

## Cosmo (COPN SW)

## Gut Feeling Still Strong; Reiterate Buy Post Cassiopea Demerger

## Key Takeaway

**The successful demerger of Cassiopea should now enable value to be ascribed to Cosmo's previously largely overlooked dermatology assets, also likely paving the way for a similar tax-efficient deal in future for US S&M of its GI portfolio. We still see substantial opportunities for novel Phase III colonoscopy diagnostic MB-MMX, antibiotic rifamycin SV MMX, and injection device SIC 8000 for removal of polyps. We reiterate our Buy rating and CHF215/share PT.**

**Focus on tax-efficient routes to maximising value:** Cosmo has retained a c.45% stake in Cassiopea (c.CHF13/share) after its recent successful Swiss listed IPO, crystallising the value of its dermatology portfolio in a tax-efficient transaction, yielding a substantial 1H15 P&L gain. We anticipate management to utilise similar innovative strategies to realise the value of US rights to its late-stage GI pipeline: MB-MMX to improve the diagnosis of colon cancer by colonoscopy; SIC 8000 to facilitate the removal of polyps; and rifamycin SV MMX for travellers' diarrhoea. Phase III results and regulatory progress for these products by 1H16E could pave the way for future "equity-for-product rights" deals with separate business unit(s) initially funded by Cosmo. Given the inherent difficulty in modelling these deal structures at this time, our forecasts still assume US GI rights are retained in-house. Importantly, despite the disparity versus the likely strategy, we believe the impact would likely be at least neutral to NPVs, albeit P&L differences could be significant.

**Significant upcoming catalysts:** (1) Phase III MB-MMX results around YE15E; (2) US FDA 510(k) clearance of SIC 8000 in Aug-Sep 2015E and EU CE mark by 2Q16E; and (3) rifamycin SV MMX Phase III results around 1Q16E. Management could also execute incremental out-licensing deals for ex-US rights to these GI products.

**Bumper 1H profit:** A substantial €259m net gain on the Cassiopea demerger boosts 1H profits, also reducing future R&D spend. SG&A costs rise on the employee profit-share scheme. We forecast a €1.5/share dividend for shareholders in 2016E, with the potential for a progressive policy in future years.

## Valuation/Risks

Our CHF215/share Price Target is based on a sum-of-the-parts valuation comprising probability-adjusted NPVs for marketed and late-stage products plus Net Cash. Risks include: (1) clinical trial failures or delays; (2) regulatory setbacks; (3) the need to execute out-licensing deals to maximise value; and (4) differentiating reformulated products.

EUR	Prev.	2014A	Prev.	2015E	Prev.	2016E	Prev.	2017E
Rev. (MM)	82.3	79.6	83.8	50.7	127.6	118.6	221.9	170.4
EV/Rev		25.7x		40.4x		17.3x		12.0x
EBIT (MM)	25.5	22.2	17.9	(20.6)	23.6	34.2	104.4	64.5
EV/EBIT		92.3x		NM		59.9x		31.8x
Cash Position	151.9	59.5	161.9	116.7	162.7	122.7	212.7	159.4
<b>EPS</b>								
FY Dec	1.91	1.15	1.16	(1.39)	1.53	2.26	6.10	4.36
FY P/E		NM		NM		65.8x		34.1x

We exclude exceptional gains/losses such as on the sale of investments and demerger of entities.

BUY

Price target CHF215.00

Price CHF161.20

## Financial Summary

Book Value (MM):	€152.3
Book Value/Share:	€10.77
Net Debt (MM):	(€48.5)
Net Debt/Capital:	(32.0)%
Long-Term Debt (MM):	€2.3
LTD/Cap:	2.0%
Dividend Yield:	0.9%
Cash & ST Invest. (MM):	€59.5

## Market Data

52 Week Range:	CHF190.00 - CHF125.20
Total Entprs. Value (MM):	CHF2,220.4
Market Cap. (MM):	CHF2,272.9
Insider Ownership:	48.5%
Institutional Ownership:	32.4%
Shares Out. (MM):	14.1
Float (MM):	11.5
Avg. Daily Vol.:	17,020

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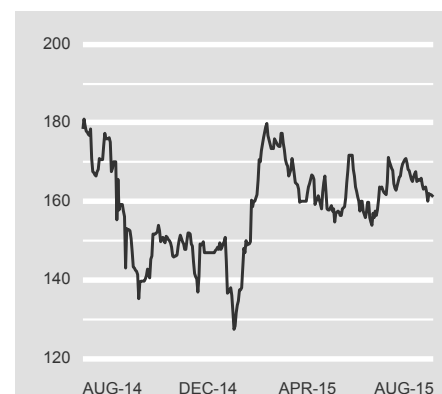
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## Price Performance



## Scenarios

## Target Investment Thesis

- Attractive profile given a relatively low risk strategy of leveraging its MMX colon drug delivery technology, maximising the value of GI products in the US market, and demerging assets as new entities to crystallise value in tax-efficient deals.
- The current share price undervalues marketed drugs Lialda and Uceris for ulcerative colitis, colonoscopy diagnostic MB-MMX, plus the late-stage pipeline.
- Our CHF 215 per share Price Target is based on an NPV sum-of-the-parts.

## Upside Scenario

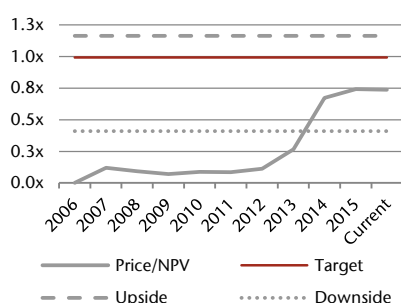
- Positive MB-MMX Phase III results in detecting CRC risk could add c. CHF 9/share.
- US FDA 510(k) clearance and an EU CE mark for SIC 8000 to remove polyps could add CHF 13/share.
- Cassiopea shares could rise towards our upside scenario boosting the value of Cosmo's investment by CHF 11/share.
- These catalysts, together with a number of smaller events, could boost our NPV derived Price Target to c.CHF 250 per share.

## Downside Scenario

- MB-MMX failing to sufficiently improve polyp/adenoma detection rates in Phase III could remove c.CHF 69/share.
- Rifamycin SV MMX Phase III failure in the European travellers study for infectious diarrhoea could remove c.CHF 16 per share from our valuation.
- SIC 8000 setbacks or delays could remove up to CHF 40/share.
- Together these setbacks could lower our NPV derived Price Target to c.CHF 90/share.

## Long Term Analysis

## Price vs NPV SOTP valuation



Source: FactSet, Jefferies estimates

## Long Term Financial Model Drivers

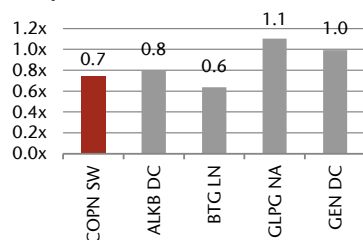
<b>2014-19E Revenue CAGR</b>	<b>+35%</b>
2014 Net Cash (EURm)	48.5
2015E Net Cash (EURm)	107.8
2016E Net Cash (EURm)	115.0

## Other Considerations

Cosmo is committed to remaining profitable and management has now begun to return excess cash to shareholders. We anticipate management to execute "equity-for-product rights" deals and/or establish NewCo's to maximise the value of US commercial opportunities in tax efficient structures.

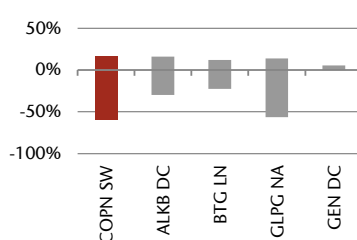
## Peer Group

## Group Price/NPV



Source: FactSet, Jefferies estimates

## Upside/Downside to base case NPV



Source: Jefferies estimates

## Recommendation / Price Target

Ticker	Rec.	PT
<b>COPN SW</b>	<b>Buy</b>	<b>CHF 215</b>
ALKB DC	Buy	DKK 1000
BTG LN	Buy	950p
GLPG NA	Buy	€47
GEN DC	Buy	DKK 600

## Catalysts

- Colonoscopy diagnostic MB-MMX Phase III results around YE15E and then filings
- SIC 8000 US FDA 510(k) in Aug-Sep 2015E and EU CE mark submission 2Q16E
- Phase III rifamycin SV MMX EU data for infectious diarrhoea during around 1Q16E
- Potential incremental out-licensing deals, including rifamycin SV MMX in Latin America and Asia, plus Uceris in Japan
- US commercial plans for the GI products rifamycin SV MMX, MB-MMX, and SIC 8000

## Company Description

Cosmo is a biotechnology company whose novel drug delivery system allows for targeted, sustained drug release in the lower colon. The company focuses on gastro-intestinal disorders such as ulcerative colitis (UC), in addition to travellers' diarrhoea and chromoendoscopy for the earlier diagnosis of colorectal cancer.

## Retain Buy with CHF 215 Price Target

**Cosmo's profile is attractive within our European universe, in our view, given its relatively low risk strategy of leveraging the MMX colon drug delivery technology, maximising the commercial opportunity of its products in the lucrative US market, and demerging assets as new companies to crystallise value with tax-efficient transactions. After the successful demerger and Swiss listed IPO of its dermatology portfolio as Cassiopea, we anticipate Cosmo could again pursue a similar strategy in future for US commercial rights to its gastrointestinal (GI) drugs MB-MMX, SIC 8000, and rifamycin SV MMX. Since inception management has maintained an efficient cost structure, typically out-licensing late-stage drugs, which we anticipate to remain the ex-US strategy. We believe the current share price undervalues marketed drugs Lialda and Uceris plus the late-stage pipeline, with upside from successful new launches and potential incremental partnership deals. We reiterate our Buy rating and Price Target of CHF 215 per share.**

## Crystallising value of dermatology franchise

On 30 June 2015, Cosmo demerged its emerging dermatology pipeline into a specialty pharmaceutical company named Cassiopea (SKIN SW, Buy, CHF 39), listed on the Swiss Stock Exchange. This transaction generated tax-free 1H15 profits of around €259m comprising a €132m net gain on deconsolidation, plus a €135m gain on the c.45% investment stake in Cassiopea retained by Cosmo, less €8m for costs. This structure aims to achieve tax efficient benefits for Cosmo from the value accretion on the potential success of its derma assets, while also enabling an independent Cassiopea to focus on accelerating the development of these novel products. Leveraging a service agreement with Cosmo enables Cassiopea to adopt a highly efficient outsourcing business model. Potential benefits of this strategy for Cosmo include the following:

- **Accelerated development from greater focus:** Under the direction of an independent management team, appropriately incentivised to focus on specific assets and goals, we believe pipeline programmes could advance more rapidly and benefit from the stewardship of a team with prior experience in the particular therapeutic area.
- **Significant tax benefits:** Cosmo relocated its domicile to Luxembourg as of 13 March 2015, hence capital gains on divesting investments are tax-free. This tax benefit could be lucrative given the significant potential gains once these programmes are independently ascribed a fair market value.
- **Earlier realisation of asset value for Cosmo:** On becoming a sub-50% shareholder in the new entity, the parent crystallised a substantial proportion of the pipeline value, while also maintaining a long-term shareholding to participate in the potential future appreciation. Furthermore, we believe the dermatology assets were previously heavily discounted within Cosmo, somewhat overlooked by investors given its commercial products and Phase III GI/endoscopy programmes. Now Cassiopea is publically listed as an independent entity it should be easier for the market to ascribe value to these assets, in our view.
- **Maintain relatively lean infrastructure:** By spinning-off the dermatology assets, the parent can focus on developing its GI and endoscopy pipeline, in addition to acting as a holding company for "equity-for-product" agreements. Cassiopea can also operate a highly cost-efficient model, utilising some functions within Cosmo under a contract service agreement, while having only a few members of senior management.

## GI portfolio

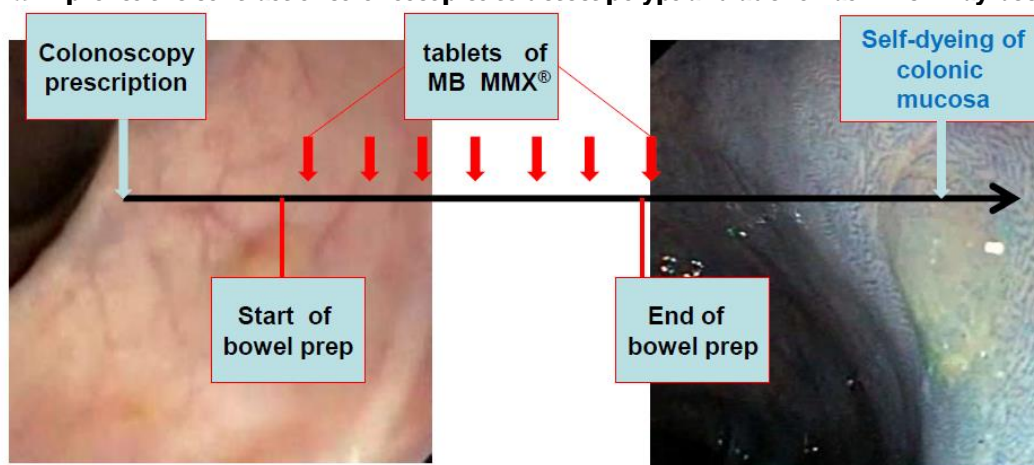
Following the success of the Cassiopea transaction, we foresee the strategy most likely pursued by management to maximise the value of its GI product portfolio in the US will be creating a separate entity that is demerged and listed on the NASDAQ to build a US S&M infrastructure. Nevertheless, given the inherent difficulty in modelling these scenarios at this time, our model still assumes US GI rights are retained in-house. Importantly, despite this disparity, we believe any deal would likely be at least neutral to NPVs, albeit the P&L impact could be significant.

### MB-MMX (CB-17-01) – Simple concept for a valuable diagnostic

- **Peak sales forecast:** \$400m with \$250m in the US
- **Valuation:** CHF 70 per share with an 80% probability of success
- **Next news flow:** Phase III results around YE15E for regulatory filings in 1H16E

MB-MMX (CB-17-01) is a novel diagnostic to assist colonoscopy procedures. We remain impressed by the simplicity of the product, using MMX to conveniently apply the well-known dye methylene blue in the colon for chromoendoscopy (endoscopy using an intravital dye topically applied to the mucosal surface). Methylene blue is selectively absorbed by normal colonic columnar cells but not dys-/neo-plastic cells, making it ideal to assist in the diagnosis of colon cancers and premalignant polyps. The dye has been used for over 20 years in food, in addition to somewhat limited use in chromoendoscopy by manual application prior to the procedure. The latter is both costly, process intensive and potentially messy for clinicians, hence we would expect a convenient tablet form such as MB-MMX to be rapidly adopted.

**Chart 1: MB-MMX improves the contrast of colonoscopies to detect polyps and adenomas which may become CRC**



Source: Cosmo presentation at R&D Day on 25 January 2013

In the open label Phase IIb trials 96 patients received a single 200mg dose as eight 25mg tablets administered at the end of the bowel cleansing preparation (drinking 2-4 litres of fluid the day before the endoscopy). In this population the polyp and adenoma detection rates in the colon were on average 1.8 and 0.9 per patient, respectively. These were detected in around 64% and 47% of patients, comparing very favourably with the c.35% and 22-36% rates reported in literature. Importantly detection rates in the typically hard to visualise right colon were 33% for polyps and 25% for adenomas. Furthermore, the majority of lesions detected were smaller than 5mm. There were no treatment-related adverse events or reported allergies suggesting MB-MMX is very well-tolerated.

The Phase III trial is enrolling 1,230 patients with polyps at 22 hospitals in North America and Europe. The number of sites has been increased from 13 to accelerate patient enrolment given the relatively onerous protocols physicians must follow for data integrity.

MB-MMX could drive greater adoption of chromoendoscopy given improved detection of colon cancer

Subjects are randomised 2:2:1 to 200mg MB-MMX versus white light endoscopy (WLE) vs. 100mg MB-MMX. The latter lower dose arm is a control cohort mandated by the FDA to exclude the potential for bias. All patients take the standard bowel preparation. The primary endpoint is the proportion of patients with at least one histologically proven adenoma/carcinoma as read by a central histopathologist. The FDA also required all endoscopies to be recorded with the videos retained and reviewed by one of five central physicians. This review is again to prevent bias, ensuring an excessive time is not spent performing the colonoscopy and an excess of biopsies are not taken. We are optimistic for Phase III success and are encouraged by Cosmo securing a Special Protocol Assessment (SPA) from the FDA June 2013 for the trial design. The trial should report results around YE15E, hence we assume initial regulatory submissions during 1H16E.

We believe distribution agreements could be signed for the ex-US markets after Phase III results, potentially once regulatory approvals are obtained, likely on a country-by-country or regional basis.

Cosmo's market research suggests on a health economics basis MB-MMX could be priced at up to \$280 if the Phase III confirms a +7-10% polyp detection rate. Importantly a price sub-\$150 would ensure broad market access and facilitate reimbursement by payors. We estimate \$110 per procedure at US launch, a premium to the c.\$75 for branded bowel prep, and a lower €40 per procedure outside the US.

We assume over one-third of the estimated 10m chromoendoscopy procedures utilise MB-MMX by 2021E, which conservatively assumes around 25% of the c.40m annual endoscopies in US/EU at that time use a dye, from c.5-10% currently. There could be significant upside if MB-MMX availability can drive greater adoption of chromoendoscopy given improved detection rates. If the Phase III adenoma detection rate is again 45-50% we believe a "blue-sky" scenario could be up to 50% of colonoscopies using MB-MMX for blockbuster peak sales >\$1bn.

#### SIC 8000 – maximising the colonoscopy opportunity

- **Peak sales forecast:** \$250m of which \$150m in the US
- **Valuation:** CHF 52 per share with an 80% probability of success
- **Next news flow:** US FDA 510(k) clearance in August-September 2015E for launch 1H16E after completion of a marketing trial. European filing for a CE mark around September 2015E to be granted by 2Q16E

SIC 8000 is a submucosal injectable composition that was developed internally by Cosmo to be administered into a polyp detected by colonoscopy, creating a cushion thereby facilitating its removal by endoscopic mucosal resection (EMR) or endoscopic submucosal dissection (ESD). Currently numerous submucosal injectable solutions are used off-label, with some hyaluronic acid (HA) based products approved in Europe and Japan but these are expensive, require special storage, and have possible safety concerns linked to promoting growth of residual tumour cells. Use of submucosal injectable solutions when excising polyps/adenomas is important to lower the risk of perforation, particularly for larger lesions using ESD, and maximise the likelihood of completely removing the tissue. Furthermore, these solutions can expedite the procedure, particularly important in the US given clinicians' economic sensitivity.

The ideal submucosal injectable solution would provide a long-lasting cushion, have a low viscosity for injection, include a dye to visualise the lesion's perimeter, be safe, and available at an affordable price. We believe SIC 8000 could fulfil these criteria offering a standardised technique with regulatory backing for the easier removal of polyps. The novel composition includes the dye methylene blue thereby improving the definition of the margin for the polyp's removal.

SIC 8000 is categorised as a class II medical device in the US and Europe, requiring FDA 510(k) approval and a European CE mark. Industrial scale bulk manufacturing has been completed, together with three biocompatibility studies and five *in vivo* animal trials. Cosmo filed for 510(k) approval with the FDA in late-March 2015, with a decision now



expected August-September 2015E after additional documents were required by the agency. We anticipate a European submission for a CE mark in September 2015E for potential clearance by 2Q16E. Commercial launches are planned for 1H16E, at the earliest, once a marketing trial has been completed and S&M plans advanced.

We forecast \$250m WW peak sales estimating 30% and 20% uptake of SIC 8000 for the removal of polyps/adenomas in the US and Europe, respectively, assuming an average 1.75 lesions per screening colonoscopy, with 20% of these being eligible for mucosal resection (rather than an electrosurgical knife or invasive surgery for larger lesions). Management estimates 1.5 vials would be required on average per lesion. We conservatively estimate \$75 and €30 per vial in the US and Europe, respectively, a marked discount to the €50-60 typical for HA-based solutions.

Longer-term we believe there could be upside from potential use of SIC for removal of tissue/polyps in the stomach, oesophagus and duodenum. These tracts are inspected by esophagogastroduodenoscopy (EGD) perhaps most commonly for surveillance of Barrett's oesophagus (severe GERD or acid reflux) and ulcers. We believe the number of EGDS performed is broadly similar to that of colonoscopies, suggesting a significant potential opportunity for SIC particularly as lesions in these tracts are typically flat necessitating an adequate cushion for safe removal.

#### **Uceris/Cortiment (budesonide MMX) – Should bounce back in 2H15E**

- **Peak sales forecast:** \$350m largely comprising \$325m in the US
- **Valuation:** CHF 42 per share with a 100% probability
- **Next news flow:** Quarterly Uceris sales if reported by partner Valeant. Potential out-licensing deal for Japanese rights.

Valeant Pharmaceuticals (VRX, \$239, Buy) acquired Salix, which has the US commercial rights to Uceris, in April 2015 hence quarterly in-market sales have not been disclosed during 2015. Salix previously disclosed inventory management issues during 3Q14, with wholesalers' stocks around five months at end-3Q. The destocking required to reduce supply channels significantly impacted 4Q14 and 1H15 US Uceris sales, as Valeant further reduced wholesalers' stocks in-line with its corporate policy. This resulted in much lower royalties and drug manufacturing revenues for Cosmo in 1H15E, but we anticipate the run-rate to normalise during 2H15E.

Our WW peak sales largely comprise over \$325m in the higher priced US market. This could prove conservative for the US given it is now backed by the greater marketing muscle of Valeant. Importantly we are increasingly confident in the duration of US Uceris sales after recent issuance of a patent outlining the unique pharmacokinetic profile (US 8,895,064) that expires in September 2031 and is listed in FDA's Orange Book. Furthermore, in December FDA issued Draft Guidance outlining the requirements for generic versions of Uceris that, similar to guidelines for other drugs targeting the GI, we believe set high hurdles for approval. Both *in vivo* pharmacokinetic studies measuring partial area under the curve (i.e. drug concentrations at various time points) and *in vitro* dissolution tests across a range of pH are required.

EU approval of Cortiment (the European brand name) under the mutual recognition procedure was received on 20 October 2014 enabling partner Ferring (private) to initiate a progressive roll-out. However, given a substantially lower price that is only 5-6% of Uceris in the US, we forecast EU peak sales of only \$15m. Importantly in volume terms we note this assumes similar peak demand in Europe to the US.

**Rifamycin SV MMX – EU Phase III results long overdue**

- **Peak sales forecast:** \$250m of which \$150m in the US
- **Valuation:** CHF 22 per share with a 70% probability
- **Next news flow:** Phase III results from EU travellers around 1Q16E

Phase III travellers' diarrhoea (TD) results from the ongoing c.1,000 subject trial of Europeans travellers is now expected 1Q16E, from mid-2015E, following further delays in recruitment after the study initially began late-2010. We highlight trial co-ordinator Dr. Falk (private) shifted the destination from India to Latin America in 1Q14 for the final c.200 participants given the challenging regulatory environment for clinical studies in the former country. Recruitment has started in Guatemala, Ecuador and Peru but we note Dr. Falk is still awaiting approval in Mexico. This trial represents the second study required for regulatory filings. If this trial successfully demonstrates non-inferiority to ciprofloxacin on the time to last unformed stool we anticipate Cosmo to file itself with the US FDA by mid-2016E, with partner Dr. Falk having licensed the majority of European rights.

Rifamycin SV MMX is a reformulated version of a broad spectrum antibiotic for oral dosing to treat infectious diarrhoea, with potentially wider use in *C. difficile* associated diarrhoea (CDAD), diverticulitis and hepatic encephalopathy (HE). The targeted release of Cosmo's MMX technology delivers the active ingredient into the colon, preserving and protecting the "good" vitamin-synthesizing bacteria that colonise the GI tract.

Our \$250m peak sales forecast assumes 15% penetration of a population that is likely to exceed 20m at a c.40% price premium to rifaximin in Europe (approved as Normix/Rifacol) and parity to Xifaxan in the US, given its potential to protect important bacterial flora in the GI tract. However, the more significant future commercial opportunity, which could offer substantial upside to our forecasts, is rifamycin SV MMX use for diverticulitis, other bacterial infections, and/or HE. We note Xifaxan is annualising over \$600m US sales highlighting the significant potential upside to our current forecasts. A Phase II trial with rifamycin SV MMX in acute diverticulitis is ongoing, with an interim analysis anticipated by YE15E. Cosmo has also developed a new formulation for diarrhoea-predominant irritable bowel syndrome (d-IBS) comprising a higher 600mg per tablet with earlier release of the active ingredient in the small intestine. A Phase I/II study in d-IBS is expected to be initiated in the near future.

Importantly Cosmo management is targeting potential US development of rifamycin SV MMX for a resistant bacterial infection, making the drug eligible for market exclusivity plus financial and regulatory benefits under the GAIN (Generating Antibiotics Incentives Now) Act of 2012.

**MoAb MMX – Clinical trials planned to begin 2H15E**

- **Peak sales forecast:** To be determined when initial clinical data available
- **Valuation:** None pending initial clinical data
- **Next news flow:** Phase I/II ulcerative colitis trial begins 2H15E

MoAb MMX delivers a "bio-better" version of anti-TNF $\alpha$  monoclonal antibody infliximab (brand name Remicade) topically in the intestine for the maintenance treatment of ulcerative colitis. Potentially this offers a biologic therapy to sustain disease remission without the need for regular injections and the adverse events associated with systemic absorption of the drug.

Cosmo has successfully demonstrated both the structure and functional activity of its anti-TNF $\alpha$  monoclonal antibody is preserved when formulated using the MMX technology. The "bio-better" infliximab is currently under scale-up with partner AIMM (private). A small 4-patient clinical trial with enemas of infliximab suggested proof-of-concept in active ulcerative colitis for topical delivery in the intestine. We expect Cosmo to initiate a Phase I/II trial in ulcerative colitis during 2H15E before then potentially out-licensing MoAb MMX for further clinical development.

## Significant “one-off” Cassiopea gain

Our underlying assumptions for the key products are broadly unchanged but P&L forecasts are highly dependent on management’s implementation of its strategy to execute “equity-for-product rights” deals and/or establish NewCo’s to commercialise the pipeline. We continue to model Cosmo building a US S&M infrastructure for the GI franchise but now assume this begins steadily from 1H16E.

Our revenue forecasts are cut largely on the removal of any future out-licensing income on the dermatology products, following the successful demerger of Cassiopea, in addition to substantially lower Uceris sales given the destocking in 1H15. R&D expenses are also reduced on removal of the Cassiopea spend, but SG&A costs increase due to the employee monetary bonus scheme, paying-out c.7% of profits above a €20m threshold for the next three years. Reported profits in 2015E are boosted substantially by the €259m net gain on the Cassiopea transaction, but we record this as an exceptional “one-off” financial income below EBIT and exclude from our adjusted forecasts.

**Table 1: Significant changes to estimates following the demerger of Cassiopea**

(EUR millions Dec YE)	2015 Old	2015 New	% Chg	2016 Old	2016 New	% Chg	2017 Old	2017 New	% Chg
Revenue	83.8	50.7	-40%	127.6	118.6	-7%	221.9	170.4	-23%
Gross Profit	61.8	28.3	-54%	98.2	91.2	-7%	182.5	136.1	-25%
Gross margin %	73.7%	55.8%		77.0%	76.9%		82.3%	79.9%	
Personnel Expenses	(30.0)	(30.0)	+0%	(32.4)	(32.4)	+0%	(34.0)	(34.0)	+0%
Other Operating Expenses	(18.6)	(24.5)	+32%	(56.9)	(38.4)	-32%	(64.5)	(55.4)	-14%
(R&D Expenses)	(28.7)	(21.6)	-25%	(30.0)	(13.0)	-57%	(25.2)	(17.1)	-32%
(SG&A Expenses)	(15.2)	(27.3)	+79%	(44.7)	(43.9)	-2%	(52.9)	(54.6)	+3%
<b>Operating Income</b>	<b>17.9</b>	<b>(20.6)</b>	-215%	<b>23.6</b>	<b>34.2</b>	+45%	<b>104.4</b>	<b>64.5</b>	-38%
Operating margin %	21.3%	(40.6%)		18.5%	28.9%		47.0%	37.9%	
Pre-tax Profit	20.7	242.4	+1071%	27.4	36.0	+32%	109.2	67.3	-38%
Net Income	16.6	238.9	+1343%	21.9	32.0	+46%	87.4	61.8	-29%
<b>Adjusted Net Income</b>	<b>16.6</b>	<b>(19.6)</b>	-218%	<b>21.9</b>	<b>32.0</b>	+46%	<b>87.4</b>	<b>61.8</b>	-29%
EPS (EUR)	1.2	16.9	+1359%	1.5	2.3	+48%	6.1	4.4	-28%
<b>Adjusted EPS (EUR)</b>	<b>1.2</b>	<b>(1.4)</b>	-220%	<b>1.5</b>	<b>2.3</b>	+48%	<b>6.1</b>	<b>4.4</b>	-28%
<b>Adjusted EPS (CHF)</b>	<b>1.2</b>	<b>(1.5)</b>	-222%	<b>1.6</b>	<b>2.5</b>	+53%	<b>6.4</b>	<b>4.7</b>	-26%
Net Cash/(Debt)	153.4	107.8	-30%	155.5	115.0	-26%	206.8	153.0	-26%

Source: Jefferies estimates



## Retain CHF 215 Price Target

Our CHF 215 per share Price Target is based on an NPV sum-of-the-parts valuation and continues to offer potential upside from the current share price.

**Table 2: Cosmo sum-of-the-parts valuation**

	Indication	Peak Sales (\$mn)	Value (EURmn)	Prob.	Adj. Value (EURmn)	CHF per share
Lialda/Mezavant	Ulcerative colitis	800	90	100%	90	6.9
Cortiment/Uceris	Ulcerative colitis	350	540	100%	540	41.5
rifamycin SV MMX	Infectious diarrhoea	250	409	70%	286	22.0
MB-MMX (CB-17-01)	Chromoendoscopy of colon	400	1,128	80%	903	69.4
SIC 8000	EMR solution for polyp removal	250	847	80%	678	52.1
Contract Manufacturing		25	26	100%	26	2.0
Investments (Cassiopea)	Dermatology	(c.4.51m shares)	164	100%	164	12.6
Net Cash/(Debt)			140	100%	140	10.8
<b>Valuation</b>			<b>3,344</b>		<b>2,826</b>	<b>217.3</b>
Potential Dilution for Funding	Min. Yrs of Cash	2.0		0%	0	0.0
<b>Potential Diluted Valuation</b>						<b>217.3</b>

Source: Jefferies estimates

**Table 3: Sources of upside potential and downside risk**

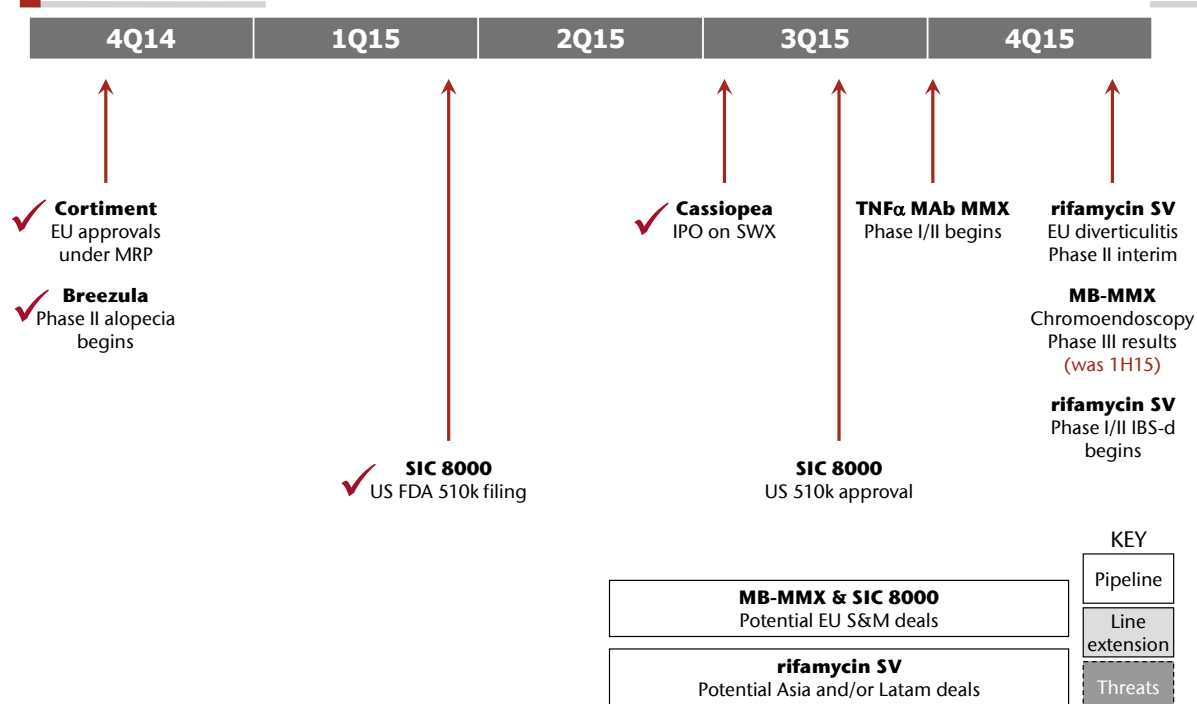
	Upside	CHF per share	Downside	CHF per share
rifamycin MMX Phase III results	Positive EU trial	3.1	Fails	(15.7)
MB-MMX Phase III results	Positive	8.7	Fails	(69.4)
Cassiopea investment	Achieves Price Target CHF60	6.5	Downside scenario c.CHF26	(4.3)
Cassiopea investment	Upside scenario c.CHF73	4.0	---	0.0
SIC 8000 US FDA 510k & EU CE mark	Approved for 2015E launches	13.0	Rejected or delayed	(39.1)
<b>Potential Upside/(Downside)</b>		<b>35.4</b>		<b>(128.5)</b>
<b>Potential Valuation</b>		<b>252.7</b>		<b>88.8</b>

Source: Jefferies estimates

## Exhibit 1: Cosmo catalysts

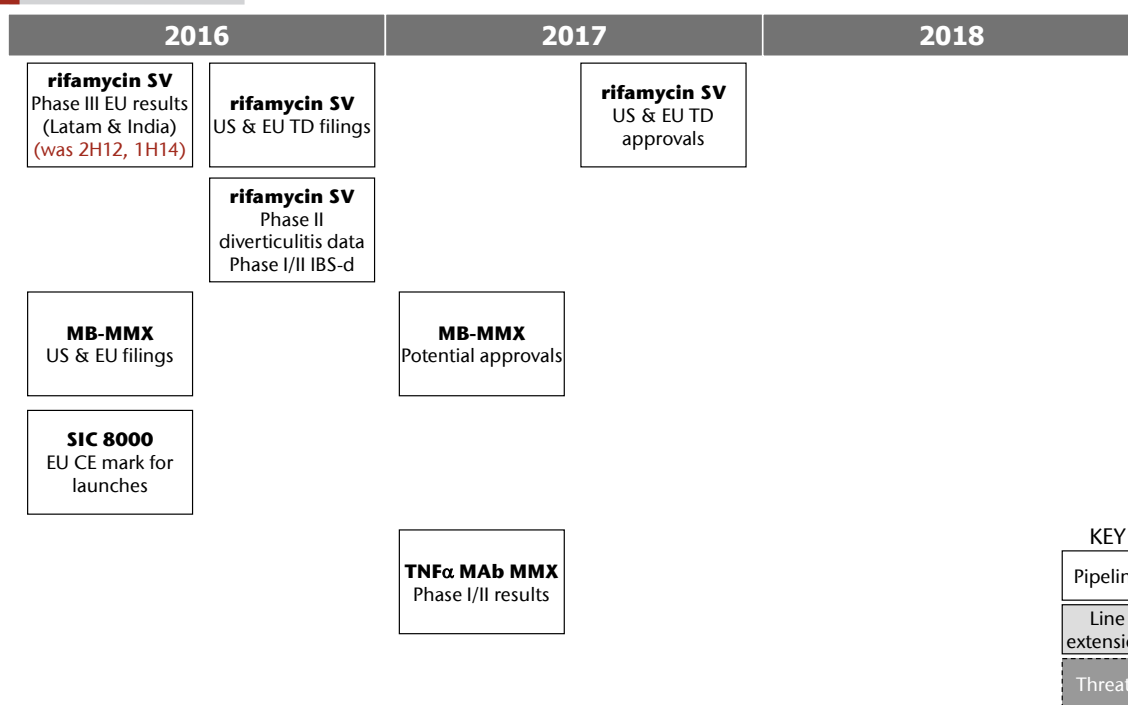
## Cosmo

## Near-term catalysts



## Cosmo

## Mid-term catalysts



Jefferies

Source: Jefferies

## Updated financial models

**Table 4: Cosmo Revenue Model**

(EUR millions Dec YE)	2015E							
	2014A	1H15A	2H15E	2015E	2016E	2017E	2018E	2019E
Contract Manufacturing	40.1	16.9	20.6	37.5	53.1	57.9	62.8	67.8
Lialda/Mezavant Royalties	6.3	0.3	0.0	0.4	0.0	0.0	0.0	0.0
Cortiment/Uceris Royalties	14.8	2.4	10.0	12.4	33.2	37.7	41.2	42.7
rifamycin SV MMX Revenue	0.0	0.0	0.0	0.0	0.0	11.3	28.8	58.8
rifamycin SV MMX Royalties	0.0	0.0	0.0	0.0	0.0	0.6	1.5	3.0
rifamycin SV MMX Sales	0.0	0.0	0.0	0.0	0.0	10.7	27.3	55.8
MB-MMX (CB-17-01) Revenue	0.0	0.0	0.0	0.0	0.0	14.0	39.9	77.3
MB-MMX Royalties	0.0	0.0	0.0	0.0	0.0	0.8	3.7	9.0
MB-MMX Sales	0.0	0.0	0.0	0.0	0.0	13.2	36.2	68.3
SIC 8000 Revenue	0.0	0.0	0.0	0.0	19.5	41.4	72.9	107.3
SIC 8000 Royalties	0.0	0.0	0.0	0.0	2.2	5.6	11.5	16.9
SIC 8000 Sales	0.0	0.0	0.0	0.0	17.4	35.8	61.5	90.5
LMW heparin MMX Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Zacol Revenue	0.6	0.0	0.0	0.0	0.6	2.1	3.2	3.9
Sales and Related Services	0.1	0.4	0.0	0.5	0.2	0.0	0.0	0.0
License Fees and Milestones	17.7	0.0	0.0	0.0	12.0	6.0	1.0	2.0
Other Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Total Revenues</b>	<b>79.6</b>	<b>20.0</b>	<b>30.7</b>	<b>50.7</b>	<b>118.6</b>	<b>170.4</b>	<b>249.9</b>	<b>359.9</b>
<b>% Change Year over Year</b>								
Contract Manufacturing	33.8%	(23.1%)	13.4%	(6.6%)	41.7%	9.1%	8.5%	8.1%
Lialda/Mezavant Royalties	(56.7%)	(94.6%)	(88.2%)	(94.3%)	(100.0%)	n/a	n/a	n/a
Sales and Related Services	(82.2%)	241.5%	313.6%	368.8%	(55.6%)	(100.0%)	n/a	n/a
License Fees and Milestones	237.8%	(100.0%)	(100.0%)	(100.0%)	n/a	(50.0%)	(83.3%)	100.0%
Other Royalties	20.8%	60.0%	(100.0%)	(44.8%)	(100.0%)	n/a	n/a	n/a
Total Revenues	41.2%	(51.3%)	(20.4%)	(36.3%)	134.0%	43.7%	46.6%	44.0%

Source: Jefferies estimates, company data

**Table 5: Cosmo Margin Analysis**

	2015E							
	2014A	1H15A	2H15E	2015E	2016E	2017E	2018E	2019E
Gross Margin	72.9%	44.6%	63.1%	55.8%	76.9%	79.9%	82.3%	84.4%
Selling, General & Admin.	20.9%	95.8%	26.4%	53.8%	37.0%	32.0%	25.4%	19.8%
Research and Development	24.1%	66.3%	27.2%	42.6%	11.0%	10.0%	8.5%	7.2%
Personnel Expenses	26.3%	125.0%	16.3%	59.2%	27.3%	20.0%	14.0%	10.0%
Other Operating Expenses	25.1%	55.0%	44.0%	48.3%	32.4%	32.5%	29.3%	25.6%
Operating Income	27.9%	(117.5%)	9.5%	(40.6%)	28.9%	37.9%	48.5%	57.3%
Pretax Profit	136.8%	1201.1%	7.3%	478.4%	30.4%	39.5%	50.0%	59.2%
Net Income	92.1%	1187.7%	4.6%	471.5%	27.0%	36.3%	40.0%	47.3%

Source: Jefferies estimates, company data

Table 6: Cosmo Profit and Loss Model

	2015E							
(EUR millions except EPS Dec YE)	2014A	1H15A	2H15E	2015E	2016E	2017E	2018E	2019E
Revenue	79.6	20.0	30.7	50.7	118.6	170.4	249.9	359.9
Cost of Sales	(21.5)	(11.1)	(11.3)	(22.4)	(27.4)	(34.2)	(44.1)	(56.3)
<b>Gross Profit</b>	<b>58.1</b>	<b>8.9</b>	<b>19.4</b>	<b>28.3</b>	<b>91.2</b>	<b>136.1</b>	<b>205.7</b>	<b>303.6</b>
Total Operating Expenses	(35.9)	(32.4)	(16.5)	(48.9)	(56.9)	(71.7)	(84.6)	(97.4)
<i>Selling, General &amp; Admin. Expenses</i>	<i>(16.7)</i>	<i>(19.2)</i>	<i>(8.1)</i>	<i>(27.3)</i>	<i>(43.9)</i>	<i>(54.6)</i>	<i>(63.5)</i>	<i>(71.3)</i>
<i>R&amp;D Expenses</i>	<i>(19.2)</i>	<i>(13.3)</i>	<i>(8.3)</i>	<i>(21.6)</i>	<i>(13.0)</i>	<i>(17.1)</i>	<i>(21.1)</i>	<i>(26.1)</i>
Of which Personnel Expenses	(20.9)	(25.0)	(5.0)	(30.0)	(32.4)	(34.0)	(35.0)	(36.1)
Of which Depreciation and Amortisation	(8.8)	(4.2)	(4.6)	(8.7)	(3.7)	(4.2)	(4.6)	(5.1)
Of which Other Operating Expenses	(20.0)	(11.0)	(13.5)	(24.5)	(38.4)	(55.4)	(73.2)	(92.2)
Other Operating Income	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Operating Exceptionals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Operating Income</b>	<b>22.2</b>	<b>(23.5)</b>	<b>2.9</b>	<b>(20.6)</b>	<b>34.2</b>	<b>64.5</b>	<b>121.1</b>	<b>206.2</b>
<b>Adjusted Operating Income</b>	<b>22.2</b>	<b>(23.5)</b>	<b>2.9</b>	<b>(20.6)</b>	<b>34.2</b>	<b>64.5</b>	<b>121.1</b>	<b>206.2</b>
Net Financial Income	4.5	5.2	(0.7)	4.5	1.8	2.8	3.8	6.8
Exceptionals	82.1	258.5	0.0	258.5	0.0	0.0	0.0	0.0
<b>Pretax Profit</b>	<b>108.9</b>	<b>240.2</b>	<b>2.2</b>	<b>242.4</b>	<b>36.0</b>	<b>67.3</b>	<b>124.9</b>	<b>213.0</b>
<b>Adjusted Pretax Profit</b>	<b>26.7</b>	<b>(18.3)</b>	<b>2.2</b>	<b>(16.1)</b>	<b>36.0</b>	<b>67.3</b>	<b>124.9</b>	<b>213.0</b>
Taxation	(35.5)	(2.7)	(0.8)	(3.5)	(4.0)	(5.5)	(25.0)	(42.6)
Minority Interests	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Net Income from Continuing Operations</b>	<b>73.3</b>	<b>237.5</b>	<b>1.4</b>	<b>238.9</b>	<b>32.0</b>	<b>61.8</b>	<b>99.9</b>	<b>170.4</b>
Net Income from Discontinued Operations	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Net Income</b>	<b>73.3</b>	<b>237.5</b>	<b>1.4</b>	<b>238.9</b>	<b>32.0</b>	<b>61.8</b>	<b>99.9</b>	<b>170.4</b>
<b>Adjusted Net Income</b>	<b>16.5</b>	<b>(21.0)</b>	<b>1.4</b>	<b>(19.6)</b>	<b>32.0</b>	<b>61.8</b>	<b>99.9</b>	<b>170.4</b>
WA Basic Shares (mn)	14.3	14.1	14.1	14.1	14.1	14.2	14.2	14.2
WA Shares Diluted (mn)	14.6	14.4	14.8	14.8	14.6	14.7	14.7	14.7
<b>EPS (EUR)</b>	<b>5.1</b>	<b>16.8</b>	<b>0.1</b>	<b>16.9</b>	<b>2.3</b>	<b>4.4</b>	<b>7.0</b>	<b>12.0</b>
<b>Adjusted EPS (EUR)</b>	<b>1.1</b>	<b>(1.5)</b>	<b>0.1</b>	<b>(1.4)</b>	<b>2.3</b>	<b>4.4</b>	<b>7.0</b>	<b>12.0</b>
<b>Adjusted EPS (CHF)</b>	<b>1.4</b>	<b>(1.6)</b>	<b>0.1</b>	<b>(1.5)</b>	<b>2.5</b>	<b>4.7</b>	<b>7.6</b>	<b>13.0</b>
Dividends per Share Interim/Final (EUR)	0.0			1.5	1.5	1.8	2.2	2.6
<b>% Change Year over Year</b>								
Revenue	41.2%	(51.3%)	(20.4%)	(36.3%)	134.0%	43.7%	46.6%	44.0%
Cost of Sales	12.4%	10.2%	(1.5%)	4.0%	22.5%	24.9%	28.9%	27.6%
Gross Profit	56.0%	(71.3%)	(28.3%)	(51.3%)	222.3%	49.4%	51.1%	47.6%
Total Operating Expenses	41.9%	97.3%	(15.4%)	36.2%	16.5%	25.9%	18.1%	15.1%
<i>Selling, General &amp; Admin. Expenses (incl. D&amp;A)</i>	<i>116.8%</i>	<i>165.0%</i>	<i>(14.2%)</i>	<i>63.5%</i>	<i>61.1%</i>	<i>24.3%</i>	<i>16.3%</i>	<i>12.4%</i>
<i>R&amp;D Expenses</i>	<i>9.2%</i>	<i>44.0%</i>	<i>(16.6%)</i>	<i>12.4%</i>	<i>(39.8%)</i>	<i>31.3%</i>	<i>23.8%</i>	<i>23.3%</i>
Of which Personnel Expenses	89.0%	230.2%	(62.6%)	43.3%	8.0%	5.0%	3.0%	3.0%
Of which Other Operating Expenses	13.3%	2.9%	45.2%	22.6%	56.7%	44.3%	32.1%	26.0%
Operating Income	71.7%	(260.9%)	(61.6%)	(192.6%)	266.3%	88.4%	87.8%	70.2%
Adjusted Operating Income	71.7%	(260.9%)	(61.6%)	(192.6%)	266.3%	88.4%	87.8%	70.2%
Pretax Profit	51.9%	202.6%	(92.4%)	122.7%	(85.1%)	86.8%	85.6%	70.5%
Net Income	6.7%	209.2%	140.5%	225.9%	(86.6%)	93.0%	61.7%	70.5%
Adjusted Net Income	56.0%	(279.1%)	(70.3%)	(218.9%)	263.6%	93.0%	61.7%	70.5%
EPS (EUR)	6.4%	216.7%	141.1%	230.9%	(86.6%)	92.6%	61.3%	70.1%
Adjusted EPS (EUR)	55.6%	(283.5%)	(69.8%)	(220.7%)	263.2%	92.6%	61.3%	70.1%

Source: Jefferies estimates, company data

**Table 7: Cosmo Cash Flow Model**

(EUR millions Dec YE)	2014A	2015E	2016E	2017E	2018E	2019E
Pretax Profit	108.9	242.4	36.0	67.3	124.9	213.0
Depreciation and Amortisation	8.8	8.7	3.7	4.2	4.6	5.1
<b>EBITDA</b>	<b>31.0</b>	<b>(11.9)</b>	<b>37.9</b>	<b>68.6</b>	<b>125.7</b>	<b>211.3</b>
Other Adjustments and Exceptionals	(61.6)	(255.0)	3.8	4.1	4.4	4.8
Decrease/(Increase) in Inventories	(0.5)	(0.0)	(0.8)	(1.0)	(1.5)	(1.8)
Decrease/(Increase) in Receivables	7.9	0.6	(5.6)	(4.3)	(6.5)	(9.0)
Increase/(Decrease) in Payables	4.6	2.2	2.2	2.6	2.8	3.0
Increase/(Decrease) in Other	(0.4)	0.0	0.0	0.0	0.0	0.0
Change in WC	11.7	2.8	(4.1)	(2.7)	(5.3)	(7.9)
Taxation Paid	(1.3)	(31.5)	(3.9)	(5.1)	(20.1)	(38.2)
<b>Net Cash Flow from Operating Activities</b>	<b>66.4</b>	<b>(32.6)</b>	<b>35.5</b>	<b>67.7</b>	<b>108.6</b>	<b>176.8</b>
Purchase of Tangible Fixed Assets	(2.2)	(2.0)	(7.1)	(8.5)	(7.5)	(9.0)
Proceeds from Sale of PP&E	0.0	0.0	0.0	0.0	0.0	0.0
Purchase of Intangible Assets	(0.3)	0.0	0.0	0.0	0.0	0.0
(Purchase)/Sale of Investments	(132.2)	0.0	0.0	0.0	0.0	0.0
(Acquisitions)/Disposals of Subsidiaries	(0.0)	107.5	0.0	0.0	0.0	0.0
<b>Net Cash Flow from Investing Activities</b>	<b>(11.5)</b>	<b>105.5</b>	<b>(7.1)</b>	<b>(8.5)</b>	<b>(7.5)</b>	<b>(9.0)</b>
Management of Liquid Resources	123.1	0.0	0.0	0.0	0.0	0.0
Capital Changes	(52.1)	0.0	0.0	0.0	0.0	0.0
Debt Changes	(0.7)	(2.0)	(1.3)	(1.3)	(1.3)	(1.3)
Equity Dividends Paid	(14.3)	0.0	(21.2)	(21.2)	(25.5)	(30.7)
Other Financing Cash Flows	0.0	(13.6)	0.0	0.0	0.0	0.0
<b>Net Cash Flow from Financing Activities</b>	<b>(67.1)</b>	<b>(15.6)</b>	<b>(22.5)</b>	<b>(22.5)</b>	<b>(26.8)</b>	<b>(32.0)</b>
<b>Increase in Cash</b>	<b>(12.2)</b>	<b>57.3</b>	<b>5.9</b>	<b>36.7</b>	<b>74.3</b>	<b>135.8</b>
<b>Change in Net Debt</b>	<b>11.5</b>	<b>(72.9)</b>	<b>(7.2)</b>	<b>(38.0)</b>	<b>(75.6)</b>	<b>(137.1)</b>
<b>(Cash Burn)</b>	<b>(68.2)</b>	<b>72.9</b>	<b>28.4</b>	<b>59.2</b>	<b>101.1</b>	<b>167.8</b>

Source: Jefferies estimates, company data

**Table 8: Cosmo Balance Sheet Model**

(EUR millions Dec YE)	2014A	2015E	2016E	2017E	2018E	2019E
<b>Non-current Assets</b>	<b>154.9</b>	<b>274.5</b>	<b>277.9</b>	<b>282.3</b>	<b>285.1</b>	<b>289.0</b>
Intangible Assets	10.4	4.0	3.1	2.2	1.3	0.4
Property, Plant and Equipment	21.4	21.2	25.5	30.8	34.5	39.3
Investments	120.8	247.1	247.1	247.1	247.1	247.1
Other Long-term Assets	2.2	2.2	2.2	2.2	2.2	2.2
<b>Current Assets</b>	<b>70.7</b>	<b>127.4</b>	<b>139.7</b>	<b>181.6</b>	<b>263.9</b>	<b>410.6</b>
Inventories	3.3	3.4	4.1	5.2	6.6	8.5
Trade Accounts Receivable	4.8	4.2	9.7	14.0	20.5	29.6
Other Current Assets	3.1	3.1	3.1	3.1	3.1	3.1
Cash and Cash Equivalents	59.5	116.7	122.7	159.4	233.6	369.4
<b>Total Assets</b>	<b>225.6</b>	<b>401.9</b>	<b>417.6</b>	<b>463.9</b>	<b>549.1</b>	<b>699.7</b>
<b>Current Liabilities</b>	<b>60.7</b>	<b>41.8</b>	<b>44.2</b>	<b>51.4</b>	<b>64.2</b>	<b>77.9</b>
Trade Accounts Payable	5.5	7.7	9.9	12.5	15.3	18.3
Other Current Liabilities	53.2	11.6	11.7	12.1	16.9	21.3
Short-term Debt	0.6	0.0	0.0	0.0	0.0	0.0
Leasing Obligations	1.4	1.3	1.3	1.3	1.3	1.3
Dividends	0.0	21.2	21.2	25.5	30.7	36.9
<b>Non-current Liabilities</b>	<b>12.7</b>	<b>11.4</b>	<b>10.1</b>	<b>8.8</b>	<b>7.5</b>	<b>6.2</b>
Long-term Debt	2.3	2.3	2.3	2.3	2.3	2.3
Leasing Obligations	6.6	5.3	4.0	2.7	1.4	0.1
Deferred Tax Liabilities	3.3	3.3	3.3	3.3	3.3	3.3
Long-term Provisions	0.4	0.4	0.4	0.4	0.4	0.4
<b>Total Shareholders' Equity</b>	<b>152.3</b>	<b>348.8</b>	<b>363.4</b>	<b>403.7</b>	<b>477.4</b>	<b>615.6</b>
Share Capital	3.7	3.7	3.7	3.7	3.7	3.7
Share Premium	47.8	47.8	47.8	47.8	47.8	47.8
Other Reserves and Adjustments	(26.1)	(50.9)	(50.9)	(50.9)	(50.9)	(50.9)
Retained Earnings	126.8	348.1	362.7	403.0	476.7	614.9
Minority Interests	0.0	0.0	0.0	0.0	0.0	0.0
<b>Total Liabilities and Shareholders' Equity</b>	<b>225.6</b>	<b>401.9</b>	<b>417.6</b>	<b>463.9</b>	<b>549.1</b>	<b>699.7</b>

Source: Jefferies estimates, company data



## Key changes to forecasts

Table 9: Summary estimates changes for Cosmo

Forecasts (EURm)	2015E New	2015E Old	% Chg	2016E New	2016E Old	% Chg
<b>Sales</b>	50.7	83.8	-40%	118.6	127.6	-7%
<b>Adj. EBIT</b>	(20.6)	17.9	-215%	34.2	23.6	+45%
<b>Adj. EPS</b>	(1.39)	1.16	-220%	2.26	1.53	+48%
<b>Net Cash/(Debt)</b>	107.8	153.4	-30%	115.0	155.5	-26%
<b>Drivers of Change</b>	Lowering Revenues on removal of out-licensing income for dermatology products, after the successful demerger of Cassiopea, plus substantially lower Uceris income given 1H15 destocking. R&D expenses are cut reflecting the Cassiopea demerger but SG&A spend rises given the employee monetary bonus scheme.					

Source: Jefferies estimates

## Company Description

Cosmo is a biotechnology company whose novel drug delivery system allows for targeted, sustained drug release in the lower colon. The company focuses on gastro-intestinal disorders such as ulcerative colitis (UC), in addition to travellers' diarrhoea and chromoendoscopy for the earlier diagnosis of colorectal cancer.

## Analyst Certification:

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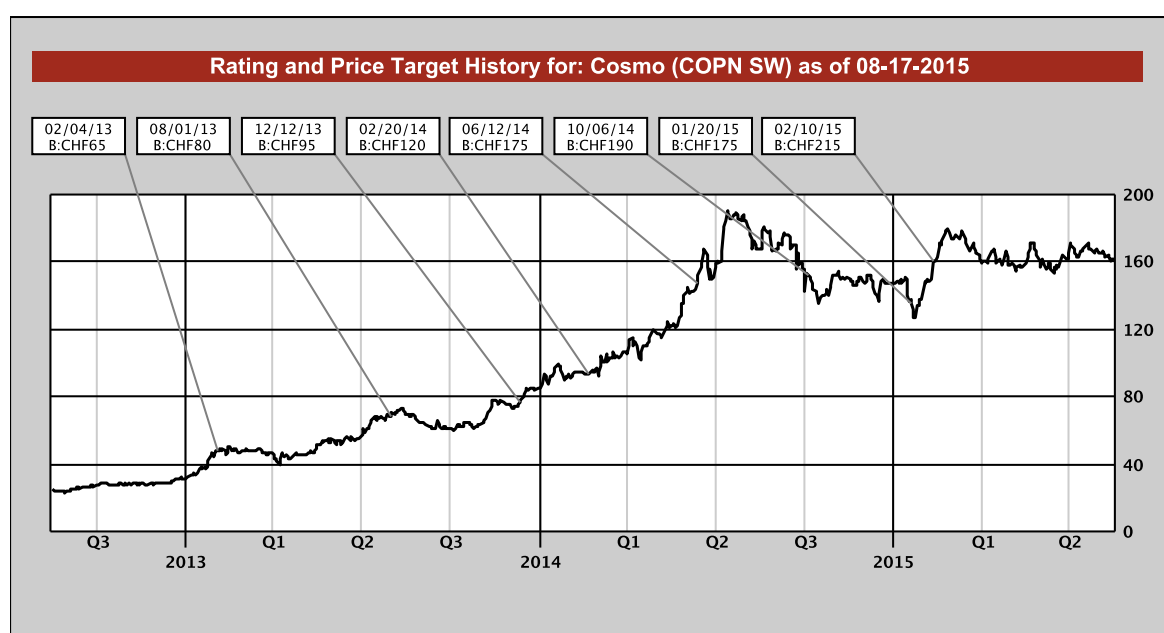
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- ALK-Abello A/S (ALKB DC: DKK812.00, BUY)
- BTG (BTG LN: p638.00, BUY)
- Cassiopea (SKIN SW: CHF37.65, BUY)
- Galapagos (GLPG NA: €53.99, BUY)
- Genmab A/S (GEN DC: DKK629.50, BUY)
- Valeant Pharmaceuticals International (VRX: \$249.75, BUY)



## Distribution of Ratings

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
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HOLD	838	40.15%	166	19.81%
UNDERPERFORM	143	6.85%	13	9.09%

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