EURAND

EURAND	KEY PERSONNEL
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DRUG DELIVERY AREA **ORAL**

COMPANY OVERVIEW

Eurand is a specialty pharmaceutical company that develops enhanced pharmaceutical and biopharmaceutical products using its drug-delivery technologies.

Eurand's principal operating offices are in Milan, Italy with commercial offices in New York, USA. The company has R&D and manufacturing facilities throughout the world, including sites in Milan and Trieste, Italy; Dayton, OH; and Paris, France.

KEY MILESTONES

- Eurand's Board of Directors accepted the terms of an all-cash offer for the company from Axcan Pharma which valued Euran at US$583 million. The deal is expected to be completed sometime in the first quarter of 2011, subject to conditions.

- November 2009 - Eurand marked the US commercial release of Zenpep (pancrelipase) delayed-release capsules, a pancreatic enzyme product indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions. The product secured FDA approval in August 2009.

- May 2009 - The FDA approved EUR-1048, which is marketed as GlaxoSmithKline's (GSK) Lamictal orally disintegrating tablet (lamotrigine). Co-developed by Eurand and GSK, Lamictal ODT uses Eurand's AdvaTab ODT and Microcaps taste-masking technologies to provide Lamictal in a 'pleasant-tasting' tablet that disintegrates on the tongue and that may be taken with or without liquid.

- June 2008 - Eurand received an approvable letter from the FDA for its NDA for EUR-1008 (pancrealipase capsules) for the treatment of exocrine pancreatic insufficiency. The NDA was accepted for review by the FDA in February 2008.

PRODUCTS / TECHNOLOGIES

TECHNOLOGIES

Eurand has four technology platforms:

- Bioavailability Enhancement
- Customised Drug Release
- Taste-Masking and Orally Disintegrating Tablets
- Drug Conjugation

Bioavailability Enhancement

Eurand's bioenhancement technologies are designed to improve the bioavailability of insoluble drugs and to allow for the development of oral dosage forms. The clinical benefits of these technologies include accelerated onset of action, lower dosage levels, decreased side effects and enhanced product performance. Eurand's bioavailability enhancement technologies enable the development and commercialisation of those new chemical entities (NCEs) that would have otherwise been shelved due to their poor bioavailability and solubility.

Eurand's Bioavailability / Solubility Technology Platform includes:

BIORISE

This technology is fully commercialised and can be applied to a wide range of compounds to enhance bioavailability and solubility. Biorise can provide additional benefits including accelerated onset of action, lower dose levels, improved market acceptability and the development of oral dosage forms that might not otherwise be possible. The technology is based on the fact that the solubility of nanocrystalline and amorphous forms of drugs is higher than that of unmodified or micronised forms. Therefore, if drug permeability is sufficient, the absorption rate and absolute bioavailability of a drug can be increased by enhancing solubility and solubilisation.

DIFFUCAPS

Diffucaps is a multiparticulate bead system comprised of multiple layers of drug, excipients, and release-controlling polymers. The beads contain a layer of organic acid or alkaline buffer to control the solubility of a drug by creating an optimal pH microenvironment for drugs that exhibit poor solubility in intestinal pH, in environments with pH>8.0, or in physiological fluids. Alternatively, the beads can contain a solid-solution of drug and crystallisation inhibitor to enhance bioavailability by maintaining the drug in its amorphous state. Diffucaps technology is especially suitable for drugs that traditionally require multiple daily doses or drugs needing customised release formulations. Each Diffucaps bead has an inert core surrounded by drug and coated with a functional polymer membrane to control the rate of drug release.

Diffucaps can also be combined with other Eurand technologies to optimise drug delivery. Diffucaps beads can be filled into capsules or compressed into orally disintegrating tablets. In addition, as a multi-particulate system, Diffucaps products produced in capsules allow for the capsules to be opened and the contents used as a sprinkle on foods, providing a flexible dosage form for patients who experience difficulty swallowing tablets or capsules.

Customised drug release

Eurand says its customised release technology platform is broad, widely applicable to a range of molecules and proven. The company has developed five technologies within this platform. Using its customised release technologies, Eurand has developed more than 75 products that are currently being marketed throughout the world.

Eurand's customised release technology platform includes:

DIFFUCAPS/SURECAPS

Diffucaps/Surecaps technologies are multiparticulate systems that provide optimum release profiles for single or combination drugs. Drug release profiles are created by layering active drug onto a neutral core such as sugar spheres, crystals or granules followed by a rate-controlling, functional membrane. Diffucaps/Surecaps beads are small in size, approximately 1mm or less in diameter. By incorporating beads of differing drug release profiles into hard gelatine capsules, combination release profiles can be achieved.

The Diffucaps/Surecaps systems offer flexibility by enabling the combination of different types of release profiles into one dosage form. Eurand can customise any combination of sustained-release, pulsatile-release and immediate-release profiles depending on the specific needs of the product.

DIFFUTAB

Diffutab technology enables customised release profiles and region specific delivery. The Diffutab technology incorporates a blend of hydrophilic polymers that control drug release through diffusion and erosion of a matrix tablet. Eurand can apply this technology to both soluble and insoluble products.

The Diffutab technology can be used in the development of high dosage products and is claimed to be extremely effective in the development of twice- and once-daily dosage forms.

EURAND MINITABS

This technology is claimed to be unique in that it offers the advantages of a tablet combined with those of a multiparticulate drug form. Eurand Minitabs are tiny (2mm x 2mm) tablets containing gel-forming excipients that control drug release rate. Additional membranes may be added to further control release rate. As a result, combination products can be developed to allow for two or more release profiles within a single capsule. Eurand Minitabs offer high drug loading, the ability to fine tune release rates for targeted delivery and content uniformity for more accurate dosing. Eurand Minitabs are reproducible and, as a result, offer controlled and very precise performance.

ORBEXA

Orbexa technology is a multiparticulate system that enables high drug loading and is suitable for products that require granulation. The technology produces beads that are of controlled size and density with a defined-based granulation extrusion and spheronisation techniques. The resultant beads can be coated with release rate controlling membranes for additional release rate control and may be filled into capsules or provided in sachet form.

This process is said to be unique in that it allows for higher drug loading than other systems, is flexible and is suitable for use with sensitive materials such as enzymes. Eurand's Orbexa technology can be used for:

* Gastro Protection
* Delayed Release
* Sustained Release
* Site Specific Delivery
* Pulsatile Delivery
* Complex Release Patterns
* Separation of Incompatibles
* Combination Products

Taste-Masking and orally disintegrating tablets (OTDS)

A drug's effectiveness can be adversely impacted by patient non-compliance with a prescribed and recommended dosing routine. It is estimated that more than 50 per cent of patients do not comply with dosing recommendations primarily due to drug properties including poor taste, difficulty in administration and general inconvenience.

Overcoming these problems can make drugs more convenient thus significantly increasing patient compliance and improving drug efficacy. Eurand has developed a range of technologies for taste masking, and development of dosage forms.

LIQUITARD

Liquid formulations of drug compounds are particularly effective in paediatric and geriatric patient populations that have difficulty swallowing pills and tablets. Liquitard technology is a delivery system that can be filled into a monodose sachet. When poured into water, the granules create a ready-to-use homogenous suspension. The suspension contains microencapsulated taste masked and/or controlled release drug substance, which can be flavoured to produce a pleasant tasting liquid dosage form.

When the contents of the Liquitard sachets are poured into a glass of water, the excipients mix with the water to form a solution that allows the taste-masked particles to be homogenously suspended. Depending on the chemical and physical properties of the compound, this technology can be used to create temporary or permanent suspensions.

Liquitard can be used for drugs that are microencapsulated to mask the taste, delay drug release and avoid gastric irritation.

MICROCAPS

Microencapsulation is a very precise coating technique used to encapsulate individual drug particles. The technology uniformly coats drug particles (droplets if the drug is in liquid form) with polymeric membranes of varying degrees of porosity using coacervation/phase separation processes. The membranes create an inert barrier between the drug and the taste buds. These processes result in individual particles of a drug substance being enveloped into a membrane. The type and level of membrane applied is determined by release rate requirements, organoleptic features and the dosage form application. Microcaps particles can be incorporated into different dosage forms including fast melt tablets, sachets, sprinkles and reconstitutable and temporary suspensions.

ADVATAB

AdvaTab tablets dissolve rapidly in the mouth within 15 to 30 seconds to allow for oral drug administration without chewing or the addition of water. The table is said to be distinct from other fast dissolve technologies as it can be combined with the Microcaps technology. According to Eurand, this pairing creates products that offer the dual advantage of a patient preferred dosage form with a superior taste and smooth and creamy mouth feel.

Drug Conjugation

The polymer/drug conjugation technology uses biocompatible carbohydrate carriers such as oligo- and polysaccharides as delivery vehicles for active compounds. Carbohydrates possess inherent functional properties that make them ideal as both inert carriers and biologically active drug transporters. They are biocompatible, highly water-soluble and have multiple sites for drug conjugation.

Based on strategic initiatives, the company has recently chosen to out-license the drug conjugation technology at this time, and will discontinue all internal investment in this technology platform.

Products for Out-Licensing

- Diltiazem - Diffucaps Diltiazem is a once-daily hypertension treatment that uses Diffucaps sustained-release technology.
- Nifedipine - Nifedipine is a sustained-release calcium antagonist product indicated for prophylaxis of chronic and stable angina and treatment of hypertension.
- Temazepam - An ODT formulation of Temazepam, a common treatment for insomnia.
- Diphenhydramine HCl - Eurand's AdvaTab technology creates an easy-to-swallow ODT formulation of this insomnia treatment. Diphenhydramine HCl is also a commonly prescribed anti-histamine.
- EUR-1008 (Ex-US) - The first new pancreatic enzyme product (PEP) developed in 15 years, Zenpep (pancrelipase) delayed-release capsules is one of three FDA-approved PEPs in the US.
- Paraffin Oil - Microencapsulated paraffin oil formulation provides a patient-friendly oral suspension without unpleasant after-taste.
- Vitamin C - Sustained-release capsules provide a 12-hour dose of vitamin C.
- Cyclobenzaprine ER - A once-daily formulation of cyclobenzaprine, a muscle relaxant, developed and manufactured by Eurand, utilising Diffucaps technology to create a once-daily extended-release formulation of cyclobenzaprine with an improved side-effect profile.
- Paracetamol - Eurand's ODT formulation of paracetamol is formulated in a range of dosing strengths for paediatrics and adults.
- Sodium Diclofenac - Once-daily formulation of sodium diclofenac formulated with Diffucaps.
- Theophylline - Designed to reduce the high drug concentrations associated with traditional theophylline formulations, Eurand's sustained-release formulations can decrease incidence of patient side effects. Eurand's Microcaps technology taste-masks even the most bitter drug particles, ensuring a smooth mouthfeel.

RESEARCH ACTIVITIES

PRODUCT PIPELINE (as at September 2010)

Product	Indication	Technology	Partner	Development Phase
EUR 1000-D	Hypertension	Diffucaps - Customised-release	GSK	ANDA under FDA reviewl
EUR-1008 (Europe) Zenpep	Exocrine Pancreatic Insufficiency	Customised-release	Eurand	Phase III
EUR 1025	Nausea and Vomiting	Diffucaps - Controlled-release	Eurand	Phase III
Various	Undisclosed	n/a	n/a	Various Stages

Other R&D News

In June 2010, Eurand reported additional data from a *post hoc* analysis of a Phase III trial with Zenpep (pancrelipase) delayed-release capsules, an FDA-approved pancreatic enzyme product (PEP) for the treatment of exocrine pancreatic insufficiency (EPI) in patients with cystic fibrosis (CF) or other conditions. The study results demonstrated that patients with EPI due to CF can be transferred effectively from their previous PEPs to Zenpep. Results from a post hoc analysis of a Phase III, randomised, double-blind, placebo-controlled crossover study in 34 patients with EPI due to CF demonstrated that patients experienced a significant and rapid symptom improvement when switched from their previous PEP to Zenpep at a comparable daily dose.

In November 2009, results from a Phase II/III study demonstrated that Zenpep capsules significantly improved fat absorption in patients with EPI due to chronic pancreatitis. Zenpep is an FDA-approved formulated pancreatic enzyme product for the treatment of EPI. It is a highly stable formulation of a porcine pancreatic extract that mimics the endogenous human pancreatic secretions necessary for proper human digestion.

AGREEMENTS

Various - In March 2009, Eurand signed three commercialisation, licence and supply agreements for the extended-release (ER) formulation of the muscle relaxant, cyclobenzaprine HCl. The following pharmaceutical partners will be marketing the product, subject to regulatory review and approval, in select countries: Nobel Ilac Sanayii Ve Ticaret (Turkey), PharmaSwiss (Israel) and Adcock Ingram (South Africa).

Daewoong Pharmaceutical - In August 2008, Eurand signed a licence and supply agreement with South Korea-based Daewoong, under which the latter would commercialise, subject to regulatory approval, Eurand's ER formulation of Cyclobenzaprine HCl in South Korea. The formulation, called Cyclobenzaprine ER, has been developed using Diffucaps technology.

X-Gen Pharmaceuticals - In June 2008, X-Gen entered into an exclusive distribution agreement with Eurand for the latter's non-branded PEP, pancrelipase. As part of the agreement, X-Gen would represent Eurand as its authorised exclusive distribution agent for its currently marketed unbranded product. Eurand has both an IND and an NDA on file for a pancreatic enzyme product and is actively seeking regulatory approval. As Eurand's exclusive distribution agent, X-Gen would supply the product in four separate strengths - 4,500, 10,000, 16,000 and 20,000 IU. Capsules are orally-administered and contain delayed-release microspheres of porcine pancreatic enzyme concentrate, predominantly pancreatic lipase, amylase and protease.

Chiesi Farmaceutici - In April 2008, Chiesi granted Eurand an exclusive licence to its gastro-resistant, controlled-release tablet formulation of the corticosteroid, beclomethasone dipropionate, in the US and Canada. The product is currently approved and marketed in the UK, Italy, Spain and Belgium. Eurand made an upfront payment and commercial milestone payments to Chiesi primarily contingent upon obtaining US regulatory approval for the product. In addition, Eurand paid royalties on net sales of the product.

GlaxoSmithKline - GSK made a milestone payment of US$1 million to Eurand, its collaboration partner, following the commencement of a bioequivalence study for an orally disintegrating tablet formulation of an undisclosed compound. GSK filed for marketing approval in the US at the end of 2007.

University of Milan and University of Sassari, Italy - In January 2006, Eurand signed research agreements with the Universities of Milan and Sassari to evaluate a new class of analgesic compounds. These compounds were said to be comparable with

opioids in terms of efficacy, but not to possess the major drawbacks of tolerance and dependence which limits the use of opioids. Under the terms of the agreements, the universities collaborated to develop and evaluate the efficacy of five novel compounds for the treatment of moderate-to-severe pain. The universities, which discovered the compounds, were responsible for their synthesis, while Eurand was responsible for the preclinical evaluation and development of the products and use its drug-delivery technologies to optimise the release profiles of the drugs. Eurand had an option for exclusive worldwide development and commercialisation rights.

KEY FINANCIAL DATA

Eurand - Key Financial Data 2005 - 2009

(EUR million)	2005	2006	2007	2008	2009	2008-09 % change
Total Revenues	72.3	82.8	84.8	98.5	120.6	22
Operating Income	0.4	3.8	-4.1	16.9	-3.4	-120
Net Income	-8.3	-5.0	-6.7	13.6	-5.9	-143
R&D	14.5	16.3	17.1	20.3	23.6	16

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