

# Half-Year Report 2008



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# Cosmo at a Glance

Cosmo Pharmaceuticals S.p.A. is a pharmaceutical company headquartered in Lainate, Milan, Italy, and is listed on the SWX Swiss Stock Exchange (SWX: COPN).

It is the Company's objective to become a global leader in the market of optimised therapies for specific Gastrointestinal Disorders. Cosmo's clinical development pipeline specifically addresses innovative treatments for Inflammatory Bowel Diseases (IBD), such as Ulcerative Colitis and Crohn's Disease, as well as for Colon Infections.

The Company has developed a proprietary multi-matrix technology (MMX™) which gives an excellent base from which to develop new, patentable yet low-risk products that are manufactured at its own plant. Currently Cosmo has two products in the market, five in clinical trials and five in preclinical phase.

This includes the Company's first new chemical entity, an anti-androgen which, in the long-term, has the potential to provide Cosmo with another element to its strategy.

## 6 months' pipeline development

Product	Drug type	Preclinical	Phase I	Phase II	Phase III	MA	Launch
<b>Lialda MMX™/ Mezavant MMX™</b> Mild to moderate Ulcerative Colitis	5-ASA						
<b>Budesonide MMX™</b> Mild to moderate Ulcerative Colitis	Corticosteroid						
<b>Rifamycin SV MMX™</b> Infectious Diarrhoea	Antibiotic						
<b>LMW Heparin MMX™</b> Mild to moderate Ulcerative Colitis	Biologic						
<b>Zacol NMX™</b> Intestinal Disorders (nutraceutical)	Dietary supplement						
<b>Rifamycin SV MMX™</b> CDAD	Antibiotic						
<b>CB-03-01 (NCE)</b> Acne, Male Pattern Baldness and Hirsutism	Steroid ester, androgen antagonist						
<b>CB-01-12</b> IBD	Anti-TNFα						
<b>CB-01-09</b> IBD	Immunosuppressant						
<b>CB-01-13</b> Colorectal Cancer prevention	Colorectal Cancer prevention						
<b>CB-01-14</b> Crohn's Disease	Antibiotic						
<b>CB-01-16</b> Opioid-induced Constipation	Opioid antagonist						

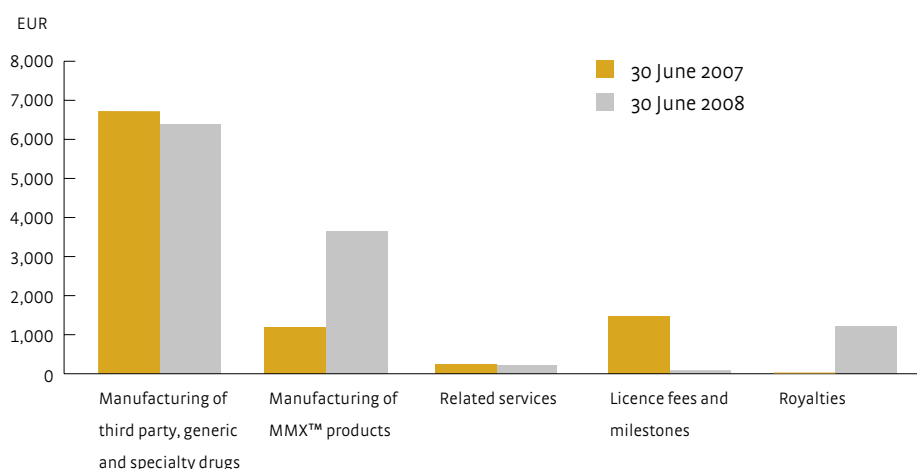
31 December 2007

30 June 2008

# Highlights

- On 21 April the Company reported highly positive results from a phase IIb trial of Low Molecular Weight Heparin MMX™ tablet (LMW Heparin MMX™). These results showed that 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.
- The Company is looking forward to strong growth in sales from Lialda™ in the USA and thereby to its own revenues. In the 1H 2008, Lialda™ had already gained a 11.3% share of the 5-ASA tablet market in the USA and was launched in Canada at the end of January.
- The Company expects to conclude a licensing agreement for Rifamycin MMX™ in Europe within 2008. A dose-finding study started in January and the preclinical database necessary for an IND (Investigation New Drug Application) is expected to be completed by the end of the year. Patient enrolment for phase III trials for Colon Infections in Mexico is scheduled to start in Q4 2008.
- On 1 April the Company initiated a phase I clinical study of its novel anti-androgen-based cream, CB-03-01, for the topical treatment of skin disorders, including Acne, Alopecia and Hirsutism.
- The Company started phase III clinical trials in the USA and EU for Budesonide MMX™.
- Total revenues increased by 20.3% to EUR 11.9 million.
- Revenue from own products increased from EUR 2.7 million to EUR 5.0 million respectively from 27.6% to 41.6% of total revenue.

## Revenue breakdown



# Dear Shareholder

We look back on a good first six months of 2008. The development of our pipeline continued as planned, revenue grew by 20.3%. Royalties on MMX™ products jumped from EUR 0.01 million to EUR 1.2 million (from the first six months of 2007) and manufacturing revenues for MMX™ products increased by 206.4% to EUR 3.7 million. Costs have been well controlled. Product costs increased only by 2.4% to EUR 6.7 million. R&D costs increased by 44% to EUR 3.2 million due to the costs of preclinical and clinical trials outsourced for a total of EUR 2.0 million. An operating loss of EUR 0.7 million is partially reduced by the net financial income. The loss before taxes amounted to EUR 0.4 million.

With reference to our pipeline of products, you will recall that we distinguish between those products that are, in essence, improvements of existing products and those products that are totally new. Lialda™ is an improvement of an existing product as are Budesonide MMX™ and Rifamycin MMX™. However, LMW Heparin MMX™ is going for a new indication and CB-03-01 takes us into the development of new chemical entities and both saw major developments during the past six months.

## Products in the market

Lialda™ is exceeding the expectations we had at the beginning of the year. On 26 March Shire Limited, to whom Lialda™ was licensed, announced that they had concluded a co-marketing agreement with TAP in the USA. TAP belongs to Takeda and has a large sales force in the USA. This means that in addition to Shire's distribution team covering the gastroenterologists, TAP's distribution organisation will cover the largest general practitioners. We believe that this will substantially increase sales of Lialda™ in the USA. To this end we have started manufacturing Lialda™ on the second manufacturing line of our new plant and are currently running at 100% capacity with one shift.

## Products in clinical development

Budesonide MMX™ has gone into the phase III clinical trials in the USA, Canada and the EU. With this drug we are focusing on all those patients with mild to moderate Ulcerative Colitis that for one reason or the other do not get satisfactory treatment with classical aminosalicylates such as Lialda™. It is presumed that this is approximately 30% of all mild to moderate patients. We believe that we can combine budesonide, which is well known as a very effective corticosteroid, with our MMX™ technology thus creating a safe and effective product. In designing the European clinical trials, we were assisted by Ferring SA, to whom we have licensed out the rights for Budesonide MMX™ in Europe. The trial in the USA and Canada is based on the EU trial design except that the FDA has required a trial prolongation at a lower dose of 6 mg for the first 150 patients that go into remission in order to evaluate the ability of Budesonide MMX™ to maintain the remission.

In February we started treating patients in a dose ranging study for Rifamycin SV MMX™ in Mexico and Turkey. This study is testing the efficacy of doses ranging from 400, 800 and 1,200 mg versus placebo per day in the treatment of Infectious Diarrhoea. We expect to receive the data of these results within the next few weeks and plan on starting work on the phase III trial shortly thereafter.

On 21 April we reported highly positive results from our phase IIb clinical trial on 120 patients treated with Low Molecular Weight Heparin MMX™ tablets (LMW Heparin MMX™). The results from the trial show that 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. This is very encouraging news for patients and for us. We reported no serious adverse events, the drug was well tolerated and the efficacy of the drug has

been shown to be excellent. More importantly, the high histologic remission rate gives room to believe that LMW Heparin MMX™ could be a disease modifying drug. This all allows us to consider the full range of options including the potential treatment of patients with moderate to severe forms of Inflammatory Bowel Diseases. We will now analyse the data in-depth with our scientific advisors in order to determine how to best position the drug and correspondingly design the phase III clinical trials both in the USA and Europe.

On 1 April we initiated the phase I clinical trials for CB-03-01 in Vienna, Austria. CB-03-01 is a novel anti-androgen based cream for the topical treatment of skin disorders including Acne, Alopecia and Hirsutism. Anti-androgens are known to be effective in controlling Acne. Acne affects about 45 million people in the USA alone i.e. around 16% of the population. The world-wide market for Acne is presumed at more than USD 2.8 billion. As for Androgenetic Alopecia, an androgen-induced male baldness affecting about 12% of all men over 20 years of age, the main drug in the market is Propecia™ from Merck, a systemically applied drug, which had sales of USD 405 million in 2007 (Medtrack). Anti-androgens are also known to be effective in controlling Hirsutism, an androgen-induced facial and body hair growth in females affecting about 10% of the female population. When anti-androgens are systemically applied, they can detrimentally affect the sex life of patients. Preclinical studies have shown that CB-03-01 could be as active as currently marketed treatments but devoid of common systemic effects since, once absorbed, it is rapidly metabolised to a physiological substance lacking anti-androgen activity. Three cohorts of eight male volunteers each were tested with single ascending doses at the Medical University of Vienna. The clinical trial was concluded very recently. No serious adverse events were observed and we are now awaiting the CRO's report, which we expect to receive within the next few weeks.

### Products in preclinical development

Our preclinical work on the anti-TNF $\alpha$  tablet, the Colorectal Cancer prevention tablet and the anti-Opioid-Induced Constipation tablet is continuing.

### Business development

It is our strategy to evaluate all possible alternatives leading to the highest possible value of our products in the market. We are collecting information on the requirements for building up a successful marketing and distribution organisation in the USA and count on being able to make the best possible risk-reward decision by no later than June 2009. In the meantime we are pursuing licensing opportunities in the other parts of the world, specifically for Rifamycin SV MMX™ and for Zacol NMX™ and believe that we will be able to conclude agreements shortly.

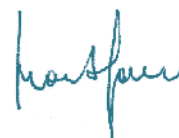
### Personnel

Per 30 of June we employed 133 persons in the group; 6.5% more than at year end.

Lainate, 29 July 2008



Rolf Stahel  
Chairman of the Board



Mauro S. Ajani  
Chief Executive Officer

# Our Key Value Drivers

**Lialda MMX™** (as the product is called in the USA) or **Mezavant™** (as it is called in Europe) is the first proprietary product Cosmo Pharmaceuticals developed, a Mesalamine MMX™.

It was introduced in the US market by Shire, who has the worldwide licence (except for Italy and other selected RoW markets which are licensed to Giuliani). Lialda MMX™ is the first once a day 5-ASA tablet indicated for the induction of remission of mild to moderate Ulcerative Colitis.

## **Budesonide MMX™;**

developed in-house, aims to become the first oral corticosteroid indicated for Ulcerative Colitis. Though known to be much more effective than 5-ASA treatments, corticosteroids have not been indicated for mild to moderate Ulcerative Colitis patients because of their severe side effects. It is estimated that between 30 and 40% of all patients with mild to moderate Ulcerative Colitis do not respond to treatments with 5-ASA. Budesonide MMX™ is licensed to Ferring SA in EU, Asia (excluding Japan) and Latin America.

## **Rifamycin SV MMX™;**

developed in-house, is targeted at Colon Infections which are frequently concomitant with Colon Inflammations. Rifamycin SV is not 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 long-term use in diseases such as Diverticulitis.

## **LMW Heparin MMX™**

is an endogenous biologic drug that retains and maximises the anti-inflammatory properties found in heparin. Developed in-house as a new formulation and administration of a well known chemical substance, LMW Heparin MMX™ is planned to be the first biological treatment topically effective in Inflammatory Bowel Diseases. Phase IIb results showed that LMW Heparin MMX™ reached the trials end points by inducing superior clinical remission in patients with active mild to moderate Ulcerative Colitis compared to the control and was well tolerated at once daily dosing.

## **CB-03-01**

is the first new chemical entity that Cosmo is developing. 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 will manufacture the cream at its GMP-approved facilities in Lainate, Milan, Italy.

# Business Strategy

Cosmo's business goal is to become a fully integrated specialty pharmaceutical company, recognised for its excellence in treating selected Gastrointestinal Disorders.

The blend of our knowledge of the colon and the unique characteristics of the MMX™ technology gives us a strong competitive edge in developing new applications for the colon without having to resort to the expensive and risky pure research process for new chemical entities. The Company's strategy has evolved accordingly and now has the following three pillars to its core strategy:

## **The product portfolio strategy**

Cosmo's product portfolio strategy is focused on diseases of the colon, primarily on Inflammatory Bowel Diseases (IBD). To date the majority of gastroenterologists treating IBD have followed a step-up strategy, first prescribing 5-ASA-based drugs to their patients, then moving on to corticosteroids, then on to immunosuppressants and finally to biologic products. So after developing the 5-ASA product, the Company set about to identify corticosteroids, immunosuppressants and biologics whose efficacy or safety profile could be improved by the MMX™ technology. This led to Cosmo's pipeline: Cosmo now has products in the market or being developed for patients of all scales of severity.

## **The distribution strategy**

Leaving aside CB-03-01, all the Company's products in clinical trials and all preclinical projects focus on applications in the colon. Generally, Colon Diseases are treated by gastroenterologists and not by general practitioners. It is commonly assumed that the approximately 8,000 gastroenterologists in the USA can be marketed to by a sales force of around 150 salespersons. This is quite a small group and the Company believes that it is possible to recruit such a

number of salespersons within a short amount of time, especially if they are offered superior products to sell. Nevertheless, there are product entry, regulatory and reimbursement issues to be considered. Furthermore, a substantial up-front investment is necessary in building-up the sales force before actual approval of the products is received. Consequently alternative distribution forms are being considered, their costs and benefits weighed.

## **The manufacturing strategy**

The experience gained by years of manufacturing was the basis for the establishment of the MMX™ technology. It allows the delivery of active pharmaceutical ingredients into the lumen of the colon through tablets in a delayed and controlled extent with the effect that the drugs can be applied to the full length of the colon. Cosmo Pharmaceuticals wants to retain and continuously expand this expertise and strives to manufacture as much of its own products as possible. The Company is increasingly moving its production capacity to products of higher complexity for which it can retain a greater part of the value added. Classical low-volatility contract drug manufacturing is the least profitable segment, the manufacturing of generics where the Company provides services that go beyond the sole manufacturing are considerably more lucrative and the highest profits can be achieved in the manufacturing of its own product. It is the Company's strategy to identify opportunities within each segment, thus not only increasing manufacturing profitability but also continuously expanding its excellence in manufacturing.



# Financials

## Condensed consolidated income statement for the six months ended 30 June 2008 (unaudited) and 30 June 2007 (unaudited)

EUR/1,000

	Notes	30.6.2008	30.6.2007
Revenue	4	11,872	9,865
Other income	5	23	245
Cost of sales	5	(6,648)	(6,494)
Research and development expenses	5	(3,232)	(2,244)
Selling general and administrative expenses	5	(2,678)	(3,838)
Operating result		(663)	(2,466)
Financial income	6	529	340
Financial expenses	6	(236)	(227)
Profit/(Loss) before taxes		(370)	(2,353)
Income tax expenses		(444)	702
Profit/(Loss) for the period		(814)	(1,651)
<b>Earnings per share</b>		(EUR)	
Basic	9	(0.059)	(0.129)
Diluted	9	(0.059)	(0.129)

These financial statements should be read in conjunction with  
the accompanying notes.

**Condensed consolidated balance sheet as  
at 30 June 2008 (unaudited) and 31 December 2007**

EUR/1,000

	Notes	30.6.2008	31.12.2007
<b>Assets</b>			
Non-current assets			
Property, plant and equipment		7,178	6,891
Goodwill		109	109
Other intangible assets		3,109	3,175
Deferred tax assets		1,125	1,434
Other non-current receivables		2,112	1,953
<b>Total non-current assets</b>		<b>13,633</b>	<b>13,562</b>
Current assets			
Inventories		2,065	1,549
Trade receivables		4,045	3,400
Current tax assets		138	273
Other receivables		4,147	2,939
Cash and cash equivalents	7	23,862	25,505
<b>Total current assets</b>		<b>34,257</b>	<b>33,666</b>
<b>Total assets</b>		<b>47,890</b>	<b>47,228</b>

EUR/1,000

	Notes	30.6.2008	31.12.2007
<b>Equity</b>			
Share capital		3,469	3,469
Share premium		29,372	29,372
Other reserves		2,278	2,162
Stock option plan reserve		347	28
Profit/(Loss) for the period		(814)	116
<b>Total equity</b>	<b>8</b>	<b>34,652</b>	<b>35,147</b>
<b>Liabilities</b>			
Non-current liabilities			
Interest-bearing loans and borrowings		3,953	3,658
Employee benefits		545	630
Deferred tax liabilities		1,165	1,213
Other non-current liabilities		2	2
<b>Total non-current liabilities</b>		<b>5,665</b>	<b>5,503</b>
Current liabilities			
Interest-bearing loans, borrowings and bank overdraft		1,468	1,540
Trade payables		5,110	4,162
Current tax liabilities		242	171
Other current liabilities		753	705
<b>Total current liabilities</b>		<b>7,573</b>	<b>6,578</b>
<b>Total liabilities</b>		<b>13,238</b>	<b>12,081</b>
<b>Total equity and liabilities</b>		<b>47,890</b>	<b>47,228</b>

These financial statements should be read in conjunction with the accompanying notes.

**Condensed consolidated statement of changes  
in shareholders' equity for the six months ended  
30 June 2008 (unaudited) and 30 June 2007  
(unaudited)**

EUR/1,000	Number of shares	Share capital	Share premium	Additional paid in capital	Other reserves	Stock option plan reserve	Profit/(Loss) for the year	Total
Net equity as at 31 December 2006	8,740,000	2,185	–	370	2,506	–	(344)	4,717
Issue of shares (January 2007)	2,460,000	615		(370)				245
Allocation of previous year profit/(loss)					(344)		344	–
Issue of shares IPO (March 2007)	2,675,000	669	32,495					33,164
Share capital issue costs			(1,585)					(1,585)
Profit/(Loss) for the period							(1,651)	(1,651)
Net equity as at 30 June 2007	13,875,000	3,469	30,910	–	2,162	–	(1,651)	34,890
Net equity as at 31 December 2007	13,875,000	3,469	29,372	–	2,162	28	116	35,147
Allocation of previous year profit/(loss)					116		(116)	–
Personnel costs for stock options						319		319
Profit/(Loss) for the period							(814)	(814)
Net equity as at 30 June 2008	13,875,000	3,469	29,372	–	2,278	347	(814)	34,652

These financial statements should be read in conjunction with  
the accompanying notes.

**Condensed consolidated statement of cash flows  
for the six months ended 30 June 2008 (unaudited)  
and 30 June 2007 (unaudited)**

EUR/1,000

	<b>30.6.2008</b>	<b>30.6.2007</b>
Profit/(Loss) before taxes	(370)	(2,353)
Income taxes paid	38	(118)
Depreciation and amortisation	771	719
Accrual to employee benefits	124	109
	<b>563</b>	<b>(1,643)</b>
Change in inventories	(516)	(974)
Change in trade receivables	(645)	(1,429)
Change in trade payables	948	35
Change in other receivables	(1,208)	(273)
Change in other current liabilities	48	(1,240)
Change in current tax liabilities	(15)	33
Payment of employee benefits	(209)	(110)
<b>Cash flows from operating activities</b>	<b>(1,034)</b>	<b>(5,601)</b>
Investments/disposals in		
Investments in property, plant and equipment	(903)	(501)
Investments in other intangibles	(94)	(56)
Disposals of property, plant and equipment	5	1,972
<b>Cash flows from investing activities</b>	<b>(992)</b>	<b>1,415</b>
Change in interest-bearing loans and borrowings	223	(3,129)
Change in other non-current receivables	(159)	(24)
Share capital increase	–	30,883
Other changes in shareholders' equity	319	–
<b>Cash flows from financing activities</b>	<b>383</b>	<b>27,730</b>
<b>Net increase/(Decrease) in cash and cash equivalents</b>	<b>(1,643)</b>	<b>23,544</b>
Cash and cash equivalents at the beginning of the year	25,505	494
<b>Cash and cash equivalents at the end of the period</b>	<b>23,862</b>	<b>24,038</b>
Cash at hand	7	5
Bank accounts	23,855	24,127
Advances on invoices and bank overdraft	–	(94)
<b>Total cash and cash equivalents at the end of the year</b>	<b>23,862</b>	<b>24,038</b>

These financial statements should be read in conjunction with the accompanying notes.

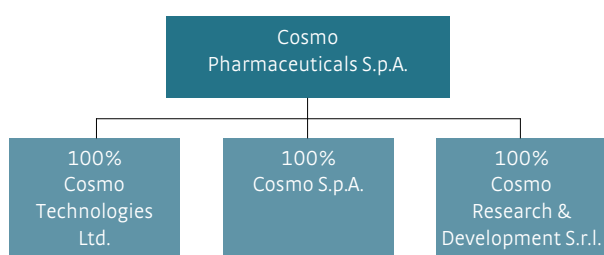
# Notes

## Cosmo Pharmaceuticals S.p.A. and Subsidiaries Notes to the Condensed Consolidated Interim Financial Statements (unaudited)

### 1. General Information

Cosmo Pharmaceuticals S.p.A. with its subsidiaries, Cosmo S.p.A., Cosmo Technologies Ltd. and Cosmo Research & Development S.r.l. (“Cosmo Pharmaceuticals” or “Company” or “Group”), is an emerging fully-integrated speciality pharmaceutical company that aims to become a global leader in the market of optimised therapies for selected Gastrointestinal Diseases. The Company’s proprietary clinical development pipeline specifically addresses innovative treatments for Inflammatory Bowel Diseases (IBD), such as Ulcerative Colitis and Crohn’s Disease, as well as for Colon Infections.

Headquarters and registered address are at via Cristoforo Colombo, 1 – 20020 Lainate (Milan), Italy. The structure of the Company as of 30 June 2008 is the following:



### 2. Basis of Preparation

The consolidated interim financial statements of Cosmo Pharmaceuticals have been prepared in accordance with the International Financial Reporting Standards (IFRS) for interim financial information and accordingly do not include all information and disclosures as required by IFRS for complete financial statements. The accounting policies used in preparation of the interim consolidated financial statements are consistent with those used in the annual consoli-

dated financial statements for the year ended 31 December 2007.

These condensed interim consolidated financial statements should be read in conjunction with the consolidated financial statements for the year ended 31 December 2007 as they provide an update of previously reported information.

Operating results for the six months ended on 30 June 2008 are not necessarily indicative of the results that may be expected for the year ending 31 December 2008.

### 3. Summary of Significant Accounting Policies and Practices

The interim consolidated financial statements are expressed in thousands of Euros unless stated otherwise, rounding the amounts to the nearest thousand. In order to provide the widest and clearest possible information on the business of the Company, starting from these interim consolidated financial statements, the Management has decided to present in this income statement the analysis of the expenses using a classification based on their function within the Group; the income statement for the six months ended on 30 June 2007 has been consequently presented with the same analysis.

The major accounting policies adopted are detailed below.

#### Principles of consolidation

The interim consolidated financial statements include the interim financial statements of Cosmo Pharmaceuticals S.p.A. and its subsidiaries Cosmo S.p.A., Cosmo Technologies Ltd. and Cosmo Research & Development S.r.l.

Subsidiaries are all entities over which the Group has the power to govern the financial and operating policies generally accompanying a shareholding of more than half of the voting rights.

Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

Intercompany transactions, balances and unrealised gains on transactions between Group companies have been eliminated in consolidation.

### **Property, plant and equipment**

Property, plant and equipment are stated at cost included related expenses, less accumulated depreciation (see below) and impairment losses.

Depreciation is recognized starting from the month in which the asset is available for use or potentially able to provide the economic benefits associated therewith, on a systematic basis, whereby the assets are depreciated over their useful lives or, in the event of disposal, until their final month of use.

Residual amounts, useful lives and the depreciation methods are reviewed at the end of every accounting period.

Improvements to third party assets are classified under property, plant and equipment depending on the nature of the asset to which it refers. The depreciation period is based on the lower of the asset's remaining useful life and the residual duration of the lease of the principal asset.

Assets held under finance leases, which provide the Group with substantially all the risks and rewards of ownership, are recognised as assets of the Group at their fair value or, if lower, at the present value of the minimum lease payments. The corresponding liability to the lessor is included in the financial statement as financial liabilities. Leases where the lessor retains substantially all the risks and rewards of ownership of the assets are classified as operating leases. Operating lease expenditures are expensed on a straight-line basis over the lease terms.

### **Other intangible assets**

Other intangible assets are recognised as assets where it is probable that the use of the asset will generate future economic benefits and where the costs of the asset can be determined reliably. Other intangible assets that are acquired by the Group are stated at cost less accumulated amortisation (see below) and impairment losses, if any.

Other intangible assets with definite useful lives are amortised on a straight line basis over their useful lives, being the estimated period over which the Company will use the assets. Residual amounts, useful lives and the amortisation methods are reviewed at the end of every accounting period.

Patents and rights are amortised over their useful lives.

Expenditures on research activities, undertaken with the prospect of gaining new technical knowledge and understanding, are recognized in the income statement as an expense as incurred.

Expenditure on development activities, whereby research findings are applied to a plan or design for the production of new or substantially improved products and processes, is capitalised if the product or process is technically and commercially feasible and the Company has sufficient resources to complete development. To date, development costs have not been capitalised. Other development expenditure is recognised in the income statement as an expense as incurred.

### **Inventories**

Inventories are stated at the lower of acquisition or production cost – in accordance with the first-in first-out (FIFO) principle – and net realisable value.

### **Trade and other receivables and payables**

Trade and other receivables are stated at amortised cost net of impairment losses. The impairment loss is calculated on the basis of recovery assessments by analysing each receivable considered unlikely to be collected and the overall risk of non-recovery of the receivables. When the payment of the sum due is postponed beyond normal credit terms offered to customers, the receivable is discounted at the effective interest rate.

Trade and other payables are measured at amortised cost which reflects the effective interest rate in the income statement and represents the rate used to discount the expected future cash flows to the carrying value of the assets.

### **Forms of remuneration involving participation in stock capital (stock option plans)**

The Group grants additional benefits to the Board and Senior Management and key employees through stock option plans. Pursuant to IFRS 2 – share-based payment – these plans represent a form of remuneration for the beneficiaries. The cost is equal to the fair value as calculated on the date the option rights are granted and is recorded in the income statement on a straight line basis over the vesting period i.e. the date between the date the stock option plan was granted and the date the rights mature. The corresponding entry is made directly to shareholders' equity. Changes in fair value after the grant date do not have an effect on the initial valuation. At each balance sheet date, the Group revises its estimate of the number of options that are expected to become exercisable. It recognises the impact of the revision to original estimates, if any, in the income statement, with a corresponding adjustment to equity. The proceeds received net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium when the options are exercised.

### **Revenue and cost recognition**

Revenue, income, costs and charges are recorded net of discounts and allowances.

Revenue from the sale of goods is recognised in the income statement when the significant risks and rewards of ownership have been transferred to the buyer. Revenue from services rendered is recognised in the income statement in proportion to the stage of completion of the transaction at the balance sheet date. The stage of completion is assessed by reference to surveys of work performed. No revenue is recognised if there are significant uncertainties regarding recovery of the consideration due, associated costs or the possible return of goods cannot be estimated reliably and there is no continuing management involvement with the goods.

Revenue from licensing contracts is recognised at the moment in which each specific development milestone defined in the license contract is reached.

Income from royalties is recognised on an accrual basis and represents income earned as a percentage of product sales, in accordance with the terms of the relevant agreement.

Research government grants are recognised at their fair value at the moment in which the party making the grant has confirmed its approval and the proceeds are definite; they are recognised in the income statement over the period necessary to match them with the costs that they are intended to compensate.

Payments made under operating leases are recognised in income statements on a straight line basis over the term of the lease.

#### 4. Revenue

In 1H 2008 revenue reached EUR 11,872 thousand up 20.3% over the same period of the previous year and is detailed here below:

EUR/1,000	30.6.2008	30.6.2007
Manufacturing on behalf of third parties:		
Manufacturing of generic products and specialty drugs	6,501	6,773
Manufacturing of MMX™ products	3,713	1,212
Related services	233	257
Other revenues from sales	70	111
Licence fees and milestones	127	1,502
Royalties	1,228	10
<b>Total revenue</b>	<b>11,872</b>	<b>9,865</b>

Revenue mainly increased through the sales of Lialda™ by Shire Limited. In 1H 2008 we delivered 47.2 million tablets at a production revenue of EUR 3,713 thousand (in 1H 2007 16.2 million tablets, EUR 1,212 thousand).

Licence fees and milestones of EUR 127 thousand refer to an agreement signed for the development of a generic product. In 1H2007 the amount of EUR 1,502 thousand referred to milestone payments received in conjunction with the US and EU approval of Lialda™/Mezavant™.

Pending Giuliani and Shire's official data on Lialda™ sales for the 2Q 2008, royalties for the 1H 2008 are prudentially estimated by considering Shire's sales of Lialda™ for the 2Q 2008 equal to actual sales for the 1Q 2008.

#### 5. Operating Expenses as per Nature of Expenses

EUR/1,000	30.6.2008	30.6.2007
Other income	23	245
Changes in inventories of finished goods and work in progress	(158)	348
Raw materials and consumables used	(2,983)	(3,265)
Personnel expenses	(3,462)	(3,922)
Outsourced preclinical and clinical trial costs	(1,961)	(977)
Other operating expenses	(3,223)	(4,041)
Depreciation and amortisation	(771)	(719)
<b>Total operating expenses</b>	<b>(12,535)</b>	<b>(12,331)</b>

#### Personnel expenses

The item, which includes the cost of the entire staff, comprises the following:

EUR/1,000	30.6.2008	30.6.2007
Salaries and wages	2,486	3,135
Social security contributions	603	667
Employee benefits	124	109
Stock options	232	–
Other costs	17	11
<b>Total personnel expenses</b>	<b>3,462</b>	<b>3,922</b>

Personnel expenses for the 1H 2008 decreased to EUR 3,462 thousand: in 1H 2007 they included a one time payment of EUR 1,021 thousand to all employees. As at 30 June 2008 the total number of Company employees was 133, as detailed below:

	30.6.2008	30.6.2007
Managers	12	11
Junior managers	8	8
Employees	57	56
Workers	56	48
<b>Total number</b>	<b>133</b>	<b>123</b>

#### Outsourced preclinical and clinical trial costs

Preclinical and clinical trials costs outsourced to subcontractors increased from EUR 977 thousand to EUR 1,961 thousand, of which EUR 708 thousand were for Budesonide MMX™, EUR 564 thousand for LMW Heparin MMX™, EUR 340 thousand for CB-03-01 and EUR 236 thousand for Rifamycin SV MMX™.

#### Other operating expenses

Other operating expenses in 1H 2008 decreased to EUR 3,223 thousand: in 1H 2007 these included EUR 1,294 thousand, as Company's estimate on a portion of the IPO costs.

Net of the above item, in 1H 2008 "other operating expenses" increased particularly due to a heavier expense for investor relation activities, for the expense for non-Executive Directors' stock options granted on 18 December 2007 and for the increase of the utilities and energy costs.

#### 6. Financial Income/Expenses

Financial income in 1H 2008 is due to the interest received on the IPO proceeds, which were placed in time deposits with banks, deriving from the IPO which took place in March 2007.

#### 7. Cash and Cash Equivalents

The liquidity of the Group as at 30 June 2008 amounted to EUR 23,862 thousand. The cash is invested in short term "time deposit" bank contracts at two top rated Italian banks, at market rates.

#### 8. Shareholders' Equity

##### Share capital

As at 30 June 2008 Cosmo Pharmaceuticals had 13,875,000 shares issued, fully subscribed and paid up, each share with a nominal value of EUR 0.25, for a total share capital of EUR 3,469 thousand.

##### Share premium

As at 30 June 2008 "share premium" of EUR 29,372 thousand refers to the proceeds from 2007 offering of new shares at the IPO.

##### Other reserves

"Other reserves" as at 30 June 2008 comprises the "contributions reserve" of EUR 357 thousand and the "capital contribution for loss coverage" of EUR 1,805 thousand and the allocation of 2007 profit amounting to EUR 116 thousand.

##### Stock option plan reserve

The stock option plan reserve was created to reflect the stock option plan that grants options to Directors and to selected employees. The options (in total 1,013,568) granted on 18 December 2007 vest after 3 years and can be exercised at a price of CHF 22 per share until 14 December 2011. The fair value of options granted, determined using the Black-Scholes valuation model, resulted in a value of CHF 3.14 per option.

The expense for the value of employees and Directors' services exchanged for the stock options

in 1H 2008 amounted to EUR 319 thousand (EUR 232 thousand for personnel and EUR 87 thousand for non-Executive Directors).

No movements incurred in the stock option plan from the above mentioned granting date of 18 December 2007 and no other stock option plans have been put in place by the Company.

### 9. Basic and Diluted Earnings per Share

Basic earnings per shares are calculated by dividing the net profit (loss) for the year attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the year. Basic earnings per share is as follows:

EUR/1,000	<b>30.6.2008</b>	<b>30.6.2007</b>
Net profit/(Loss) attributable to shareholders (EUR/1,000)	(814)	(1,651)
Weighted average number of ordinary shares	13,875,000	12,813,287
<b>Basic earnings per share (in EUR)</b>	<b>(0.059)</b>	<b>(0.129)</b>

Diluted earnings per share are calculated by dividing the net profit for the year attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the year, plus the weighted average number of shares that would be issued on the conversion of all the potential options into ordinary shares.

The only categories of potential ordinary shares are the stock options granted to employees and Directors. During the presented periods these were anti-dilutive, as their conversion would have decreased the loss per share. Thus, the values of the basic and diluted loss per share coincide.

### 10. Related Party Transactions

Lease agreement with Cristoforo Colombo Real Estate S.r.l.

The Company rents plant, equipment and some offices in Lainate from Cristoforo Colombo Real Estate S.r.l., a company controlled by Cassiopea S.A., which controls Cosmo Holding S.p.A., the main shareholder of the Company. The duration is for 6 years, the lease expires in 2012 and it is renewable at the same terms for an equal period of time.

On 1 June 2008, the Company rented some additional space from Cristoforo Colombo Real Estate S.r.l., namely a 3-floor office building in the Lainate complex, at the following terms:

- the ground floor of approximately 750 sqm, at an annual rent of EUR 90 thousand, six-year duration, renewable at the same terms for an equal period of time;
- second and third floor, plus meeting and conference rooms at the basement, for a total of approximately 1,800 sqm, at a rent of EUR 160 thousand, one-year duration, renewable at the same terms for an equal period of time.

In the six months ending on 30 June 2008, the total cost for rent paid by the Company to Cristoforo Colombo Real Estate S.r.l. amounts to EUR 754 thousand (it was EUR 729 thousand in the same period of 2007).

### 11. Subsequent Events

As at the date of presentation of these financial statements there were no material events after the balance sheet date. Cosmo is continuing to develop its products pipeline, in line with plans and programmed activities.

# Information for Investors

## Capital structure

Major shareholders	No. of shares	% of share capital
Cosmo Holding S.p.A.	8,740,000	63.00%
dievini Hopp Biotech GmbH & Co. KG	1,476,876	10.60%

## Share price data

EUR/1,000	Price	Date
Issue price	22.00	12.3.2007
First day trading	22.30	12.3.2007
Lowest	18.90	21.1.2008
Highest	25.30	25.2.2008
Last trading day	21.00	30.6.2008
Market capitalisation 30.6.2008	291.4	

## Stock exchange information

Listing	SWX Swiss Exchange, Main Board
Security ID	COPN
ISIN	IT0004167463
Swiss security number (Valor)	2862650
Number of shares	13,875,000

## Research coverage

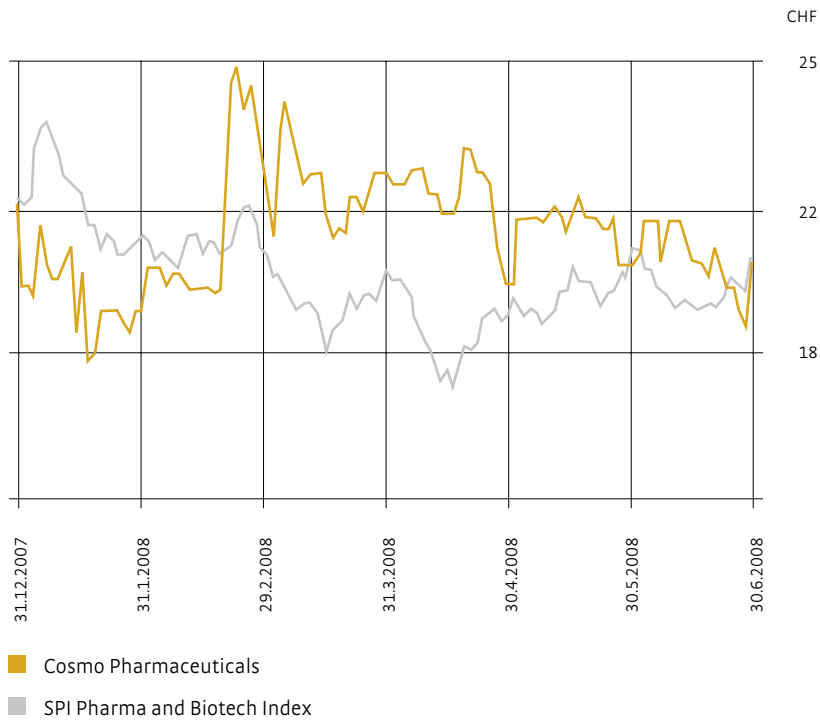
Fortis	Geraldine O'Keeffe	Tel. +31 20 527 9150
Lehman Brothers	Peter Welford	Tel. +44 20 7102 9458
Sal. Oppenheim	Martin Vögtli	Tel. +41 44 214 2365
Vontobel	Andrew C. Weiss	Tel. +41 58 283 7152

## Calendar

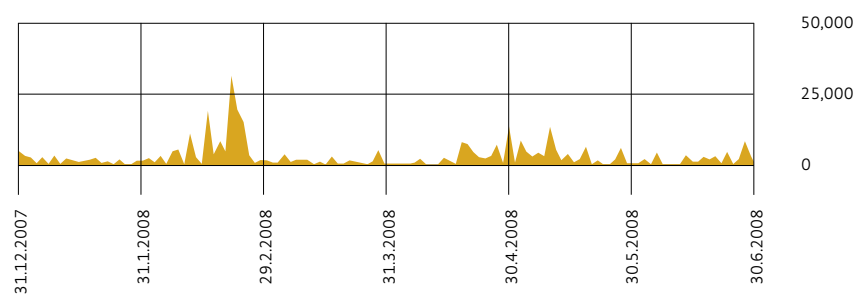
### Key reporting dates in 2009

Fiscal year 2008 will close on 31 December 2008  
2008 Financial Statements/Annual Report –  
23 March 2009  
Annual General Meeting – 20 April 2009

## Share price



## Trading volumes



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