

# BIO WORLD<sup>®</sup> TODAY

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PAGE 1 OF 7

## Follow-On Biologics Spur Much Dialogue At Generic Policy Event

**By Aaron Lorenzo**  
**Washington Editor**

WASHINGTON – Drug companies that have fought against easy approvals for follow-on protein products aren't letting up these days, but their generic counterparts may be gaining some footholds as they clearly have their sights set on the lucrative and growing biopharmaceutical market.

Known under a litany of labels – biogenerics, follow-ons, generic biologicals – they “represent an extraordinary opportunity” for generic companies, said Kathleen Jaeger, the president and CEO of the Generic Pharmaceutical Association (GPhA). Eyed as “the future” by Bernard Hampl, the president and CEO of Sandoz U.S. Inc., biogenerics were a primary topic at the GPhA's first policy conference held here last week.

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*Mid-America VentureForum*

## Drug-Eluting Stents Help Pave Way For Drug/Device Combos

**By Jennifer Boggs**  
**Staff Writer**

MINNEAPOLIS– The convergence of the medical device and drug industries is inevitable, especially given the early success of drug-coated stents and inhaled insulin, but it could be years before the approval of combination products becomes everyday news, panelists said at the BIO Mid-America VentureForum.

Since the Midwest is known more for its established medtech and medical device industry, a workshop dealing with the reality of biotech drugs being packaged with devices seemed more than natural. But one panelist in a workshop at the Hilton Minneapolis Hotel warned not to put too much hope in the immediate future.

Peyton Anderson, CEO of Affinergy Inc., a Research Tri-  
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*Financings Roundup*

## Transgenomic Raises Funds To Eliminate Debt, Grow Business

**By Aaron Lorenzo**  
**Washington Editor**

An equity offering disclosed Friday brought in some fresh funding for Transgenomic Inc.

The Omaha, Neb.-based company, which develops research tools and related consumable products for drug companies, is grossing a little more than \$15 million. The private placement garnered commitments from a group of institutional investors to purchase 15 million common shares at \$1.01 apiece. The transaction, which is expected to close by Oct. 31, also includes warrant coverage for 6 million more shares exercisable at \$1.21.

Transgenomic said it would use its net proceeds of just above \$13 million to repay about \$9 million in fully convertible debt to Laurus Master Fund Ltd. in New York, and

*See Transgenomic, Page 6*

## Renovis Raises \$54M Publicly To Fund Multiple Programs

**By Karen Pihl-Carey**  
**Staff Writer**

Renovis Inc. priced a public offering on Friday that will bring the company \$54 million in gross proceeds for research and development expenses.

The South San Francisco-based company is offering 4 million shares at \$13.50 each, a discount to its closing stock price of \$13.92 on Thursday. The stock (NASDAQ:RNVS) gained 1 cent Friday to close at \$13.93.

New York-based Goldman, Sachs & Co. is acting as the sole book-running manager, while CIBC World Markets Corp. and SG Cowen & Co. LLC, both of New York, and Minneapolis-based Piper Jaffray & Co. are co-managers. They have been granted an overallotment option for an additional 600,000 shares. The offering should close by Wednesday.

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## Renovis

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Net proceeds are expected to be \$50.4 million, or \$58 million if the underwriters exercise their overallotment option in full. The money will go toward research and development, including clinical trials for any future product candidates, and working capital and other general corporate purposes, according to the company's prospectus. Renovis declined comment due to SEC quiet-period rules.

Most recently, Renovis has had a string of setbacks, including a missed primary endpoint in a Phase II sciatica trial for REN-1654, and the delay of a regulatory filing for its stroke drug Cerovive. (See *BioWorld Today*, July 29, 2005, and Aug. 29, 2005.)

In the spring, the company also said it would end development of REN-850, its leukocyte-traffic inhibitor for multiple sclerosis due to unexpected pharmacokinetics in a Phase Ia trial.

But investors still are showing a great deal of interest in the company, mainly because of its lead drug Cerovive, a neuroprotectant that has been shown to limit damage to brain tissue and preserve brain function.

The delay of a regulatory filing in the U.S., from the second half of 2006 to the second half of 2007, is mostly due to the company's decision to increase patient enrollment in a Phase III trial.

The trial, called SAINT II, is enrolling 3,200 patients instead of the originally planned 1,700 to make sure it is powered enough to support the results of SAINT I, completed earlier this year.

In May, Renovis and its partner AstraZeneca plc, of London, reported positive results from the Phase III SAINT I trial involving more than 1,700 patients. Cerovive achieved its primary endpoint by showing a statistically significant reduction vs. placebo of disability in patients after an acute ischemic stroke ( $p=0.038$ ) as measured using the modified Rankin Scale (mRS).

The product also displayed an excellent safety profile and was well tolerated, showing efficacy regardless of time to treatment, stroke severity and treatment with tPA (tissue

plasminogen activator; Activase), the only approved product to treat acute ischemic stroke in the U.S.

Yet, the therapy did not hit a co-primary endpoint by showing a significant effect on neurological impairment as measured using the National Institutes of Health Stroke Scale (NIHSS). The company believes, however, that the primary endpoint, measured using the mRS, will be sufficient evidence of efficacy. In addition to raising the number of patients enrolled in SAINT II, Renovis also added an endpoint that will show a certain reduction of intra-cerebral hemorrhage in tPA-treated patients, and it has modified the statistical analysis of the neurological impairment endpoint as measured by NIHSS.

As the only approved treatment, South San Francisco-based Genentech Inc.'s tPA comes with an increased risk of intra-cerebral hemorrhage and is used to treat fewer than 5 percent of stroke patients, potentially offering Cerovive a large chunk of the market. If the product gains approval, Renovis would be entitled to receive mid-teen percentage royalties on worldwide net sales from AstraZeneca.

At the earlier stage of development, Renovis is working on small molecules that inhibit vanilloid receptor (VRI) to develop a new class of treatment for inflammatory pain, neuropathic pain, urinary incontinence and other disorders. In May, the company entered into a \$187 million pre-clinical research deal with New York-based Pfizer Inc. for products that inhibit VRI. (See *BioWorld Today*, June 1, 2005.)

The company also is collaborating with Genentech to discover and develop drugs that inhibit angiogenesis and promote nerve re-growth following nervous system injury.

Independently, Renovis is pursuing development of next-generation compounds that act similarly to Cerovive to treat myocardial infarction, kidney disease, stroke, neurodegeneration and other diseases in which ischemia plays a role.

Founded in 2000, the company went public in February 2004, raising \$66 million. As of June 30, it had \$68.9 million in cash, cash equivalents, restricted cash and marketable securities.

Following this offering, the company has 28.9 million shares outstanding. ■

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**THOMSON**



## Mid-America

*Continued from Page 1*

angle Park, N.C.-based firm formed 18 months ago to develop site-specific biodelivery technologies, said combination products "in the short term are way overhyped, and in the long-term are way undervalued."

Though drug-eluting stents, such as those developed through a collaboration between Angiotech Inc. and Boston Scientific Corp., might have started the game, "we're in maybe the second inning," he said. "We had two leadoff homers" with the stents, "but we've got a lot of pitches left."

Anderson estimated that "we are about 20 to 30 years away" from drug/device combination products becoming widely used and widely accepted.

All panelists agreed that the biggest hurdle standing in the way is the regulatory requirements. Only in 2002 did the FDA establish definitions for combination products, and the final version of those regulations came out this year, said Annemarie Moseley, chairman of San Francisco-based Repair Technologies Inc., a biotech start-up focused on endogenous repair of tissue injury.

"The reality of this field is that it's just now beginning to affect us," she said.

Combination products can refer to drugs and devices that are developed together, or developed separately and packaged together, or developed and packaged separately but approved for jointly treating certain indications. Oftentimes, the greatest source of confusion is which part of the agency has the last word on product approval, and that's where the Office of Combination Products comes in.

Moseley said the OCP reviews products and determines by evaluating the primary mode of action whether a product is essentially a device or a delivery technology that introduces drugs into a patient's system. For example, she said, drug-eluting stents are devices that hold vessels open so the drug can take care of the secondary need. But an inhaled insulin product's mode of action is based on the drug's action upon the body.

At the start of the regulatory process, companies will have the OCP review their products to determine whether the drug or device side of the FDA will take the lead on the approval process.

That "makes the process more complex up front," Moseley said, but it prevents one side from "delaying things

at the point of approval."

As the vice president and chief scientific officer of Northridge, Calif.-based Medtronic MiniMed Inc., Bill van Antwerp said he has had some experience with regulatory process for combination products, and not all of it has been pleasant. The company has an insulin pump therapy.

Antwerp said the OCP "seems to really get it," but the problem arises when companies are asked to duplicate clinical trials on existing products. MiniMed purchased a marketed drug from Indianapolis-based Eli Lilly & Co. to use with its pump technology, and the "drug guys at the FDA made us repeat the impurity profile," which ended up costing MiniMed an additional \$2 million.

Conversely, he said, companies might have clearance for a device, such as a pump, but are required to "prove again that the pump works.

"It's that level of craziness that I don't think they've gotten to yet," Antwerp said.

But not all the challenges are regulatory-related. The development of drug/device combinations also requires the collaboration between biotech and medical device companies, and those working arrangements can spark some culture shock.

"It's a Mars and Venus thing," Anderson said, adding that collaborations with device companies usually require members of his staff "to go around and educate the engineers about biology."

To that, Antwerp replied that "our engineers also have to work with biologists," and joked that "the loneliest guy in the world is the drug guy at a device company."

Companies also have to consider the time frames, since drugs typically require longer development and trial periods before they're ready for approval. So, "when you partner, make sure you have it up front that it's going to take a lot longer than you think," Antwerp said.

Moseley said she sees the last several years as "a wake-up call" for medical device companies, which are finding they will have to learn about drug-approval processes and good manufacturing practices before they can consider combination products.

A lot of progress has been made over the last few years, she said, and "I think we'll see a lot more awareness to new products and new innovations."

The conference ended Friday. ■



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## Biogenerics

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And it's easy to see why: Analysts estimate that \$18 billion worth of the drugs will come off patent by 2010, by which point more than \$60 billion in total sales are forecast for such products, but it's a market that innovators aren't readily ceding.

Still, in anticipation of that horizon, many generic and pioneer drug companies are awaiting much-anticipated guidance from the FDA and its accompanying white paper to provide a clearer view of biogeneric regulatory pathways. At this point, the agency's issuances are many months overdue, and it is catching flak for its delays.

Sen. Orrin Hatch (R-Utah), a longtime ally to the generic industry, is pressing the FDA on the matter. While he told conference attendees that biogenerics "are not front-burner issues" right now in Congress, he has inserted language into the FDA funding bill, which remains under committee consideration, to require the agency to report on its efforts to develop a biogeneric policy. Hatch added that FDA Commissioner Lester Crawford recently assured him that the agency would issue guidance "hopefully by the end of this year."

But Hatch cautioned that opposing language attached to the same appropriations bill could preclude the FDA from exploring whether an existing approval mechanism, Section 505 (b)(2) of the Food, Drug and Cosmetic Act, can be applied to biogenerics. He also acknowledged that many, if not all, biogenerics "will require at least some form of truncated human clinical testing."

That concession mirrored comments from the FDA's Steven Kozlowski, its acting director of the Office of Biotechnology Products. "There may be certain circumstances where [clinical trials] can't be replaced," he said.

Issues of safety at the risk-averse agency are a clear factor in establishing a biogeneric approval policy.

"I think the consideration of each product and product class, based on risk profile and other things, is going to determine the best steps to take," Kozlowski told *BioWorld Today*, adding that a "broad distinction" between different types of products could lead to a case-by-case system of evaluating biogenerics. He declined, though, to put a timeline on guidance documents from the FDA.

Hatch said that in the end, a biogeneric approval pathway might require legislation along the lines of that which passed more than 20 years ago, the generic drug industry-enabling Hatch-Waxman Act. Rep. Henry Waxman (D-Calif.) also spoke at the conference and told attendees that "the uniqueness of biological products suggests that we need a case-by-case approach for evaluating each type of product."

To that end, Waxman advocated a system similar to that being set up in Europe, where product-specific guidances are being established for biogeneric approvals. He also criticized brand-name pharmaceutical firms for seeking "loopholes" to block generic companies from entering the market, and later singled out abuses of the Citizens Petitions process as an example.

Many GPhA members have charged that the vetting process is improperly employed by innovator companies to delay the FDA from establishing a biogeneric regulatory pathway. Such feelings were echoed by a new face at the FDA who could prove most friendly to generic companies. Sheldon Bradshaw, the agency's new chief counsel, noted that misuse of Citizens Petitions represents attempts "to delay unnecessarily approval of competitors' products," adding that such a practice has "jumped out" at him and is "particularly troublesome."

He suggested putting Citizens Petitions on a separate review track from that of marketing applications to save the review process from lengthy delays. "Frankly, I've been considering whether or not we can implement something that would allow the agency to point out for all the world to see when Citizens Petitions are specious, untimely, or otherwise appear intended to delay competition," said Bradshaw, who previously worked in the Department of Justice, "rather than to assist the agency to review and approve drug applications in accordance with the law and sound science."

Economic forces also could force the issue. The GPhA has said that a one-day supply of biological drugs costs an average of \$45, compared to a \$1.66 daily average price of traditional small-molecule drugs. With the federal government set to become the biggest buyer of all drugs when Medicare's drug-benefit plan kicks in Jan. 1, the potential cost savings of biogenerics also could force a change in policy.

"Cost factors alone compel a full examination of public discussion of the merits of developing and implementing a fast-track review and approval system that can reduce the price of biopharmaceuticals once patents expire," Hatch said. He later hedged his comments by saying that "much groundwork" needs to be done before any biogeneric approval process is adopted. "I believe it should always be the goal of government to employ the least burdensome regulatory approach, without compromising other important considerations, such as in this case patient safety and intellectual property."

Those latter points continue to underlie arguments against shortened biogeneric approval pathways. According to Charles Lucas, a vice president and the general counsel at the Biotechnology Industry Organization (BIO), patient safety cannot be assured because product equivalence is not possible. Heterogeneity issues cloud precise characterization and comparison of pioneer biologicals to biogenerics, he told conference attendees. He also argued against the use of an innovator company's clinical data in considering a biogeneric marketing application, and charged that the FDA cannot use trade secrets in establishing its guidance as that would violate the constitutional "takings clause," the same section of federal law that permits eminent domain.

But several other speakers countered that scientific progress has advanced to the point of showing structural equivalence, while others disagreed with BIO's stance on the takings clause. With that back-and-forth continuing, both sides continue to await the FDA's determination. ■

## Genentech Stops Avastin Trial Due To Rate Of GI Perforations

By Karen Pihl-Carey  
Staff Writer

Genentech Inc. halted enrollment in a multicenter, single-arm Phase II study of Avastin (bevacizumab) in platinum-refractory ovarian cancer due to a high rate of gastrointestinal perforations.

The decision was made by the South San Francisco-based company in consultation with the FDA.

While GI perforations are a known possible side effect of Avastin, there was a higher rate of them in this patient population than in previous Avastin studies. Of the 44 patients enrolled in the proposed 53-patient study, five experienced GI perforations.

Those enrolled in the trial will be informed of the new

safety information, and may continue to receive treatment with Avastin or elect to discontinue it. Patients in the study had more advanced disease, which typically involves the bowel, and had received more prior chemotherapy than in previous clinical trials of Avastin in ovarian cancer, which could explain the higher rate of GI perforations.

Genentech expects to continue studying Avastin in earlier-stage ovarian cancer and other tumor types. The therapeutic antibody is designed to inhibit vascular endothelial growth factor, a protein that plays a role in tumor angiogenesis and maintenance of existing tumor vessels.

FDA-approved in February 2004, Avastin is indicated as a first-line treatment for metastatic colorectal cancer in combination with intravenous 5-FU-based chemotherapy. It had sales of \$246 million in the second quarter.

The company's stock (NYSE:DNA) dipped \$2.17 on Friday, to close at \$85.83. ■

## OTHER NEWS TO NOTE

• **Amarillo Biosciences Inc.**, of Amarillo, Texas, said a study to test low-dose oral interferon alpha in 40 patients with rare bone marrow proliferative disorders is now open to enrollment. Amarillo will provide product for the study, which will enroll 20 patients, each with either polycythemia vera or primary thrombocythemia. They will be given low-dose oral interferon alpha daily as a treatment to relieve the signs and symptoms associated with the disorders.

• **Biomira Inc.**, of Edmonton, Alberta, is delaying the start of its planned Phase III study of BLP25 liposome vaccine (L-BLP25) for non-small-cell lung cancer into next year. It was expected to begin at the end of this year, but an accelerated stability issue discovered during the manufac-

turing process has arisen. The company said it may have been due to excess moisture in the product. The change will allow Biomira and partner **Merck KGaA**, of Darmstadt, Germany, to address the problem. The companies, which are working with the contract manufacturer, also announced the simultaneous publication in this month's issue of the *Journal of Clinical Oncology* of previously reported Phase IIb data indicating a 4.4-month longer median survival for patients randomized to the L-BLP25 arm (88 patients) compared to the best supportive care arm (83 patients).

• **Biophage Pharma Inc.**, of Montreal, and **Integrated Environmental Technologies Ltd.**, of Little River, S.C., formed an agreement that enables both companies to market an end-to-end pathogen-detection and control system. The combined marketing efforts will promote IET's EcaFlor equipment and Biophage's PDS Biosensor.

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## Transgenomic

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apply the remainder to general working capital needs in an effort to grow its service and instrument businesses.

"Our capital structure has been complex, to say the least," Michael Summers, Transgenomic's chief financial officer, told *BioWorld Today*. "The major impetus for this financing was the need for some capital to progress [our business segments], and to put that debt behind us and make our balance sheet a little cleaner and more transparent for those trying to watch us. It will eliminate all of our debt, which we think is important for a \$30 million company in our space, and it will eliminate a significant amount of confusion with regard to the convertible features in that facility."

Transgenomic's BioSystems business segment sells products for genetic variation detection and single- and double-strand DNA/RNA analysis and purification. Its flagship instrument platform, called the WAVE System, has applicability to genetic research and molecular diagnostics, and about 1,250 have been installed worldwide. Recent publications authored by a range of users have been relevant to translational research into targeted therapies for oncology.

"Its forte is very high sensitivity mutation detection," said Robert Pogulis, Transgenomic's director of strategic planning. "It is both a substitute for and a complement to projects that might otherwise be tackled by a resequencing approach."

The company also pairs the WAVE System with an enzymatic mutation detection product called Surveyor Nuclease to give users alternative approaches to discovering mutations and analyzing genetic variations.

A related business that stems from such systems entails service, maintenance and customer support for that installed base. Summers said such operations generate about \$15 million in annual recurring revenue for the company, representing about half its total revenue.

It also offers WAVE-based biomarker discovery and validation services in support of translational research, pre-clinical and clinical studies. "We see a lot of upside in that business," he added, "not only from a pharma perspective but also from a diagnostics perspective."

Profitability appears to be just down the road a bit for Transgenomic, which also operates a smaller nucleic acid business. Recent overall growth helped narrow its quarterly net loss to \$1 million for the period ended June 30, which it ended with \$1.7 million in reserve cash, cash equivalents and short-term investments. It had 34.2 million shares outstanding at the time.

The investment was led by Lehman Brothers Inc., of New York. It remains subject to shareholder approval and other customary conditions, and its exclusive placement agent was Oppenheimer & Co., also of New York.

On Friday, the company's stock (NASDAQ:TBIO) lost 4 cents to close at 99 cents.

### Acusphere Raises \$17.5M In Offering

Acusphere Inc. raised net proceeds of about \$17.5 million through a public offering.

The Watertown, Mass.-based specialty pharmaceutical company sold about 3.6 million common shares at \$5.25 apiece, a per-share price that reflected an 11.5 percent markdown from the previous day's \$5.93 closing bid on the stock. On Friday, the shares (NASDAQ:ACUS) dropped 44 cents to \$5.49.

For Acusphere, which is developing new drugs and reformulating existing products with its microparticle technology, the financing essentially covers its recently posted net loss of \$16.4 million for the quarter ended June 30. The company had cash reserves of \$60.2 million at that date, and about 17.8 million shares outstanding.

Its three initial product candidates are being developed for applications in cardiology, oncology and asthma.

Piper Jaffray & Co., of Minneapolis, is acting as the offering's sole manager. ■

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## OTHER NEWS TO NOTE

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• **Flamel Technologies SA**, of Lyon, France, reported positive preliminary Phase I/II data demonstrating the safety, tolerability and long-acting activity of IFN-alpha-XL in patients with chronic hepatitis C virus infection. Findings also showed that the product had positive effects on viral load and interferon activity biomarkers. IFN-alpha-XL uses the company's Medusa nanoparticle technology to provide a long-acting formulation of interferon alpha that may have enhanced efficacy and reduced toxicity compared with unmodified or PEG-modified interferon formulations. Flamel plans to present the full data at a future medical conference.

• **Gene Logic Inc.**, of Gaithersburg, Md., said the value of the goodwill asset that resulted from its April 2003 acquisition of TherImmune Research Corp. is impaired. The Company expects to finalize and announce the amount of such impairment by Nov. 9. Prior to this impairment, the goodwill asset for the now renamed Gene Logic Laboratories Inc., its nonclinical services subsidiary, was valued at \$43 million. It is not expected that this potentially substantial impairment charge will result in any future cash expenditures. Gene Logic has reduced its revenue growth and financial performance assumptions for that business and is reviewing the impact of those decreased expectations on its full-year financial outlook, though the company declined to update its financial guidance. On Friday, its stock (NASDAQ:GLGC) fell \$1.04, or 18 percent, to close at \$4.62.

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## OTHER NEWS TO NOTE

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• **GTx Inc.**, of Memphis, Tenn., said it is delaying its proposed public offering of 5 million shares due to market conditions. GTx is focused on the discovery, development and commercialization of therapeutics for cancer and serious conditions related to men's health.

• **Imcor Pharmaceutical Co.**, of San Diego, **Alliance Pharmaceutical Corp.**, also of San Diego, and its wholly owned subsidiary, Molecular Biosystems Inc., concluded an agreement with **GE Healthcare Ltd.**, of Chalfont St. Giles, UK, to resolve claims in a patent dispute. Imcor gets \$1M, Alliance gets \$200,000 and all parties granted each other a nonexclusive, royalty-free cross-license with the right to sublicense their respective ultrasound contrast agents.

• **Life Therapeutics**, of Atlanta, reported the signing of a binding agreement to acquire privately held Pyramid Biological Corp., of Los Angeles, for \$13 million plus assumption of \$7 million in debt. An additional \$5 million is subject to achievement of milestones. Terms of the acquisition originally were agreed to in July. Life Therapeutics has four divisions: Life Sera, Life Gels, Life Diagnostics and Life Manufacturing.

• **Marc Pharmaceuticals Inc.**, of Stamford, Conn., said university scientists recently completed a 17-day study on laboratory animals showing that one of the company's water-soluble drug candidates (a betulinol derivative) slowed prostate tumor growth in mice. Betulinol is a naturally occurring compound that is isolated from the outer layer of the bark of the white birch tree.

• **Mesoblast Ltd.**, of Melbourne, Australian, reported approval to commence the first human orthopedic trial of its adult stem cell technology. Approval from The Royal Melbourne Hospital's Human Research Ethics Committee is for a pilot trial in up to 10 patients suffering from non-union of long bone fractures, which affects up to 2 million people each year in developed countries. The trial will be an independent assessment of the safety of the technology.

• **Microbix Biosystems Inc.**, of Toronto, said that it will be collaborating with a third party to test the company's yield-enhancement technology in the production of influenza vaccine, including avian influenza. The company said the patent-protection strategy is moving through the process on schedule in several countries including the U.S. Patent Office.

• **Nektar Therapeutics**, of San Carlos, Calif., agreed to sell \$275 million of 3.25 percent convertible subordinated notes due 2012 to qualified institutional buyers. The company also granted the buyers an option to purchase up to an additional \$40 million of notes to cover overallocments. The debt will be convertible into common stock at an initial conversion rate of 46.4727 shares per \$1,000 of notes (subject to adjustment in certain circumstances), which is equivalent to an initial conversion price of about

\$21.52 per share. They will be subordinated to all present and future senior debt of Nektar, which also repurchased about \$71 million of other outstanding obligations in the process. The offering is expected to close Sept. 28, subject to customary conditions.

• **Novavax Inc.**, of Malvern, Pa., completed the sale of certain products deemed non-core to **Pharmelle LLC**, of Gilbert, Ariz. The total proceeds from the sale of AVC Cream, NovoNatal and NovaStart, including existing inventory, was \$2.5 million. In addition, the company may receive future royalties if product sales exceed certain predetermined levels.

• **Protherics plc**, of London, said it received preliminary approval from the Nasdaq Stock Market to establish a Level II American Depository Receipt program in the U.S. The Bank of New York has been appointed as the depository bank to administer the ADR program. Trading is expected to begin Tuesday under the ticker symbol "PTIL." The ADRs will trade on the basis of 10 Protherics ordinary shares for every one ADR. Protherics focuses on critical care and oncology.

• **Serologicals Corp.**, of Atlanta, said its wholly owned subsidiary, Chemicon International Inc., of Temecula, Calif., launched a new Amplifluor ID pan-enterovirus detection reagent. The product rapidly detects pan-enterovirus, and is the first of many infectious disease detection products offered using Chemicon's fluorescent detection technology.

• **Tercica Inc.**, of South San Francisco, presented three scientific posters at the ESPE/LWPES 7 joint meeting of pediatric endocrinology in Lyon, France. Presentations included the first available data from six children who received Increlex (mecasermin [rDNA origin] injection) treatment for severe primary insulin-like growth factor-I deficiency. Results also were presented from a pharmacokinetic study comparing once-daily dosing vs. twice-daily dosing of Increlex in children with primary IGF-I as well as results of a comparative study of four IGF-I assay systems for the biochemical detection or diagnosis of IGF-I deficiency.

• **Viragen Inc.**, of Plantation, Fla., received a deficiency letter from the American Stock Exchange Tuesday advising that the company is not in compliance with Amex's requirements since it has stockholders' equity of less than \$4 million and losses from continuing operations and/or net losses in three out of four most recent fiscal years. It also is not in compliance with the five-year performance criteria.

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