Cytogenics Ltd recently announced a restructuring of Cytomatrix, its Boston-based subsidiary. The restructuring is to achieve two objectives: (1) the transfer of technology and technical expertise to its new Australian and Singapore stem cell technology facilities, necessary to drive its stem cell expansion and artificial thymus clinical trials efforts; and (2) to reorientate Cytomatrix from being a research group, to a company focused on technology commercialization and revenue generation.

The technology transfer has been underway for some months. The company is also expanding its medical and scientific headcounts globally.

With this restructuring, Cytomatrix will focus on supporting the group’s clinical trials and driving its vaccine/drug screening business. This business uses patented and proprietary cellular assays to elucidate the effects and potency of candidate drugs and vaccines for pharmaceutical and biotechnology partners.

Many vaccines have millions of dollars invested during development, often to find that they are ineffective in people. Addressing this need, new, innovative assays utilizing cells to screen drugs and vaccine are proving to be increasingly informative during drug development. CyGenics’ cellular assays using its proprietary T cell technology platform holds the promise of improving the outcome of vaccine development, potentially saving millions of dollars and years of effort by differentiating effective vaccines from ineffective ones earlier in the development cycle.

To spearhead this effort, the company has hired Dr. Michael Michalek as Director of Cellular Screening Services. Dr. Michalek brings 17 years of immunology, cell assay, and commercial biotechnology experience to the company and has served in senior management positions with several biotechnology companies. He received his PhD in immunology from Rush University in Chicago, USA, and a BS from Notre Dame University.

With the restructuring, Dr. Mark Pyllett at Cytomatrix will transition over the next few months to a non-executive position on the Board of Directors and Chairman of the group’s Scientific and Medical Advisory Board, serving key areas of its clinical trials and providing scientific directions.

“CyGenics is on track to meet its stated clinical milestones and the emphasis to commercialize its technologies” said Steven Fang, Group CEO, CyGenics. “As such, we are enthusiastic about the progress with our clinical trials, vaccine/drug screening business, and the refocusing of our Cytomatrix business unit toward revenue generation, all of which we believe will translate into tangible shareholder value.”

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About CyGenics
CyGenics Ltd is a biotechnology and immunotherapy company focused on the development and commercialization of stem cell-related products, services, applications and technologies.

From its headquarters in Australia, CyGenics operates three divisions: Singapore-based CordLife (tissue banking services, in particular, cord blood banking) and Cell Sciences (consumable cell culture products), and Cytomatrix (cell therapeutics and technology development) based in the US.
Indian drug company Wockhardt Limited will be setting up joint ventures in Mexico and South Africa to follow the lead of larger Indian companies to capitalize on the growing demand for generic drugs. The company will take up majority stakes in these joint ventures, and is expected to file up to 18 abbreviated new drug applications (ANDAs) in the United States in 2005.

In Mexico, Wockhardt signed a joint venture agreement for a 51% stake in Wockhardt Mexico with the remaining 49% held by Representaciones E Investigaciones Medicas — the joint venture will initially market insulins made by Wockhardt and eventually market other diabetology products and biopharmaceutical products.

The South African joint venture named Wockhardt South Africa, also on a 51%–49% basis with Pharma Dynamics, will use the regulatory, sales and marketing expertise of Pharma Dynamics to sell Wockhardt’s pharmaceutical and biopharmaceutical products. Another plan in the near future for Wockhardt is the establishment of a wholly owned subsidiary in Brazil.

For Wockhardt, biotechnology is now a strategic business unit. “We are now establishing building blocks of our global footprint in biopharmaceuticals with major joint ventures in Mexico, South Africa and a subsidiary in Brazil,” said Wockhardt chairman Habil Khorakiwala.

“We have already received nine approvals for our biopharmaceuticals and we expect another 25 approvals during the year in Russia, former CIS countries, South America, South East Asia and North Africa,” he added.

A world-scale biopharmaceuticals complex at Aurangabad, inaugurated by President Dr. APJ Abdul Kalam last September, has also been fully stabilized. The company has received nine registrations for its biotech products from South America, Central and South East Asia — and according to Wockhardt, more are in the pipeline.

About Wockhardt Limited
Established nearly four decades ago, Wockhardt Limited is among India’s top research and technology-oriented pharmaceutical companies, with global presence. Wockhardt has emerged as a leading player in domestic as well as international markets, with widely accepted and efficacious drugs and formulations. The company has developed leading brands in anti-infectives, pain and inflammation, cough, psychiatry, medical nutrition and biotechnology segments.

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On April 1, 2005, Yamanouchi Pharmaceutical and Fujisawa Pharmaceutical will be merging into Astellas Pharma Inc. The aim is to develop a completely new company that will possess a highly competitive edge not only in the Japanese pharmaceutical market, but also in the global pharmaceutical market, with excellent R&D capabilities and strong sales and marketing infrastructure. Under the agreement, Yamanouchi will be the surviving company and Fujisawa will be dissolved. One Fujisawa share will be exchanged for 0.71 shares of Astellas.

The name “Astellas” expresses the idea of “aspired stars” and “advanced stars”, based on the Latin “stella”, Greek “aster”, and English “stellar”, which all refer to “stars.” “Astellas” also sounds like in Japanese “a-su wo te-ra-su” which means “to shine on tomorrow.” The name of the new company thus signifies their aim to deliver hope for the future to all those who wish for good health through their state-of-art pharmaceuticals, and to develop into a global, mega-pharmaceutical company that originated in Japan.

Yamanouchi Pharmaceutical Co., Ltd., has built a solid reputation as a research-oriented company and a leader in Japan’s pharmaceutical industry since its establishment in 1923. In Japan, the major therapeutic area on which Yamanouchi is focusing is adult and geriatric diseases, which are anticipated to grow in importance due to the ongoing aging of the population.

Fujisawa Pharmaceutical Incorporated in 1930 and headquartered in Tokyo, Japan, Fujisawa is a research-driven pharmaceutical company with a firm commitment to innovative research in its quest to satisfy unmet medical needs and contribute to the progress of medical care.

In Japan, the major therapeutic areas in which Fujisawa is focusing are transplantation and dermatology, strokes and neurodegenerative diseases, bacterial and fungal infections, and diabetes.

About Yamanouchi Pharmaceutical
Guided by its corporate philosophy, “Creating and Caring... for Life,” Yamanouchi Pharmaceutical Co., Ltd., has built a solid reputation as a research-oriented company and a leader in Japan’s pharmaceutical industry since its establishment in 1923.

In Japan, the major therapeutic area on which Yamanouchi is focusing is adult and geriatric diseases, which are anticipated to grow in importance due to the ongoing aging of the population.

About Fujisawa Pharmaceutical
Incorporated in 1930 and headquartered in Tokyo, Japan, Fujisawa is a research-driven pharmaceutical company with a firm commitment to innovative research in its quest to satisfy unmet medical needs and contribute to the progress of medical care.

Fujisawa operates laboratories in Osaka, Nagoya and Tsukuba in Japan as well as in the UK and the US. Their R&D efforts are focused on four therapeutic areas: immunology/inflammation, cerebral diseases, infectious diseases, and metabolic diseases. In particular, they are looking at transplantation and dermatology, strokes and neurodegenerative diseases, bacterial and fungal infections, and diabetes.
Fujisawa Healthcare has recently announced that the US Food and Drug Administration (FDA) has approved the use of micafungin sodium, an antifungal product for prophylaxis of Candida infections in patients undergoing hematopoietic stem cell transplantation and the treatment of esophageal candidiasis. The newly approved agent will be marketed in the US under the name Mycamine™ (micafungin sodium for injection).

Invasive candidiasis kills 10-40% of infected immunocompromised patients. “Immuno-compromised patients whose white blood cell contents are lowered are highly susceptible to candida infections,” said Ira D. Lawrence, M.D., Senior Vice President, Research and Development. “Mycamine can be an effective preventative therapy for immunocompromised patients who undergo bone marrow or stem cell transplants and are highly susceptible to candida fungal infections.”

The approval is based on 32 clinical studies, a total of 2402 subjects, conducted in the US, Canada, Japan, South America, Europe and Africa. Subjects in the Mycamine studies included a broad range of individuals who had a confirmed, or were at risk for, candida fungal infections, including patients with hematologic malignancies, bone marrow transplant recipients, and HIV-positive patients. In large, well controlled, clinical trials, Mycamine has been shown to have an overall safety profile, and discontinuation rate, similar to that of fluconazole.

About Mycamine
Mycamine is a member of a new class of antifungal agents, the echinocandins, that inhibit cell-wall synthesis. The novel mechanism of action of echinocandins specifically targets the wall of fungal cells to treat the infection.

Mycamine is contraindicated in patients with hypersensitivity to any component of the product. Patients receiving Mycamine have reported isolated cases of serious hypersensitivity (anaphylaxis and anaphylactoid) reactions (including shock), significant hemolysis and hemolytic anemia.

The most common side effects experienced in the clinical trials included changes in liver and renal function. Possible histamine-mediated symptoms have been reported with Mycamine, including rash, pruritus, facial swelling, and vasodilatation. Injection site reactions, including phlebitis and thrombophlebitis have been reported, at Mycamine doses of 50–150 mg/day.

About Fujisawa Healthcare
Fujisawa Healthcare, Inc., headquartered in Deerfield, Ill., develops, manufactures, and markets proprietary pharmaceutical products in the United States and abroad. Fujisawa Healthcare, Inc. is a subsidiary of Fujisawa Pharmaceutical Co., Ltd. based in Osaka, Japan. Fujisawa Pharmaceutical Co., Ltd., founded in 1894, is a leading pharmaceutical manufacturer and is actively developing its international operations in North America, Europe, and Asia. Fujisawa Healthcare, Inc. established its presence in the anti-fungal market with the launch of AmBisome® (liposomal amphotericin B) in 1997.

On April 1, 2005 Fujisawa Pharmaceutical Co., Ltd. and Yamanouchi Pharmaceutical Co., Ltd. will merge to form Astellas Pharma Inc.

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Kissei Pharmaceutical and Dainippon Pharmaceutical have recently entered into a license agreement for “KGA-2727”, a novel agent for the treatment of diabetes discovered by Kissei.

Under this agreement, Dainippon obtains from Kissei the right for the development and marketing of “KGA-2727” in Japan, while Kissei receives from Dainippon an up-front payment and milestone payments at each stage of development. Kissei continues to own the right for this agent outside Japan, including the right for development, manufacturing and marketing.

“KGA-2727” is a selective inhibitor for Na⁺-dependent glucose transporter (SGLT1) and an agent for treating diabetes with a novel mechanism of action — it improves postprandial hyperglycemia by inhibiting glucose absorption in the gut. This has been confirmed in various animal models for diabetes.

Subsequently, Kissei will continue to conduct non-clinical studies while Dainippon will conduct clinical development and marketing in Japan. Kissei reserves the right to participate in the clinical development to be conducted by Dainippon as well as the right to co-market the agent.

About SGLT1
SGLT1, or Sodium-dependent Glucose Transporter 1, is one of the transporters involved in transporting glucose in the body. It exists abundantly in the small intestine and plays a major role for glucose absorption in the gut. The SGLT1 inhibitor is expected to improve postprandial hyperglycemia by directly inhibiting the function of SGLT1, resulting in suppressing glucose absorption in the gut. The α-glucosidase inhibitors delay the glucose absorption after the meal by inhibiting the enzyme decomposing disaccharide in the small intestine resulting in suppressing the decomposition of disaccharide.

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It was recently announced that Sanwa Kagaku Kenkyusho Co. Ltd. (SKK) and Quark Biotech Inc. will be entering into an agreement for the latter company to license the phase II compound BT16 to the former for the treatment of dyslipidemia.

Dyslipidemias, including elevated triglyceride states, are blood lipid disorders that result in abnormal lipid and lipoproteins levels in the blood stream, leading to a significantly increased risk of cardiovascular diseases. The disease currently affects approximately 10% of the global population and its prevalence is increasing — an estimate of 20% to 30% of the dyslipidemic population needs alternative therapies to current treatments.

SKK possesses exclusive development, manufacturing and marketing rights for the compound in Japan and other Asian countries. According to the terms of the agreement, Quark will receive an upfront payment as well as payments at development milestones with additional royalties on sales. Quark is seeking additional licensees in Europe and US to work closely with SKK for developments in this area.
Satoshi Terao, vice president of SKK, said “We are very excited at licensing BT16 from Quark, since we are focusing our R&D efforts on diabetes-related areas, the potential of BT16 as a metabolic syndrome therapy makes this product a very important addition to our R&D pipeline.”

In trials, BT16 was found to be able to suppress triglyceride levels in animals and humans, as well as being safe and well tolerated. Further studies also demonstrated that it also has insulin-sensitizing properties and the future possibility of this compound being developed as a metabolic syndrome therapy has been suggested.

Dr. Daniel Zurr, chief executive officer of Quark, was pleased for his company to be collaborating with SKK, which he described as an established Japanese pharmaceutical company that pioneers development of new drugs for the treatment of metabolic syndrome constituents.

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About Quark Biotech Inc.
Quark Biotech Inc., a privately held US company, is pioneering Endpoint Driven Drug Development (ED3) to efficiently develop superior therapeutics to treat complex diseases. ED3 is a vertically integrated drug development approach that starts with defining a desired clinical endpoint in any specified disease, to identify drug candidates that achieve the desired endpoint.

The company is currently focused on therapeutics to treat metabolic disorders, cancer and cardio/renal diseases. Quark's global team consists of approximately 250 employees. R&D facilities are located in Fremont, California, Cleveland, Ohio, and Ness-Ziona, Israel.
Researchers from the National University of Singapore (NUS) have discovered a uniquely-derived component within horseshoe crabs that exhibits great potency in recognizing, binding to, neutralizing and removing endotoxin. Endotoxins are toxins associated with Gram-negative bacteria. They often induce high fever and are generally associated with symptoms of bacterial infections, costing the healthcare industry over US$17 billion per year.

In view of this discovery, the university has signed an exclusive licensing agreement with BioDtech, Inc. (BDT), a biotechnology company based in Nashville, Tennessee, for the new technology. The licensing agreement was effected through NUS’ Industry and Technology Relations Office (INTRO) and gives BDT an exclusive worldwide license to use and further develop the technology. The license includes several patents issued or pending in the US, Europe and Singapore.

This licensing deal is because of the discovery made by a team of researchers led by Prof. Jeak Ling Ding from the NUS’ Department of Biological Sciences and Assoc. Prof. Bow Ho from the NUS’ Department of Microbiology. In their research, they established that a certain domain within a protein involved in blood clotting of the horseshoe crab had a strong ability to bind to endotoxins. BDT intends to develop a rapid and user-friendly endotoxin assay based on this new technology and this assay is needed by several markets which include pharmaceutical and medical device manufacturing, environmental health, medical hygiene and clinical diagnostics. In addition, BDT will investigate the use of the technology to treat microbial infections associated with sepsis, cystic fibrosis (CF) and AIDS.

“We are very excited to be licensing partners with NUS, helping to advance our company’s detection platform,” said Dr. Michael Pepe, President and CEO of BioDtech. “This licensing agreement will allow us to develop novel products for medical, diagnostic and industrial uses. Our products will permit the direct detection and identification of biological toxins, resulting in faster, simpler and more accurate measurements. Future applications of this promising technology range from other infectious disease detection to possible applications for homeland security.”

About BioDtech, Inc.
Established in September 2003, BioDtech, Inc. (BDT) offers new technologically superior products for the bioresearch and bioscience markets, which are designed exclusively for the detection, neutralization and removal of endotoxin. These products address all of the concerns of the endotoxin market and will eliminate common critical issues associated with current methods. Three key factors differentiate BDT from other organizations involved in the detection of endotoxin:

• detection products focus exclusively on endotoxin;
• provides the ability to not only detect but neutralize and remove endotoxin associated with Gram-negative bacteria; and
• have the ability to provide both quantitative and qualitative results to the end user.

In addition to the NUS BDT partnership, BDT has also begun to scope out strategic partnerships with other biopharmaceutical, pharmaceutical and medical device companies that could utilize its technology with their existing portfolio of products. In the years ahead, BDT anticipates that its technology will possibly change forever the way in which infectious disease management is practiced.

Singapore
NUS and BioDtech Collaborate to Develop Endotoxin Detection and Removal Technology
“I anticipate that BioDtech will pursue a vigorous research and development program that will move the invention from a prototype to production phase within three to six months,” said Dr. Pepe. “When delivered, these products will be an enhancement to those currently available in the marketplace.”

Commenting on the licensing agreement, Prof. Ding and Assoc. Prof. Ho said: “We are encouraged by the enthusiasm of BioDtech on the "techno-vative" product of our research which is made possible by the untiring efforts of our research team and the support from funding bodies.” The research had received funding from NUS and the National Science and Technology Board (NSTB), now known as the Agency for Science, Technology and Research (A*STAR).

Technology transfer officers at INTRO are delighted that BDT recognizes this high-growth opportunity in the endotoxin detection, removal and neutralization markets. Commenting on the licensing agreement, Prof. Jacob Phang, CEO of NUS Enterprise said: “NUS is home to many world-class research groups. Prof. Ding and Ho repeatedly prove that university research can be used for real world applications. INTRO constantly seeks opportunities to work with interested parties to commercialize university research results to address the needs of society and benefit the community.”

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