

Corporate information

Background

Cosmo Pharmaceuticals ("Cosmo") is a specialty pharmaceutical company that aims to become a global leader in the development of optimised therapies for selected gastro-intestinal ("GI") and selected topically treated skin disorders.

Cosmo's products address all stages of GI disease. The company started in manufacturing in 1997 through the purchase of the Milan-based drug manufacturing unit from Parke-Davis. After identifying significant unmet patient needs in the field of GI, the company made a strategic decision to focus on these and developed its Multi Matrix MMX® technology. Using well-known off-patent compounds and improving their effectiveness or reducing their side effects, Cosmo secured new patents for a wide range of applications focusing primarily on Inflammatory Bowel Diseases (IBD) as well as colon infections. In addition, Cosmo is developing a new chemical entity for the treatment of Acne, Alopecia and Hirsutism.

Cosmo is now engaged in two fields, the Development, manufacturing and commercialization of proprietary GI and skin drugs and the manufacturing of pharmaceutical products for third parties. The company is publicly-traded on the SIX Swiss Exchange under the symbol COPN and headquartered in Lainate, Milan, Italy.

Product Pipeline

Cosmo is currently developing a range of drug candidates, most of which are based on its Multi Matrix MMX® technology. This technology allows the delivery of active pharmaceutical ingredients primarily into the lumen of the colon through tablet dispersal in a delayed and controlled manner. This has the beneficial effect that the active pharmaceutical ingredients can be applied to the full length of the colon to greater effectiveness.



The most common age for diagnosis is between 10 & 40 (although diagnosis can occur at any age)

The company's proprietary clinical development pipeline mainly addresses innovative treatments for IBD, with one product launched in the USA (Shire plc's Lialda™), one launched for the local market in Italy, seven products in clinical and three in preclinical development. Leveraging on its MMX® technology, Cosmo has developed a broad-based pipeline within the GI field:

Lialda™: developed in-house from a well-known chemical entity (5-ASA mesalamine) and licensed to Giuliani and Shire plc. It is the first once daily tablet indicated for the induction of remission of mild to moderate ulcerative colitis in the USA and additionally for maintenance of remission in the EU.

Budesonide MMX® has the potential to become the first oral corticosteroid indicated for ulcerative colitis. Though known to be much more effective than 5-ASA treatments, corticosteroids have not previously been indicated for mild to moderate ulcerative colitis patients because of their severe side effects, circumvented by the MMX® technology. Budesonide MMX® is licensed to Santarus in the USA and to Ferring in the EU, Asia (excluding Japan) and Latin America.



LIALDA is the first and only FDA-approved once daily oral formulation of mesalamine

Rifamycin SV MMX® is a broad spectrum, semi-synthetic antibiotic targeted at colon infections which are frequently concomitant with colon inflammations. Rifamycin SV is non absorbable when taken as a tablet which makes it ideal for long term use because of the reduced side effects. Cosmo's MMX® technology allows the targeted focus on colonic infections with the potential for use in diseases such as diverticulitis and CDAD. Rifamycin SV MMX® is licensed to Santarus in the USA and to Dr. Falk in the EU (excluding Italy) and Australia.

LMW Heparin MMX® is an endogenous biologic drug that retains and maximizes the anti-inflammatory properties found in Heparin and is targeted at all bowel diseases of inflammatory and immune-modulating nature. In a Phase IIb trial LMW Heparin MMX® reached its primary and secondary end points by inducing superior clinical remission in patients with active mild to moderate ulcerative colitis and was well tolerated at once daily dosing.

Methylene Blue MMX® is the first diagnostic application of MMX. A new formulation of Methylene Blue is delivered to the colon where this substance stains the colon and depicts cellular structures in such a way that pre cancerous lesions and polyps can be detected easier.

CB-03-01 is the first new chemical entity patented by Cosmo. It is a steroid ester androgen antagonist derived from 11-deoxycortisone, which tightly mimics the profile of an ideal anti-androgen for topical use. Anti-androgens are primarily used in applications to treat prostate-related diseases but are also known to be effective in controlling Acne, Androgenetic Alopecia, and Hirsutism. Cosmo is planning to file an IND in the US shortly.

Management

Cosmo has grown based on a strong, focused management team encompassing skills across the spectrum of disciplines required for an emerging fully integrated specialty pharmaceutical company. The company has an internationally experienced and entrepreneurial management team of pharmaceutical industry executives and recognized experts in their field with diverse backgrounds and complementary skills in research, development, regulation, manufacturing, sales, marketing and finance.

- **Mauro Ajani** – Founder, majority shareholder and Chief Executive Officer. Over 25 years industry experience particularly in the commercialization of pharmaceuticals in Italy
- **Dr. Chris Tanner** – Chief Financial Officer. Member of the board of various companies. More than 30 years of experience in the financial sector, most recently as investor and advisor and eight years as head of corporate finance and capital markets at UBS in Zurich
- **Dr. Luigi Moro** – Chief Scientific Officer. Joined Cosmo in 1999. Over 30 years of industry experience, including positions at Farmitalia – Carlo Erba, Recordati Industria Chimica e Farmaceutica S.p.A. and Poli
- **Dr. Giuseppe Cipriano** – Chief Operating Officer. More than 15 years experience running businesses including Gian Carlo Ferrè
- **Giancarlo Naccari** – Head of IBD Business Development. Over 30 years of industry experience, including positions at Centocor, Giuliani
- **Massimo Pedrani** – Head of Generics Business Development. Over 25 years of industry experience, since 1997 has worked as a pharmaceutical business development consultant through his own company

Funding

Initially Cosmo SpA was funded with 2.2m equity. In 2005 a total of 20.4m was raised to fund a subsidiary Cosmo Bioscience which was de-merged prior to the IPO of Cosmo Pharmaceuticals (holding company of Cosmo SpA) in 2006. In March 2007, Cosmo Pharmaceuticals completed an IPO on the SIX Swiss Exchange raising 30m.

Strategy

Cosmo's key objective is to be positioned as one of the leading specialty pharmaceutical companies in the Inflammatory Bowel Diseases (IBD) arena, by following key elements of its business strategy:

- Creating long-term value by developing and marketing its own range of proprietary drug formulations
- Funding the clinical trials for the majority of its development programmes with its own financial resources and bringing its own products to market
- Leveraging the benefits of the MMX® platform in the creation of new pharmaceutical products
- Entering licensing agreements with renowned IBD companies

- Retaining and continuously expanding its colon expertise and to manufacture as many of its own products as possible

Collaborations

In 2001 Cosmo out-licensed Mesalamine MMX®, now known under the brand name of Lialda™ in the US and Mezavant® in Europe, to Giuliani S.p.A. who sub-licensed it to Shire plc. In 2002 Cosmo entered into an agreement to manufacture the product for Shire plc. Cosmo manufactures Lialda™ for Shire plc for the North American market and Mezavant® for the European markets in its FDA approved, purpose built plant. Lialda™ was launched in the US in March 2007, in the UK in December 2007 and in five further European countries in 2008.

In October 2007, Cosmo signed a licensing agreement with Ferring for Budesonide MMX®, granting Ferring an exclusive worldwide license (excluding Japan and the USA).

In November 2008, Cosmo entered into an agreement with Dr. Falk Pharma GmbH for the licensing of Rifamycin SV MMX® (CB-01-11) for all of Europe (excluding Italy) and Australia.

In December 2008, the company signed a licensing agreement with Santarus, Inc. (NASDAQ: SNTS) granting Santarus exclusive rights to develop and commercialize Budesonide MMX® and Rifamycin SV MMX® for the U.S. market.

Shareholders

Approximately 53% of the shares are held by the management and Board. dievini Hopp BioTech Holding GmbH & Co. KG, the investment company of Dietmar Hopp and his family, owns 9.8% of the shares.



The 2 main types of IBD are Crohn's disease and Ulcerative Colitis

Contacts

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