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PAGE 1 OF 8

Washington Roundup

Bill Permitting Much-Needed SBIR, STTR Grants in Senate

By Donna Young
Washington Editor

WASHINGTON – Legislation introduced earlier this month by Sens. Mary Landrieu (D-La) and Olympia Snowe (R-Maine) to reauthorize the Small Business Innovation Research and the Small Business Technology Transfer programs was quickly passed last week by the Senate Committee on Small Business and Entrepreneurship.

Those programs fund more than \$2 billion annually in early-stage R&D projects at small technology companies, including biotechs. If not reauthorized, the SBIR program will sunset July 31, while the STTR program is set to end Sept. 30.

If enacted, the SBIR/STTR Reauthorization Act of 2009, S. 1233, would permit small companies that receive the
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Biotech's Leaders Tell Their Tales

Women CEOs Proving It: Glass Ceiling Can Break

By Catherine Hollingsworth
Staff Writer

They entered the industry at a time when women were still somewhat of an oddity in the field, when their very presence in a board meeting was an issue for some men. Shaking off prejudices that they faced early on in their careers, these women went on to do what few women achieve in the biotech field: They became CEOs.

Offering a rare glimpse into the lives and careers of the female biotech CEO, four women in the industry shared with *BioWorld Today* their views on what it took to make it to the top, and why so few women are starting or leading biotech firms. Veteran CEOs Una Ryan, of Waltham Technologies Inc.; Anna Gluskin, of Generex Biotechnology Corp.; Tina Nova, of Genoptix Inc.; and Carol Nacy, of
See CEOs, Page 4

Another Cousin for Bortezomib

Immunoproteasome Blocker as Weapon Against Arthritis

By Anette Breindl
Science Editor

Inhibiting the proteasome has proven to be a winning strategy against hematological cancers: Velcade (bortezomib), from Takeda subsidiary Millennium Inc., works by inhibiting the proteasome, and several other proteasome inhibitors are in clinical trials.

In the June 14, 2009, issue of *Nature Medicine*, scientists from South San Francisco biotech Proteolix Inc. – whose proteasome inhibitor carfilzomib is in clinical trials for several hematological cancers – and colleagues from the German University of Konstanz showed that the pre-clinical compound PR-957 might be useful to ameliorate rheumatoid arthritis. PR-957 specifically blocks one sub-unit of the immunoproteasome, a version of the protea-

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NEW CO NEWS

Adimab Yeast-Based Platform Draws Big Pharma's Attention

By Catherine Hollingsworth
Staff Writer

At a time when some small biotechs are having a harder time securing early stage partnerships, Adimab Inc. pulled off two major drug discovery deals this month and is in ongoing discussions with many of the top 15 drug-makers for possible future collaborations.

Adimab founder and CEO Tillman Gerngross said, "We expect this momentum to continue for some time."

Pretty good for a firm founded only in 2007 with a simple business model to deliver yeast-based antibodies with greater speed and in greater numbers.

Yeast was a natural choice for cultivating antibodies,
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FINANCINGS ROUNDUP

• **Abraxis BioScience Inc.**, of Los Angeles, filed a shelf registration statement to offer, from time to time, up to \$400 million of its debt securities, common stock, preferred stock or warrants. Specific terms will be disclosed at the time of any offering. Proceeds will go toward general corporate purposes. The firm's selling stockholders also filed to offer, from time to time, up to 2 million shares of common stock, though Abraxis will not receive any proceeds from those sales. Shares of Abraxis (NASDAQ:ABII) closed at \$38.44 Friday, down 48 cents.

• **Advaxis Inc.**, of North Brunswick, N.J., received about \$1 million in gross proceeds in debt financing. The firm issued senior secured promissory notes at an original issue discount of 15 percent. It also granted an option for an additional investment of about \$1 million. The company said funds will be used to advance Phase II development. Advaxis develops *Listeria monocytogenes* cancer vaccines.

• **AEterna Zentaris Inc.**, of Quebec City, said it received commitments to purchase \$10 million of units comprising common shares and warrants in a registered direct offering. The company will sell 5.3 million common shares priced at \$1.88 each and issue warrants to acquire an aggregate of 1.9 million shares at an exercise price of \$2.06 each. Net proceeds are expected to total about \$9.25 million and will be used for general corporate purposes, including clinical development of oncology and endocrinology compounds. The offering is set to close no later than June 24. Shares of AEterna Zentaris (NASDAQ:AEZS) fell 14 cents to close Friday at \$1.82.

• **EpiCept Corp.**, of Tarrytown, N.Y., is raising about \$8.9 million in net proceeds in agreements to sell about 12 million shares of common stock priced at 80 cents per share and warrants to purchase up to 4.2 million shares at an exercise price of 90 cents each. Proceeds from the offering, expected to close on or about June 23, will be used to

meet working capital needs and for general corporate purposes. EpiCept intends to apply a portion of the net proceeds to fund certain expenses necessary for its named patient program for Ceplene (histamine dihydrochloride), for the filing applications for marketing approval of Ceplene in the U.S. and Canada and to prepare for the commercial launch of the drug in Europe. Proceeds, plus existing cash, are expected to carry the company into the second quarter of 2010. Rodman & Renshaw LLC acted as the exclusive placement agent. Shares of EpiCept (NASDAQ:EPCT) fell 14 cents to close Friday at 76 cents.

• **GTC Biotherapeutics Inc.**, of Framingham, Mass., entered agreements for LFB Biotechnologies, a wholly owned subsidiary of **LFB SA**, of Les Ulis, France, to provide a total of \$12.3 million in cash to GTC, with an option to provide up to an additional \$6.4 million. The financing consists of bridge debt and convertible preferred stock. LFB also is providing \$3.5 million of term debt for GTC to pay off the remaining net principal amount of its GE Capital loan. Meriman Curhan Ford acted as financial advisor.

• **Sagent Pharmaceuticals Inc.**, of Schaumburg, Ill., said it entered a \$15 million revolving credit facility with MidCap Financial LLC. Proceeds will be used to support working capital requirements and for general corporate purposes.

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AHC Media LLC

Washington Roundup

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majority of their financing from venture capital to be considered eligible to compete for SBIR grants, overturning eligibility requirements added in 2003 that disqualified firms with venture-capital investments greater than 50 percent.

Since that 2003 reinterpretation, the applicant pool at the National Institutes of Health has been shrinking, said Jim Greenwood, CEO of the Biotechnology Industry Organization.

"For six years, more than half of all small private U.S. biotech companies have not been allowed to compete for SBIR grants due to a bureaucratic ruling," Greenwood said, adding that under the new Senate bill, more biotech startups will be allowed to compete for the funds.

Reauthorizing the SBIR and STTR programs, Snowe said, would "unleash the groundbreaking innovation potential of our nation's small businesses," noting that the grants are needed now more than ever, given the economic climate.

"By assisting thousands of pioneering small businesses with the development and promotion of scientific breakthroughs, the SBIR and STTR programs keep America ahead of the curve," Snowe said.

The SBIR program was established by Congress in 1982 and the STTR program in 1992 to provide competitive grants to small businesses in the U.S. to encourage exploration of new technologies.

Federal agencies with an annual external R&D budget of more than \$100 million must allocate 2.5 percent of their extramural R&D dollars to the SBIR program.

Agencies with an annual external R&D budget of more than \$1 billion must allocate an additional 0.3 percent to the STTR program.

The last comprehensive reauthorization of the SBIR program occurred in 2000. That program, which was reauthorized for eight years, received two temporary extensions, first to March 20 and the most recent to July 31. The STTR was last reauthorized in 2001, also for eight years.

If enacted, the bill would reauthorize the programs for 14 years and would adjust the amount of SBIR and STTR awards to reflect inflation costs.

Similar bills were introduced in the 110th Congress, but stalled. (See *BioWorld Today*, Oct. 22, 2007, and April 28, 2008.)

FDA Deems Elan Antibiotic OK for Use Again

The FDA said last week that results of meta-analyses conducted by the agency indicated that Elan Corp. plc's Maxipime (cefepime), a broad-spectrum cephalosporin antibacterial, remains an appropriate therapy to treat Gram-negative and Gram-positive infections due to susceptible strains of microorganisms. However, regulators said they were continuing to review the drug's safety.

Regulators conducted the meta-analyses after an arti-

cle in the May 2007 issue of the *Lancet Infectious Diseases* raised questions about increased deaths linked to use of the drug. According to that article, the all-cause mortality was higher with Maxipime than other betalactams and for the subgroup of patients with febrile neutropenia.

Results from the FDA's follow-up trial-level meta-analysis, which included data from 88 clinical trials – the 38 trials from the *Lancet*-published meta-analysis plus data from an additional 50 trials – demonstrated there was no statistically significant difference in mortality between Maxipime and the comparators, regulators said.

The FDA also conducted a patient-level meta-analysis, which included 35 comparative clinical trials. Those results also showed no statistically significant difference in mortality with Maxipime and the comparator drugs, the agency said.

Dublin, Ireland-based Elan, which markets Maxipime in the U.S., obtained rights to the drug from Bristol-Myers Squibb Co.

Bill Seeks Proper Disposal of Unused Meds

Sens. Amy Klobuchar (D-Minn.), Charles Grassley (R-Iowa) and Dianne Feinstein (D-Calif.) introduced legislation last week aimed at providing patients with a safe, legal way to dispose of outdated or unused prescription drugs. A companion bill was introduced in March in the House by Reps. Bart Stupak (D-Mich.) and Lamar Smith (R-Texas).

While the Secure and Responsible Drug Disposal Act of 2009 could make it easier for people to legally and safely dispose of their prescription drugs, it is unclear how such a program would be paid for, and if drugmakers or the pharmacy community will be asked to foot the bill or chip in on the costs.

Stupak spokesman Nick Choate said the Drug Enforcement Administration would be responsible for implementing the program.

Under current law, consumers are prohibited from giving many prescription drugs to pharmacies for disposal, and long-term care facilities are not allowed to dispose of prescription medications on behalf of their residents. Regulators have urged people not to flush their leftover medicines, because of water supply contamination concerns, or to simply throw them into the trash unsecured, where the products could be consumed by animals or found by other people and abused.

The Pharmaceutical Research and Manufacturers of America said it believed drugs could be safely disposed of in the community trash as long as they are secured first. The trade group opposes so-called drug take-back or recycling programs.

"Requiring the pharmaceutical industry to design, implement, and fund a drug take-back or recycling program would do a disservice to communities where education might better serve patients and families in addressing these issues," PhRMA said in a statement. ■

CEOs

Continued from page 1

Sequella Inc., offered their candid views on overcoming stereotypes, juggling work-family issues and handling the ups and downs of running a company.

For Gluskin, the journey has been bittersweet. Her mentor and Generex co-founder, Mark Perri passed away and she herself endured an acute illness. But, though there have been some "moments of despair," she said, there also have been some big career highlights, such as becoming a patent holder and taking products to market.

Ryan admits that there have been personal sacrifices and "a couple of divorces along the way." But overall, she said she has led a very satisfying life.

For each of the four women, science was their first love and their initial calling was in academia or medical science. But their leadership skills took them on a different path.

Climbing the Ladder

Ryan decided at the age of 5 that she wanted to save lives after watching a documentary about a boy with leprosy. The Malaysian-born Brit, who recently founded Waltham Technologies, had a successful career as an academic researcher. She became an expert on the endothelium, an area of work that paved the way for ACE inhibitors, a widely used class of blood pressure medication.



Una Ryan,
Waltham Technologies

"I was not at the time tempted to go into the industry," said Ryan, who as a researcher had a negative perception of the drug business. She had ignored calls from a headhunter who tried to recruit her to work for Monsanto Co.

She finally relented after a slogan on her daughter's T-shirt – "If you're so smart, why aren't you rich?" – reminded her that she had not yet saved any lives, despite all her accomplishments to that point.

She's authored 11 books and more than 500 published papers, and had brought in hundreds of thousands of dollars in grant funding to her institution.

After 20 years as an academic researcher, Ryan decided to take the job at Monsanto in Chicago, where she learned first-hand how a company can grow by acquisitions. After three to four years at Monsanto, she decided that she would rather work for a smaller company.

She landed at T Cell Sciences Inc. (now Celldex Therapeutics Inc.) where she worked as chief scientific officer and spent a great deal of time presenting the science to Wall Street. As a result, she became the public face of the company, and in 1997 was suddenly thrust into the CEO position. While at T Cell, Ryan turned the company around. She completed a PIPE, settled a lawsuit with a landlord and

sealed a partnership with Swiss drugmaker Novartis AG.

"If you can do all that, you can run a biotech company," she said.

Ryan went on to found Avant Immunotherapeutics Inc. through a merger. In 2007, Avant and Celldex merged, combining the antibody pipeline of privately held Celldex with Avant's public listing and vaccine technologies. While Ryan was at the helm, Avant focused on diseases that cause diarrhea, and under her leadership the company received grants from the Gates Foundation and developed Rotarix a vaccine for rotavirus that was licensed to GlaxoSmithKline plc in 1997.



Anna Gluskin,
Generex Biotechnology Corp.

In her current role at Waltham Technologies, Ryan is working to develop clean water technologies using bioengineered blue-green algae, a system that could be useful to the food and beverage industry and possibly find use in therapeutic development in the future.

The road was a little different for Generex's Gluskin, who came from a family of doctors and had studied microbiology and genetics in Moscow. She was among the three founders of Generex, along with the brother-sister team of Mark and Rose Perri (who is now chief financial officer).

Gluskin made a promise to Mark Perri, that she would get the company's oral insulin drug, Ora-lyn, approved in the U.S.

The company has begun global Phase III trials of Oral-lyn in the U.S., Canada and countries in Europe. The product is approved in India and Ecuador.

Worcester, Mass.-based Generex recently presented positive Phase II data showing no significant differences in glucose levels during standard oral glucose tolerance tests with four or six Oral-lyn doses compared to baseline.

Without tapping any venture capital, Gluskin and the Perris used their own funds and support from family and friends to start Generex.

Biotech was just emerging when Tina Nova, of Carlsbad, Calif.-based Genoptix (former president of diagnostics firm Nanogen Inc.), who was on track to become a professor, felt the industry's pull.

Though it was a difficult decision to leave academia, "I felt like it was a better fit," she said. She took her first biotech job at Hybertech Inc. and was hooked.

Early in her career, Nova helped with work that led to the development of the prostate-specific antigen test.

Another career highlight would come ringing the bell when Genoptix went public. And she is proud of the fact that even in tough economic times, her company has more than \$100 million in the bank.

But Nova also has felt the blow of having an idea go

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CEOs

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bust, resulting in the spin-off of the instrument side of the business. Taking Genoptix in a new direction paid off, when in January 2007, the company became profitable.

Meanwhile, Sequella founder Nancy said her intention had “always been to be a scientist.”

She came to the industry following a nearly 20-year academic career.

Nancy ran a lab at the Walter Reed Army Medical Center, which focused on product development aimed at soldiers. It was the business side of the work that “intrigued me,” she said. That experience “gave me a taste for how you organize and structure a more business-like atmosphere.”



Carol Nancy,
Sequella

Running the lab provided a smooth transition to Nancy's executive roles, but it also helped to have role models like her former boss at Walter Reed, Wayne T. Hockmeyer. He founded Molecular Vaccines, which went public in 1991 after changing its name to MedImmune.

Nancy went on to help build EntreMed Inc., where she was second-in-command, and then went to Anergis Inc., a 10-year-old public company that was later acquired

by Corixa Corp., which itself was acquired by GSK.

She learned an important lesson at Anergis, which ran into the so-called “Valley of Death,” the period before a drug reaches the clinic, and faced lackluster investor interest.

For Nancy, it “taught me the value of getting to late-stage as quickly as possible.”

Rockville, Md.-based Sequella, which develops products to improve diagnosis and treatment of infectious diseases, has completed a Phase III trial of a tuberculosis patch diagnostic and a Phase I study of a TB antibiotic. Although Nancy said she is thrilled to be developing products for global health, she said she won't be satisfied until Sequella is cash flow positive.

Nancy, a mother of five, compared being a CEO to running a family. “Keeping your company alive is a huge responsibility,” she said.

Nancy's husband also was working as a scientist when they were raising their children. The couple didn't begin using daycare until the last child was about 3-years old. So her kids ended up spending a great deal of time with their mom, traveling to scientific meetings. She recalled using a “baby backpack” to hold her infant child at a poster session or presentation.

Ryan said she didn't try to keep work and family life separate. “I involved my children in my work,” she said, not-

ing that they sometimes had to tag along to the lab with her.

Women CEOs ‘Tend Not to Fail’

Women are well represented in middle management in areas such as marketing and production, Gluskin said. It's the next tier, she said, “where you really have an issue. . . . The glass ceiling is very much there.” But Hillary Clinton's historic run for the presidency in 2008 has helped to put more “nicks in the ceiling” and that gives Gluskin hope.

Perhaps one reason why there are so few women CEOs in biotech is that those women who do make it to the top tend to stick with that same company, Nancy surmised. However, venture capitalists like to see veteran CEOs who have led multiple firms, she said.

Not having serial CEO experience also could be a positive sign that women CEOs “tend not to fail,” said Nancy, who serves on the board of Women in Bio, a Maryland-based organization that provides networking opportunities and business education for female entrepreneurs, executives and researchers in the life sciences.

At Genoptix, there are three women on the board, including Nova. She said she certainly has met enough women who are “aggressive enough in a positive way” to lead companies. But she said she believes that some women are comfortable with getting to a vice president or directors position. In other cases, she said that the lack of women CEOs “may be a question for the VCs who hire these people.”

Sometimes, stereotypes alone can stand in a woman's way. Nova, at five-foot, three inches, has always looked younger than her age, and said it was even harder to overcome some of the biases against her. “It was blatant, and it was obvious. . . . I feel like you have to prove yourself more.”

Nova added that women are sometimes “put through a much bigger test than men in the same circumstances.”

Nancy has also faced the stereotypes, when people assumed she was a secretary or assistant, but “I didn't let it bother me.”

There also may be some unspoken rules for women, such as no bad hair days or red eyes. “A woman has to look her best, that's just part of the package,” said Gluskin, who always packs a change of clothes.

And who says it's taboo to be emotional? “I'm proud that I'm emotional and a human being,” Gluskin said. “Without my passion for the business, we wouldn't have been able to raise \$270 million for the company over 10 years.” ■



Tina Nova,
Genoptix

Arthritis

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some found mainly in immune system cells.

“Many people think of the proteasome as the trash disposal of the cell” that degrades misfolded and otherwise defective proteins, Christopher Kirk told *BioWorld Today*. But another, and perhaps more accurate way to think of the proteasome is as a regulatory system. Through “very coordinated and highly specific protein degradation” the proteasome controls cellular processes such as progression through the cell cycle.

Earlier work indicated that the immunoproteasome helps determine the antigen repertoire of T cells; in their new paper, Kirk, who is director of biology and pharmacology at Proteolix, and his colleagues showed that the immunoproteasome also controls the production of pro-inflammatory cytokines by several different cell types. Inhibiting LMP7 decreased the production of pro-inflammatory cytokines both in cells from healthy persons and from patients suffering from rheumatoid arthritis.

Inhibiting LMP7 also blocked T-cell precursors from differentiating into a specific type of T cell: T helper type 17, or TH17 cells. Those cells, Kirk said, have “a predominant role in pathogenic inflammation and a redundant role in infection,” making them a preferred target in autoimmune disease. Overall numbers of killer and helper T cells, as well as B cells, macrophages, lymphocytes and natural killer cells, were not affected.

When the researchers tested PR-957 in mice with two different forms of rheumatoid arthritis, they found that the compound inhibited the production of pro-inflammatory proteins including TNF-alpha, interleukin-1beta and interleukin-6, and also blocked joint inflammation and lowered the levels of autoantibodies.

In a direct comparison of PR-957 and the TNF-alpha blocker Enbrel (etanercept, Amgen Inc.) in arthritic mice, the authors found that mice treated with PR-957 improved more rapidly than those treated with etanercept. The compound also was more effective than etanercept in a model of aggressive arthritis.

Kirk said that, from the animal data, it appeared that PR-957 may have several strengths. In the studies, a single administration was able to ameliorate disease for long periods of time – up to 14 days. Kirk said that mouse models of rheumatoid arthritis are quite aggressive and occur on a much more rapid time scale than the human disease, adding that “the fact that a single dose of PR-957 had an effect that lasted two weeks is quite surprising in light of published knowledge with compounds like biologics. Therefore, we are hopeful that PR-957 may be effective with infrequent administration in the clinic,” though he cautioned that the optimal dosing schedule could only be determined empirically.

PR-957 has a mechanism of action that is different from both bortezomib and carfilzomib, which work partly by causing a pile-up of proteins that appears to push myeloma cells into apoptosis. During treatment with PR-

957, “there is not an accumulation of proteins, and, in fact, cells don’t die” – probably part of the reason why PR-957 does not have an overall immunosuppressive effect. Mice that were infected with a virus during treatment with PR-957 cleared the infection normally, a situation that is “very different from what is seen with broad-based immunosuppressive drugs,” Kirk said.

Because PR-957 specifically targets the immunoproteasome, it also appears to have a wider therapeutic window than either bortezomib or carfilzomib, both of which start having anti-inflammatory effects only near their maximum tolerated dose. PR-957 had anti-inflammatory effects at doses that were as low as one-tenth of its maximum tolerated dose.

In their paper, the authors called PR-957 “a powerful tool for understanding the role of LMP7 in immune responses.” And Proteolix CEO John Scarlett added that data “definitely support” the clinical development of PR-957 for the treatment of rheumatoid arthritis.

The company plans to file an investigational new drug application for the compound by mid-2010. ■

CLINIC ROUNDUP

• **Cephalon Inc.**, of Frazer, Pa., said its pivotal trial of lestaurtinib (CEP-701), when given in sequence with standard induction chemotherapy, failed to show increased benefit in overall survival compared to induction chemotherapy alone in patients with relapsed acute myelogenous leukemia expressing FLT3 activating mutations. An analysis of the study showed that patients who received lestaurtinib showed similar rates of complete response but no added survival benefit. Cephalon said the outcome of the study has no impact on its 2009 financial guidance, and analysts had not placed much value on lestaurtinib. Bret Holley, of Oppenheimer & Co. Inc., wrote in a research note that the drug’s failure was not unexpected given that FLT3 inhibitors “have had a poor track record in AML.” Lestaurtinib was designed to inhibit several tyrosine kinases, including FLT3 and JAK2. Cephalon’s stock (NASDAQ:CEPH) was unaffected Friday, closing at \$59.33, up \$1.80.

Congratulations

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Adimab

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since Gerngross and co-founder Dane Wittrup, a professor at MIT who has made key discoveries in the field, both are considered to be world leaders in yeast biotech. Gerngross previously founded GlycoFi Inc., a pioneer in glycoengineering, which allows the making of proteins such as monoclonal antibodies in yeast.

It offers some key advantages over other possible hosts. For example, human B-cell/hybridoma cell lines take days to generate a measurable readout, while Adimab's fully human, yeast-based platform provides a readout in hours, resulting in accelerated discovery and maturation cycles, according to the company.

"Eight weeks later, you walk away with 100 different antibodies," Gerngross said, whereas other approaches may take six months to a year to make a dozen antibodies.

Adimab's technology recently attracted the attention of Roche Holding AG and Merck & Co. Inc. In separate deals, Adimab will use its proprietary yeast-based antibody discovery platform to identify fully human antibodies against targets selected by the drug firms.

Roche has chosen a single target, while Merck has chosen more than one target.

Under the terms of the agreements, Adimab will receive various up-front payments, preclinical milestones and licensing fees. In addition, it is eligible to receive clinical development milestones and commercial milestones and royalties on therapeutic and diagnostic product sales.

Adimab already has a bit of a Merck connection. Gerngross's previous company GlycoFi was acquired by Whitehouse Station, N.J.-based Merck in 2006 for \$400 million in cash. Under the merger, Merck gained access to GlycoFi's yeast-based technology that provides the ability to make proteins such as monoclonal antibodies.

Antibodies that can be used to target surface proteins or ligands are "the fastest growing area in drug discovery right now," Gerngross said. For large pharmaceutical companies looking to tap into the high growth area of biologics, "access to antibody discovery is a must," he said.

In 2007, the top eight best-selling monoclonal antibodies had total sales of \$24.6 billion, said Janice Reichert, a researcher at the Tufts Center for the Study of Drug Development in Boston, citing figures from MedAdNews. The 2007 global sales were more than \$25 billion, she said.

According to sales data by IMS Health, one category of mAbs, antineoplastics such as Avastin and Herceptin (Genentech), Rituxan (Biogen Idec) and Erbitux (ImClone Systems), had U.S. sales of \$7.5 billion in 2008. Other categories of mAbs include anti-infective and immunological.

Adimab's recent antibody deals with Merck and Roche are just the latest examples of large pharmaceutical companies farming out drug discovery efforts to biotech firms.

In another recent deal, a Merck affiliate turned to privately held Canadian firm Xenon Pharmaceuticals Inc. to

carry out small-molecule, cardiovascular discovery work for Merck. (See *BioWorld Today*, June 12, 2009.)

Xenon's deal with Merck would bring in up to \$94.5 million for the first therapeutic target and up to \$89.5 million for each subsequent target selected for drug discovery. That partnership marked Xenon's fifth collaboration with a drugmaker; its previous deals were with Roche, Takeda Pharmaceutical Co. Ltd., Novartis Pharma AG and Pfizer Inc., formerly Warner-Lambert Co.

While Xenon conducts its own in-house drug development as well as drug discovery work for other firms, Adimab is solely involved in the drug discovery business – and wants to keep it that way.

As Gerngross noted, the company is "well capitalized right now," and by the end of the year, Adimab expects to be cash flow-positive. ■

CLINIC ROUNDUP

• **Forest Laboratories Inc.**, of New York, reported positive results from two Phase III studies of antibiotic ceftaroline in community-acquired bacterial pneumonia. Top-line data in each of the pivotal trials demonstrated that the drug met its primary objective of noninferiority and achieved high clinical cure rates compared to ceftriaxone in patients with moderate to severe pneumonia requiring hospitalization. Integrated efficacy data showed a clinical cure rate of 84.3 percent for the ceftaroline group vs. 77.7 percent in the ceftriaxone group. Last year, Forest reported that ceftaroline, which it picked up by acquiring Alameda, Calif.-based Cerexa Inc. in 2007, met its endpoints of noninferiority in two Phase III trials in complicated skin and skin structure infections. (See *BioWorld Today*, June 20, 2008.)

• **Human Genome Sciences Inc.**, of Rockville, Md., said partner **Novartis AG**, of Basel, Switzerland, completed enrollment and initial dosing in a Phase IIb trial of Albuferon (albinterferon alfa-2b) given monthly in combination with ribavirin in treatment-naïve patients with genotypes 2 and 3 chronic hepatitis C. The study involves 391 patients randomized to receive either Albuferon or peginterferon alfa-2a for a 24-week treatment period. The primary endpoint is sustained virologic response at week 48.

• **Oculus Innovative Sciences Inc.**, of Petaluma, Calif., reported preliminary results from its 40-patient feasibility study, which suggest that an enhanced version of its Microcyn Technology-based hydrogel might reduce the need for laser treatments and chemical peels caused by acne or acne treatments. The company plans to use that information to evaluate the potential of near-term market opportunities, while exploring longer-term partnerships.

OTHER NEWS TO NOTE

• **Geneart AG**, of Regensburg, Germany, said it was awarded a contract for the design and production of two DNA vaccine candidates against HIV by the UK HIV Vaccine Consortium. The genes, optimized and customized by Geneart, are to be used as the basis for clinical trials.

• **Lytix Biopharma AS**, of Tromsø, Norway, and Korean company **KAEL-GemVax** said they agreed to test their respective lead compounds, LTX-315 and GVI001, as a combination therapy for cancer. LTX-315 has demonstrated in preclinical testing the ability to result in necrotic killing of cancer cells, while GVI001, a telomerase peptide vaccine in Phase III trials, has shown broad use in a range of cancer types. Under the terms, both firms will contribute scientific and regulatory, as well as financial support to the planned study, and will share results for use in future clinical pro-

grams. Financial terms were not disclosed.

• **MDRNA Inc.**, of Bothell, Wash., said it completed negotiations with **RiboTask ApS**, of Odense, Denmark, to eliminate all downstream financial consideration resulting from collaborations established between MDRNA and potential partners, which gives MDRNA full financial and transactional control of its UNA (Unlocked Nucleobase Analog) technology. The UNA platform, when used in the synthesis of short interfering RNA, is designed to provide drug-like properties to an siRNA. Terms of the agreement were not disclosed.

• **The Medicines Co.**, of Parsippany, N.J., said the FDA granted pediatric exclusivity for Angiomax (bivalirudin), a direct thrombin inhibitor, based on studies submitted in response to a written request by the agency to investigate the drug's use in patients ranging from birth to 16 years of age. With that additional six months of exclusivity, the FDA will not authorize commercialization of generic versions of bivalirudin prior to September 2010.

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