Roche’s 454 Life Sciences and SeqWright bring their technologies to bear on the human exome to help understand dilated cardiomyopathy

BY JEFFREY BOOLEY

BASEL, Switzerland—Roche Applied Science and its 454 Life Science center of excellence are teaming up with Houston, Texas-based SeqWright and the University of Miami Miller School of Medicine in a collaboration aimed at using complete sequencing of the coding portion of the human genome to help elucidate the underlying genetic causes of heart disease.

The goal of the collaboration between Roche, SeqWright and the University of Miami Miller School of Medicine is to elucidate the genetic causes of heart disease.

This collaborative research effort is focused on identifying possible genetic variants associated specifically with dilated cardiomyopathy, and in this collaboration SeqWright is using NimbleGen Sequence Capture Human Exome Arrays to enrich more than 180,000 exons from DNA samples from individuals affected with this particular heart disease.

Using the Genome Sequencer FLX technology available from 454 Life Sciences, SeqWright is sequencing the enriched exons to detect genetic variants within genetic samples, including single nucleotide polymorphisms (SNPs) and insertions and deletions. This particular technology is being used because Roche’s

Targeted immunotherapy tag team

Genentech and Bayhill Therapeutics partner on development of antigen-specific immunotherapy candidate for type 1 diabetes in deal that could exceed $350M

BY AMY SWINDERMAN

SOUTH SAN FRANCISCO, Calif.—In a deal intended to further its focus on immunology drug development—and one marking its first partnership on a diabetes treatment—Genentech Inc. will work with Bayhill Therapeutics Inc., a clinical-stage biopharmaceutical company that develops novel and targeted treatment candidates for autoimmune diseases, to bring an antigen-specific immunotherapy candidate for type 1 diabetes (T1D) to market.

The exclusive, worldwide license agreement was announced by the companies last month and is centered on the development and commercialization of Bayhill’s BHT-3021, a plasmid encoding proinsulin designed to target specific pathogenic immune cells responsible for the autoimmune response in type 1 diabetic patients. The compound is currently in a Phase 1/II clinical trial in patients with T1D.

Bayhill will complete the ongoing Phase 1/II trial, which Genentech will fund and then take on the responsibility of all future research development and commercialization efforts. For this promising program, Genentech will pay Bayhill $25 million in cash and equity upfront in addition to development, regulatory and sales milestone payments that could exceed $325 million. Although both companies have yet to put a dollar figure on Bayhill's

A new extension for Microsoft

Software giant acquires Rosetta Biosoft assets from Merck, boosting Amalga Life Sciences platform

BY LLOYD DUNLAP

REDMOND, Wash.—Microsoft Corp. has signed an agreement with Merck & Co. Inc. to acquire the assets of Rosetta Biosoft, a business unit of Rosetta Inpharmatics LLC, a wholly owned subsidiary of Merck. The assets include the patents, software, branding and key employees. Concerning the latter, the company says it is “filling specific roles that are deemed critical to the smooth transition of incorporating Rosetta technologies into Amalga Life Sciences.”

The deal enables Microsoft to incorporate genetic, genomic, metabolomic and proteomic data management software into the Microsoft Amalga Life Sciences platform for enhanced translational research capabilities. The platform was introduced April 28 at the Bio-IT World Conference & Expo and shortly thereafter adopted by the nearby Fred Hutchinson Cancer Research Center.

The key drivers behind the deal were significant synergies

ON-SITE SHOW SECTION

IBC Life Sciences’ 14th annual Drug Discovery & Development Week heads to Boston! SEE PAGE 17

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CAMBRIDGE, Mass. — Aileron Therapeutics, a biotechnology company discovering and developing a novel class of therapeutics called Stapled Peptides, announced in June a $40 million Series D financing round co-led by new investors SR One Ltd., the independent corporate venture fund of GlaxoSmithKline plc., and Excel Medical Fund. The round also included major participation by existing investors: Apple Tree Partners, the founding investor of Aileron, and Novartis Venture Fund. Lilly Ventures and Roche Venture Fund also participated in the offering.

Aileron Therapeutics was first funded in 2005 by Apple Tree Partners to develop and advance a therapeutic modality and class of drugs called Stapled Peptides that are based on discoveries made at Harvard University and the Dana-Farber Cancer Institute. Stapled Peptide drugs represent the first general solution for modulating intracellular protein-protein interactions. As such, Stapled Peptide drugs offer a unique opportunity to exploit potentially thousands of currently “undruggable” targets across all human diseases.

According to Joseph A. Yanchik III, Aileron CEO, the company has demonstrated in multiple preclinical studies the powerful potential that Stapled Peptides represent in the treatment of cancer.

“The timing of the financing round and the caliber of the participants is further validation of the growing belief in the transformative potential of this novel class of therapeutics and the need for breakthrough technology platforms that will offer significant new growth avenues for the pharmaceutical industry,” Yanchik says.

The program could represent a “fourth estate” in therapeutics, emerging as a major class akin to small molecules, antibodies and vaccines, says Dr. Michael Diem, partner at SR One.

As part of the closing of this financing transaction, Diem and Dr. Enrico Petrillo, managing director of Excel Medical Fund, will join the board of directors of Aileron, joining Yanchik and existing board members Dr. Seth Harrison, chairman of Aileron and managing general partner of Apple Tree Partners, and Dr. Campbell Murray, managing director of Novartis Venture Funds.
**Pharmaceutical and Biotech Market Indices**

**Amex Pharmaceutical Index**

**Burrill Select**

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**Biotech shows glimmer of an upward trend**

**Burrill & Company**

San Francisco—The markets closed out May in positive territory following on from their April performance, which was their best month in nine years. The Dow Jones industrial average posted its third straight monthly gain closing up 4 percent with the Nasdaq close behind—up 3.3 percent in May. The positive market trend helped biotech with the Burrill Biotech Select Index posting a modest monthly gain of 0.4 percent.

“There is just a glimmer of an upward trend for biotech as evidenced by the performance of the Burrill Mid-Cap Biotech Index, whose members have been particularly hard hit during this economic downturn,” said G. Steven Burrill, CEO of Burrill & Co. “For the past couple of months, some of the companies in the Index, such as Cougar Biotech, Geron, and Dendreon, have been on a tear pushing the year-to-date performance of the Index up a remarkable 16 percent, with a 5 percent jump in May alone.”

Vaulting development-stage biopharma Cougar Biotechnology’s share value by 33 percent in May was the news that Johnson & Johnson bid approximately $970 million cash to acquire the company and gain access to compounds in development for the treatment of prostate cancer and multiple myeloma.

“The predicted land grab of biotech by Big Pharma because of their depressed valuations has not yet panned out, with pharma companies preferring to acquire each other, said San Francisco-based venture capital firm Burrill & Co. However, the firm says we may see an upswing in M&A activity heading into the summer months, since Johnson & Johnson’s May 22 acquisition of Cougar Biotechnology may prompt pharma, who have generally been sitting on the sidelines, to “pull the trigger” on biotech deals so that they don’t lose out to their competitors.

“While the industry overall is still going through tough times, and we predict it is still going to take many more months before biotech starts on the road to full recovery, it is encouraging to see that investors are prepared to reward biotech companies that do achieve significant milestones,” Burrill noted.

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**Clinical Data’s Q4 loss widens on higher R&D costs**

**Newton, Mass.—**Despite strong revenue growth, Clinical Data Inc. reported a wider loss in the fourth quarter due to higher research and development expenses related to Phase III trials of its antidepressant drug, vilazodone, and its recent acquisition of Avalon Pharmaceuticals.

For the fourth quarter, net loss widened to $23.9 million, or $1.05 per share, from $14.7 million, or 70 cents per share, compared to the previous year. Loss from continuing operations for the period was $21.5 million, or 94 cents a share, compared to $11 million, or 52 cents a share, in Q4 2008. R&D costs increased 140 percent to $12.8 million from $5.3 million due to the vilazodone Phase III clinical and safety trials initiated in late 2008 and completed last month. Q4 revenue grew 103 percent to $3.2 million from $1.6 million due to the expansion of the Qiagen health sales and marketing force and increased payor coverage in the last months.

For the full fiscal year 2008, net loss widened to $132.4 million, or $6.03 per share, from $53.5 million, or $1.65 per share. Loss from continuing operations was $123.7 million, or $1.69 a share, compared to $32.3 million, or $0.63 a share, last year. Revenues for the year rose 104 percent to $10.4 million from $5.1 million in 2008. R&D expenses increased 161 percent to $44.1 million from $16.9 million.

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**Enzo Biochem posts record revenues in third quarter**

**New York—**Enzo Biochem Inc. last month reported a 22 percent increase in its third-quarter revenues. Total revenues increased to a Q3 record of $23.1 million, compared with $18.9 million in the third quarter of 2008, due to a 50 percent spike in product revenues, a 20 percent increase in royalty and license fee income from its Life Sciences division and increased service revenues from Enzo Clinical Labs. Gross profit increased 8 percent to $10.1 million in Q3 2009 from $9.3 million in Q3 2008.

Net loss, including $1.3 million of non-cash expenses as a result of acquisitions, was $4.2 million, or 12 cents per share, compared to a net loss of $2.1 million, or 6 cents per share, in the year-ago third quarter.
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Novartis nabs Austria’s Ebewe

Swiss drugmaker expands specialty generics business with $1.2 billion purchase of injectable drug unit

BY DAVID HUTTON

BASEL, Switzerland—Novartis AG has reached an agreement to purchase Austrian drug developer Ebewe Pharma’s injectable-drug unit for $1.2 billion in cash to gain generic copies of oncology medicines. The acquisition gives Basel, Switzerland-based Novartis, Europe’s second-largest drugmaker, 15 approved cancer medicines and another 20 experimental ones. The three most promising drugs in Ebewe’s pipeline are copies of medicines that command annual sales of more than $5 billion.

“The addition of Ebewe Pharma’s leading portfolio of oncology medicines fits our strategy and improves our ability to help cancer patients around the world by providing easier access to therapies,” said Dr. Daniel Vasella, chairman and CEO of Novartis, in a statement. “Ebewe Pharma will further strengthen our pipeline with many planned near-term launches.”

Under the terms of the agreement, Novartis will take over the R&D and manufacturing assets of Ebewe’s business. This includes tangible assets, such as a production site in Austria, intellectual property and related expertise. The deal, however, excludes Ebewe’s separate, smaller neurological products business.

Novartis said the transaction would give its generic pharmaceuticals division Sandoz the opportunity to create a “strong global platform” for future growth. Ebewe deals primarily in generic injectable cancer treatments, including paclitaxel, epirubicin and carboplatin, which are standard ingredients of chemotherapeutic drug programs for various types of cancer.

Deuterium discovery deal

GSK and Concert Pharmaceuticals to develop deuterium-modified drugs in deal worth up to $1 billion

BY AMY SWINDERMANN

LONDON—GlaxoSmithKline plc will collaborate with Concert Pharmaceuticals on the development and commercialization of deuterium-modified drugs, the companies announced last week. Including milestone payments, the deal could bring Concert $1 billion for its R&D programs.

The deal includes three of Concert’s research and development programs; namely, CTP-518, a protease inhibitor for the treatment of HIV expected to enter Phase I clinical trials in the second half of 2009, a preclinical compound for chronic renal disease, and a third, unspecified research product in Concert’s pipeline. Concert will also provide GSK with deuterium-modified versions of three GSK pipeline compounds for GSK to develop.

Under the terms of the agreement, Concert will receive $35 million in upfront payments, including a $16.7 million equity investment by GSK. Concert is eligible to receive milestones and tiered, double-digit royalties, giving Concert the potential to earn more than $1 billion in total milestone and upfront payments from GSK spread across all programs.

For each of its pipeline programs, Concert will have R&D responsibility through completion of pre-agreed clinical trials. After the completion of clinical trials for each program, or earlier if it chooses, GSK may elect to obtain an exclusive, worldwide license to product candidates within the program.

GSK will assume responsibility for development and commercialization, while Concert will retain full rights to further develop and commercialize its product candidates in any program GSK chooses not to license.

“With GSK’s continued focus on HIV therapies—an effort boosted recently by GSK’s partnership with Pfizer on HIV drug development—the agreement fits into the company’s goal of accessing “the best science and technology platforms worldwide,” says Janet Morgan, a GSK spokeswoman.

“In keeping with our strategy of seeking external collaborations and forming alliances, we were looking for different scientific approaches, and what Concert is doing came to our attention,” says Morgan. “Concert has a very promising technology that could work across a wide range of diseases.”

Dr. Roger Tung, Concert president and CEO, added that

France’s Cerep inks deal with Lilly

BY DAVID HUTTON

PARIS—Cerep has announced an agreement with Eli Lilly & Co. covering the use of its kinase assay platform to study undisclosed drug targets. Under the terms of the agreement, Cerep will provide Lilly with access to the company’s expanded kinase assay platform for research into undisclosed drug targets. The agreement, announced in June, is an extension of an already existing arrangement between the companies covering access to Cerep’s GPCR screening portfolio. Financial terms of the agreement were not released.

“This is an example of...
Sciele claims Victory in pain battle with $150M acquisition

BY LORI LEO

ATLANTA—In a move orchestrated to diversify and take a bite out of the profitable U.S. pain management market, Atlanta-based Sciele Pharma Inc., a subsidiary of Shionogi & Co. of Osaka, Japan, has acquired Victory Pharma Inc., a U.S. specialty pharmaceutical company based in San Diego. Victory’s lead product is Naprelan, a non-steroidal anti-inflammatory drug (NSAID).

Under the terms of the agreement, announced May 18, Sciele will pay $150 million at closing. The transaction is expected to take place in the second quarter of 2009. The deal is subject to clearance under the Hart-Scott-Rodino Antitrust Improvement Act and other customary closing conditions.

Victory markets Naprelan (naproxen sodium), a trademark of Elan Corp., controlled-release tablets and other pain products to pain management specialists, rheumatologists, orthopedic surgeons and selected primary care physicians through its physician office-based field sales force.

Matthew Heck, Victory Pharma president and CEO, declined to comment on this story due to confidentiality issues. However, Heck stated in a press release, “Naprelan exhibits a good gastrointestinal safety profile, and with the well-publicized cardiovascular toxicity concerns regarding COX-2 inhibitors, the treatment paradigm is shifting back to traditional NSAID therapies in the U.S. and other countries. Naprelan is well-positioned for this shift, and the franchise appears to have additional growth potential.”

Founded in 2004, Victory Pharma is a privately held specialty pharmaceutical company focused on acquiring, developing and marketing products to treat pain and related conditions.

“Over the past several years, we have been pleased with our progress at Victory,” Heck stated. “We have built an outstanding pain franchise and believe that Sciele has the resources to maximize the potential of Victory’s marketed products and its research and development pipeline.

Joseph T. Schepers, Sciele Pharma’s director of investor relations, explained the company’s decision to approach and acquire Victory in this way: “In business and development, we are always looking for new opportunities to grow and diversify. Sciele has focused on the therapeutic areas of cardiovascular, diabetes, women’s health and pediatrics. And Victory’s expertise in pain medication is part of Sciele’s diversification strategy.”

Sciele Pharma’s Web site states the company “is committed to continue its growth through business development initiatives—primarily licensing and acquiring products and/or companies. Licensing and acquiring late stage and commercialized products for sale in the United States are key to our near- and long-term success.”

Sciele’s cardiovascular and diabetes products treat patients with high cholesterol, hypertension, high triglycerides, unstable angina and type 2 diabetes; and its pediatrics products treat allergies, asthma and attention deficit and hyperactivity disorder (ADHD).

Victory listed its net sales in 2008 at $57 million, and Sciele has the resources to further accelerate the growth of the newly acquired products, Schepers said. With 720 Victory employees in the sales force all over the U.S., Sciele will market its newly acquired products only in America.

Ed Schutter, Sciele’s president and CEO, said in a company press release, “The acquisition of Victory is another important step in the implementation of Sciele’s strategic plan to further diversify our product portfolio and generate additional growth for Sciele. This acquisition provides an immediate expansion into the pain market for Sciele, establishes a platform from which to acquire additional pain management products and aligns Sciele with Shionogi’s focus in pain management.”

The pain market has been one of Shionogi’s target therapeutic areas. Shionogi will further accelerate the development of its drug candidate for the alleviation of opioid-induced adverse effects and other preclinical compounds.

Sciele claims Victory in pain battle with $150M acquisition

GLOBAL NEWS

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For more information, visit www.DrugDiscoveryNews.com
Boehringer Ingelheim and DxS in lung cancer diagnostic deal

BY LLOYD DUNLAP

INGELHEIM, Germany—Boehringer Ingelheim and DxS have partnered on a clinical trial to identify likely responders to new treatment for non-small cell lung cancer, the companies announced in June. Financial terms of the agreement were not disclosed.

Boehringer Ingelheim has chosen DxS as a partner because of the company’s diagnostic kit for measuring mutations in the epidermal growth factor receptor (EGFR) in patients with lung cancer.

“We now wish to work together to adapt this kit for use in Boehringer Ingelheim’s global multi-center, Phase III clinical trial of BIBW 2992 (Tovok) and ensure that the kit is available for the subsequent worldwide commercialization,” says Dr. Manfred Haehl, corporate senior vice president of medicine at Boehringer Ingelheim. He adds that DxS is a company at the forefront of developing diagnostic solutions for personalized medicine.

BIBW 2992 is a novel tyrosine kinase inhibitor that acts by irreversibly blocking the EGFR/HER2 receptors, which are promoters of tumor growth. As with other tyrosine kinase inhibitor therapies, patients with mutations in the EGFR gene will be more likely to respond to a medication that targets these receptors, thereby allowing doctors to prescribe the most effective and individual treatment. Furthermore, BIBW 2992 has demonstrated preclinical activity against erlotinib- and gefitinib-resistant mutations. Neither of the compounds blocks the target receptors irreversibly.

Clinical data published to date suggests that BIBW 2992 offers a marked increase in efficacy in comparison to standard treatments for lung cancer patients carrying mutations in the EGFR gene. The drug is currently in Phase III clinical development in non-small cell lung cancer (NSCLC). As epidermal growth factor receptor (EGFR) and human epidermal growth factor receptor 2 (HER2) play a pivotal role in many solid tumors, BIBW 2992 is also being investigated in other indications, including breast, colorectal, head and neck cancers and glioblastoma.

Prediminary data were presented at ASCO 2009 for the first 73 second-line patients, all of whom had previously received one regimen of chemotherapy. Sixty-seven patients were evaluable for response. Interim data show that 64 percent of patients taking BIBW 2992 in the second-line setting experienced a partial response, with 31 percent experiencing stable disease. Median progression-free survival (PFS) in the second-line setting was 10.2 months.

The DxS EGFR companion diagnostic is a real-time PCR assay, designed to detect the most common mutations in the EGFR gene. The diagnostic has been developed and manufactured at DxS’ head office in Manchester, UK, and will be available later in the summer for Boehringer Ingelheim’s global, multi-centre Phase III clinical trial for BIBW 2992.

Commenting on this announcement, Dr. Stephen Little, CEO of DxS, says “This is another great endorsement of our companion diagnostic assays for predicting patient response to targeted therapies. It is an exciting step forward for personalized medicine, and DxS is pleased to be at the forefront of this revolution in cancer treatment.”

Little notes that there are two sets of hurdles to overcome in genetic testing when looking at tumor tissue rather than SNPs.

“When you’re looking at tumors, the detection technique must work on the tumor biopsy—there isn’t just one tumor cell for analysis, but rather background,” he notes. The second challenge is consistency: “In academic and other settings, ‘home brews’ don’t have the necessary consistency. Our tests must work every time over 10,000 or even 100,000 samples,” he states.

Privately held DxS has an expanding portfolio of cancer mutation products. Its TheraScreen range of CE-marked clinical diagnostic kits can identify genetic tumor mutations that affect how patients respond to cancer therapies. DxS markets two clinical diagnostic kits, K-RAS and EGFR-29. The K-RAS Mutation kit is a companion diagnostic for Vectibix (Amgen) and Erbitux (Merck KGaA) for the treatment of colorectal cancer. DxS has an exclusive global distribution agreement with Roche Diagnostics for the distribution of its K-RAS and EGFR-29 mutation kits.

The partnership wasn’t built overnight and the companies’ demonstrated abilities in the field played a role in the developing collaboration. Bielefeld-Sevigny says that with regard to benefiting patients, Cerep’s arrangement with Eli Lilly & Co. is aimed at more efficient and timely profiling of kinase inhibitor leads for faster identification of better and safer therapeutics.

The partnership wasn’t built overnight and the companies’ demonstrated abilities in the field played a role in the developing collaboration. Bielefeld-Sevigny notes, adding that PerkinElmer has built a reputation as a provider in kinase screening and profiling technologies for both drug discovery and basic research.

“Our assays are used to enable research of hundreds of targets in several diseases including cancer, inflammation, diabetes or cardiovascular disorders,” she says. “Cerep has world-class profiling services with a compelling value proposition for pharma research organizations. This synergistic value proposition formed the basis of the successful collaboration inaugurated a year ago.”
NOVARTIS
CONTINUED FROM PAGE 6
In particular, Ebeve offers broad and highly complementary capa-

bilities in their portfolio, with more than 15 marketed generic injectable medicines, as well as a differentiated R&D portfolio,” he says. “Injectables are a key com-

ponent of Sandoz’s differentiation strategy, which focuses on high-

er-value ‘difficult-to-tackle’ products. Combined, these factors offer the

opportunity to improve access to injectible cancer drugs for patient

worldwide.”

Ebeve Pharma, an Austrian company with approximately 500 associates, also has a differenti-

ated development portfolio with more than 20 distinct molecules that include significant near-term launch opportunities.

“As the world market for generic injectables to treat cancer continues to expand, our specialty generics business will enjoy a much broad-

er global reach as part of Sandoz. We will also be able to offer greater benefits to patients and healthcare providers while creating a more competitive growth platform for our complementary businesses,” says Friedrich Hillebrand, Ebeve’s

CEO.

It is likely that the Ebeve acqui-
sition alone won’t breathe new life into Novartis’ generics business, Vasella stated. The key reasons for the unit’s lackluster performance in recent quarters were a lack of new product launches in the U.S., and the withdrawal of one prod-

uct, also in the U.S., he said.

The deal boosts Novartis’ offering

of cancer products and under-

lines the drugmaker’s strategy of offering its customers medicines ranging from cheap generics, when available, to branded products.

“It is the same customers—
hospitals—that are buying the branded drugs and the generics,” Vasella said.

Given the significant cost pres-
sures in cancer therapy, Vasella said he expects the use of gener-

ic drugs to increase. The use of cheaper generics for standard treatments helps preserve cash that can be redeployed to be used on treatment with newer, more effective drugs, which are also more expensive, he said.

The Novartis deal comes in the wake of other recent over-

seas acquisitions, including GlaxoSmithKline PLC’s recent acquisition of a 16 percent stake in African generic drugmaker Aspen Pharmacare Holdings Ltd. and sanofi-aventis’ takeover of Czech generics company Zentiva.

Business will enjoy a much broader

injectables to treat cancer continues

more than 20 distinct molecules

associated, also has a differenti-

at novartis.com/europe

For more information, visit www.DrugDiscoveryNews.com

CONCERT
CONTINUED FROM PAGE 6
the collaboration is a major step forward in the Lexington, Mass.-
based company’s strategy to advance a broad pipeline of novel deuterium-modified therapeu-
tics. Since it was founded in 2006, Concert has raised more than $100 million from venture capitalists and institutional investors, including SR One Ltd., GSK’s healthcare venture fund.

“Our approach is one that has resonated well with investors,” Tung says. “Deuterium has been explored by other companies, but always in the context of a particu-

lar program. We believe this has the potential to have a lot of applica-
tions across a variety of small-
molecule therapeutics.”

A non-radioactive relative of hydrogen that can be isolated from sea water, deuterium is heavier than hydrogen, forming a stronger chemical bond to a carbon atom of a molecule. This bond obtained by selective deuterium modification may substantially improve the drug’s metabolic properties, potentially resulting in better safety, tolerability and/or efficacy of an isotopl of hydrogen.

Deuterium has been used extensively in human metabolic and clinical studies. According to Concert, CTP-518 has the potential to be the first HIV protease inhibi-
tor to eliminate the need to co-dose with a boosting agent. Current standard of care is to co-adminis-

ter HIV protease inhibitors with ritonavir, which is associated with significant complications. CTP-

518 replaces certain key hydrogen atoms of atazanavir with deute-

rium.

In preclinical studies, Concert has demonstrated that selective deuterium modification of atazana-

vir fully retains its antiviral poten-
ty but can markedly slow hepatic metabolism, thereby increasing half-life and plasma trough levels.

To date, Concert has filed more than 100 patent applications on deuterium-substituted drugs, several of which could cover the drugs as new chemical entities, giving GSK and Concert a competitive edge and guarding against the patent cliff facing Big Pharma in the next few years. 

For more information, visit www.DrugDiscoveryNews.com
Getting personal about personal genetics

BY ANY SWINDERMANN

I OFTEN FEEL THAT I have one of the most interesting and gratifying jobs a person can have—reporting on the latest life science breakthroughs in the world of pharmaceutical discovery, advances that may impact the bottom line of large pharma and small biotechs right now, but will have significant, potentially life-altering, meaning for all of us later. As a writer and an editor, I am drawn to these stories especially when your sources are passionate about what they do. But once in a while, a story hits especially close to home, and I can’t help but cast my red pen aside and view it from the perspective of a patient.

I have fibromyalgia, a chronic pain disorder. I am also the co-founder of a support group for fibromyalgia patients in Northeast Ohio. As most of you readers probably know, fibromyalgia is considered a controversial condition because it affects patients differently and there are no laboratory or medical imaging tests to identify the condition. The disease is characterized by a lengthy—years, sometimes decades—process of elimination before receiving a fibromyalgia diagnosis. After that, the real battle begins: finding a doctor knowledgeable about the disease; experimenting with the various “drug cocktails”; finding ways to explain your condition to family, friends and colleagues; making appropriate adjustments to your lifestyle.

In the past few years, many pharma companies have begun to focus on developing therapies for fibromyalgia and the pain management market has been identified by many research firms as a worthwhile R&D investment for years to come. None of this is reported by the mainstream media, of course. Very little of what is being done in the field of fibromyalgia research and development is known to doctors and patients, so most fibro patients, who are already weary of hearing “fibromyalgia is very difficult to treat,” from their doctors have the impression that very little is being done to help them.

In the Genomics & Proteomics section of this issue, you will see two stories about firms dedicated to the concept of personal genomics—companies that offer partial genetic scans that assess the risk of genetic disease, directly to the consumer. For example, for $999, you can spit in a tube and mail it to 23andMe, which will analyze your DNA in four to six weeks and enable you to explore your genome. 23andMe, like any other company, wants to make money, so if you are a 44-year-old woman with a family history of breast cancer, you will have a higher chance of being diagnosed with breast cancer, and you will want to have a mammogram every year.

In my small sample of a half dozen companies that assess the risk of genetic disease, directly to the consumer, the concept is one that is extremely empowering to patients, especially those afflicted with a condition like fibromyalgia, because it gives us insight into what is going on with our health and reasons to adapt our lifestyle in order to achieve a better quality of life.

That goal is one all pharma claims is their reason for existence, but controversy surrounds the concept of personal genomics, for many reasons. One viewpoint in particular troubles me: as a patient: the notion, as 23andMe’s Lizzie Dorfman put it, that some patients may not be able to “handle” knowing more about their health, and that some doctors feel it’s not their responsibility to “explicate” the outcome of these personal genetic tests to their patients.

If true progress is going to be made in life sciences and medicine, if patients are to achieve and maintain good quality of life, we must all assume some degree of responsibility. I see this situation as a domino effect: If patients are given the choice of getting more involved in their healthcare, will they charge their doctors to do more than write a prescription and move on to the patient in the next room? Doctors will be compelled to keep abreast of the latest disease research and provide their patients with more personalized care. I believe it is important to explain honestly and clearly answer, but there are consequences. It’s one of those questions where there is no clear answer, but there are consequences.

I’d like to dedicate this column to the patients in my fibromyalgia support group who inspired me to speak out about this issue, as they are tired of suffering in silence behind the roadblock of having a “difficult” disease. We want more, and we deserve more. We must give patients the credit and choices they deserve. 


Beware the gatekeeper of information

BY PETER T. KISSINGER

REAL LEADERS AVOID secrecy like nature abhors a vacuum. Tyrants want to understand the problem and are a part of the solution. Teach them how to read financial statements. Welcome their input.

According to multiple research studies, the leadership style of a CEO is the biggest influencer on a company’s performance. Managers at all levels can exhibit the tendency to protect turf by controlling information and not sharing it. They share it, discuss it and maintain good quality of life, we must all assume some degree of responsibility. I see this situation as a domino effect: If patients are given the choice of getting more involved in their healthcare, will they charge their doctors to do more than write a prescription and move on to the patient in the next room? Doctors will be compelled to keep abreast of the latest disease research and provide their patients with more personalized care. It’s one of those questions where there is no clear answer, but there are consequences.

I believe it is important to explain honestly these ambiguities and not hide them. In technology companies, we have a lot of smart people, but we don’t all know about everything. If we are allowed to contribute our ideas, this will be appreciated even if a decision goes against us. The imperious among us like to shut off debate before it has started.

Managers at all levels can exhibit the tendency to protect turf by controlling information. I never want to work with a person like this. Either should you. Leaders don’t fear information getting out. They share it, discuss it and seek alternative points of view. This is a sign of confidence and strength. It is not a sign of weakness. Hiding the truth is convenient at times, and wrong! 


Peter Kissinger is chairman emeritus of BASI, CEO of Prosigma in Indianapolis and a professor of chemistry at Purdue University.
Fixing the U.S. Food and Drug Administration: More money and power, or more competition?

BY JOHN R. GRAHAM

All President Obama’s high-profile appointments, Dr. Margaret Hamburg’s nomination as U.S. Food and Drug Administration (FDA) commissioner was probably the easiest. Coasting through the Senate Health, Education, Labor and Pension (HELP) committee to an unqualified chorus of praise, the eminently qualified Hamburg takes over an agency that many people believe is underfunded, understaffed and ill-equipped to face the threats of a world in which food and drugs move across borders and out of laboratories with barely a glance of a regulatory eye passing over them.

At least, that’s what the senators confirming Dr. Hamburg’s appointment seemed to think, promising to vote more money and power to her office. With respect to prescription drugs, the HELP committee revisited the case in 1997. But rather than fund a new office, a law was passed in 2002, ensuring that any additional funding was divvied up among the ~100,000 representatives of new medicines.

At least, that’s what the senators confirming Dr. Hamburg’s appointment seemed to think, promising to vote more money and power to her office. With respect to prescription drugs, the HELP committee revisited the case in 1997. But rather than fund a new office, a law was passed in 2002, ensuring that any additional funding was divvied up among the ~100,000 representatives of new medicines.

The FDA is understaffed and has an enormous workload. For example, in 2002, the FDA had a budget of about $500 million for 2007, which is 50 times more productive than the FDA, the FDA made the FDA’s user fees are also significantly higher than those of comparable regulators in other countries. In 2001, the FDA charged manufacturers approximately $250,000 for reviewing each new medicine, whereas the European regulatory agencies charged the equivalent of between $90,000 and $100,000. Unfortunately, this has not resulted in increased productivity. The three other countries are also significantly more productive, by this definition.

Leviathan’s Drug Problem: Federal Monopoly of Regulation, conducted from which this viewpoint is adapted. The recent success of the FDA, the Center for Drug Evaluation and Research (CDER), has a budget of about $500 million for 2007, of which about $250 million was from user fees. Since 2004, user fees have accounted for most of the CDER’s budget than appropriations. Similar to 2004, the number of staff for new drug review supported by user fees, 1,320 was higher than the number supported by appropriations (1,287) for the first time. The FDA’s user fees are also significantly higher than those of comparable regulators in other countries. In 2001, the FDA charged manufacturers approximately $250,000 for reviewing each new medicine, whereas the European regulatory agencies charged the equivalent of between $90,000 and $100,000. Unfortunately, this has not resulted in increased productivity.

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Objections to the FDA’s user fees are also significantly higher than those of comparable regulators in other countries. In 2001, the FDA charged manufacturers approximately $250,000 for reviewing each new medicine, whereas the European regulatory agencies charged the equivalent of between $90,000 and $100,000. Unfortunately, this has not resulted in increased productivity.

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QUITE THE PAIR

Ingenuity-Integromics integration offers comprehensive genomics analysis

BY JEFFREY BOULEY
REDWOOD CITY, Calif.—Ingenuity Systems and Madrid-based Integromics S.L. announced in mid-June the integration of RealTime StatMiner and Integromics Biomarker Discovery (IBD) for Tibco Spotfire with Ingenuity Pathway Analysis (IPA).

This combined platform is intended to offer researchers “a uniform solution to visualize and statistically assess microarray gene expression data, and then identify relevant biological processes and pathways,” according to the companies.

Reportedly, researchers can now leverage a streamlined workflow to send the data from RealTime StatMiner, a step-by-step workflow-oriented solution for RT-qPCR data analysis directly into IPA. Likewise, data from IBD for Tibco Spotfire, an application to pre-process, normalize and interpret raw microarray gene expression data, can also be sent directly into IPA. The result, the companies say, is better modeling, analysis and understanding of biological data.

The overriding objective is to provide joint customers with relevant workflows that help them best understand their gene expression data, says Tuan Nguyen, vice president of partner and professional services for Ingenuity Systems. “We felt it was important to provide a streamlined way for researchers to move from raw data analysis to understanding relevant biology, RealTime StatMiner and IBD for Tibco Spotfire together with IPA offer a complete and reliable platform to provide researchers with confidence in their data analysis and interpretation.”

For E-Notebook system, it’s official

University of Antwerp selects CambridgeSoft’s E-Notebook for university-wide research use

BY JEFFREY BOULEY
CAMBRIDGE, Mass. — Following a one-year pilot effort during which selected researchers at the University of Antwerp in Belgium used CambridgeSoft’s E-Notebook system as the primary laboratory notebook to replace their traditional paper record-keeping, the tool has now found a more permanent home there. In mid-June, CambridgeSoft announced a university-wide deployment of E-Notebook that will encompass all members of the medical chemistry, organic synthesis, genomics, biochemistry pharmacology and other disciplines that have benefited from the data from their laboratory experiments, not just in terms of analytical instrument output but also including data within Microsoft Office documents, chemical and biological structures, and images.

According to Michael G. Tomasic, president and CEO of CambridgeSoft, data within E-Notebook is securely stored...

INFORMATICS

Waters and Dotmatics collaborate on metabolism elucidation solution

PHILADELPHIA—Waters Corp. and Dotmatics Ltd. in June announced an agreement to develop an integrated advanced metabolism elucidation tool to complement Waters’ time-of-flight mass spectrometry products and Xevo MS and SYNAPT G2 products. The agreement will focus on developing a fully integrated solution for metabolism elucidation between the Dotmatics and Waters MassLynx informatics platform that will provide scientists the capability to identify the nature and site of metabolism of a candidate pharmaceutical compound, allowing them to accelerate optimization in drug discovery. Financial terms of the partnership were not disclosed.

“We are delighted to be continuing our collaboration with Waters,” says Mike Hartshorn, director and CSD at Dotmatics. “Through this agreement, we will be able to deliver cutting-edge MS analysis software to scientists across the drug discovery industry.”

ICF International receives $60 million NIH award

FAIRFAX, Va.—The National Institutes of Health (NIH) last month awarded ICF International, a health informatics group, a five-year contract valued at more than $60 million to provide support for biomedical and clinical services, such as data collection and analysis, information dissemination and outreach initiatives for multiple NIH institutes and centers, including the National Library of Medicine, the National Cancer Institute, the National Center for Complementary and Alternative Medicine, the Office of Dietary Supplements and the Office of Rare Disease Research. ICF will support key programs related to HIV/AIDS, genetics, cancer, rare diseases, dietary supplements, clinical trials, treatment guidelines and other initiatives.

BioXpr and DNAVision launch microarray analysis platform

NAMUR, Belgium—Bioinformatics company BioXpr SA announced in June that it has joined forces with DNAVision, a genetic analysis service firm, to offer the pharmaceutical and red biotech industries a service that covers the design, experimentation, analysis and interpretation of microarray projects. According to the companies, the microarray analysis platform will enable researchers to easily integrate genomixics data into biology. Customers’ gene expression profiling data will be automatically linked to the corresponding relevant impacted signaling pathways, which will be visualized and associated with any other available experimental data, such as mass spectrometry or next-generation sequencing data. Financial terms of the deal were not disclosed.

Down the in silico discovery pathway

Gene Network Sciences, UCSF use Bayesian network model for project

BY LLOYD DUNLAP
Cambridge, Mass.—Gene Network Sciences Inc. (GNS) has entered into a research collaboration with the University of California San Francisco Cancer Center (UCSF) aimed at accelerating cancer research and drug development across several therapeutic areas. This pathway continued on page 14.
**Creating a cheminformatics connection**

University of Cambridge selects IDBS as its data management provider and commences an R&D collaboration

**BY DAVID NUTTEN**

CAMBRIDGE, U.K.—The University of Cambridge has selected IDBS as its data management provider and has entered into a collaboration in which the university will use IDBS’ e-Chemistry lab notebook and jointly develop and commercialize informatics tools with the company. The R&D initiative, announced in June, will provide both organizations with significant cheminformatics assets and opportunities.

According to Chris Molloy, vice president of corporate development at IDBS, the Department of Chemistry at the University of Cambridge will deploy his company’s E-WorkBook and IDBS’ suite of chemistry technologies across its broad spectrum of research areas, and will use the system as a platform for many of its ongoing national and international collaborative programs.

Molloy points out that IDBS and the Department of Chemistry will also set up a joint research and development effort, which will play a significant role in bringing many of the most promising new cheminformatics technologies to the market through IDBS products.

“Integrity of our products is really what drove this part-nership. Genios is about making sure that the data researchers are generating is available and accessible. Once you have all that data, we can help you manage it, but you also need to analyze it. That is where JMP Genomics comes in, because they are very good at dealing with huge amounts of data.”

Dr. Shannon Conners, JMP Genomics product manager, says the partnership will provide a valuable entry into the next-generation data market, as JMP Genomics links advanced statistics with graphics, whether the data comes from traditional microarray studies or from summarized results produced by next-generation technologies.

“Next-generation sequencing is an important market for us, and our core competency is downstream statistical analysis. To get users to the point of needing those analytics, we work closely with partners who can provide solutions for sequence data,” Conners says. “We first connected with Genoligos last year at a conference, and realized our products and users shared complimentary goals with respect to generating, managing and analyzing next-generation data.”

Genios, a configurable lab and data management system, supports sample and workflow management, automates pipelines and consolidates data enabling analysis. The system is part of a broader suite of informatics solutions for research labs that can enable integrated data analysis for experiments across multiple sciences and systems biology initiatives.

Conners says the latest release of JMP leaders in cheminformatics,” he adds. Cambridge Professor Steven Ley, CBE, FRS, says professional management of chemical information is now essential in a modern laboratory.

“This partnership will provide the envi-ronment whereby experimental data is cap-tured and retained in such a way that it can be searched electronically by its chemical context,” Ley says.

In addition to providing data manage-ment options to Cambridge, Molloy said the deal provides a great opportunity to work with them in a joint R&D effort.

“Our solutions will be used to capture, secure and retrieve all research data that is generated within the department,” Molloy said.

A steering committee has been developed through the collaboration to handle the commercialization of any informatics tools developed through the collaboration.

Ultimately, the success of the collabora-tion will be measured in what it brings to the client, according to Molloy.

“We measure success in terms of what our clients are getting in terms of value from the solutions,” he says. “We do that by talking to the clients and listening to their feedback. Adoption by other groups at the university would also be another measure.”

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**DATA DELUGE DAM**

GenoLogics and SAS team up to create end-to-end analysis solution for large genomic data sets

**BY AMY SWINDERNAN**

VICTORIA, British Columbia—As genomic research centers continue to struggle with the dreaded DNA data deluge, GenoLogics and SAS have constructed a deal to bridge the gap between raw sequence reads and data analysis.

According to an announcement made in late May, the deal involves the integra-tion of GenoLogics’ Genius lab and data management solution with the statistical discovery application of SAS’ business division, JMP Genomics. The integration is intended to enable research organizations to generate high-quality genomic data sets and apply specialized statistical analysis tools to identify crucial nuggets of informa-tion hidden in long lists of candidate genes or biomarkers. Financial terms of the deal were not disclosed.

Counting instrument vendors such as Illumina and ABI as its partners, GenoLogics found JMP Genomics as a nat-ural fit to enable downstream analysis for its clients, says Sal Sanci, vice president of products for GenoLogics.

“The informatics ecosystem out there is large, complex and does everything,” Sanci says. “The whole goal of this integration is to provide more of an end-to-end solution for our customers. The complementary fit of our products is really what drove this part-nership. Genios is about making sure that the data researchers are generating is available and accessible. Once you have all that data, we can help you manage it, but you also need to analyze it. That is where JMP Genomics comes in, because they are very good at dealing with huge amounts of data.”

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Conners says the latest release of JMP Genomics’ desktop software package, JMP Genomics 4, incorporates even more func-tionality for researchers, including new pro cesses for examining paired data types, sup port for genotype data sets of up to 15,000 individuals and 1.5 million SNPs for selected processes, new and enhanced workflows, and graphical features and grid-enablement of selected processes.

“The researcher will have a protocol he wants to run on a number of samples,” Sanci explains. “He will run them through Genius, which will take him through the lab workflow so he is able to track what he does. If there is any QC processing that needs to be

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**PAIR**

CONTINUED FROM PAGE 12

“This integration enables scientists work-ing with microarrays to perform an in-depth statistical analysis using Integromics’ tools such as RealTimeStatMiner and Integromics Biomarker Discovery,” says Heidi Bullock, director of marketing for Ingenuity Systems, “and then with a single click, move to IPA to identify relevant biological functions, dis-eases or pathways associated with the data.”

It is increasingly important to incorpo-rate different technologies and strategies to fully examine a complex system, she notes, and by including statistical analysis of gene expression data and or RT-qPCR data, and then incorporating knowledge for signifi-cant genes and pathways, scientists can have more confidence and build a stronger experimental model.

“Integromics’ data analysis solutions have been well adopted in the market as easy-to-use tools for researchers to analyze there expression data for statistical and bio-logical significance,” says Alberto Pascual, vice president of research and development for Integromics. “Once significant genes are identified, researchers can now easily leverage the power and capabil-ities in IPA to gain a deeper understanding of biological context and functions involved in their dataset.”

Integromics provides researchers with excellent tools for visualization and statisti-cal analysis of genomics data, Bullock notes, while the content in IPA covers a broad range of therapeutic areas, drugable classes of proteins and regulatory events. As such, scientists can rapidly go from creat-ing testable hypotheses to understanding mechanism of disease, drug mechanism of action, identifying or validating targets or assessing toxicity and safety.

“We were both pleasantly surprised by how quickly [our] customers leveraged the integration, and how they continually come up with novel ways to use the most out of the tools,” Bullock adds. 

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"We’re hearing feedback from many different people in the field that next-generation sequencing, while powerful, is creating a huge amount of data that people are struggling to interpret and summarize in a way that they can make sense of," she points out. "There is also a challenge with costs. People want to make it straightforward to get from raw sequence data to summarization. This integration will allow people to create a workflow to manage and store the data, and then visualize in a format that allows the sequence data to be summarized and analyzed."
MICROSOFT CONTINUED FROM PAGE 1 between Amalga Life Sciences and Rosetta’s technologies. According to the company’s Jim Karkanias, senior director of applied research and technology, Microsoft Health Solutions Group, Microsoft realized that “combining them would allow us to provide a full-featured platform for accelerating personalized medicine. Acquiring Rosetta Bio software assets will allow for genetic, genomic, metabolomic and proteomics data management software to be incorporated into Amalga Life Sciences, improving management and analysis of genomic, biological and research data. Ultimately, this will help to bring life-saving drugs and therapies to market faster.”

Per the agreement, Microsoft is entering into a long-term strategic relationship with Merck and the two companies will collaborate on the direction, evolution and development of Amalga Life Sciences. Merck will become a Microsoft customer and Microsoft will provide Merck with updates on early releases of the technology for product testing purposes. “This is part of our previously announced strategy designed to improve the effectiveness and efficiency of our basic research operations to ensure long-term pipeline productivity,” said Rupert Vessey, vice president of Merck Research Laboratories.

Microsoft is blunt in stating its rationale for creating Amalga: “Shifting consumer behaviors, low research productivity and a failing drug business model have caused pharmaceutical and biotech companies to pursue personalized medicine more than ever before,” Karkanias states. “While the current offering of healthcare and life sciences solutions provides storage and sharing capabilities, they are doing little to enable the discovery of new, personalized treatments. To address this, Microsoft developed Amalga Life Sciences, a new software system designed to transform health and life sciences research data into the critical knowledge needed for the discovery of new personalized treatments. This new technology manages data as a network of facts. From this, researchers gain new insights into the data they already have, and organizations that use Amalga Life Sciences to capture new types of data elements and support changing experimental results, discoveries and technologies can rapidly respond to emerging and future research requirements.”

Asked about the five-year goals for Amalga, Karkanias sets the bar very high. “We are working toward connecting data across the entire health ecosystem,” he says. “As more scientists use Amalga and create more robust data stores, we’d like to see, for example, a physician look at the genetics of a breast cancer patient and make an informed decision about care based on the latest research, all by connecting the data through Amalga.”

The deal between Microsoft and Merck was to close at the end of June. The Amalga Life Sciences platform incorporating Rosetta Bio software technologies is slated to be available in early 2010. Over the past 12 years, Microsoft has steadily increased its investments in health, with a focus on addressing the challenges of health providers, health and social services organizations, payers, consumers and life sciences companies worldwide. Microsoft collaborates with a broad array of partners, as well as developing its own health solutions, such as Amalga and HealthVault.

We are working toward connecting data across the entire health ecosystem.”

—Jim Karkanias, senior director of applied research and technology at Microsoft Health Solutions Group
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Five keynoters grace Drug Discovery & Development Week

**BOSTON**—IBC Life Sciences invites you to take advantage of the opportunity to just “sit back and listen” to insightful presentations from leaders in drug discovery and development research, by attending the keynote presentations. The dates and topics are as follows:

**Tuesday, Aug. 4—**Quantitative Prediction of Anti-Tumor Antibody Macro and Microdistribution.


**Wednesday, Aug. 5—** Skirting Drug Safety Potholes in the Critical Path to POC.

**Wednesday, Aug. 5—**Build-Couple-Pair Strategy for Diversity-Oriented Synthesis Yields a Unique Compound Collection for Probe Development and Drug Discovery.

**Wednesday, Aug. 5—**From Empiric to Specific: How Can We Translate Science into Cancer Treatments and Get It Right More Reliably?

In addition to the keynoters, IBC also invites all attendees to attend an industry leadership forum on Tuesday, Aug. 4 that is titled “Oligonucleotide Therapeutics—Are We Leverage on the Promise?”

**Not just a bunch of booths**

**BOSTON**—According to Conference Director Michael Keenan, the exhibit hall at Drug Discovery & Development Week 2009 isn’t going to be a standard walk-through affair this year. He and the rest of IBC are encouraging conference attendees to take part in any of a number of customized exhibit hall attractions.

“Of course, we want people to come and see under one roof the key companies that are providing tools and services,” Keenan says. “But more than that, we have the product showcase tours and interviews to highlight new products, as well as interactive discussions with poster presenters and speakers in the hall. The exhibition hall is really designed to be a key networking opportunity this year.”

**Getting to know you**

**BOSTON**—Also on the agenda for the Drug Discovery & Development Week 2009 event is the Face-to-Face Scientific Exchange: Tuesday Night Cocktail Reception, which will give a chance for personal interaction with the industry experts, academic leaders and others at the event to exchange of information and scientific ideas.
Getting around: Feet, don’t fail me now

Boston is compact, and it’s built for walking, so why not stretch your legs a bit while you’re there?

BY JEFFREY BOULEY

Boston—If you live anywhere near Boston or have ever driven in the city, one of two things probably applies: You either feel comfortable enough with the area to drive around, or you know better than to try and you’re leaving your car at home. For those from farther away who haven’t had the experience, you might want to skip renting a car and let your feet do the work, or take advantage of the plentiful public transportation and taxi cabs.

Given that one of Boston’s nicknames—yes, it has far more nicknames than simply Bean town—is America’s Walking City, you’ll even be doing a favor to its reputation by hoofing it. Part of that walking tradition is because Boston has a very compact and high-density nature, which makes walking the most efficient, effective and popular mode of transportation for many. In fact, the city has the seventhhighest percentage of pedestrian commuters of any city in the United States, while the neighboring community of Cambridge has the highest.

According to the U.S. Census Bureau, the city has a total area of 89.6 square miles, but 41.2 square miles of that is water. So, Boston is the nation’s fourth most densely populated city that is not a part of a larger city’s metropolitan area—with New York City, San Francisco and Chicago holding the top three spots. Furthermore, of U.S. cities with more than 600,000 people, only San Francisco is smaller in land area than Boston.

The other reason that feet are such a fine way to get around compared to cars is that downtown Boston’s streets are not organized on a grid pattern. Instead, they grew from meandering horse and cart paths in many cases, meaning they’ve been that jumbled since the 17th century in some cases, and that’s clearly not going to change now. Some roads are even based on cow paths of days gone by, leading some to comment that Boston is a city designed by bovines. Roads sometimes change names and add or lose lanes of traffic seemingly at random. Streets in the Back Bay, East Boston, the South End, and South Boston do follow a grid system, but overall, walking might be your best bet during the conference, supplemented with cabs or public transportation.

In fact, nearly one-third of Bostonians use public transit for their commute to work, according to 1996 U.S. Census figures. The Massachusetts Bay Transportation Authority (MBTA) operates what was the first underground rapid transit system in the United States and is now reportedly the fourthbusiest rapid transit system in the country, going by the nickname of the “T.” The MBTA also operates the nation’s sixth busiest bus network, as well as water shuttles, and the nation’s fifthbusiest commuter rail network, totaling more than 200 miles, extending north to the Merrimack Valley, west to Worcester and south to Providence.

Certainly, many automobile traffic problems in the city were resolved when the massive “Big Dig” project concluded in 2007 after 16 years of work and more than $20 billion, rerouting the Central Artery (Interstate 93) through the heart of Boston into a 3.5-mile tunnel under the city instead. The project also included the construction of the Ted Williams Tunnel, which extended Interstate 90 to Logan International Airport; the Leonard P. Zakim Bunker Hill Memorial Bridge over the Charles River; and the Rose Kennedy Greenway in the space vacated by what had previously been an elevated portion of Interstate 93.

Of course, downtown Boston’s solution to its highway traffic woes had its own repercussions for more outings areas, so you still might want to rethink a car trip if you can. According to a analysis of state highway data documents by the Boston Globe late last year, the bottlenecks that once plagued downtown Boston were simply pushed outward, as more drivers compete for the limited space on the major commuting routes.

Beantown culture

BY JEFFREY BOULEY

Boston—With so many renowned academic institutions, museums, and other arts, science, and culture-oriented places to spend your free time, this show section can’t hope to do justice to all there is to do while in the city. But there are some highlights for you all the same.

As the Greater Boston Convention and Visitors Bureau puts it on its www.bostonma.com Web site, “Our museums are among the finest in the country. Whatever your interest, Boston has a museum for you: Fine art, contemporary art, hands-on-science exhibits, historical relics, the latest computer technology and over 3,000 glass flowers.”

In addition, there is the New England Aquarium for those who like to be near the denizens of the lakes, seas and oceans, or the Skywalk Observatory for those who want to be 50 stories above the street and take in a 360-degree panorama view of Boston and beyond. If you have kids with you for the trip, consider the Boston Children’s Museum. If you want to keep your scientific hat on even in the off-hours of the conference, a couple time-honored options are the Museum of Science, which features more than 600 exhibits, and the Harvard Museum of Natural History, which has more than 21 million specimens to admire.

Many special events at local museums will have come to a close long before IBC’s Drug Discovery & Development Week begins, but one exception is the “Titian, Tintoretto, Veronese: Rivals in Renaissance Venice” feature at the Museum of Fine Arts, which runs until Aug. 15. This is said to be the first major exhibition dedicated to the artistic rivalry of the three greatest Venetian painters of the sixteenth century.

According to the Boston USA Web site, “Juxtapositions of two, three, and sometimes four paintings demonstrate how much these three artists were influenced by one another and how they used their paintings to critique. The exhibition includes approximately 60 paintings from the most important museums in Europe and the United States, as well as pictures that have remained over the years in the settings for which they were painted—churches in Venice.”

ATTENDEE DEMOGRAPHICS

BY JOB TITLE

32% Research scientist, principal investigator, scientists or senior scientist
30% CEO, CFO, CIO, president, executive, director, VP or director of finance or info systems
18% Group leader, project manager, lab or department director, research director, VP of research or analyst
7% Academic department head, chair postdoctoral, student, professor or instructor
8% Business development, financial, investment, analyst or marketing director
2% Engineer or technology analyst
1% Consultant
8% Other

BY JOB FUNCTION

26% Director
24% C-level executive
22% Manager
20% Research scientist
8% Academic
“Especially in this economic environment, people need to be able to come to a conference and see things that directly apply to their jobs, so that when they leave after several days, they get a good idea for not only what’s happening in drug discovery and development but what’s working—and what might work for them, too.”

Three of the conferences focus on therapeutic areas: antibody therapies, oligonucleotide therapies and cancer drug development. The other two are more broadly strategic, with one focusing on the linking of targets to diseases and the other focusing on drug safety strategies.

But the thread linking all five, Keenan says, is that they mesh to form a roadmap to success and reining in their risks. “It’s not that these areas cover technology alone, so too has IBC decided to evolve its own annual show to match that,” Keenan says.

Being held Aug. 3-6 at the World Trade Center Boston, Drug Discovery & Development Week 2009 is being billed as “the industry’s premier, international conference and exhibition to provide education on the most vital topics in drug discovery and development to help accelerate products to market.”

More than just a place to find out about technology, IBC wants it to provide a meeting place for attendees from around the world to network; to find business and scientific partners; and to discuss scientific advances, research and development strategies, business alliances and informatics solutions in drug discovery and development.

“Our goal was to create five focused niche conferences for the event to appeal to scientists working in drug discovery and development and give them practical strategies and example of how to do their jobs better,” Keenan explains.

But the thing everyone got caught up in the past was new technology and sometimes the promise of that technology didn’t live up to expectations. But in covering the topics we have chosen to cover, what we see are a lot of people and companies being more inventive and creative in increasing their chances of success and reining in their risks and costs. To that end, we’ve really looked for people in the industry who are on the cutting edge, many of them having never presented at meetings before.”

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- Bi-specific Antibodies and Antibody Combinations
- Expanding our Grasp of Binding Sites in the Human Immune System and their Novel Application
- Exploring the Limits of Tumor Targeting with Molecular Formats
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- Pre-Conference Workshop: Working with IMGT and other Ab-Sequence Databases

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One bird with two stones

Agilent establishes two collaborations that continue its goal to find strong partners who can help it bring novel and effective solutions to researchers

By JEFFREY BOYLE

SANTA CLARA, Calif.—At the end of May and beginning of June, Agilent Technologies Inc. completed a pair of deals: One on the other side of the country, with Washington, D.C.-area-based Anderson Forschung Group (AFG), and the other across the Atlantic with Cambridge, U.K.-based Owlstone Nanotech Inc. In many ways, the deals Agilent struck are as far removed from each other thematically as the two new partners are physically from each other, but both deals point to a single strategic goal at Agilent.

“One of the two deals are along different tracks and don’t cross over each other at all except in terms of timing,” says Gustavo Salem, vice president and general manager of Agilent’s Biological Systems Division. “But what they do represent as a unit is the continued balance of our interests in driving both hardware and technological developments that will enable better solutions for customers, and our continued effort to develop applications that are not only new and interesting, but also serve real value in the scientific community.”

In the case of the AFG collaboration, the goal is to develop quantitative peptide assays to speed protein biomarker discovery and validation. The effort will combine AFG’s stable isotope standards and capture by anti-peptide antibodies (SISCAPA) technology with Agilent’s 1200 Series HPLC-Chip and 6400 Series triple quadrupole mass spectrometers. The combination will be used to develop methods for measuring the amounts of large numbers of peptides in digests of complex samples such as plasma.

“One of the greatest challenges to delivering useful knowledge using the protein biomarker discovery paradigm is achieving effective, reproducible and highly sensitive peptide quantitation,” Salem notes.

“Agilent is a relatively new participant in the mass spectrometry marketplace, only for the last few years, so they are quite innovative and have thought a lot about what the potential for mass spectrometry technologies is, all the way into the direction of biomarkers and clinical assays,” says Leigh Anderson, CEO of Anderson Forschung Group. “So their capabilities and understanding of the potential for mass spec to measure important clinical analytics is an attractive package as we look to bring very high performance to these kinds of assays.”

This is the right time for a collaboration like this, Anderson adds, because the SISCAPA technology being implemented on Agilent’s LC/MS systems.

Double-teaming for twice the productivity

Applied Biosystems, MDS Analytical Technologies double mass spec throughput to speed drug development

By LLOYD DUNLAP

CARLSBAD, Calif.—Using a multiplexing switching system, Applied Biosystems and its mass spectrometry (MS) joint-venture partner of more than 25 years, MDS Analytical Technologies, have launched Cliquid MPX-2, a high-throughput, mass spectrometry system that promises to double the speed of analysis for pharmaceutical and clinical research. The workflow system integrates a new software application with mass spectrometers, high-performance liquid chromatography systems and auto-samplers to increase throughput for faster results within Good Laboratory Practice (GLP) standards of regulated markets.

Cliquid is a four-click process to set up and acquire MS results. MPX-2 is a “new thing,” stresses Nick Levitt, Applied Bio’s senior product manager for quantitative applications within the company’s proteomics and small molecule division. “It’s brand new software that integrates with existing hardware. MPX-2 works with Cliquid software, but also with our Analyst software, which most pharmaceutical labs will use.”

Systematic knockdown

PMCC expands cancer research efforts with Caliper’s automation tool

BY AMY SWINDERMAN

VICTORIA, Australia—The Peter MacCallum Cancer Centre (PMCC) is working with Caliper Life Sciences Inc. to automate oncology-related lab discovery experiments, speeding up its efforts to understand how to treat and prevent cancer through biological tissue research and pathology that adds non-targeted molecular information and “molecular contrast” to histology.

In the collaboration, announced last month, the Functional Genomics Group of PMCC, a prestigious cancer research organization in...
Screening Stem Cells: 
From Reprogramming to Regenerative Medicine 
September 2 - 3, 2009 • Boston, MA, USA

Program Overview: 
Stem cells and regenerative medicine is an emerging field of drug-discovery research. Reprogramming somatic cells to a pluripotent state could generate a rich supply of patient-specific stem cells and mature cells for regenerative medicine and compound screening. It has been shown that viral-mediated gene delivery of four transcription factors, including two potential oncogenes, can directly reprogram somatic cells to induced pluripotent stem (iPS) cells. Unfortunately, the resulting iPS cells are unsuitable for many therapeutic applications because the viral transgenes can spontaneously reactivate a process that has led to tumor formation. Therefore, discovering small molecules through high-throughput technologies capable of reprogramming cells—without relying on viruses or oncogenes—would be extremely valuable for therapeutic applications. Furthermore, using stepwise differentiations of pluripotent cells and/or embryonic stem cells to terminally differentiated functional cells via small molecule treatment would be useful for transplantation therapy, identifying targets for drug discovery and for toxicology testing. High-throughput screening (HTS) and high-content screening (HCS) technologies against stem cells offer great potential for identifying novel small molecules to reprogram cells and to induce formation of terminally differentiated functional cells.

Scientific sessions will encompass these core topics:
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• Stem Cell Screening Systems
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• Therapeutic Applications

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Explore the program by visiting www.sbsonline.org/stemcells/

Advances & Challenges in 
Label-Free Technologies for Drug Discovery 
November 2 - 3, 2009 • San Diego, CA, USA

Program Overview: 
Label-free technologies in drug discovery are allowing scientists to address some of the outstanding fundamental questions of productivity that contemporary Pharma R&D is struggling with. Label-free technologies present the opportunity to address issues such as limited access to tractable therapeutic targets, early exploitation of chemical genomics, poor predictability of the therapeutic action of chemical compounds in biological assays, and inadequate selection of candidate molecules that fulfill the right biological and physicochemical profile of a drug. Label-free methodologies positively impact assay development by enabling the direct monitoring of molecular and cellular interactions on native systems of biological relevance in a non-destructive and generic manner.

The symposium will showcase the latest scientific and technological advances where label-free technologies have proven their value in the discovery and characterization of new drugs and therapeutic targets. Case studies from formation of multi-component biomolecular complexes to phenotypic alterations in native cells, from the detection of the interaction between small organic molecules and isolated proteins to the redistribution of mass within a cell upon activation of a particular receptor, from screening of compound libraries to hit (in)validation or elucidation of the mode of action of lead compounds, from agonist trafficking to receptor panning will draw the interest of the meeting participants. The technological challenges and uncertainties that drive the wide adoption of label-free by the drug-discovery community will be also presented.

Learn from a research innovator in a keynote presentation delivered by:
• Manfred Auer, PhD – University of Edinburgh, Scotland

Explore the program by visiting www.sbsonline.org/labelfree/
Thermo Fisher announces biomarker assay collaboration between BRIMS Center and NextGen Sciences

**BY DAVID HUTTON**

WALTHAM, Mass.—Thermo Fisher Scientific announced in June it has reached a collaboration arrangement in which its Biomarker Research Initiatives in Mass Spectrometry (BRIMS) Center will collaborate with NextGen Sciences to apply new technologies to that company’s biomarker assay services.

Under the terms of the agreement, the BRIMS Center will work with NextGen to add its latest technologies to the company’s BiomarkerExpress platform—a set of biomarker services that rely on a mass spectrometry-based approach called selected reaction monitoring, sometimes called multiple reaction monitoring (MRM)—to assay proteins and peptides in biofluids and tissues.

Under the new agreement, NextGen will have access to the most recent Thermo Scientific mass spectrometry technology, which the company will add to its existing Thermo Scientific-based workflow.

NextGen Sciences CEO Dr. Michael Pisano says his company has been diligent in its search for best-in-class instrumentation.

“When we were putting in place the infrastructure for our biomarker services, it was important that we looked for reliable and accurate instruments, and Thermo Scientific technology was found to be just that,” he says. “In concert with our expertise at NextGen Sciences, Thermo Scientific technology delivers the highest quality results to our customers. The combination of Orbitrap technology and triple quad capability enables NextGen Sciences to go from discovery or named proteins to a single or multi-protein assay in a very short timeframe.”

Pisano says his company performed proper due diligence in “test driving” and found Thermo Fisher to offer the best instruments to “fit our needs and at the same time better our capabilities.”

“According to Dr. Mary Lopez, director of the BRIMS Center, the collaboration is a good fit because of what the partners both bring to the table. “While we were putting in place the infrastructure for our biomarker services, it was important that we looked for reliable and accurate instruments, and Thermo Scientific technology was found to be just that,” she says. “In concert with our expertise at NextGen Sciences, Thermo Scientific technology delivers the highest quality results to our customers. The combination of Orbitrap technology and triple quad capability enables NextGen Sciences to go from discovery or named proteins to a single or multi-protein assay in a very short timeframe.”

The result is that researchers can quickly assess whether or not putative biomarkers have any real clinical value. However, Lopez points out that the BRIMS Center is not involved in developing diagnostics.

“While we were putting in place the infrastructure for our biomarker services, it was important that we looked for reliable and accurate instruments, and Thermo Scientific technology was found to be just that,” she says. “In concert with our expertise at NextGen Sciences, Thermo Scientific technology delivers the highest quality results to our customers. The combination of Orbitrap technology and triple quad capability enables NextGen Sciences to go from discovery or named proteins to a single or multi-protein assay in a very short timeframe.”

PerkinElmer gets chance to work with a ‘legend’

**PerkinElmer, BioLegend announce custom immunoassay development collaboration for drug discovery research**

**BY DAVID HUTTON**

WALTHAM, Mass.—PerkinElmer Inc. has entered into an assay development and sample testing collaboration with BioLegend, a San Diego-based company providing immunological reagents to biomedical research communities.

Under the agreement, BioLegend will offer immunoassay development and biochemical testing based on PerkinElmer’s “no-wash,” homogenous bead-based AlphaLISA assay technology. Financial terms of the agreement were not disclosed.

According to Dr. Martina Bielefeld-Sevigny, vice president and general manager, Drug Discovery and Research Reagents, Bio-discovery, PerkinElmer, there were several factors that made BioLegend an attractive partner for PerkinElmer.

“The PerkinElmer and BioLegend collaboration is particularly relevant to the academic market. BioLegend is known for its strong ties to academia, which serves to complement PerkinElmer’s existing reach in academic research labs,” says Bielefeld-Sevigny.

“Additionally, BioLegend’s antibody content was a factor in deciding to collaborate, given that it can be leveraged to develop niche custom assays based on PerkinElmer’s AlphaLISA ‘no-wash’ technology.”

AlphaLISA comprises highly sensitive and quantitative assays with broader ranges than standard enzyme-linked immunosorbent assays (ELISAs), saving time in laboratory workflows and eliminating labor-intensive wash steps that are difficult to automate.

These assay development and testing services integrate BioLegend’s strong position in high quality antibody production and assay development capabilities with PerkinElmer’s unique technology and instrumentation.

The collaboration provides scientists with broader access to the AlphaLISA technology and offers assays with extremely high detection sensitivities, currently very difficult to achieve with many existing ELISA assays. Furthermore, the advantages of AlphaLISA technology allow for easy integration into automated high-throughput testing systems, including the JANUS liquid handling system from PerkinElmer.

Bielefeld-Sevigny says the collaboration fits well
AGILENT

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platform is one that is being used in a couple very large projects for biomarker assays right now. “Ultimately the thought is to use these kinds of assays to quantitate the whole human proteome,” he says, as part of something called the hPDQ project. He also believes that the SISCAPA assays for candidate biomarkers can benefit substantially from the reproducibility and sensitivity of Agilent’s platform.

The deal with Owlstone Nanotech, on the other hand, represents a phase one agreement to develop that company’s field-asymmetric ion mobility spectrometers (FAIMS) filter as a front-end separation module for Agilent’s Accurate Mass time-of-flight mass spectrometers. The goal is to deter-

mine how the systems can work together to enable identification of previously unresolved analytes. The collaboration will also explore how FAIMS can speed up liquid chromatographic separations, saving valuable analysis time.

“The fast scanning speed of the Owlstone micro-scale FAIMS device now makes it feasible to acquire ion mobility spectra from LC/MS separations in real time,” says John Fieldsted, Agilent LC/MS research and development director. “In particular, our TOF and QTOF systems with Agilent Jet Stream Technology are uniquely suited for coupling to high-speed ion mobility separations by virtue of very high spectral acquisition rates and an excellent analyte desolvation design.”

“The collaboration with Agilent gives us the opportunity to integrate our technology onto highly sensitive mass spectrometers that are ideal for demonstrating the benefit of the uniquely high-field, fast scanning ability of our FAIMS device,” says Bret Bader, Owlstone CEO.

Accurate Mass time-of-flight mass spectrometers. The goal is to deter-

LEGEND

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cumbersome wash steps, academic researchers can measure even very low affinity interactions,” she says. “The technology’s sensitivity and homogeneity also enables savings in precious sample and antibodies usage.”

According to Brad Kraft, president of BioLegend, the future of high-throughput assays lies in an increased need for automation.

“Many current immunological assay platforms have major drawbacks when it comes to meeting requirements for automation in the lab,” adds Kraft. “We feel this collaboration with PerkinElmer is therefore a timely and highly promising advance that gives researchers greater understanding of basic disease biology and pathobiology, particularly when applied to biomarker assays.”

Dr. Richard M. Eglen, president of Bio-Discovery at PerkinElmer, notes that the company remains committed to extending the benefits of its proprietary AlphaLISA platform to researchers globally, across pharma, biotech and academic laboratories.

“Combining PerkinElmer’s technologies with BioLegend’s unique immunoassay development capabilities enables scientists to benefit from reduced barriers to discovery such as time or resource constraints,” he notes.

As the collaboration unfolds, Bielefeld-Sevigny points out that there will ultimately be one true measure of success that everyone is anticipating.

“There are a number of criteria that will be measured throughout the course of the collaboration, but one key goal is to generate new customer projects through the combination of PerkinElmer technology and BioLegend custom assay development services,” she says.
BRIMS may be an option for research in osteoarthritis. Lopez says, “NextGen was a perfect partner for demonstrating inter-lab reproducibility of the assay. This was immediately tested by the Harvard clinical researchers who needed to run large numbers of samples to see if their putative biomarkers could segregate disease from normal samples in a large, blinded cohort.”

Lopez also notes that NextGen is carrying advanced work on the development of assays targeting other protein biomarker candidates in synovial fluid. “The company has the infrastructure and expertise necessary to develop and apply peptide assays in a commercial CRO setting,” Lopez says. “Above all, NextGen Sciences has a track record for delivering the highest quality data to the client, meeting short deadlines and providing excellent support through all stages of its research projects.”

Historically, immunoassays have been the gold standard for monitoring levels of protein biomarkers in samples. While these assays can provide high quality data, the development of multiplexed, quantitative protein assays has been a bottleneck in clinical research. NextGen is addressing this bottleneck by developing protein and peptide biomarker assays using mass spectrometry-based SRM. SRM has been used for more than 20 years to monitor small molecule concentrations. In peptide SRM, proteotypic (unique) peptides from protein biomarker candidates are monitored. Availability of reproducible assays has been a major barrier for biomarker research and development.

According to Pisano, the bio-marker assay development pipeline at NextGen Sciences is iterative and can handle large numbers of proteins, permitting investigators to empirically validate and select all of their biomarkers. Utilizing Thermo Fisher’s new mass spectrometry technology and software can boost NextGen Sciences’ efforts and capabilities with regards to BiomarkerExpress.

“If adds the latest line of instrumentation and software that enables NextGen Sciences to remain at the cutting edge, giving us the ability to offer best-in-class services,” notes Pisano.

As the collaboration unfolds, Lopez points out that the results have been very encouraging because the tests run at BRIMS and at NextGen are consistent in demonstrating that Thermo Fisher’s technology platform for SRM assays delivers a high degree of reproducibility across different sites.

“NextGen will eventually offer this test on a fee-for-service basis to other researchers,” she notes. “That shows that we have successfully been able to take putative biomarkers, translate them into a quantitative SRM-based assay and then, through a CRO partner, offer the assays to researchers who would like to test their clinical samples.”

The ultimate measure of success is that the BRIMS Center has been able to develop the workflow, translate it to another lab and demonstrate that it is robust and reproducible and that the results are reliable, she says.

“Over the past few years, several research teams and academic consortia have been trying to accomplish site-to-site reproducibility of SRM assays and to date, I think the results have not been very encouraging,” concludes Lopez. “It is one of the big challenges in proteomics and I believe that in this focused collaboration, we have been able to achieve some measure of success.”

For more information, visit www.DrugDiscoveryNews.com

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U of Maryland receives $20M for genome sequencing hub

Baltimore, Md.—The University of Maryland School of Medicine’s Institute for Genome Sciences (IGS) has been awarded $20 million from the National Institutes of Health (NIH) to create a Genomic Sequencing Center for Infectious Diseases. The contract, the largest for Genome Sciences has earned since its founding two years ago, makes IGS a national hub for genetic information on infectious disease. The Institute will use the funding to sequence and analyze the genomes of infectious organisms such as agents of bioterrorism and new or emerging diseases. The contract encourages collaboration between the IGS and outside clinicians or other scientists who have unusual or significant pathogen samples they would like to see sequenced and analyzed. The contract will cover the cost of the sequencing and analysis at the IGS, and create a library of such information for sharing with researchers throughout the country.

NIH expands Human Microbiome Project

Bethesda, Md.—The National Institutes of Health (NIH) last month awarded the Human Microbiome Project, a five-year research effort launched in 2007, more than $42 million to expand its exploration of how the trillions of microscopic organisms that live in or on our bodies affect human health. In the new round of funding, the Human Microbiome Project will support the work of the large-scale DNA sequencing centers that participated in the initial phase of the project to sequence at least 400 microbial genomes. Another approximately 500 microbial genomes are already completed or in sequencing pipelines and supported by individual NIH institutes and internationally funded projects.

Creating Qatar’s first proteomics facility

Doha, Qatar—Qatar Science and Technology Park (QSTP) has launched a joint venture with deltaDx, a developer of technologies for the separation and analysis of biomolecules based in London, to develop a world-class proteomics research and testing facility in Qatar. The Proteomics Service Laboratory is expected to open officially later this year and will provide training and work opportunities for young Qatari scientists. The facility’s contract research and development services will initially be offered to key stakeholders in Qatar and later globally. Initial projects will include biomarker studies for breast and colorectal cancer and the metabolic content of proteins. QSTP will contribute $15 million towards the partnership, while deltaDx will provide staff, support and an exclusive regional license to its technology.

MISSION: GAPS NO MORE

Broad Institute researchers employ Roche-454 technology to close some gaps in the human genome that resist traditional bacterial cloning methods

By Jeffrey Bouley

Cambridge, Mass.—While the Human Genome Project has done a great deal to advance genomics, and many up-and-coming technologies present the possibility of relatively affordable whole-genome sequencing in the near future, things still aren’t perfect, as evidenced by the fact that the most recent release of the finished human genome contains 250 euchromatic gaps, excluding chromosome Y. Researchers at the Broad Institute of MIT and Harvard may have found a simple and easily scalable method to close nearly half of these gaps, using the GS-20 FLX instrument from Roche’s 454 Life Sciences division.

In their article, “Closing gaps in the human genome using sequencing by synthesis,” published in BioMed Central’s open-access journal Genome Biology, the Broad team noted that there are three classes of gaps. Type I gaps are subtelomeric, with nine gaps in subtelomeric regions containing telomere-associated repeats, while type II gaps contain duplicated euchromatin—this includes 30 percent of the gaps and 94 gaps flanked by segmental duplications. Both of those types of gaps are “structural” gaps according to the Broad research team, which notes that they “arise from unresolved structural complexity in the genome and can be attacked by the methodology of carefully reassembling existing tiling paths or by reassembling the

Advancing Avestagenome

Avestagen and Harvard agree to share genomics knowledge, services

By Lodd Dunlap

Bangalore, India—Avestagen Ltd., which claims to be India’s leading integrated systems biology platform company, has entered into a long-term genomics research collaboration with Harvard Medical School’s Department of Genetics. The Indian firm clearly sees the agreement as a validation of its position as a world-class genomics firm, but most notably four direct-to-consumer genomics firms—23andMe, deCODE Genetics, Knome and Navigenics—Illumina has unveiled a program to provide high-quality personal genome sequencing for consumers, offering what is said to be the first service to offer complete coverage of the human genome for under $50,000. The service launches $48K consumer sequencing

By Jeffrey Bouley

San Diego—in collaboration with several companies, but most notably four direct-to-consumer genomics firms—23andMe, deCODE Genetics, Knome and Navigenics—Illumina has unveiled a program to provide high-quality personal genome sequencing for consumers, offering what is said to be the first service to offer complete coverage of the human genome for under $50,000. The service
**A story, canines, and collaboration**

North Carolina State University and UNC Lineberger team up to combat cancer in man—and man’s best friend

**BY LORI LESKO**

RALIEGH, N.C.—With a focus on the proverbial man’s best friend, researchers from the North Carolina State University College of Veterinary Medicine and its neighbor, the Lineberger Comprehensive Cancer Center, are combining their expertise to pinpoint the cause of non-Hodgkin lymphoma in humans and canines. The animal and human docs hope their collaborative effort leads to the identification of gene components resulting in more humane and earlier treatments.

"The hope is that the canine can help his "best friend" understand how to diagnose and treat lymphoma. The dog is an excellent model to study human cancer, particularly lymphoma," says Dr. Steven Suter, a veterinarian and NCSU professor of clinical sciences. The disease is biologically similar in human and canine patients.

Suter, Matthew Breen, professor of genomics, along with statistics professor, Alison Motsinger-Reif and Dahlia Nielsen, research assistant professor of genomics, represent the North Carolina college component.

Kristy Richards, geneticist and clinical oncologist, leads a team of researchers at the University of North Carolina Lineberger. The researchers are recruiting pet dogs diagnosed with lymphoma to collect tissue samples for study. The simple and speedy procedure at the NCSU Veterinary Teaching Hospital causes no discomfort to the dog, and owners receive $1,000 for their pet’s participation.

“There are very few places in the country where a top-rate veterinary program is in such proximity to a top-rate medical school with a comprehensive cancer center,” says Richards. “We aim to take full advantage of this partnership to discover, develop and test new treatments much faster than could be done in either organism alone.”

Labs from both institutions will study tissue samples from human and canine patients, targeted toward creating a genomic profile of non-Hodgkin lymphoma to give oncologists and veterinarians greater insight into the disease’s biology and improve their ability to diagnose the illness early.

"Canine lymphoma cells look similar microscopically and share similar staining for cell surface proteins commonly used in diagnosis," Richards says. “These similarities make us hopeful that the remainder of the underlying biology, most importantly the pathways linked to lymphoma development and progression, will be similar as well.”

Genomic profiling is only possible after the full genome sequence of a lymphoma is known, she says. The human genome sequence was published in 2001 and the canine genome sequence was published in 2005.

“We plan to look at all areas of the genome for changes in DNA copy number and the activity of genes (expression levels),” Richards says. “We’ll also be looking for particular DNA mutations that are specific to lymphomas and then see how much of this biology is shared between canine and human lymphomas. Certain breeds such as boxers and golden retrievers are more predisposed to lymphoma than others, probably due to genetic predispositions concentrated in particular breeds during the selective breeding process, she says. Also, veterinary oncologists use similar chemotherapy regimens on dogs as humans, the same four-drug regimen (called CHOP) that human oncologists use.

“If we know how the canine lymphomas mimic human lymphomas, and we direct our new drug therapies to those proteins/tissues, we can provide value added information that will speed the development of the therapies for use in humans,” Richards says.

Statistics show more than 66,000 people each year are diagnosed with non-Hodgkin lymphoma, making it the fifth most common type of cancer. The most common subtype, which is also the most common subtype in dogs, is diffuse large B-cell lymphoma, affecting nearly 25,000 people per year—and about half of those people will die of their disease.

“Statistics on dogs are harder to compile of course, because not all owners take them to the vet, and even then, there are no national registries to keep track,” Richards says. “But it is estimated that 4 million dogs get cancer every year, and up to 25 percent will be affected by lymphoma, resulting in most of the affected dogs’ deaths.

“The goal is not just to improve treatments for CANINE CONTINUED ON PAGE 31

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**The ‘democratization’ of genetic research**

23andMe, PatientsLikeMe team up to study Parkinson’s disease, pursue personal genetics

**BY AMY SWINDERMAN**

MOUNTAIN VIEW, Calif.—Personal genomics company 23andMe has teamed up with PatientsLikeMe, an online patient community and platform for collecting and sharing patient data, on a large-scale genetic study of Parkinson’s disease, the companies announced in June.

The study, which seeks to recruit 10,000 people with Parkinson’s to share and compare information about their symptoms, progression, and treatment, aims to find genetic and environmental modifiers to Parkinson’s, its symptoms and progression, as well as the effectiveness of different treatments. Ultimately, the data collected from patients will be used to evaluate the effects of genetics on variation in the Parkinson’s population, but the companies have another, more patient-centric goal they would like to achieve.

“This is part of a movement I like to call the ‘democratization’ of genetic research,” says Lizzie Dorfman, 23andMe’s alliance manager. “We want to empower patients to make decisions about their healthcare, research and personal genetics.

James Heywood, co-founder and chairman of Cambridge, Mass.-based PatientsLikeMe, points out that technology is also moving faster than the research establishment.

“We are excited to see what happens when you give patients the ability to see variations of their disease and compare it to their own, while enabling them to easily define their personal genomics,” Heywood says. 23andMe is already working with two non-profit research groups, the Parkinson’s Institute in Sunnyvale, Calif., and the Michael J. Fox Foundation, to design and validate Web-based clinical assessment tools and a social networking platform to facilitate the development of communities and research projects to find common traits in Parkinson’s patients. Seeking to leverage the power of the Internet to research those areas, though he didn’t confirm whether SeqWright will be tapped for other disease areas as well.

For this collaboration on dilated cardiomyopathy, Harkins did note that Roche was attracted to SeqWright’s extensive contacts with the clinical research community, its position “on the hub of translational research, and the combination of "great data quality and great turnaround" that it offered.

As to why the focus on this particular disease right now: “Dilated cardiomyopathy is a leading cause of heart failure that carries a high mortality rate,” says Dr. Nadine Norton, a research assistant professor from the University of Miami Miller School of Medicine. "We know that familial dilated cardiomyopathy can be explained by mutations in more than 20 autosomal and two X-linked genes, yet mutations in these genes account for only one-third of the cases. By using an experimental strategy that employs the sequencing of all coding regions within the human genome, we hope to identify other mutations in other genes, some that cause this terrible disease.”

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**Genomics & Proteomics**

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GENOMICS & PROTEOMICS

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Controversy swirls around the subject of personal genetics

Since 23andMe exploded onto the genetics testing scene in 2006—garnering an "Invention of the Year" award from Time Magazine in 2008 for its pioneering work in retail genomics—the Silicon Valley startup and companies that offer consumers information about their genes have become the subject of much criticism and controversy. Most of the rub questions whether patients should be able to obtain their genetic information from labs that are not government-certified or without doctor approval, but there is also growing debate over privacy issues.

In April 2008, the New York State Department of Health sent warning letters to six online genetic testing companies, including 23andMe, barring them from offering New York residents genetic tests without a permit or doctor authorization. California regulators followed suit two months later, issuing cease-and-desist letters to 23andMe and other genetic-testing companies, notifying them to stop offering tests until they provide proof of state and federal clinical lab certification and until genetics test results are only issued when ordered directly by a physician.

23andMe responded that they are in compliance with California law and will continue to operate in the state as their tests are “educational,” not “diagnostic,” in nature. The latter case is a process bound by much stricter regulations. 23andMe received a license allowing it to continue to conduct business in California, but currently, only 25 states permit direct-to-consumer (DTC) genetics tests without restriction.

There is also growing concern that consumers who use personal genetic testing services are unaware of certain risks to their privacy. On June 5, Stanford University’s Center for Biomedical Ethics published a study in the American Journal of Bioethics which argues that a paradigm shift has occurred in how the public values their medical information and incorporates it into how they behave and plan for their futures. According to the report, “Research 2.0: Social Network and Direct-to-Consumer Genomics,” a few companies enable consumers to share their genetic data with others via a social networking Web site, but there are no laws governing the exchange of genetic information online, raising privacy risks as genetic testing becomes more common.

Dr. Sandra Soo-Jin Lee, a co-author of the study, says personal genetic information is relevant not only for the individual who orders a test, but for other family members.

“For example, if you receive information on your breast cancer risk and share it with others, you might also be revealing information about your daughter’s risk for breast cancer—even though she never consented to have that information shared,” she says.

23andMe’s Dorfman acknowledges the importance of such concerns, but stresses that the company is transparent about the services it provides and puts the level of information that is gathered and shared in the hands of the customer.

“Everything about our service is voluntary,” Dorfman says. “Patients can look at as much or as little information as they want. They don’t even have to look at their risk profile if they choose not to.”

“Some people are economically threatened by what we do, and there is a certain rub over who will be required to do the work of explaining the information to patients,” Dorfman admits. “There is a degree of paternalism in medicine, the idea that you have to protect the patient from themselves. When it comes to patients living with a disease for decades, we need to be responsible in how we communicate information about their disease. Currently, we require that a physician be the one to do that. While it’s true that genetics is complicated, one of the things we would fail at as a business is if we were not able to educate people on the basic fundamentals of genetics. Patients need to be empowered to make that decision.”

PatientsLikeMe’s Heywood agrees: “We have in place a system of ‘doctor knows best’ that is reinforced through regulation and guidance, but that doesn’t allow for the empowerment of the patient. The whole system is stacked to say no at every level, and patients can’t figure out who has the ability to say yes. It is quite intrusive. If you pay attention to the dialogue on our Web site, you will see that patients want to be more involved.”
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$48K
CONTINUED FROM PAGE 26
vice will take advantage of both Illumina’s Genome Analyzer technology and a recently certi-

fied CLIA laboratory.

The $48,000 price tag includes sequencing of an individual’s DNA to 30 times depth, providing infor-
mation on SNP variation and other structural characteristics of the genome such as insertions, dele-
tions and rearrangements.

“Rapidly decreasing costs have made sequencing a pervasive technology that can begin to be accessed at the consumer level,” says Jay Flatley, CEO and presi-
dent of Illumina. “We are entering a new era in genomic health, where information from an individual’s genome will begin to inform lifestyle decisions and ultimately assist with health management.”

With other companies touting the availability of less expensive personal genomics sequencing, with prices as low as $5,000 or $10,000, what makes Illumina’s service worth the price it’s charg-
ing? According to Philomena Walsh, associate director of corpo-
rate marketing for Illumina, it’s the sheer depth of the information

“We are offering a service to sequence the entire genome, which has 3 billion bases. With DNA sequencing, the genome is decod-
ed,” she says. “This tells you your genetic code, which can be used in the future for more interpretation as new discoveries are made. The limitation with genotyping is that only one certain number—thousands to hundreds of thousands—of known variants is assessed. If new variants are discovered after your genotyping has been completed, you will likely have to be geno-
typed again to include the new ‘content’.”

In addition to the sequencing service, Illumina is establishing a protocol, infrastructure and com-
munity to enable large-scale adop-
tion of personal sequencing.

As part of the CLIA certification process, Illumina sequenced its own CEO, Jay Flatley, and is cur-
rently processing three other individ-
uals’ genomes.

Hermann Hauser, partner, Amadeus Capital Partners Ltd, is the second person to have his genome sequenced through this service, and both he and Flatley will deposit their complete genome sequence into the public domain.

The two other people being sequenced using the service are Henry Louis “Skip” Gates Jr., who serves as a Harvard professor and director of the W.E.B. Du Bois Institute of African and African American Research, and his father Henry Louis Gates Sr.

The question remains, of course, as to whether even a $48,000 com-
plete sequencing can catch on.

“Costs have come down enough to make this accessible to a thin slice of the market,” Walsh notes. “We are doing this now because we think that it’s time for the pro-
cess to begin. We want to perfect this process before it becomes rou-
tinely used. We want to scale our infrastructure, understand how the physician network is going to work. And we also want to build an ecosystem around partners to help us do data analysis.”

Drugs Discovery News
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The Avestagenome Project will attempt to determine the genetic basis of longevity and age-related disorders. The popular genomics-based study will use genome-wide arrays as a means to discover novel DNA polymorphisms using the Affymetrix Platform and SNP6.0 DNA Chip, says Patell. The case-control study design, in conjunction with the Avesthagen database that is a repository of participant data, will enable the linkage of novel polymorphisms to a specific trait. Ultimately, such linkages will be validated across other, non-Parsi populations.

“In addition, the transcriptome, proteome and metabolome of the samples will also be analyzed from the sample set used for genomic analysis,” Patell adds. “Furthermore, the peripheral blood mononuclear cells obtained from the disease cohort will be used to screen for novel disease biomarkers and drug targets.”

Under the memorandum of understanding with Harvard, Avesthagen will be involved in providing data sets from genome-wide array experiments along with other data sets that arise from other experiments analyzing population structure. In addition to providing data sets to HMS, Avesthagen will also deliver genotype data from anonymized individuals. The project is currently being funded by The Avestagenome Project International Pvt. Ltd. Funding sources for ongoing collaborations between Avesthagen and Harvard Medical School are under discussion and include grants and other opportunities.

Avesthagen’s focus is “a broad systems biology model that can only be pulled off in India,” says Patell.

“Cost-effective innovation is a way to move forward for India to bring it right up there in the global order where it belongs,” she states.

The company works to achieve convergence of food, pharma and population genetics leading to predictive, preventive and personalized healthcare. It has established what the company describes as world class, state-of-the-art laboratory facilities in Bangalore, where it employs about 400 people. Launched in 2001, its activities include, in addition to its agri-biotechnologies product pipeline development of clinically-validated botanical bioactives derived from Indian medicinal plants, as well as the development of a pipeline of biosimilar drugs. The company has four strategic business units: biopharmaceuticals, bio-nutrition, bio-agriculture and science and innovation.

Avesthagen is in the process of developing biosimilars for cancer, hematological, and auto-immune diseases. The first biosimilar will enter the clinic this year and three others are in pre-clinical trials, Patell says. She expects the first one will be ready for market launch in late 2010.

In terms of the preventive bio-actives pipeline, Avesthagen has launched Teestar, a clinically-validated bioactive that maintains glycemic health. Patell expects this will be followed by two others that are involved in bone development and cardiovascular care. **DOH**

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Watson aims for global generic footprint with $1.75 billion Arrow Group acquisition

CORONA, Calif.—On June 17, Watson Pharmaceuticals Inc., a drugmaker with a broad portfolio of generic products, announced that it will pay $1.75 billion to acquire Arrow Group, a privately-held generics drug manufacturer with operations in four continents. Under the terms of the agreement, Watson will acquire Arrow for cash and stock consideration of $1.75 billion. The total consideration will include a cash payment of $1.05 billion, and the issuance of approximately 16.9 million shares of Watson common stock valued at $500 million, based on Watson’s closing five-day average stock price of $29.51, both paid at closing. The remaining $200 million will be paid in the form of zero-coupon preferred stock redeemable three years after closing of the transaction.

According to Watson, the deal creates a global pharmaceutical company with more than $3 billion in revenue, commercial operations in more than 20 countries and a robust product portfolio and pipeline.

Alder Biopharmaceuticals expands CNS collaboration with Schering-Plough

BOTHELL, Wash.—Alder Biopharmaceuticals Inc. announced in June the expansion of its collaboration with Schering-Plough Corp. on the development of therapeutic monoclonal antibodies for central nervous system disorders. The collaboration continues to be successful in identifying numerous high-quality therapeutic monoclonal antibody lead candidates. Under the terms of the agreement, Alder will receive an upfront payment, committed funding for Alder personnel who are engaged in the project and milestone payments associated with the advancement of a therapeutic candidate as well as future product royalties.

Kemin acquires Analyte Pharmaceuticals in bid to expand pharma business

DES MOINES, Iowa—Kemin Industries, a developer of agricultural, food ingredients, pet food and human health and pharmaceutical products, announced in June its acquisition of San Francisco-based biopharma Analyte Pharmaceuticals Inc. According to Kemin, the company was looking for a strategic partner to help advance its clinical-stage pharmaceutical programs, which includes antibacterial, antiviral and anti-inflammatory compounds, as well as establish a footprint in Europe and Asia. The new company will operate as a separate, wholly owned subsidiary of Kemin under the name of Analyte Pharmaceuticals LLC.

Heavy water keys collaboration between BMS and KineMed

BY LLOYD DUNLAP
EMERYVILLE, Calif.—Using deuterium-labeled proteins to measure the transport time of protein down the molecular escalator of axons, KineMed Inc. will team with Bristol-Myers Squibb to facilitate metabolic and cardiovascular disease, cancer, inflammation and musculoskeletal diseases.

“Bristol-Myers Squibb is committed to helping patients prevail over serious diseases through personalized medicine,” Cuss notes. “KineMed has a unique approach to identifying biomarkers for neurodegenerative diseases. We value KineMed’s expertise ... and look forward to working together in the fight against neurodegenerative diseases.” By “personalized medicine,” Cuss says, “at this stage we’re really talking about ‘stratified’ medicine. The near-term opportunity is to identify strata of patients—responders, non-responders, those who demonstrate serious side effects. It’s a way of providing more cost-effective medicine.”

According to both Cuss and KineMed CEO Dr. Robert B. Stein, each company brings its own strengths. KineMed has pioneered the use of heavy water to study protein dynamics. Proteins are transported by axons. When labeled with heavy water, it is possible to measure the amount taken up and the rate of transport down the axon. A key concept is that it’s relatively non-invasive, and therefore a very reasonable alternative to radioisotopes.

In addition to its collaboration with BMS, KineMed is developing a broad range of therapy areas, including oncology antibodies for $94.5 million.

BMS says it will use KineMed’s novel biomarkers for two years to assess potential treatments for Alzheimer’s disease. The collaboration will apply KineMed’s stable isotope technology to identify novel biomarkers that can be used to assess the extent and treatment of the disease. The length of the collaboration is specified to be two years and, when asked, Dr. Francis Cuss, senior vice president of discovery and exploratory clinical research at BMS, confirms that “We will be using KineMed markers for two years and hope to introduce something to the clinic by the end of that period.”

Cuss notes that BMS is “constantly sweeping for outside opportunities. KineMed came up in such a sweep, and we came to a quick agreement,” he says.

KineMed is a privately held biotech specializing in translational and personalized medicine. Its proprietary technology uses the administration of stable (non-radioactive) isotopes to provide “high-definition” pharmacological measurements of disease activity and drug effects across a wide range of therapy areas, including diseases of the nervous system, metabolic and cardiovascular disease, cancer, inflammation and musculoskeletal diseases.

Cellnex acquires CuraGen and its oncology antibodies for $94.5M

BY LORI LESKOE
NEEDHAM, Mass.—Cellnex Therapeutics has agreed to pay $94.5 million to acquire Branford, Conn.-based CuraGen Corp., thus gaining a portfolio of 11 oncology-focused antibodies. This includes CuraGen’s most advanced—and valuable—therapy, CR01, currently in Phase II studies for breast cancer and unresectable Stages III and IV melanoma.

The deal, announced May 29, also bolsters Cellnex’s financials as CuraGen brings a cash balance of at least $84.5 million to the table, thus allowing Cellnex to advance its clinical development programs into 2012.

Dr. Thomas Davis, Cellnex’s chief medical officer, stated in a company release, “Cellnex’s expertise in developing novel antibody-based therapeutics will enable us to seamlessly integrate CuraGen’s antibody programs into our precision targeted immunotherapy platform and selective ly identify and advance the candidates we believe hold the most therapeutic promise.”

Sean Cassidy, CuraGen’s vice president and CFO, referred to the deal as a “merger” which is expected to close in the third quarter. It has not yet been determined whether Cellnex will hire CuraGen employees—and Cassidy is unsure whether he has a position with the company.

The negotiations for acquisition began after CuraGen hired an investment bank to market its assets. According to both Cuss and KineMed president and CEO Timothy Shannon stated in the same press release: “We ended 2008 with $80 million of cash and investments on hand, have a clinically active, attractive Phase II development asset and over $500 million in net operating loss carry-forwards. Yet, our stock price does not reflect the intrinsic value of our assets.”

In the most recent press release, Shannon said, “We believe Cellnex’s immunotherapy expertise and platform technology provide an excellent fit for our antibody portfolio, industry collaborations, technological assets and intellectual property.” Shannon has been invited to join the Cellnex board of directors.

CuraGen’s tentative position was ripe for the taking—and Cellnex moved fast. The chance to acquire CuraGen “was a unique opportunity to conduct a deal like this that brings two product candidates, both fully-owned antibody targets and enough cash that, when combined with our current balance, provides a runway into 2012,” says Daniel Budwick, a Cellnex company spokesman.

The acquisition also “fulfills a major initiative of the company to identify and bring value-creating, synergistic assets in-house and strengthen the company’s balance sheet ... and provides us fully owned targets from Amgen/Abgenix, with either ready for preclinical development,” Budwick says. “So this really fuels the future of the new Cellnex company pipeline.”

CuraGen is expected to deliver $66.6 million in cash, including transaction fees, severance payments and a closing balance sheet adjustment. At the close of the transaction, Cellnex will assume $14.1 million of CuraGen’s 4 percent convertible debt, due in February 2011.

For more information, visit www.DrugDiscoveryNews.com
Taking aim at tuberculosis

TB Alliance announces four drug discovery collaborations to stock TB pipeline

BY DAVID NUTTON

WASHINGTON—Thwarting the spread of tuberculosis is the focus of the Global Alliance for TB Drug Development (TB Alliance), and the not-for-profit development partnership is taking the wraps off four drug discovery collaborations aimed at boosting that effort.

All four projects, announced in June, have the potential to generate compounds active against drug-resistant tuberculosis and show promise to advance the science of TB drug development.

The TB Alliance has 20 potential TB drugs in development, and the four collaborations announced are the latest in a series of drug collaboration agreements to advance the organization's development portfolio.

According to Dr. Mel Spigelman, CEO of the TB Alliance, the partnerships support the organization's efforts to aggressively increase the depth and strength of its portfolio to ensure that promising new TB drugs continue moving toward the clinic.

"Tuberculosis is responsible for the death of one person approximately every 20 seconds—and there is a significant need for novel medications to combat growing bacterial resistance to current drugs and to reduce the duration and complexity of therapy," he says.

In one partnership program, TB Alliance will work with Anacor Pharmaceuticals Inc., a biopharmaceutical company developing small-molecule therapeutics derived from its boron chemistry platform, to explore a novel anti-bacterial drug target for use in tuberculosis therapy. Anacor will provide the TB Alliance with a non-exclusive, royalty-free worldwide license for any compounds ultimately registered for a TB indication.

David Perry, CEO of Anacor, says funds from public-private partnerships like the TB Alliance will make it possible to both meet his company's responsibilities to its shareholders and help reduce the burden of neglected diseases. "As these programs are successful, we hope to expand our current efforts and establish programs in new disease areas," he adds.

The TB Alliance also reached an agreement with Colorado State University to test whether inhibition of menaquinone biosynthesis—a key component of the energy generation system in M. tuberculosis (MtB)—has the potential to eradicate the disease in vitro.

According to Spigelman, the most promising compounds will be employed in an animal model of TB, and a more advanced discovery program could be developed if the drugs are successful. Inhibition of menaquinone biosynthesis is a novel approach and therefore compounds that inhibit this process have the potential to be effective against drug-resistant disease.

The third collaboration, with the Institute of Microbiology (IMCAS), a member institute of the Chinese Academy of Sciences, will discover and develop novel anti-TB agents from natural sources, including microbial metabolites and traditional Chinese medicines.

The fourth collaboration announced is with New York Medical College to explore the type 1 topoisomerase (Topo 1) enzyme that facilitates the unwinding of DNA, which is required during normal cell processes.

On all four projects, the TB Alliance and its partners will work collaboratively based on a well-defined research plan with clearly assigned responsibilities. Spigelman points out that collaborations on early stage projects bolster the strength of the TB Alliance's development portfolio.

"The nature of tuberculosis requires that it be treated with several different drugs at once so a patient can be fully cured, and therefore, stop the emergence of resistance," he points out. "Though we are optimistic about our drugs in clinical development, as well as drugs developed by others that have reached clinical stages, no one or two new drugs will act as a magic bullet."

Spigelman says discovery and development at TB Alliance and within its collaborations aims at identifying targets and regimens that will have maximum impact on TB treatment and control.

"New drugs should meet one or more of the major unmet medical needs in current TB therapies as well as being affordable, widely adopted and available to those who need them," Spigelman says.

The TB Alliance programs seek to produce drugs that meet most of its criteria, including to shorten the duration of treatment; prove effective against sensitive and resistant diseases; possess improved safety profiles; elicit no significant drug-drug interactions, including with ART; and will be suitable for once-daily oral treatment. Discovery and development programs are selected, based on the balance in resource needs, through a rigorous, multi-layered process.

"Following preliminary evaluation by TB Alliance staff, project proposals are reviewed by expert independent consultants, as well as the TB Alliance scientific advisory committee and board of directors," says Spigelman. "At the discovery stage, it is not always possible to be certain to the extent in which a project will ultimately fit the above criteria. However, all four projects focus on novel targets or mechanisms of action, which indicates the potential to be active against both drug-sensitive and drug-resistant disease, and were to determined to have promising profiles in relation to the above criteria."

According to Spigelman, the TB Alliance must ensure a steady supply of promising drug candidates progresses toward the clinic and work to maintain the momentum driven by a recently reinvigorated global TB drug development infrastructure.

"Additionally, it is natural and expected that our portfolio will experience attrition as projects progress. To maintain its strength it is essential that we continue to populate our portfolio with promising discovery-stage projects that are our priority and make use of innovative science."

As a result, the TB Alliance will continue to seek mutually beneficial collaborations, according to Spigelman.

"The TB Alliance has assembled the largest pipeline of potential new TB drugs in history, but this process is only possible with the commitment of our partners. Tibotec has tremendous scientific prowess, a commitment to fighting infectious diseases, and is an essential long-term partner in our fight to end one of the greatest epidemics of our time."

Under the terms of the agreement, J&J will continue to develop TMC207 for the treatment of multiple-drug resistant TB, and approval will establish an access program to ensure the compound reaches people in developing countries.

The collaboration grants the TB Alliance a royalty-free license for the worldwide development and access to TMC207 in the field of drug-susceptible TB.

In addition, J&J will collaborate with the TB Alliance on a discovery research program to identify new compounds for the treatment of TB. The rights for any new compounds will belong to the TB Alliance under a royalty-free license.

Dr. Paul Stoffels, global head of pharmaceutical research and development at Johnson & Johnson, says that to make a meaningful contribution to the global fight against TB, the company knew it had to take a novel approach.

"Our collaboration with the TB Alliance represents a major step forward in the fight against TB as the two organizations combine their expertise and resources in the quest to make new TB treatments available," he says.

This announcement marks the first collaboration initiated by the newly created Tibotec Global Access and Partnerships Program. The program is creating a sustainable portfolio of medicines—both marketed and in development—that are designed to address major health challenges in resource-poor countries.
Breast cancer Dx beyond borders

ExonHit purchases exclusive rights from Institut Gustave Roussy for novel breast cancer diagnostic assay

BY LORI LESKO

PARIS—ExonHit Therapeutics has licensed the exclusive worldwide rights from the Institut Gustave Roussy to a novel breast cancer diagnostic assay through FNA (fine needle aspiration) sampling. Signed May 22, this license agreement, covering IGR’s existing know-how and cancer signature, strengthens ExonHit’s diagnostic pipeline and paves the way to future development and commercialization opportunities.

IGR, based in Villejuif, France, pioneered the routine use of FNA in place of the more invasive core biopsy, says Prof. Gilles Vassal, head of Clinical and Translational Research at IGR. The assay that ExonHit plans to develop could improve the accuracy of FNA, thus opening the door to more medical centers using the less invasive—and less expensive—diagnostic procedure.

Breast cancer is the leading cause of death by cancer in women, with 465,000 estimated deaths worldwide in 2007. Early detection of breast cancer significantly increases survivability. If this collaborative venture is successful, a highly accurate diagnostic test for breast cancer will be as invasive as a pinprick.

Assuming successful clinical validation, ExonHit, headquartered in Paris with a U.S. office in Gaithersburg, Md., will first launch the test as a research-use-only product within 12 months, the company says. Then, following further validation, the test will be launched as a clinical diagnostic.

In return, IGR will receive an upfront payment, as well as development milestones and royalties on future sales. Detailed financial terms were not disclosed.

IGR, in collaboration with the CNRS unit IFR 3909, identified a novel breast cancer signature, with an accuracy of more than 95 percent, based on ExonHit’s proprietary SpliceArray™ platform, according to an article published Feb. 26 in Lancet Oncology. This new signature allows for the discrimination between malignant tumors and benign lesions from cells sampled through FNA. The research was conducted by Dr. Fabrice Andre and his team at IGR, starting with 165 breast samples obtained by fine needle aspiration.

The results of the study left Andre cautiously optimistic.

“Many exons are differently expressed by breast cancer and benign lesions, and alternate transcripts contribute to the molecular characterization of breast cancer,” Andre wrote in the Lancet article. “Development of molecular classifiers for breast cancer diagnosis with fine-needle aspiration should be possible.” Typically, if a breast abnormality is detected with mammography or physical exam, a woman will be referred for additional breast imaging with diagnostic mammography, ultrasound or other imaging tests.

Depending on the results of these follow-up tests, she may be referred for fine needle aspiration (FNA) or a breast biopsy to confirm diagnosis with or exploratory surgery.

If ExonHit marches forward as planned, women worried about breast cancer and frightened of exploratory surgery, can rest assured: FNA is coming to America, he says.

“Our focus is on the United States, but we are not at all closing the door for Europe,” Maurel told Reuters. “We initially looked at a soup-to-nuts strategy to reinforce our diagnostic portfolio. It is estimated that it is a cytologist is unable to provide a definitive diagnosis in to 20 percent of cases where FNA samples are taken. ExonHit aims to better the odds.”

GLOVES

CONTINUED FROM PAGE 1
important signal promoting cancer cell survival. Preclinical evidence indicates that combined administration of the two compounds could enhance their anticancer properties.

“The notion that a single agent is going to be dramatically active in a broad population of cancer patients is unrealistic,” says Alan Barge, vice president and head of oncology at London-based AstraZeneca. “Drug cocktails are widely used in cancer treatment, but regimens are typically developed only after the medicines are in late-stage trials or already on the market.”

Barge points out that advances in cancer research have led to a new generation of drugs designed to precisely target features specific to cancer cells while minimizing the effect on healthy cells.

“Several of these drugs provide patient benefit as monotherapy, but increasingly, the ability of cancer cells to adapt and develop resistance has become apparent,” he says. “Research suggests that combination therapies that include drugs with different mechanisms of action impacting cancer cells in multiple ways may provide an improved anticancer benefit and decrease the risk of relapse.”

According to Dr. Ian McConnell, a Merck spokesman, the collaboration has a lot of built-in flexibility.

“We believe this is the first deal of its type between large pharma companies in early development,” McConnell says. “That is the novelty of this deal. We believe the collaboration will more quickly advance a potentially promising anticancer treatment.”

Usually, combinations of novel anticancer agents would only be studied in clinical trials when one component of the regimen is at a late stage of development or when one compound has received marketing approval. McConnell notes that this agreement is pioneering in that two major pharmaceutical companies, each with one component of the combination regimen in its pipeline, are collaborating at an early stage in development, so that effective treatments may be brought to patients as rapidly as possible.

The flexibility of the agreement will enable the companies to hammer out a new collaborative arrangement as the research moves through the various phases of study.

“We initially looked at a soup-to-nuts agreement and it was decided it would be too complicated,” McConnell adds. “Controlling all of the parameters in one contract would be too complicated. Once the data is in for the Phase I clinical trials, we will then re-evaluate the collaboration.”

McConnell notes the collaboration brings together two leading companies with a wealth of expertise in oncology.

“Through this agreement, we are well-positioned to implement a detailed and timely evaluation of the therapeutic potential of this novel combination, with the aim of bringing this potentially effective regimen to patients as rapidly as possible,” he adds.

Barge points out that AstraZeneca decided to partner with Merck because it wanted to bring a more effective therapy to patients as soon as possible.

“Going with our own AKT inhibitor would have delayed this, whereas Merck already has evidence of Phase 1 data,” he notes. “MK-2206 is the leading AKT inhibitor. It is an allosteric and therefore highly selective, which offers an opportunity to combine two highly selective inhibitors, with a strong scientific rationale in a timely fashion. Through this collaboration, we are taking an innovative approach to early-stage cancer drug cooperation based on AstraZeneca’s and Merck’s mutually determined to develop therapies that improve patients’ lives.”

Molecular profiling of human solid tumors has shown that both the MEK and AKT pathways are frequently abnormally activated. Preclinical studies have suggested that simultaneously inhibiting both of these pathways may have synergistic effects on tumor cell growth.

McConnell points out that MEK and Akt “are two critical pathways in oncogene signaling. If we shut down one, the other comes up to compensate.” The hope is that by hitting both pathways at once, “we will shut down the escape routes.”

The collaboration between AstraZeneca and Merck on a combination treatment is unusual, normally occurring when each company has a drug either already on the market or in final human testing.

“This is really, really early,” analyst Steve Brozak of WBB Securities told the Associated Press. “This is good news, as such partnerships can help produce the next generation of cancer drugs.”

According to Brozak, the collaboration is a consequence of industry consolidation, with companies that or merging or cutting costs having already reduced spending on administration and other areas.

“What they’re trying to do is cut their research expenses by combining programs,” he says.

Senior vice president and franchise head of Oncology at Merck Research Laboratories, “in order to harness the true potential of the combined administration of the compounds, AstraZeneca and Merck have established a pioneering, early-stage collaboration based on our mutual determination to develop impactful therapies that improve patients’ lives.”

“Molecular profiling of human solid tumors has shown that both the MEK and AKT pathways are frequently abnormally activated. Preclinical studies have suggested that simultaneously inhibiting both of these pathways may have synergistic effects on tumor cell growth.”
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BAYHILL
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BHT-3021’s market potential, the clinical candidate has the potential to be the first to treat the underlying mechanism of T1D—an autoimmune disorder that affects both adult and pediatric patients and for which there are currently no disease-modifying therapies, says Caroline Pecquet, a spokeswoman for Genentech.

“We believe that Bayhill’s BHT-3021 molecule, while in the early stages of clinical development, is a very promising clinical candidate,” Pecquet says. “We believe that this molecule has the potential to be a best-in-class and first-in-class treatment for type 1 diabetes.”

The deal is Genentech’s first collaboration on a potential diabetes treatment, Pecquet notes, and a new way for the Roche group company to continue to pursue products that address unmet medical needs and work through the biological mechanisms being explored in its key research focus areas, including immunology.

But the deal is even more pioneering for San Mateo, Calif.-based Bayhill Therapeutics and its 14 employees, which have been honing their antigen-specific therapy technology since the company’s founding seven years ago by Stanford University researchers, according to Dr. Mark Schwarz, Bayhill’s president and CEO.

“The day we announced this partnership was a very big day for us,” Schwarz says. “While many small biotech companies have been successful, there aren’t many companies that have become successful on the original technology they were founded on.”

Current immunosuppressants take a broad-based approach to treating autoimmune disease—“turning off” a general portion of the immune system, ameliorating the symptoms of an autoimmune disease, but also inducing a wide range of side effects, some of which are mild, but some of which may lead to death. In some cases, the immune system becomes so weakened by the powerful immunosuppressants that patients develop cancer. Bayhill’s research efforts use a different tactic to treat autoimmune diseases—restoring the patient’s immunological “tolerance” to self-antigens to a normal state by selectively eliminating specific, harmful immune responses while leaving the rest of the immune system intact.

BHT-3021 is designed to induce antigen-specific tolerance by selectively turning off the errant autoimmune response attacking the pancreas. The compound has shown promise in non-obese, diabetic mice models. In the current Phase I/II trial, patients receiving BHT-3021 demonstrated preservation of C-peptide, no serious adverse events and an acceptable safety profile.

This highly specific immunomodulation action could result in the preservation of pancreatic function and improved long-term health in T1D patients, Schwarz says.

“Currently, there are no disease-modifying agents for type 1 diabetes,” he notes, “and there are only a few in development. All type 1 diabetics are treated with insulin, which does nothing to attack the root cause of the disease. At the same time, immunosuppressants don’t get at the root cause of a disease, either—they just get a range of root causes. This collaboration is unique in the diabetes space for two reasons: it moves toward increasing the efficacy of drugs, and it also refines their targets.”

The deal also grants Bayhill the right to opt-in on future development and co-promotion of BHT-3021 as well as competitive escalating royalties on annual net sales.

Partnering with Genentech obviously gives Bayhill the resources and expertise it needs to see its work on BHT-3021 to fruition, but perhaps more importantly, it will also allow Bayhill to develop additional products from its BHT-DNA platform, Schwarz says. While Bayhill’s initial indications of focus are T1D, multiple sclerosis and myasthenia gravis, Bayhill hopes to develop a robust pipeline of product candidates targeting autoimmune diseases for which the target protein self-antigens are known—and a total 28 different such diseases have been identified, according to published research.

“That’s why we are so gratified by our partnership with Genentech,” Schwarz says. “Genentech itself is a highly innovative company that has pioneered many innovative therapies, so they have the right cultural mindset to bring this forward. If we can get this to the finish line, it will be a tremendous benefit to diabetes, but really good for autoimmune diseases in general.”

E070903
**NEW PRODUCTS**

**Drug Discovery News**

**Plate handling system automatically seals and unseals microplates**

**Hamilton Storage Technologies**

According to Hamilton Storage Technologies, the active sample manager of SealTitle technology is the world's only plate handling system that automatically seals and unseals microplates using Hamilton's unique SealTitle technology. The asmServer ST module serves as the interface between the asmServer ST modules and downstream assay automation. The asm ST offers complete environmental control through sample conduction, storage and retrieval for optimal compound integrity and stability.

Hamilton Storage Technologies
508-544-7050
www.hamilton-storage.com

**Benchtop simulated moving bed chromatography instrument**

**Sembia Biosciences**

Sembia biosciences’ primary product, the Sembia Octave SMBD platform, is a fully automated, benchtop deployable, continuous-flow chromatography system for research and preparative-scale molecular purification. Simulated moving bed chromatography (SMBC), a powerful approach to chromatographic fractionation, has been well-established for industrial scale fractionation, including chiral separations. The countercurrent flow central to SMBD enables the highest yields of purified product with the smallest investment in chromatography resins and mobile phases, bringing dramatic increases in operational efficiency. The same benefits SMBD brings to large-scale chromatography are realized on a smaller scale with the innovative Sembia Octave System.

Sembia Biosciences
608-310-4457
www.sembia.com

**Workstation enables high-throughput, high-content cellular assays**

**Fluxion Biosciences**

Fluxion Biosciences introduces the BioFlux 1000 Workstation, a cell analytics system that integrates the company’s White Light Microfluidic technology with automated microscopy for high-throughput shear flow assays. BioFlux 1000 extends Fluxion’s line of systems for plate-based, live-cell imaging that includes the BioFlux 200, introduced several years ago. The 1000 workstation delivers high-throughput and unattended operation with integrated microscopy and a fully automated stage that enables fast scanning of the BioFlux plates. Ideal applications include research in cell and platelet adhesion, cancer biology, microbiology and biofilms.

Fluxion Biosciences
866-266-8381
www.fluxionbio.com

**Multiplex detection system enables multiplexing, quality data and increased productivity**

**Promega Corp.**

The Promega GloMax Multi+ Detection System provides cross detection functionality with its ability to work in fluorescence, luminescence and absorbance read modes. Scientists can easily multiplex their experiments and read luminous and fluorescent cell-based assay data from the same microplate well. The benefits to scientists, in addition to multiplexing, include quality data and increased productivity, all in less time.

Promega Corp.
608-274-4330
www.promega.com

**Real-time PCR system**

**Roche Applied Science**

The LightCycler 1536 System from Roche Applied Science utilizes a proprietary 1536-well plate and is capable of performing high-speed, qPCR-based DNA/RNA analyses in an array-like format. The instrument is based on the LightCycler 480 Platform architecture. It comes with a novel thermal cycle module tailored for heating and cooling miniaturized qPCRs in a multiwell plate with individual reaction wells. The LightCycler 1536 Instrument supports the combination of two excitation filters with two detection filters, which are optimized for detecting green intercalating dyes as well as monoclonal and dual-color hydridization probes. This makes optical read-out as specific as possible for chemical detection formats, while reducing the overall complexity of experimental layouts in a high-throughput scenario.

Roche Applied Science
+49 8956 60 4830
www.roche.com

**Next-generation sample preparation product**

**Pressure Biosciences Inc.**

The PCT Micro Tube Adapter Kit includes an ergonomically designed, space-saving working platform, MicroTubes and MicroCaps and specialized tools to enable the user to process up to 48 samples simultaneously in Pressure Biosciences’ primary product, the PCT Sample Preparation System. The PCT MicroTube is made of a state-of-the-art polymer with unique features that separate it from competitive products, including extreme chemical resistance, broad useable temperature range, clean washing, easy centrifuging, surfacing, negotiable protein and nucleic acid binding, and the ability to efficiently transmit pressure from the pressure-generating instrument to the sample. The new PCT MicroCap was designed with an added feature to allow it to easily excise and transfer protein gel spots to the PCT MicroTube for processing, allowing for increased functionality in many mass spectrometry labs that is currently done by cutting the protein spots out by hand, or by expensive robotic systems.

Pressure Biosciences Inc.
508-230-1828
www.pressurebiosciences.com

**Improve transfection of ion channels and other targets for cell-based assays**

**MaxCyte Inc.**

Thermodynamic analyses are available Transfection System features transfecting 1E10 cells in less than 30 minutes; more physiologically relevant, cell-based assays; faster turnaround and productivity; transfection efficiency and cell viability of less than 90 percent; and cryopreserving cells after transfection. The system is consistent and scalable and can be used for primary cells, stem cells, stem cells, cell lines, DNA, RNA, proteins, labile reagents and other molecules.

MaxCyte Inc.
301-944-1700
www.maxcyte.com

**Single-use solution eliminates downtime and increases throughput**

**Millipore Corp.**

Millipore’s scalable CellReadi 3L Bioreactor is a ready-to-use, three-liter bioreactor that demonstrates all the benefits typically associated with single-use processing, while incorporating standard design features familiar to customers already using benchtop, stirred-tank bioreactors. Designed to replace traditional glass benchtop bioreactors, the CellReadi 3L Bioreactor has a standard stirred tank format for use in development and optimization of cell culture processes. This vessel design provides a higher degree of predictability during process scale-up when compared to formats utilizing alternative vessel designs and agitation methods. It features a universal design, ensuring compatibility with most benchtop bioreactor control systems. By eliminating time-consuming steps associated with cleaning, assembly and sterilization, the CellReadi 3L bioreactor significantly reduces the turnaround time typically associated with glass bioreactors.

Millipore Corp.
800-645-5476
www.millipore.com

**White wells can improve qPCR results**

**Eppendorf North America Inc.**

Eppendorf’s twin.tec real-time PCR plates offer researchers the ability to significantly improve real-time PCR data. twin.tec real-time PCR plates feature titanium dioxide, which gives the reaction chambers a bright white, opaque color. This results in up to a 10-fold increase in reflection of fluorescence, providing better data for cutting-edge applications such as low-volume qPCR. Additionally, white wells significantly reduce interfering background fluorescence and lead to increased homogeneity of replicates and reproducible results. This new consumable helps researchers performing real-time PCR reach the crucial goal of optimization and achieve accurate, reproducible results.

Eppendorf North America Inc.
800-645-3050
www.eppendorfna.com

**Multiplex analysis of heat shock proteins**

**Assay Designs Inc.**

Assay Designs has released the first commercially available multiplex assay dedicated to the analysis of heat shock proteins and molecular chaperones, the MultiBed HSP/Chaperone 8-Plex Kit. The bead-based multiplex immunosassay enables measurement of HSP client proteins (Akt and AKT phospho Ser473) and HSPs (Hsp27 phospho Ser15, Hsp27 phospho Ser10, Hsp40, Hsp60, Hsp70 and Hsp90 alpha) in cell lysates. The assay utilizes monoclonal antibodies or affinity affinity purified polyclonal antibodies covalently coupled to latex beads. The detection antibodies are conjugated to biotin followed by a streptavidin-PE conjugate and analyzed on a dual-laser flow cytometer. The HSP/Chaperone panel provides a sensitive, rapid and specific method for accurately determining analyte levels in cell lysates.

Assay Designs Inc.
871-423-4548
www.assaydesigns.com

**Next-generation, high-end quadrupole time-of-flight mass spectrometer**

**Waters Corp.**

Taking qualitative and quantitative quadrupole time-of-flight mass spectrometry to new heights, Waters’ SYNAPT G2 system serves as a platform for continuous and multi-channel analysis. The SYNAPT G2 System is capable of outstanding qualitative and quantitative performance for both MS and the elevated data acquisition rates of SYNAPT G2 HDMS analysis. For scientists, this means performance in excess of 40,000 FWHM resolution, class-leading sensitivity, a data acquisition rate of 20 spectra/second, exact mass (1 ppm RMS) information and a dynamic range of up to five orders of magnitude. When paired with Waters ACQUITY Ultraperformance LC (UPLC) technology, Waters SYNAPT G2 Mass Spectrometer makes maximum use of the power and speed of UPLC outclassing all other LC/MS and LC/MS/MS systems. Waters expects to deliver the first SYNAPT G2 units during the fourth quarter of 2009.

Waters Corp.
508-478-2000
www.waters.com/synaptg2

**Pyrosequencing technology for quantifiable methylation and mutation analysis**

**QIAGEN**

Epigenetic researchers can now detect changes in methylation status in a real-time format using high resolution, high throughput multiplex pyrosequencing. QIAGEN’s EpTec HRM PCR kit provides a master mix format for the detection of changes in the CpG methylation status of bisulfite converted DNA. The kit is designed to run on all real-time cyclers, including the Rotor-Gene Q. QIAGEN’s real-time PCR cycle, which provides a highly specific melting curve enables, for the first time, life science researchers who require these capa-

QIAGEN
800-426-8157
www.qiagen.com

**New assay capabilities for high-sensitivity protein quantitation and fragment screening**

**ForteBio Inc.**

ForteBio has launched two assay modules—for high-sensitivity protein quantitation and fragment screening—respectively—for use on the company’s Octet instrumentation platform. The new modules are available via software upgrades and will...

ForteBio Inc.
650-322-1360
www.fortebio.com
Research firm finds selection of automation technology key to pharma, biotech industries

DEDHAM, Mass. – Automation expenditures in the pharmaceutical and biotechnology industries are expected to exceed $8 billion by 2012, according to a recent report by ARC Advisory Group, a research and advisory firm for manufacturing and systems in the pharmaceutical and biotech industry continues to be moderate to strong.

“However, much of the current automation focuses on projects with immediate return on investments, projects that are the result of consolidation of manufacturing operations and standardization of applications across the entire enterprise,” says John Blanchard, the principal author of ARC’s report.

According to the report, as new drug lifecycles continue to decrease and drug development expenses continue to rise, shortening time-to-commercialization is vital. However, traditional industry growth drivers of R&D and sales and marketing are slowing and competition is intense, the report notes. APO and expedient manufacturing and sourcing have become global. This is placing new emphasis on manufacturing to drive margin and growth, ARC says.

“The Darwinian concept of ‘adapt or die’ is on the mind of every senior executive, and proper selection and deployment of automation technology have become vital to success,” the report states. Some suppliers have a strong presence in one or two geographic regions, the report states. Others have a strong presence in all four geographic regions, including a strong support infrastructure. Less presence in a geographic region can be an opportunity for the supplier. However, ARC points out that user manufacturers must evaluate a supplier’s regional support capabilities and commitment to their industry needs. The Latin American market is the fastest-growing, but also a small market. Asia is the second fastest-growing market and growing in market share. India and China are playing a significant role in this market in terms of automation expenditures, CRM and CMO capabilities and domain expert IT services.

Although ARC predicts that acquisitions will continue in 2009, the firm notes that acquisitions are one of several factors inhibiting deployment of new automation products and systems.

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