Industry Watch

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Biotechnology Frontiers Ltd. (BTF) has recently announced it had successfully secured AUD 780,000 (US$528,000) R&D START Grant from the Australian Federal Government. The grant has been awarded to support the development of the company’s revolutionary new BioBall technology. The BioBall has been developed by BTF to provide a precise number of bacteria in a sample that laboratories can use to accurately benchmark the performance of their testing.

Mark Gauci, CEO of BTF said on the announcement, “The successful completion of the BioBall development program will significantly extend BTF’s unique range of Precision Reference Materials for the Life Sciences.”

In addition to being used in the global drinking water testing industry, where BTF is already the leading supplier of Precision Reference Materials, the BioBall technology will be used in the larger food and pharmaceutical manufacturing industries.

The R&D START Grant will ensure the continued rapid development of the BioBall product range, so that BTF takes advantage of its leading position in the emerging global market for Precision Biological Reference Materials.

About BTF

BTF is a bioscience company based in Sydney, Australia. BTF develops, manufactures and markets a unique range of Precision Reference Materials for life sciences.

The need for Precision Reference Materials to benchmark and harmonize the results of biological tests is growing rapidly. Demand for precision is growing as biological test results become increasingly critical to the quality of consumer products, the maintenance of public health and the satisfaction of government standards. Currently available Biological Reference Materials lack the precision required and therefore do not fill this need.

Since forming in 1999 BTF has positioned itself to capitalize on this emerging opportunity by developing a suite of patented technologies, unique product offerings and instantly recognizable brands that are now defining a new category in the global laboratory consumable market.

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This invaluable book tells the reader how to invest in the healthcare biotechnology and life sciences sector, one of the fast-growing sectors of the US economy. Aimed at biotech investors as well as bioentrepreneurs and venture capitalists, it has been written from the perspectives of risk management and asset management/allocation. It strives to teach readers how to fish, rather than giving them fish.

Contents:
- Biotech Stock for Wealth Growth; The Basics of Investing; An Introduction to Biotechnology and Genomics; Understanding Biotechnology Invention and the FDA Process; Introduction to Biotechnology Investing; How to Value and Invest in a Biotech Company; Investing in Biotechnology Mutual Funds; Healthcare Biotechnology Index Investing — Strategies Using Exchange-Traded-Funds (ETFs), Biotech iShares, and BOXES; Risk Management Consideration for Biotech Investors with Concentrated Equity Positions; Managing Biotech Stock Options: Your Employee Benefits; An Introduction to Healthcare Biotechnology Hedge Fund Investing; An Introduction to Healthcare Biotechnology Private Equity Investing; Retirement Planning Considerations for Biotech Executives and Investors; Charitable Disposition of Appreciated Biotech Stocks; Managing Your Bio-Wealth — Estate Planning for Biotech Investors, Executives, and Founders.

Readership: Individual biotechnology investors, investment advisors/professionals, venture capitalists, entrepreneurs, portfolio managers, scientists, CPAs, legal professionals, industry analysts and graduate students.

by
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World Scientific
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Queensland pharmaceutical Benitec Ltd. (ASX: BLT), the first company to demonstrate RNA interference (RNAi) in human cells, recently announced the grant of its core technology patents in UK and US. These patents, with priority dating to 1998, describe a revolutionary method for silencing any gene in any cell using DNA directed RNA interference (ddRNAi). US Patent 6573099 is entitled “Genetic constructs for delaying or repressing the expression of a target gene” and U.K. Patent 2353282 is entitled “Control of gene expression”. Both patents contain world first claims that describe the effect of RNAi in human cells and the DNA constructs, which trigger RNAi. The patents were jointly granted to Benitec and The State of Queensland, Australia and Benitec holds exclusive worldwide rights to both patents under a partnership agreement with The State of Queensland.

“These broad patents confirm Benitec as a pioneer in the effective application of RNAi to humans and the leader in ddRNAi technology,” stated John McKinley, Chairman and Chief Executive Officer of Benitec, Ltd. “We will now leverage our dominant IP (Intellectual Property) position to secure further commercialization opportunities, add to our licensing partners and expand our efforts to develop ddRNAi targets for drug development.”

According to Ken Reed, Director of Research & Technology with Benitec, RNAi is the simplest and most precise method of gene silencing and ddRNAi is the most versatile method of triggering RNAi in human cells. In contrast to RNAi induction using double-stranded RNA, ddRNAi does not provoke the natural interferon response in cells. Critical to the biopharmaceutical industry, ddRNAi can also manipulate gene silencing for either transient or permanent effect, and can be used to reduce gene expression or silence it completely. It also has more versatility with respect to delivery vehicles, further increasing options for development of therapeutics. As a bonus, manufacturing costs are significantly less.
About ddRNAi

DNA directed RNAi (ddRNAi) is a method to trigger the natural gene suppression process called RNAi that operates by destroying messenger RNA (mRNA), the courier that delivers instructions to the ribosomes within the cell to manufacture the proteins coded for by DNA. By introducing a DNA construct into a cell, Benitec’s ddRNAi technology triggers the production of double stranded (dsRNA), which is then cleaved into small interfering RNA (siRNA) as part of the RNAi process, resulting in the destruction of the target mRNA and knocking-down or silencing the expression of the target gene.

About Benitec Limited

Benitec, based in Queensland Australia, has key Intellectual Property in the field of gene silencing using DNA to trigger RNA interference. The Company was the first to demonstrate RNA interference, a gene silencing mechanism, in animal and human cells; a natural mechanism now recognized worldwide as the simplest and most precise method for silencing genes. The technology is immediately applicable to and promises to revolutionise the field of functional genomics - the determination of gene function. Benitec’s technology can also be applied to the treatment of major human diseases such as cancers, autoimmune disorders and viral infections through the shutting down of disease causative genes. Other applications include plant improvement and the breeding of viral resistant livestock.

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Melbourne biotechnology company Amrad Corporation Ltd (ASX:AML) and Merck Sharp & Dohme (Australia) Pte Limited announces one of the largest biotechnology collaborations in Australian history, with a potential value of US$112 million plus royalties.

Amrad and MSD, the Australian subsidiary of one of the world’s leading research-based pharmaceutical companies, Merck & Co., Inc., have signed an exclusive licensing and multi-year research collaboration agreement. Based on the results of the collaboration, Merck will seek to develop drugs with therapeutic potential in areas such as asthma, other types of respiratory disease and oncology.

Under the agreement with MSD, Amrad will receive an upfront payment of US$5 million. Total potential payments to Amrad by MSD based on the successful development of a human health product for all indications would amount to a total of US$112 million. Amrad would also receive royalties for commercialised products. Amrad and MSD will work together to investigate drug candidates, with Merck being solely responsible for all clinical development and marketing.

Announcing the agreement at BIO2003 in Washington DC, Amrad Managing Director, Dr. Sandra Webb, said the deal demonstrates the value of Amrad’s drug discovery program and intellectual property.

“We are delighted to enter this collaboration with Merck as its strong skills in development and marketing make Merck an ideal partner. More importantly, we believe that by collaborating with Merck we can accelerate the preclinical investigation and clinical development of drugs based on this exciting target,” Dr. Webb said.

Dr. Peter S. Kim, President of Merck Research Laboratories, cites this agreement as a significant entry by Merck into the biologics arena and consistent with Merck’s renewed emphasis on external partnerships to supplement its world-class research capabilities.

Victoria Premier Steve Bracks joined in hailing the deal as a major coup for Victoria and a vote of confidence in the Victorian biotech industry. The state government has a 16 percent share in Amrad and has identified the biotech industry as an important spur to economic growth and employment in Victoria.

It is hoped that the collaboration will emulate an earlier partnership between Merck and Australian researchers, which has led to the development of a therapy offering hope in the fight against cervical cancer. The vaccine for the Human Papilloma Virus (HPV), believed responsible for the development of most cervical cancer cases, has now entered final clinical trials.
About Amrad Corp.

Amrad Corporation Limited is an Australian drug discovery and development orientated biotechnology company. Amrad’s in-house R&D expertise is focused on five priority status projects in the areas of allergy and inflammation, antiseptics and neurological indications.

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About Merck Sharp & Dohme (Australia)

MSD is the subsidiary of global research-based pharmaceutical company Merck & Co., Inc. With a portfolio of more than 60 medicines and vaccines, MSD is among Australia’s top 40 firms investing in research and development.

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NCPC’s 2002 Exports Performance

North China Pharmaceutical Co. (NCPC) hit US$110 million in exports in 2002, a record high and an increase of 15 percent over 2001. Anticipating China’s entry to the WTO, NCPC is strengthening its foreign trade business. It has established an overseas registration department and currently 44 of its products have been registered abroad. Huasheng Co., a division of NCPC, has the largest streptomycin production base worldwide and has won the silver medal in local State Product Quality Awards. NCPC’s is also the foremost exporter of penicillin and vitamin B12 in China.

Lukang’s 2002 Exports Performance

Shandong Lukang Pharmaceutical Group hit a record high of US$30 million in exports in 2002. The company’s bulk products include pharmaceuticals and antibiotics and it is making efforts to seek international clients in order to boost its overseas network.

China Worldbest Constructs Non-PVC Parenteral Production Facility

Construction has commenced of a new non-PVC parenteral (intravenous delivery) production facility in Wuxi Huishan Life Sciences Park. China Worldbest Group, which backs the project, a multinational corporation ranked among the top 50 largest enterprises in China. The total investment in the project is US$24 million and the facility, when completed, is expected to produce 50 million packages of non-PVC parenteral solutions and plastic bottle infusion solutions per annum.

Nanjing Medicines Established in Hefei

Through restructuring of the former Hefei Medicines Company and Hefei Medicines Station in cooperation with Nanjing Medicines Company, Nanjing Hefei Tianxing Pharma and Nanjing Hefei Tianrun Pharma have been established in Hefei, capital city of Anhui Province. Tianxing Pharma has registered capital of US$4.8 million, 51 percent of which is controlled by Nanjing Medicines. It carries out drug wholesaling, delivery and retail chain businesses. The new company is to take
advantage of the widespread marketing network of the former Hefei Medicines Company and will deal in traditional Chinese medicines, bulk chemical drugs and reagents, antibiotics, diagnostic drugs, medical devices and health supplementary products. Tianrun Pharma has registered capital of US$2.1 million, with 60.7 percent controlled by Nanjing Medicines. It aims to become a modern drug logistics firm, providing a drug delivery and sales network extending across the entire province.

**First Private Drugstore Chain Opens in Jiangsu**

Hengtai Drug Chain Co., the first privately owned drugstore chain in China, has opened for business in Suqian City of Jiangsu Province. Hengtai Chain Company now controls 28 drugstores and plans to open another 20 soon. Jiangsu Province has already issued business licenses to three private chain drugstore companies, including Nanjing Hongyuan Drug Retailing Co.

**Guangzhou Baiyunshan Forms Alliance with Gist**

Guangzhou Baiyunshan General Pharmaceutical, which specializes in antibiotics production, has signed an agreement with DSM-Gist, a Dutch pharmaceutical giant and a leading company in the production of pharmaceutical bulk active ingredients. It is the most important supplier of antibiotic intermediates to Chinese antibiotic producers. Under the agreement, cooperation between the two companies will take place in three stages. In the first stage, Gist will supply antibiotic intermediates and bulk drugs to Baiyunshan as well as 200 to 300MT of amoxicillin in 2003, which alone is expected to bring in US$18 million in sales to Baiyunshan. During the second stage, both sides will work on improving product quality, drug purity and formulation technology with the aim of developing test-free products. In the third stage, both companies will work closely together to carry out research and development of new antibiotics.

**About Guangzhou Baiyunshan**

Guangzhou Baiyunshan General Pharmaceutical Co. is a controlled subsidiary of Guangzhou Baiyunshan Pharmaceutical Co. In 2002, the company achieved sales of US$62.6 million, placing it among the top thirty pharmaceuticals in all of China, and 13 percent growth in sales of antibiotics, which account for 90 percent of revenue generated. Baiyunshan has become a well-known brand across the country and offers a wide range of both patented and generic antibodies in the market.
Herbicure Pte. Ltd., a Kolkata-based emerging natural healthcare and biotechnology company, has clinched a marketing and distribution deal with Amrutanjan of Chennai for creating a national market for its products.

According to Managing Director and CEO of Herbicure, S. R. Dasgupta, Herbicure’s natural healthcare products such as Spirulina Pacifica, Asmacure and Panecure have already been well accepted in the Eastern Region and Amrutanjan’s wide and remote distribution network will provide a nationwide reach to these products.

Dasgupta said that it was necessary for a company like Herbicure to find a strong marketing partner so that it can concentrate on research and patentable formulations. “Amrutanjan has evinced a tremendous enthusiasm to offer our products to a large audience,” said Dasgupta.

P. Eswaradas, Executive Vice President of Amrutanjan, agreed with Dasgupta and said Amrutanjan’s extensive dealership network would ensure maximum visibility to Herbicure’s products even at the remotest corners of the country. He is confident that the partnership would enable both companies to reap enormous benefits given the tremendous possibilities natural healthcare products offer in today’s world.

The growing popularity of natural products is based on the fact that more and more people in the world are beginning to acknowledge their benefits. Incidentally, Herbicure’s products have been clinically tested in US and are beginning to attract large number of consumers.

“The fact that we have tied up with Department of Pharmaceutical Technology, Jadavpur University, for developing the products and Cynatech Corporation, Hawaii, US, for clinical trial of our products should drive away any doubts about the pedigree of our collaborations,” commented Dasgupta.

The company has also developed two more new products, Livocure and Amekure, which are ready for launch in the hepato-protective and anti-amoebic segments respectively. The introduction of these products would be done in a phased manner through the new partnership with Amrutanjan.
About Herbicure Pte. Ltd.

Herbicure, which was incorporated in early 1999, is primarily engaged in biotech and herbal healthcare products. Keeping research and quality on top priority, the company has created an autonomous research foundation to protect the products against obsolescence. It also plans to venture into the application of genetic engineering in the field of agriculture. The company has an equity capital base of Rs4 crore (US$860,000).

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About Amrutanjan Ltd.

Amrutanjan Depot began as a Patent Medicine business in 1893 at Bombay (Mumbai). The Head Quarters of Amrutanjan Depot shifted to Madras (Chennai) later. It became a Public Limited company in 1936 with the name of “Amrutanjan Limited” which markets a wide range of OTC Health Care Products. Its products have earned a very good brand equity according to the recent market survey by “Financial Express-MODE Survey Company”.

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ThinkGen Ltd. — Bangalore-based bioinformatics company — plans to set up a US$5 million biotech incubation fund to help integrate pharma, biotech and healthcare through IT solutions.

“Through this fund, we are looking at small companies or individuals to address the issue of part-financing technologies in integrating chemistry and biology,” said V. Rama Subramaniam, ThinkGen Managing Director.

The company is targeting at high-end technologies in the areas of healthcare deliverables, including DNA technologies, especially those that have already been patented and require incubation. Since its inception in 2000, ThinkGen had been working with hospitals in setting up the genotyped electronic medical records (GEMR) database. A GEMR is an useful extension of an electronic medical record (EMR). In essence, the genetic information (genomic) of an individual will be mapped, stored in silico, digitized and appended to the EMR.

Equipped with GEMR, the company is now considering contract manufacturing, for which it is eyeing a large US distribution company to source nutraceuticals, pharma and biotech products from India.

“Since the volumes involved are very large, ThinkGen is looking to network with at least 9-10 good-size contract manufacturers who have the intent to graduate to United States Food and Drug Administration (USFDA) quality norms in a short time scale,” said Subramaniam.

Since access to regulated markets requires filings with the USFDA, a time-consuming process, ThinkGen also provides start-ups with help in bagging orders from less regulated markets. To suit the needs of the USFDA, the company is also prepared to provide customized solutions to cater to the specific needs of the US buyers.

ThinkGen has pioneered solutions that speed up abbreviated new drug applications (Anda) and has a repository of standard operating procedures (SOPs) and protocols that can help achieve USFDA compliance in the shortest time cycle.
About ThinkGen Limited

ThinkGen is a company specializing in Domain Centric Process oriented Software solutions. Armed with an unique methodology ‘Core process based re-engineering’ patented and trademarked under the name “Imagineering”. Imagineers (as our Consultants are called) at ThinkGen are a team of focussed consultants who can not only Re-engineer the processes but also re-orient the processes to make an organization Core-Process Driven. This re-orientation of Business Process Re-Engineering (BPR) is referred at ThinkGen as “Imagineering”. In addition to this unique methodology our teams for process innovation can quickly prototype processes and deploy them using state-of-the-art software design and application development methodologies.

ThinkGen’s GEMR architecture coupled with a protocol driven processes for mining information in partnership with almost every player in the Global Health Care space provides an ideal Multi-dimensional and Multi-disciplinary research processes.

Eight Bio-Informatics Hubs at strategic locations across the world are being set up, and inturn 18 Database gateways will pipe information into these Hubs.

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With the country becoming an important base for clinical trials, TNT India, a wholly-owned subsidiary of US$12 billion Netherlands-headquartered TPG, is experiencing a huge surge in business of biomedical shipment service.

By 2005, India will have to adhere to the global product patent norms for drug development. This also has led to a heightened research and development activity in the pharmaceutical and biomedical industry.

Most of the global research today in new drug discovery is outsource to large central laboratories, which are contracted by pharmaceutical companies. Consequently, there is a large dependence of contract research organizations on logistics in clinical trials.

“As India has attracted 20 clinical trial companies, to cater to this business we are investing on human resources and training personnel in dangerous goods handling,” said Ni Sheng Jie, Life Science General Manager, TNT Asia.

Biomedical samples that require quick transportation include blood, serum, plasma, urine, stool, bacteria, enzymes, virus, skin and hair. These biomedical samples collected in India need to be sent to Central Labs based overseas for further research.

Already, a team of 30 has been trained in the handling of life science products across 26 locations in India and the company has around 250 personnel (out of 550) involved in operations. TNT began developing its global life science network four years ago and is currently accounting for five percent of TNT’s revenues.

To operate and cater this life science network, the company also has developed a product — “Medpak” — to carry a wide range of clinical trial and other biomedical samples at various temperature conditions. “Medpak has been positioned as a single-window solution for biomedical shipments as it would provide the complete logistics service to the pharma sector and the contract research organizations,” said Sanjiv Kathuria, TNT India’s Head of Sales, Marketing & Customer Service.

TNT India estimates that the outsource logistics contract business market in India is around Rs300 crore (US$65 million) a year currently.

About TNT India

TNT India incorporated in September 1993, is the first multinational express distribution company to enter the Indian market through a wholly owned subsidiary. Headquartered in Bangalore, TNT India has branches in 16 cities across the country and employs nearly 600 people. TNT India specializes and operates in international express distribution only.
Takeda’s International Business Restructuring

Takeda Chemical Industries, Ltd. has announced that its Pharmaceutical International Division will be re-organized into three regional units — Division of Americas, Department of Europe and Department of Asia — and each regional unit to operate independently.

Under the new organization, each regional business unit will report directly to the top management. In doing so, Takeda hopes that the communication between the headquarters and overseas subsidiaries/affiliates would become more effective, thereby enhancing Takeda’s overseas operation, especially in US which holds the world’s largest pharmaceutical market.

With this change, Takeda also hopes that it would be able to formulate business strategies and conduct operations more efficiently by taking a region-specific approach. Such an approach would take into account the differences such as the different business environments and market sizes and needs of the US, Europe and Asia. At the same time, the move will ensure that the operational responsibility for each regional unit will become clearer.

In addition, two departments in the Pharmaceutical International Division, namely, the Administration & Coordination Department and Product Management Department will be transferred to Corporate Strategy & Planning Department and Strategic Product Planning Department respectively.

About Takeda Chemical Industries, Ltd.

Takeda is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the industry’s leaders worldwide, Takeda is committed to strive toward better health for individuals and progress in medicine by developing superior pharmaceutical products.

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