Jefferies Healthcare Conference

New York – June 9, 2016

COSMO Pharmaceuticals

Safe Harbour

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2016 First Half Highlights

- Successful completion of EU Phase III trial for Rifamycin
- Rifamycin NDA filing forecasted 1 Q 2017
- Decision to set-up own commercial infrastructure in the US
- Agreements with US management team close to finalization
- SIC 8000 (re-named Eleview™) EU approval expected by end of June
- MB phase III trial close to completion
- Significant expansion of Cortiment® franchise

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Ample resources to fund growth

- 2015 consolidated profit after tax increased by 238.5% to € 248.2 million
- Substantially strengthened financial position
  - Equity increased to € 403.6 million with practically no debt
  - Total cash & liquid investments of € 240.6 million
- Share price increased by 7.2% from end 2015 to June 6 2016

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Rifamycin SV MMX
The new addition to the GI Pipeline

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Rifamycin SV MMX
general background

- The market is desperately seeking for new antibiotics
- Rifamycin SV MMX (Rifamycin) is a new broad-spectrum **ANTIBIOTIC**, with negligible systemic absorption and lower probability of resistance than other comparable antibiotics, delivered topically in all colonic districts throughout the MMX® technology
- Rifamycin has excellent anti-inflammatory/immunomodulatory properties, **IDEALLY SUITED FOR THE TREATMENT OF COLONIC INFECTIONS**
- Rifamycin is a **NEW CHEMICAL ENTITY (NCE)** in the US
- Rifamycin will enjoy **10 YEARS OF EXCLUSIVITY IN USA** under the NCE/GAIN Act combined rules

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Rifamycin
a little science

- Rifamycin has bactericidal activity interfering with the synthesis of nucleic acids by inhibiting DNA-dependent RNA polymerase

- Rifamycin has a broad spectrum of activity targeted to the main enteropathogen microorganisms:
  - E. coli (ETEC, EPEC, EHEC, EIEC)
  - Salmonella
  - Shighella
  - Enterobacter faecalis
  - Staphilococcus aureus
  - Mycobacterium Tuberculosis

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Rifamycin
Trial design

Two phase III trials jointly requested for US and EU registration:

- **Phase III US trial Superiority vs. Placebo (completed by Santarus in 2012)**
  - Randomized, double-blind, multi-centre, placebo-controlled study to evaluate the efficacy and safety of Rifamycin SV MMX for the treatment of travellers' diarrea

- **Phase III EU trial Non-inferiority vs. Cipro (by Dr. Falk Pharma)**
  - Randomized, double-blind, double-dummy, multi-centre, comparative parallel-group study to evaluate the efficacy and safety of oral daily Rifamycin SV MMX 400 mg b.i.d. vs. Ciprofloxacin 500 mg b.i.d. in the treatment of acute infectious diarrhoea in travellers

- Both trials had positive outcomes with endpoints successfully reached

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Rifamycin
Trial Results Outline

- **All clinical endpoints successfully reached**
- **Overall number of patients treated: over 1200**
- **No Safety issues**

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Rifamycin
indications sought

US (rights owned by Cosmo)

Travellers' Diarrhea
To be extended to: **IBS D**
Development Timeline: Phase II DR to start in Q3 16

EU (licensed to Dr. Falk)

Infectious Diarrhea/Colitis
To be extended to: Uncomplicated Diverticulitis
Development Timeline: Phase II P.O.C. ongoing
interim analysis in H2 2016

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Rifamycin
US case

- Rifamycin is a sister molecule of Rifaximin, the API of Xifaxan®
- Xifaxan® first indication was Travellers' Diarrhea – launched in 2004 - achieved yearly peak sales under first indication of USD 117m (2009)
- Xifaxan® second indication was Hepatic Encephalopathy - launched in 2010, achieved yearly peak sales under both indications of USD 650m (2014)
- Xifaxan® third indication is IBS-D - launched in 2015
- Xifaxan® expected 2016 sales in excess of USD 1,1 b

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Rifamycin
wrap-up

- A new antibiotic ideally suited for colonic infections with no resistance issues
- A NCE in the US with 10 yrs exclusivity
- A product with an easily traceable peer (Xifaxan®)
- A wider indication at onset for the EU (Infectious Colitis)
- **All in all, a significantly undervalued asset in Cosmo's pipeline**

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Products on the market

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Lialda®/Mezavant®/Mesavancol®

- **Indication**
  - Induction and maintenance of remission for patients with Ulcerative Colitis of mild to moderate severity

- **Net Sales of Lialda ®/Mezavant®**
  - 2014: $ 633 m (+19.7%)
  - 2015: $ 684 m (+8.6%)

- **Tablets manufactured**
  - 2014: 251.2 m
  - 2015: 285.7 m (+ 13.8%)

- **biggest individual 5ASA product in USA with 33% market share**

- **Cosmo Income**
  - 2014: €22.8 m; € 6.3 m royalties, € 16.5 m manufacturing
  - 2015: €20.2 m; € 0.7 m royalties, € 19.5 m manufacturing

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Uceris®/Cortiment®

- **Indication**
  - Induction of remission for patients with active Ulcerative Colitis of mild to moderate severity

- **Prescriptions written**
  - 2014: 3'183'092; + 103.4%
  - 2015: 3'863'500; + 21.4%

- **Net Sales**
  - 2014: $ 150 m
  - 2015: $ 108 m (inventory effect)

- **Cosmo Income**
  - 2014: € 45.0 m (royalties of €14.8 m; milestones of €17.7 m; manufacturing revenues of €12.5 m)
  - 2015: € 29.7 m (royalties of €12.0 m; milestones of €8 m; manufacturing revenues of €9.7 m)

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Cortiment®
continues worldwide expansion

- Cortiment is licensed to Ferring in all markets outside of US
  - Launched in 11 countries
  - approved in 34 countries
  - Pending registration in 14 countries
  - Submissions planned in 33 countries

- Cosmo has just licensed Cortiment to Ferring for Japan
  - € 8m down-payment at signing
  - Double digit royalties
  - Exclusive supply

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Pipeline update
Approved Products

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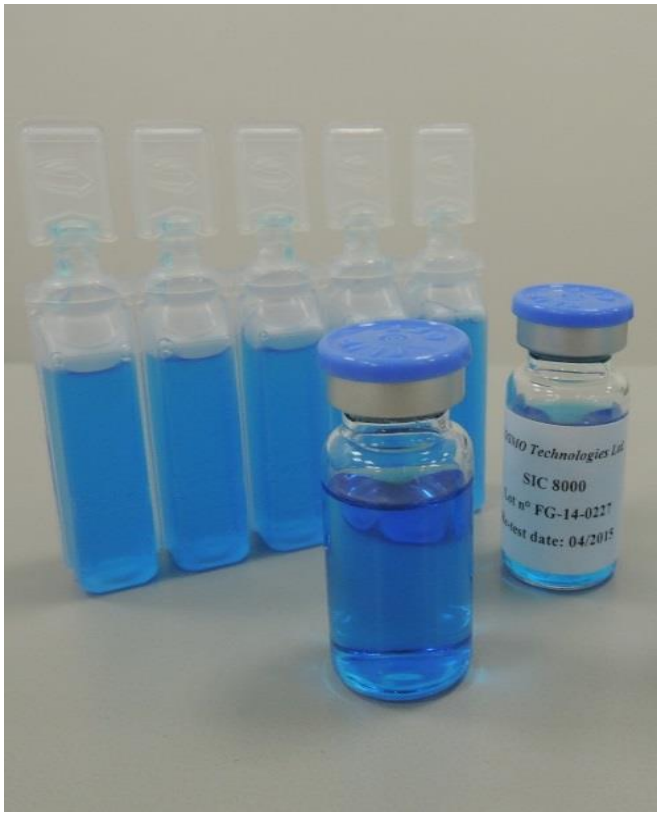
ELEVIEW™ (SIC 8000)
First medical device approved in US and filed in EU



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Once certain polyps are found during colonoscopies, they need to be removed

- To avoid risk of perforation, endoscopists need to create a **"safety cushion"** between the polyps and the deep layers of the GI wall
- Current procedures foresee the injection of normal saline solution, which is easy to inject but dissipates quickly
- Longer lasting cushions are sometimes obtained with expensive Hyaluronic Acid solutions or self made cocktails
- Strong need to obtain similar long lasting effect with alternative solutions. Ideal product should:
  - have low viscosity to facilitate injection
  - Provide a long lasting cushion (> 30 min)
  - Include a dye to enhance borders definition
  - be safe and bio-compatible
  - Affordable in terms of pricing

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ELEVIEW™

- **Eleview™ is a Submucosal Injectable Composition**, easy to be injected, developed to be used in all endoscopic polyp removal procedures in the GI tract
- **Eleview™ creates a long lasting cushion** which is essential for a successful Endoscopic Mucosal Resection (EMR) or Endoscopic Submucosal Dissection (ESD)
- **Eleview™ is dyed with methylene blue**, so it helps in visualizing the lesion and performing the resection procedure, minimizing risk of perforation
- **Eleview™ is covered by two international and one US patent applications filed in 2014** (priority 2013)

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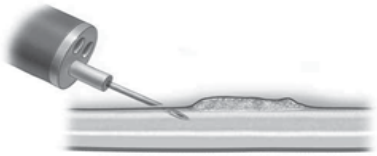
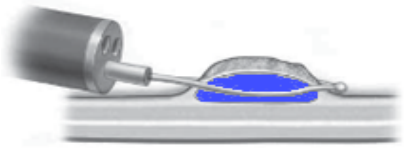
ELEVIEW™ will be used in Endoscopic Mucosal Resection (EMR) …

- The mucosa is between 1-3 mm thick; key perforation risk
- various techniques have been developed to take out lesions
- EMR for the removal of mucosal lesions that are **smaller than 2 cm**, or piecemeal removal of larger lesions (> 2 cm)
- A **cushion** is needed to lift the lesion and facilitate its removal, reducing perforation-risk and damage to the deep layers of the GI wall



Injection in the submucosa



Capture with the snare

Removal

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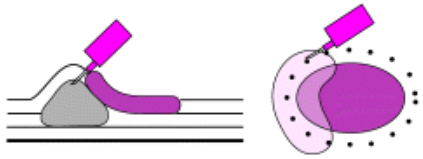
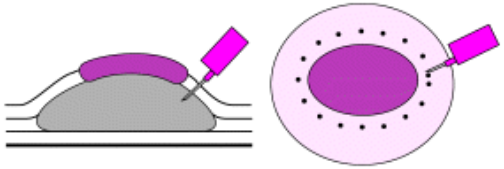
… as well as in Endoscopic Submucosal Dissection (ESD) (used to excise lesions >2 cm)

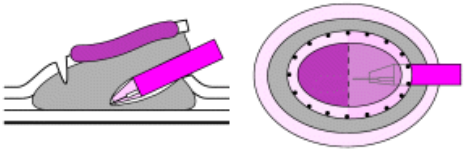
- Predicted to replace conventional surgery
- Intention to mitigate risks of higher rate of perforation and bleeding complications
- Submucosal injection is essential in ESD, and a high and long lasting submucosal cushion is needed for a safe cutting
- **Eleview™** needed if large lesion is to be removed in one piece



Circumferential injections



Mucosal elevation



Submucosal dissection

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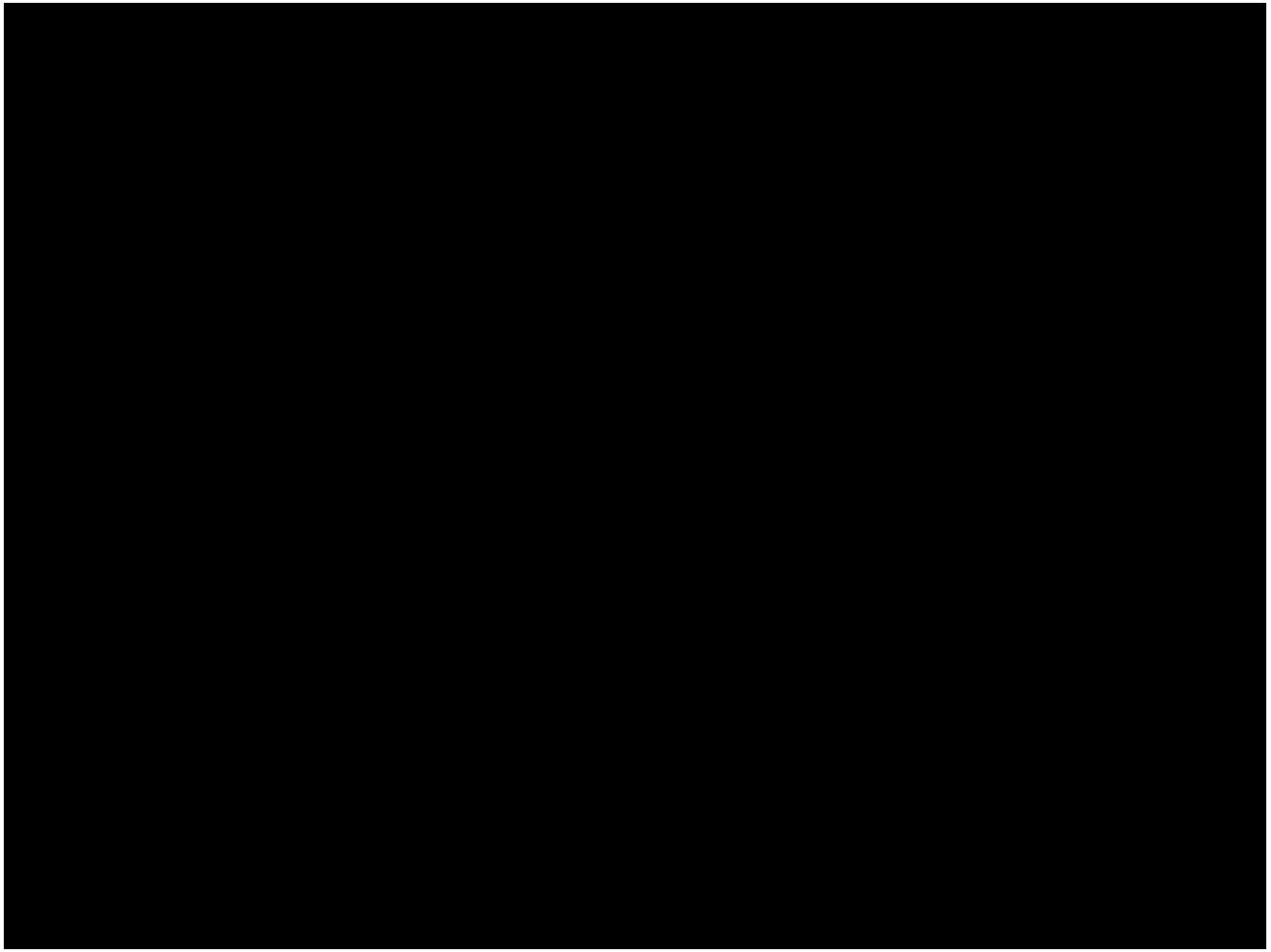
Polyp removal with saline solution



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Polyp removal with **Eleview™** in comparison

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Eleview™
Development Timeline

- **Eleview™ is a class II medical device approved by FDA on September 4, 2015**

- **Currently a trial for marketing purposes is ongoing in USA with 3 top KOLs in endoscopy**
  - Douglas Rex, Indiana University; Mike Wallace, Mayo Clinic; Prateek Sharma, Kansas City University Hospital
  - 150 subjects, **Eleview™** vs best practice
  - **Eleview™** will prove to be make polyps removal safer and faster

- **First US sale envisaged 2H 2016**

- **EU approval expected by Q2 2016**
  (European CE mark filing made in July 2015, manufacturing site audit successfully closed in March)

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Eleview™
market potential estimate (colonoscopies only)

Eleview™ Market estimates	2016	2017	2018	2019	2020
polyps/adenomas per colonoscopy in phase II	1,75	1,75	1,75	1,75	1,75
% of polyps/ adenomas removal requiring Eleview™	20%	20%	20%	20%	20%
Minimum vials per colonoscopy	1,5	1,5	1,5	1,5	1,5
estimated price in US	100	100	100	100	100
market penetration in US	10%	20%	30%	40%	50%
estimated price in EU	40	40	40	40	40
market penetration in EU	7%	15%	25%	30%	30%
estimated price in RoW	30	30	30	30	30
market penetration	3,5%	7,5%	12,5%	15,0%	15,0%
Revenue (millions)	68,5	143,1	227,8	298,6	353,6

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Eleview™
market potential from additional indications

The tissues of the esophagus, stomach and duodenum are quite similar to those of the colon. Inspection of these three tracts is conducted by Esophagogastroduodenoscopy (ECG). **Eleview™** can be used in all these tracts.

As many ECGs are performed as colonoscopies, both in the US and Europe.

During ECG, removal of tissues/polyps is frequently necessary and will require **Eleview™** as per below examples:

Barrett Esophagus
- Caused by GERD, ~ 1,6% of population affected
- Requires an ECG every 3 years
- Tissue removal required in ~ 10% all cases

Stomach & duodenal polyps
- polyps requiring extraction are found in around 0,7% of all procedures

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Eleview™

approaching the market !

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Pipeline update
Products completing development

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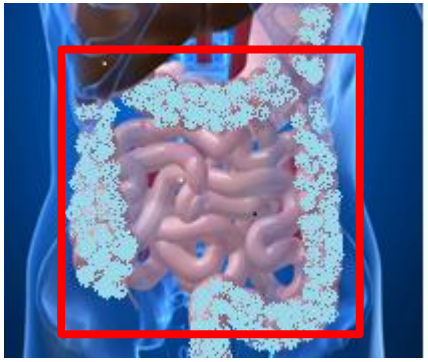
Methylene Blue (MB):enhancing visual detection

MB: a revolutionary tool for early cancer detection

Normal Procedure Time



Whole Colon stained, overcoming operator subjectivity

Sharp increase in Detection Rate, especially for flat/small lesions*

* According to Phase II Clinical Data, 51% more polyps and 47% more adenomas were found with MB

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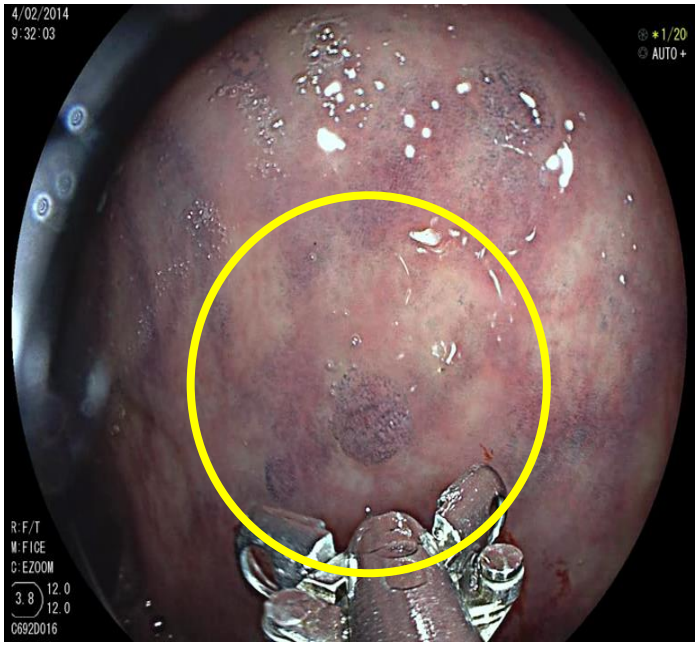

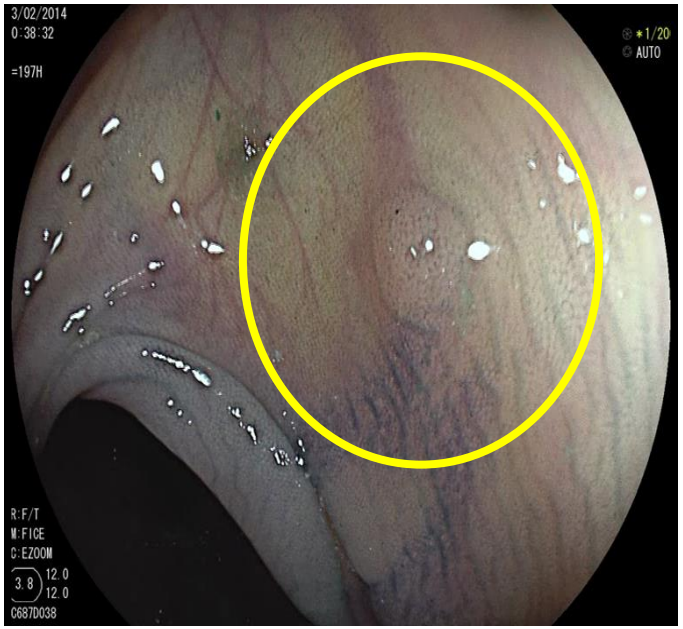

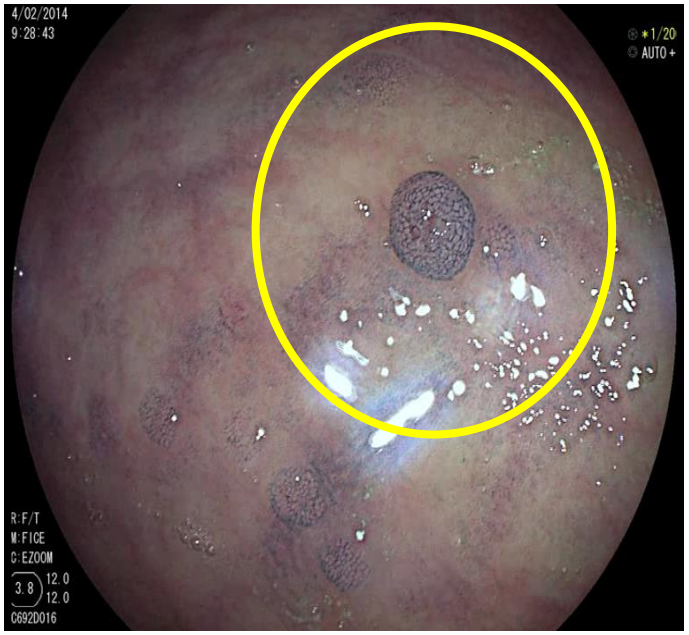

MB Main Target

Polyps not otherwise visible

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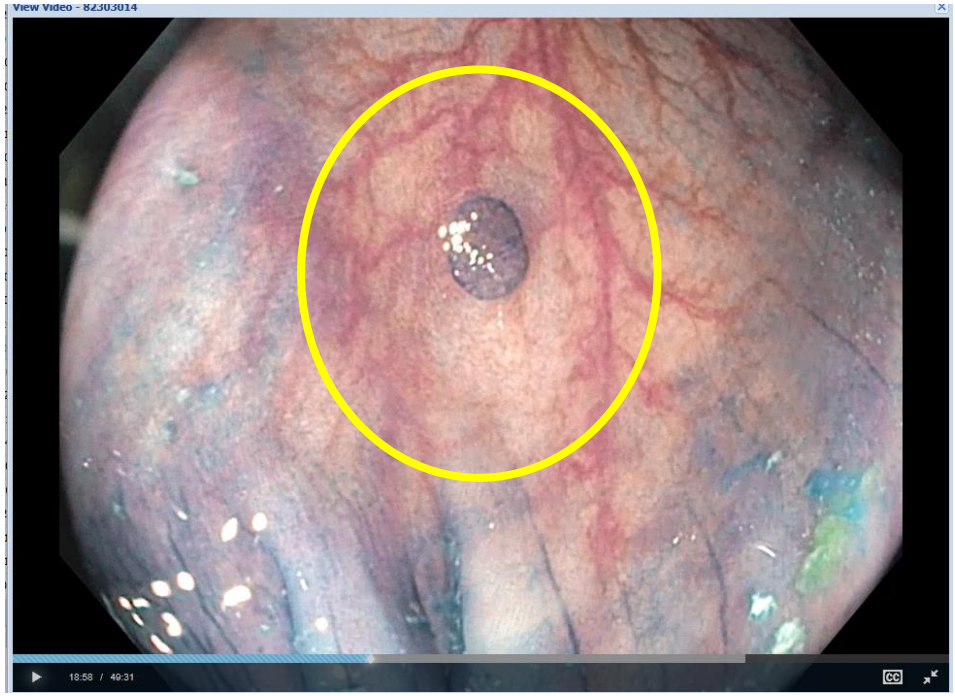

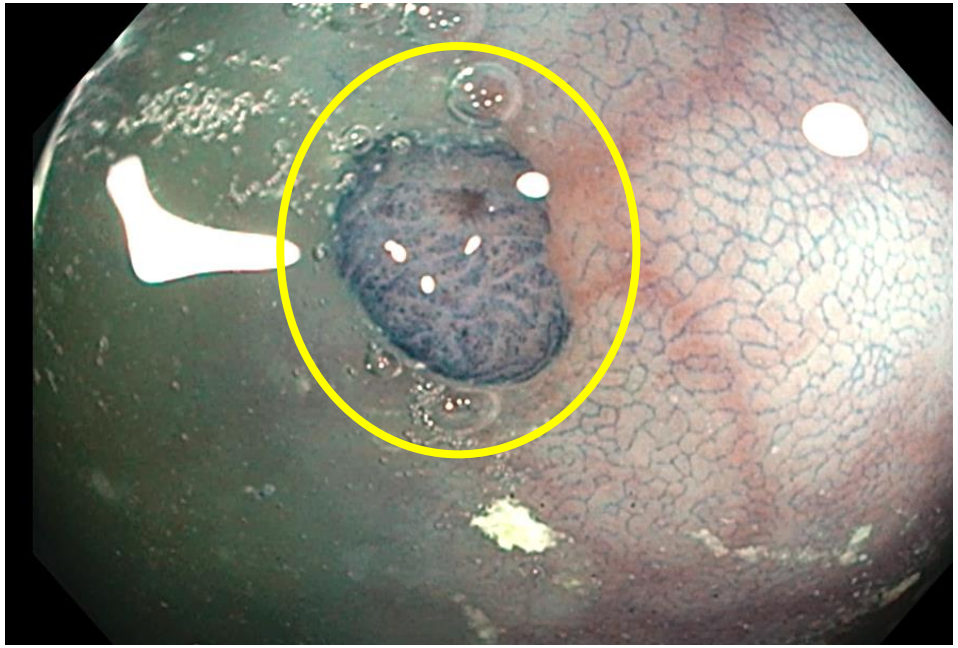

MB Main Target

Polyps not otherwise visible

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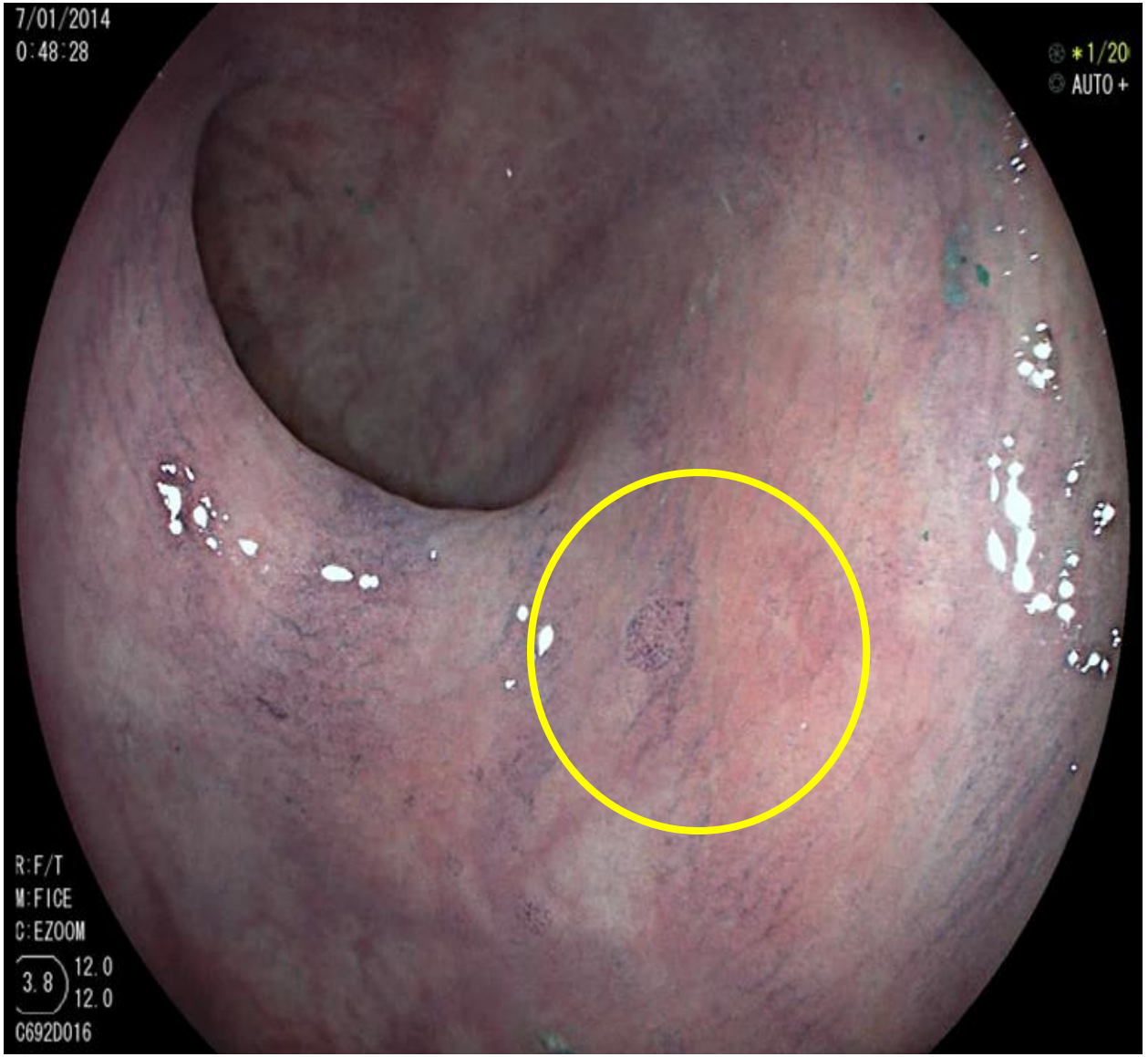

INVISIBLE WITHOUT MB

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MB clinical trial - status

- 20 sites between US and EU
- 1,270 patients, nearly completed, un-blinding forecasted by **end of June**
- Primary endpoint: proportion of subjects with at least one histologically proven adenoma or carcinoma vs. white light endoscopy
- Centralized Registration Application granted in EU under EMA
- Special Protocol Assessment (SPA) granted by FDA

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MB market potential estimate

MB Market potential	2017	2018	2019	2020	2021
non SSRI colonoscopies in US in m	12.6	12.8	12.9	13.1	13.2
market penetration	5%	10%	15%	20%	20%
minimum price	120	120	120	120	120
colonoscopies in EU	17.4	17.6	17.8	18.0	18.3
market penetration	5%	10%	15%	20%	20%
minimum price	50	50	50	50	50
colonoscopies in RoW	24.8	26.8	29.0	31.5	34.2
market penetration	0%	2,5%	5,0%	7,5%	10,0%
minimum price	30	30	30	30	30
total revenues in EUR m	**119.1**	**261.2**	**409.6**	**564.8**	**602.4**

Pipeline update
Products under development

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Monoclonal Antibody MMX

Monoclonal antibody MMX

- Proven preservation of Infliximab antibody activity in tablets and in colonic environment
- Currently developing industrial scale up of Bio-better
- API manufacturing scale up process ongoing
- Phase I/II trial to begin in 4Q 2016
- Potential indication: Ulcerative Colitis (maintenance)

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Cosmo 2016 Outlook

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Outlook
imminent growth catalysts

1) EU approval of SIC 8000

2) Successful conclusion of Phase III Rifamycin trial & start of NDA drafting

3) Start build-up of US GI commercial infrastructure

4) Conclusion of Phase III Methylene Blue clinical trial

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Outlook
Next strategic steps

1. Begin scouting for further opportunities and/or in-licensing to strengthen endoscopy/GI franchise
2. Out-license products in RoW
3. Further expand existing pipeline
4. Potentially list US GI on Nasdaq

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Outlook
Financials

- Historical revenues (CDM, Lialda, Uceris/Cortiment) of ~ € 75 million expected
- Net operating expenses of ~ € 52 million expected
- Potential additional revenues from Eleview™ and MB licensing in RoW
- Potential additional costs for set up of own organisation in USA

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2016 Guidance

EUR/Million	G 2016	
Traditional contract manufacturing and other revenue	9	
MMX® products manufacturing	39	
MMX® products royalties	25	
Revenues from products under development	100	(1)
Total Revenues	**173**	
Base Operating expenses	(49)	(2)
Profit based compensation	(11)	
EBITDA	**113**	
Depreciation and amortization	(3)	
Operating result	**110**	
Sale of "equity for product" stake		
Net financial income	2	
Profit before taxes	**112**	

Potentially replaceable with “equity for product” transactions

(1) Assumes SIC & MB licensed in RoW

(2) Operating expenses without bonuses and before expenses for US organisation

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Information	Contacts
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