeta	Alpharadin	bone metastases from prostate cancer	Phase I/II trials planned enrolling 60 subjects in the U.S.	+47 23 00 79 90 www.algeta.com
Ark Therapeutics Group	Vascular Endothelial Growth Factor-D	peripheral vascular disease	Phase I/IIa trials initiated in Finland	+358 (0) 17 240 875 www.arktherapeutics.com
Allergan	Botox (botulinum toxin type A)	urinary tract symptoms/ benign prostatic hyperplasia	Phase II trials planned enrolling 274 subjects internationally	(714) 246-4500 www.allergan.com
Ironwood Pharmaceuticals	IW-6118	pain following tooth extraction	Phase II trials planned enrolling 90 subjects in Utah	(617) 621-7722 www.ironwoodpharma.com
Mesoblast	NeoFuse	degenerative disc disease	Phase II trials planned enrolling 12 subjects in Australia	+61 3 9639 6036 www.mesoblast.com
Advaxis	ADXS11-001	cervical cancer	Phase II trials initiated in the U.S.	(732) 545-1590 www.advaxis.com
Morria Biopharmaceuticals	MRX6	contact dermatitis	Phase II trials initiated enrolling 80 subjects in Israel	(917) 361-5210 www.morria.com
NeoPharm	LE-DT	pancreatic cancer	Phase II trials initiated enrolling 40 subjects in the U.S.	(847) 887-0800 www.neopharm.com
Theravance	TD-1211	opioid-induced constipation	Phase II trials initiated enrolling 50 subjects	(650) 808-6000 www.theravance.com
Prana Biotechnology	PBT2	Alzheimer's disease	Phase IIb trials planned enrolling 525 subjects in Australia	+61 3 9349 4906 www.pranabio.com
Nuon Therapeutics	NU1618	chronic hyperuricemia	Phase IIb trials planned	(650) 645-1800 www.nuontherapeutics.com
Lotus Pharmaceuticals	Laevo-Bambutero	asthma	Fast Track status granted by China's State Food & Drug Administration	+86 10 6389 9868 www.lotuspharma.com
SuppreMol GmbH	SM101	idiopathic thrombocytopenic purpura	Orphan drug status granted by the FDA	+49 (0)89 30 90 50 680 www.suppremol.com
Alexion Pharmaceuticals	Soliris	paroxysmal nocturnal hemoglobinuria	Approved in Japan	(203) 272-2596 www.alxn.com
Novartis	Zortress (everolimus)	prevention of organ rejection in kidney transplant patients	FDA approved	(888) 669-6682 www.novartis.com

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Trial Results

Endocrinology

- **Phenomix** released positive results from a phase III trial of **dutogliptin** for the treatment of type 2 diabetes. This 24-week, international, randomized, double-blind, parallel-group, placebo-controlled study (PROT301) enrolled 542 subjects with moderately elevated baseline hemoglobin A1c (HbA1c) levels. The subjects received dutogliptin 400mg or 200mg once daily or placebo. The primary endpoint was statistically significant reductions of HbA1c compared with placebo at Week 24. Reductions in HbA1c corrected for placebo effects were 0.59% for the 400mg dose ($p<0.0001$) and 0.28% for the 200mg dose ($p<0.0138$). Statistical significance was also observed at the 400mg dose for all secondary endpoints, including change from baseline in fasting and peak postprandial plasma glucose, change from baseline in glucose AUC (0 to 2 hours) after a standard test meal, and percentage of subjects reaching treatment goal of HbA1c of less than 7.0%. Additional phase III trials are currently under way.

Infectious Disease

- **Biolex** issued positive interim results from a phase IIb trial of **Locteron**, a controlled-release interferon alpha for the treatment of hepatitis C. This trial enrolled 116 treatment-naive subjects with genotype-1, chronic hepatitis C. The subjects were randomized into one of four dosing cohorts, the 320, 480 or 640 µg dose of Locteron (administered once every two weeks) or a control arm consisting of standard of care, PEG-Intron (1.5 µg/kg, administered every week); all subjects received weight-based ribavirin. The treatment duration was 48 weeks. These interim results are through 36 weeks of treatment. The two highest doses of Locteron demonstrated reductions in viral loads (mean changes in HCV RNA from baseline) that were comparable to that achieved with PEG-Intron administered once per week; 41%, 52% and 50% of the subjects had undetectable HCV RNA, respectively. Treatment was well tolerated, and there were no unexpected adverse events. Biolex plans to continue with the development of Locteron.

Oncology

- **Abraxis** reported positive results from a phase I/II trial of **Abraxane** plus gemcitabine for the treatment of pancreatic cancer. This open-label study enrolled a total of 67 subjects. In the phase I portion, the subjects received weekly doses of Abraxane (100, 125, or 150mg/m2) in combination with gemcitabine (1,000mg/m2) for three weeks (on Days 1, 8 and 15) with one week of rest. The primary safety endpoint was the identification of the maximum tolerated dose and dose-limiting toxicities. The recommended dose for the phase II portion was determined to be 125mg/m2 Abraxane plus 1000 mg/m2 gemcitabine. In the 44 subjects treated at this dose, the median overall survival time was 12.2 months, doubling the historical control of gemcitabine administered alone. The combination also resulted in a confirmed overall response rate in 50% of the subjects and a disease control rate of 68%. In the overall study (n=67), three patients achieved a complete response. A phase III trial evaluating this combination is currently under way.

Respiratory

- **Stallergenes** released positive results from a phase III trial of their sublingual grass pollen immunotherapy tablet, **Oralair**. This U.S.-based randomized, double-blind, placebo-controlled study (VO61.08) enrolled 473 adults with grass pollen-induced rhinoconjunctivitis. The subjects received either placebo or 300IR sublingual tablet taken daily for approximately six months starting four months before the grass pollen season and over the grass pollen season. The primary endpoint a reduction of the Average Combined Score, a combination of the Rhinoconjunctivitis Total Symptom Score and the Rescue Medication Score, compared with placebo. This endpoint was reached with statistical significance. Oralair was well tolerated. Development of Oralair will move forward as planned.

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Biotech Review

From *BioWorld Today*

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- **Celgene** and privately held **Agios Pharmaceuticals** have entered a preclinical collaboration in the area of cancer metabolism, a deal that will bring in a hefty $130 million upfront for Agios, including an equity investment. In return, Celgene has an exclusive option to license any clinical candidates resulting from the Agios cancer metabolism research platform at the end of phase I. Once the exclusive collaboration period is up, Celgene may extend the deal through additional funding. Agios also could receive up to $120 million in milestones as well as royalties on sales, and also may participate in the development and commercialization of certain products in the U.S. Agios will lead discovery and early translational development for all cancer metabolism programs, and Celgene will lead and fund global development and commercialization of licensed programs.

- **Mersana Therapeutics** signed a $334-million deal with **Teva Pharmaceuticals Industries** for XMT-1107, a preclinical revival of the old antiangiogenic drug fumagillin. Teva agreed to pay $334 million in upfront and milestone payments, as well as royalties, for rights to XMT-1107 worldwide except in Japan, where Mersana plans to seek a regional partner. Teva also is covering all development costs except those specific to Japan. Teva has contracted with Mersana to run a phase I solid tumor trial, which is slated to begin this quarter.

- Just days before **Javelin Pharmaceuticals** and **Myriad Pharmaceuticals** were to close on a merger deal, a competing "superior" bid came in from **Hospira**, and now Javelin plans to nix its agreement with Myriad. Javelin said that it intends to terminate its agreement with Myriad shortly, unless that company ups its terms. If the agreement is terminated, Myriad would be entitled to repayment, in full, of the outstanding balance under the $8.5 million loan and security agreement with Javelin, with accrued interest, as well as stipulated expenses of up to $1.5 million plus a termination fee of $2.9 million following termination. Hospira and its wholly owned subsidiary, Discus Acquisition, have made a binding offer to buy out Javelin at a per-share price of $2.20. In addition, Hospira will, subject to certain conditions, provide Javelin a working capital facility under which Javelin may borrow up to $4.5 million to fund its operating activities prior to closing a merger with Hospira; Javelin's repayment of the principal and accrued interest incurred under its arrangement with Myriad; and $4.4 million for Javelin's payment of the termination fee and certain stipulated expenses that the company may be required to pay Myriad following termination of its merger agreement.

- **Dynavax Technologies** is raising $44 million through a public offering of stock and warrants, providing cash to push beleaguered hepatitis B vaccine Heplisav through its final phase III trials and toward a biologics license application filing next year. Dynavax is selling 30.3 million units priced at $1.4525 apiece. Each unit consists of one common share and one five-year warrant to purchase one half of an additional share with an exercise price of $1.50. Wedbush PacGrow Life Sciences served as the sole underwriter for the financing.

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