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PLAINTIFFS TRIAL EXHIBIT
P-28846_00001

Pipeline Committee Meeting

October 19, 2011

PROJECTS FOR IN-HOUSE DEVELOPMENT

	Oxycodone/Naloxone Prolonged release tablets • 5 mg/2.5 mg, 1 mg/5 mg, 20 mg/10 mg and 40 mg/20 mg → **NEW PROJECT APPROVAL**
	Alendronate/Vitamin D • 70 mg/2800 IU and 70 mg/5600 IU → **NEW PROJECT APPROVAL**
	Fondaparinux solution for injection • 1.5 mg, 2.5 mg, 5 mg, 7.5 mg, 10 mg → **NEW PROJECT APPROVAL**
	Busulfan concentrate for solution for infusion • 6 mg/ml → **NEW PROJECT APPROVAL**

Project opportunity for Oxycodone/Naloxone

Status 19 October 2011 (PC Meeting for approval)

Project ID:	Oxycodone naloxone

Suggestion from PoM: Go for in house development

Product information

INN	Oxycodone / naloxone
Dosage form	Prolonged release tablet
Dosage strengths	5mg/2,5mg; 10mg/5mg; 20mg/10mg;
Indication(s)	Moderate to severe persistent pain
Brand name	Targin
Originator	Mundipharma

Product information (in 000s)

NPV (start of project)	€ 2.793,8
IRR (start of project)	49%
Peak sales	€ 8.039,7
Peak year	2017
IP Costs	
Registration	249,7
Total investments	€ 2.244,7
Development costs	
2011	€ 0,0
2012	€ 590,0
2013+	€ 1.405,0

Summary of opportunities (in 000s)

Countries (Top10 by sales)	Sales (2011)[1]	Growth (10/11)[1]	Data exclusivity*	Patent expiry**
Germany	112.525	25%	May 2014	TBC
United Kingdom	5.311	60%	May 2014	TBC
Switzerland	3.088	733%	May 2014	TBC
Spain	2.682	NA	May 2014	TBC
Italy	1.570	NA	May 2014	TBC
Norway	740	99%	May 2014	TBC
Finland	644	229%	May 2014	TBC
Canada	638	NA	May 2014	TBC
Sweden	389	416%	May 2014	TBC
Austria	236	57%	May 2014	TBC
Top 10 markets	127.824	35%		

[1] IMS MAT Q2 2011

*Assumption in BC is that data exclusivity is valid by May 2014 (and market exclusivity by May 2016) based on new Pharma Law. In case that old Pharma Law is relevant then 6 years countries could be available for submission from 2012.

** We can probably launch upon data exclusivity subject to sucesfull oposition of pending patent aplications

Brief Project Description & Target

To get PCM approval for in house development of Oxycodone / Naloxone retard tablets. Launch ASAP after data exclusivity expiry and potentialy even challenge / circumvent it

Timeline

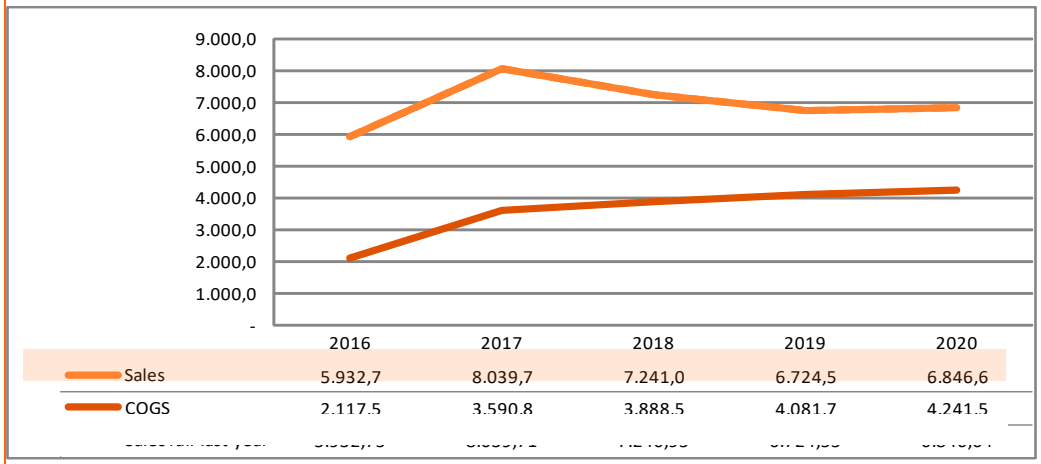
Project start	October-11
Dossier ready	Dec 2013
1st MA	EU 2016
1st Launch ()	2016

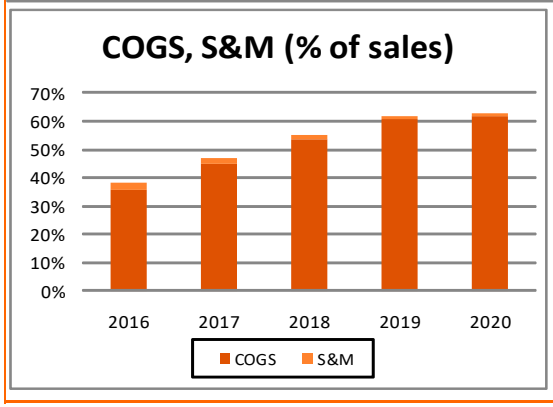
Overview project evaluation for Oxycodone/Naloxone

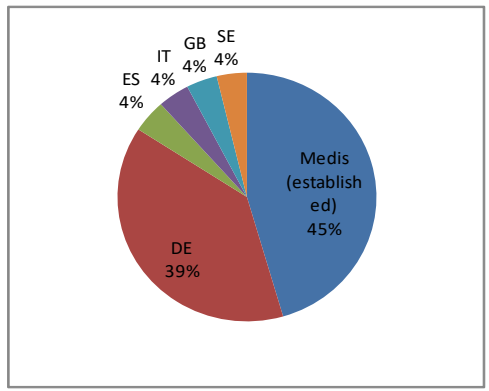
Status 19 October 2011 (PC Meeting for approval)

Financial valuation ('000 EUR) **B (2/5)**

Project name	**Oxycodone naloxone**				
First launch	- € May 2016		Project NPV		2.794
Start of investment	2011		Peak sales (in year)	(2017)	8.040
Expected investment	2.245		Present value of		
Sales total	37.689		final working capital		376







Strategic fit / opportunity 1 ☐ 2 ☐ 3 ■

Market access

Majority of sales in pharmacy segment, fit with the rest of pain portfolio

Competition (Low/Med/High):

Less competitors expected

Therapeutic / pharmaceutical relevance:

Improved profile against mono product

Risk assessment 1 ☐ 2 ■ 3 ☐

R&D risks:

Medium to high risk

IP risks:

Low to meidum

Commercial risks:

No

Qualitative evaluation

Overall score B

Recommendation from PoM Go for development

This is important line extension of oxycodone. Together with fenthanyl, oxycodone is the most important product in severe pain. Nice fit with existing pain segment. Early launch potential exist that should be investigated more deeply.

Financial assessment for Oxycodone/Naloxone

Status 19 October 2011 (PC Meeting for approval)

EUR '000	2012	2013	2014	2015	2016	2017	2018	2019	2020	Total
Total Sales	-	-	-	600,0	5.932,7	8.039,7	7.241,0	6.724,5	6.846,6	37.689,1
% growth						36%	-10%	-7%	2%	
CoGS	-	-	-	-	2.117,5	3.590,8	3.888,5	4.081,7	4.241,5	19.346,0
Gross Margin	**-**	**-**	**-**	**600,0**	**3.815,3**	**4.448,9**	**3.352,4**	**2.642,8**	**2.605,1**	**18.343,1**
% sales				100%	64%	55%	46%	39%	38%	49%
Selling & Marketing (S&M)	-	-	-	-	144,8	173,9	108,7	66,7	70,8	588,9
EBITDA	**-**	**-**	**-**	**600,0**	**3.670,5**	**4.274,9**	**3.243,7**	**2.576,2**	**2.534,3**	**17.754,1**
% sales				100%	62%	53%	45%	38%	37%	47%
Working capital	-	-	-	-	2.304,9	2.420,6	2.321,2	2.255,4	2.322,0	
Increase in working capital	-	-	-	-	2.304,9	115,7	-99,4	-65,7	66,5	2.329,3
CAPEX	590,0	1.405,0	-	-	-	-	-	-	-	1.995,0
Capitalised registrations	-	-	124,9	124,9	-	-	-	-	-	249,7
Free cash flow	**-590,0**	**-1.405,0**	**-124,9**	**475,1**	**1.365,6**	**4.159,3**	**3.343,2**	**2.641,9**	**2.467,8**	**13.180,2**
PV of Cash Flows	**-491,7**	**-975,7**	**-72,3**	**229,1**	**548,8**	**1.392,9**	**933,0**	**614,4**	**478,3**	**2.793,8**

Sum of PV of Cash Flows / NPV	**2.793,8**
Present value of final working capital	**376,2**
IRR	**49%**

Excluding any tax implications

Overview by country for Oxycodone/Naloxone

Status 19 October 2011 (PC Meeting for approval)

Country	2015	2016	2017	2018	2019	2020	2021	Total	NPV
Total	600	5.933	8.040	7.241	6.725	6.847	2.305	37.689	2.794
Germany	-	2.320	3.588	2.807	2.237	2.368	789	14.109	2.257
United Kingdom	-	154	236	275	302	328	115	1.409	93
Sweden	-	153	237	250	293	325	114	1.373	130
Italy	-	152	251	272	318	334	117	1.444	113
Spain	-	179	276	292	334	351	123	1.555	175
Medis (established ma	600	2.975	3.452	3.345	3.241	3.141	1.047	17.799	1.490

Excluding any tax implications

Assumptions on key drivers of sales for Oxycodone/Naloxone

Status 19 October 2011 (PC Meeting for approval)

actavis
think smart medicine

Originator market development, market entry & launch situation

Oxycodone / Naloxone was approved / launched in Germany by Mundipharma in 2006. Launch in rest of Europe delayed to 2009/2010. It was not launched in USA and Japan.

Current European sales is Euro 128 m and growing 35% in value and 40% in volume. Total oxycodone sales (including both mono and combo products) in Europe is 459 m (+15%). Growth is mainly driven by combo product although even plain oxycodone is still growing.

Gx market formation and Actavis positioning

Gx market will be formed in EU latest in 2016 but potentially it could be much sooner

Limited competition expected.

Early launch potential in case of circumvating data exclusivity. To be additionally investigated. Oral form of naloxone not marketed.

Excluding any tax implications

Development and Regulatory Oxycodone/Naloxone

Status 19 October 2011 (PC Meeting for approval)

Development

Due to the large number of BE studies and complicated manifacturing of the brand (melt extrusion) this is consideret a moderate to difficult development with significant risks.

Assumption in BC is that dossier is ready by the end of 2013.

Assumed development budget is close to 2 mil

Regulatory and IP

Preliminary evaluation suggests that its hard to establish the primary marketing constraint a generic of Oxycodone / Naloxone. Data exclusivity could be a limiting factor but it is not clear which Regulation/Directives should be referred to, so data exclusivity will either follow the 6/10 or 8+2+(1). The 40/20 strength is currently patented through most of Europe till 2026, however Actavis has until April 2012 to oppose this patent at EPO, potentially opening the market earlier.

It might be possible to circumvent DE by referring to each active, however in this case it is expected to be hard since Naloxone is not available in oral dosage form by itself.

Excluding any tax implications

Project opportunity for Alendronic/colecalciferol

Status 19 October 2011 (PC Meeting for approval)

actavis
think smart medicine

Project ID:	alendronic acid; colecalciferol

Suggestion from PoM: Go for in house development

Product information

INN	Alendronic acid + colecalciferol
Dosage form	Tablets
Dosage strengths	70mg/2800IU and 70mg/5600IU
Indication(s)	Osteoporosis
Brand name	Fosavance
Originator	Merck

Product information (in 000s)

NPV (start of project)	€ 5.369,7
IRR (start of project)	110%
Peak sales	€ 6.048,0
Peak year	2018
IP Costs	
Registration	306,5
Total investments	€ 1.171,5
Development costs	
2011	€ 0,0
2012	€ 865,0
2013+	€ 0,0

Summary of opportunities (in 000s)

Countries (Top10 by sales)	Sales (2011)[1]	Growth (10/11)[1]	Data exclusivity	Patent expiry
France	57.320	-22%	24.8.2015.	Open
Italy	39.794	11%	24.8.2015.	Open
Spain	36.094	1%	24.8.2015.	Open
Australia	21.248	16%	TBD	Open
Portugal (Retail)	18.107	-16%	24.8.2015.	Open
Germany	11.407	-8%	24.8.2015.	Open
Belgium	11.133	-24%	24.8.2015.	Open
Greece (Retail)	8.403	-15%	24.8.2015.	Open
Turkey	5.991	-1%	24.8.2015.	Open
Netherlands	5.463	0%	24.8.2015.	Open
Top 10 markets	214.962	-8%		

[1] IMS MAT Q2 2011

Although combo product sales value is falling down, volume is increasing slightly. Total alendronate market (including mono product) in Europe is Euro 0,5bn slightly decreasing in volume. Combination product represent 44% of value and 25% of total European volume.

Brief Project Description & Target

To develop dossier for combo product. In case of circumventing data exclusivity there is a chance to come first to market with fixed combination

Timeline

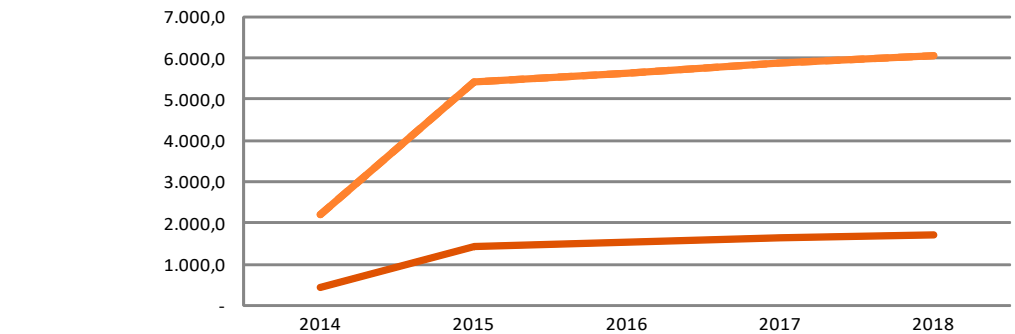
Project start	October 2011
Dossier ready	April-13
1st MA	Q3 2013
1st Launch ()	Sep 2014

Overview project evaluation for Alendronic/colecalciferol

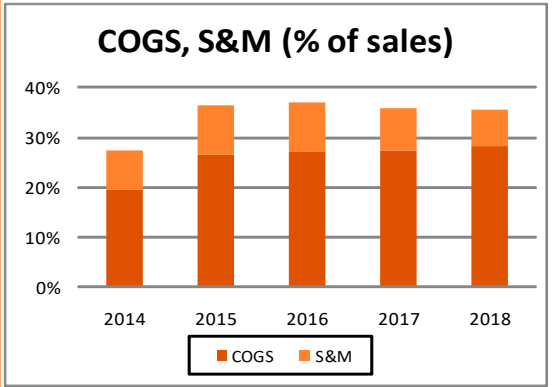
Status 19 October 2011 (PC Meeting for approval)

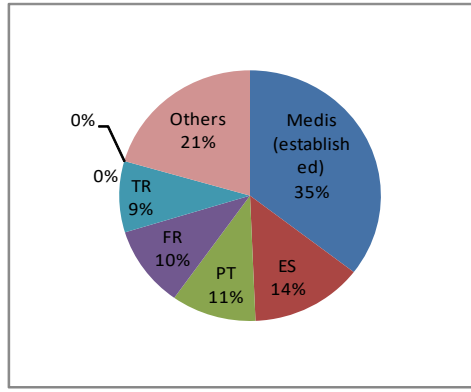
Financial valuation ('000 EUR) **A (3/4)**

Project name	**alendronic acid; colecalciferol**				
First launch	- €	Sep 2014	Project NPV		5.370
Start of investment		2011	Peak sales (in year)	(2018)	6.048
Expected investment		1.172	Present value of		
Sales total		29.663	final working capital		441



	2014	2015	2016	2017	2018
Sales	2.209,3	5.410,8	5.645,6	5.888,2	6.048,0
COGS	434,1	1.440,5	1.527,9	1.622,6	1.716,6





B (4/6)

Strategic fit / opportunity 1 ☐ 2 ☐ 3 ■

Market access:
No limitations; Defined sales channel. Fits well into female heatlhcare

Competition (Low/Med/High):
We have chance to be the first to market. Mono alendronate market is crowded but less competitors expected

Therapeutic / pharmaceutical relevance: Certain advantage if offered for the same price as mono product

Risk assessment 1 ■ 2 ☐ 3 ☐

RD risk
Difficult to make product.

IP risk
Risk related to data exclusivity circumventing

Commercial risks:
No commercial risk is associated with this product apart from price erosion. Prices of combo already went down significantly

Qualitative evaluation

Overall score

Recommendation from PoM: Go

We recommend to go for in-house development due to solid financials and nice fit of product with female health. Chance to be the first generic to market.

Financial assessment for Alendronic/colecalciferol

Status 19 October 2011 (PC Meeting for approval)

EUR '000	2012	2013	2014	2015	2016	2017	2018	Total
Total Sales	-	500,0	2.209,3	5.410,8	5.645,6	5.888,2	6.048,0	29.662,9
% growth				145%	4%	4%	3%	
CoGS	-	-	434,1	1.440,5	1.527,9	1.622,6	1.716,6	7.921,6
Gross Margin	**-**	**500,0**	**1.775,2**	**3.970,3**	**4.117,7**	**4.265,7**	**4.331,4**	**21.741,3**
% sales		100%	80%	73%	73%	72%	72%	73%
Selling & Marketing (S&M)	-	-	171,5	529,9	558,4	496,6	445,0	2.499,4
EBITDA	**-**	**500,0**	**1.603,7**	**3.440,4**	**3.559,3**	**3.769,0**	**3.886,5**	**19.241,9**
% sales		100%	73%	64%	63%	64%	64%	65%
Working capital	-	-	1.325,7	1.584,5	1.717,8	1.858,1	1.908,6	
Increase in working capital	-	-	1.325,7	258,8	133,3	140,3	50,5	1.895,1
CAPEX	865,0	-	-	-	-	-	-	865,0
Capitalised registrations	-	153,3	153,3	-	-	-	-	306,5
Free cash flow	**-865,0**	**346,7**	**124,7**	**3.181,6**	**3.426,0**	**3.628,7**	**3.835,9**	**16.175,3**
PV of Cash Flows	**-720,8**	**240,8**	**72,1**	**1.534,4**	**1.376,8**	**1.215,3**	**1.070,5**	**5.369,7**

Sum of PV of Cash Flows / NPV	**5.369,7**
Present value of final working capital	**440,7**
IRR	**110%**

Excluding any tax implications

Overview by country for Alendronic/colecalciferol

Status 19 October 2011 (PC Meeting for approval)

Country	2013	2014	2015	2016	2017	2018	Total	NPV
Total	500	2.209	5.411	5.646	5.888	6.048	29.663	5.370
France	-	259	428	483	528	592	2.724	666
Spain	-	130	586	738	854	854	3.625	1.049
Italy	-	48	155	164	172	180	835	221
Serbia	-	47	164	219	297	297	1.222	96
Netherlands	-	127	199	121	87	89	684	195
Czech Republic	-	57	223	254	286	318	1.351	210
Romania	-	19	125	147	149	137	655	101
Portugal	-	117	669	605	544	514	2.742	698
Australia	-	19	99	164	232	300	1.066	159
Turkey	-	73	352	444	516	579	2.394	347
Denmark	-	46	131	83	52	47	386	62
Hong Kong	-	27	163	213	247	299	1.172	187
Singapore	-	38	108	102	110	119	564	36
Medis (established markets)	500	1.203	2.009	1.908	1.813	1.722	10.245	2.067

Excluding any tax implications

Development and Regulatory for Alendronic/colecalciferol

Status 19 October 2011 (PC Meeting for approval)

actavis
think smart medicine

Development

Estimated development budget is Euro 865k. BE study is 400k, API 50k, other external costs 50k and internal costs 350k

A combination of unusual manufacturing method, very low dose, instability and high BE variability makes this a potentially risky and difficult development

Regulatory and IP

Preliminary IP evaluation suggests that in the EU the primary marketing constraint for Fosavance is the data exclusivity expiring 24-Aug-2015. Product patent expired and dose patent (for 70mg) was recently revoked, combination patent is invalid.

It may be possible to avoid data exclusivity in case we refer to the data for each compound rather than the combination but this has to be evaluated in more details

Excluding any tax implications

Assumptions on key drivers of sales for Alendronic/colecalciferol

Status 19 October 2011 (PC Meeting for approval)

actavis
think smart medicine

Originator market development, market entry & launch situation

Merck launch combination product in order to prolong life cycle of alendronate franchise. Total alendronate sales (including mono product) in Europe is 0,5 bn

European sales of Fosavance is 220 m Euro. It is mature in volume slightly decreasing in value due to price erosion.

No generics with combination (with exception of combo pack with vit D3 and calcium in couple of markets) however huge competition with plain alendronate.

Gx market formation and Actavis positioning

Actavis was late with plain alendronate and have chance to strongly enter alendronate segment with combo product..

In case of circumventing data exclusivity there is potential to be the first to market with generic combination product. Data exclusivity probably not sustainable for this product theefore we estimate market formation before 2015 (data exclusivity expiry)

Excluding any tax implications

Busulfan concentrate for solution for infusion - status

9 Oktober 2011

PoM evaluation results

- Discussed as development for US and possible extension for Europe

- Interest is very limited: DE, FR, IT and NO only, other EU markets rejected.

- Potential interest for Italy only.

GLOBAL IN-LICENSING PROJECTS

	Rilmenidine tablets • 1 mg **→ NEW PROJECT APPROVAL**
	Perindopril/Indapamide • 2 mg/0.625 mg, 4 mg/1.25 mg, 8 mg/2.5 mg **→ NEW PROJECT APPROVAL**
	Candesartan/HCT film-coated tablets • 32 mg/12.5 mg and 32 mg/25 mg **→ NEW STRENGTHS: Extension of current IL agreement**
	Tianeptine tablets • 12.5 mg **→ NEW PROJECT: Recommendation no go**
	Cilostazol tablet • 50 mg and 100 mg **→ NEW PROJECT: Recommendation no go**

Project opportunity for Rilmenidine

Status 19 October 2011 (PC Meeting for approval)

Project ID: Rilmenidine

Suggestion from PoM: Go

Product information

INN	Rilmenidine
Dosage form	tablets
Dosage strengths	1mg
Indication(s)	Hypertension
Brand name	Hyperium, Tenaxum
Originator	Servier

Product information (in 000s)

NPV (start of project)	€ 1.835,9
IRR (start of project)	181%
Peak sales	€ 2.693,6
Peak year	2017
IP Costs	
Registration	18,4
Total investments	€ 98,4
Development costs	
2011	€ 40,0
2012	€ 20,0
2013+	€ 20,0

Summary of opportunities (in 000s)

Countries (Top10 by sales)	Sales (2010)1	Growth (09/10)1	Data exclusivity	Market exclusivity
France	30.378	-3%	*Launched by Actavis*	
Czech	8.707	14%	Open	Open
Hungary	5.532	9%	Open	Open
Slovakia	4.654	14%	Open	Open
Austria	3.932	10%	Open	Open
Lithuania	2.829	12%	Open	Open
Portugal	1.915	-7%	Open	Open
Turkey	929	6%	Open	Open
Russia	853	-1%	Open	Open
Latvia	801	10%	Open	Open
Romania	792	10%	Open	Open
Bulgaria	590	49%	Open	Open
	61.913	4%		

Brief Project Description & Target

A niche local IL opportunity for Hungary. PoM evaluated interest in other markets, too.

Dossier supplier is Delpharm/IDL (France).

Actavis is already selling the product in France from the same supplier. 3Y 2010 plan sales for 2011 is 220k EUR

Timeline

Project start	Oct. 2011
Dossier ready	available
1st MA	Q1 2013
1st Launch (Hungary)	2013

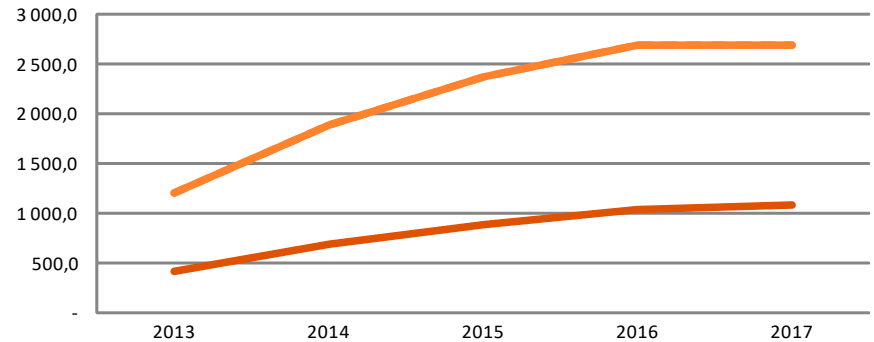
1 Current molecule/form expectation based upon 2010; in '000 EUR

Overview project evaluation for Rilmenidine

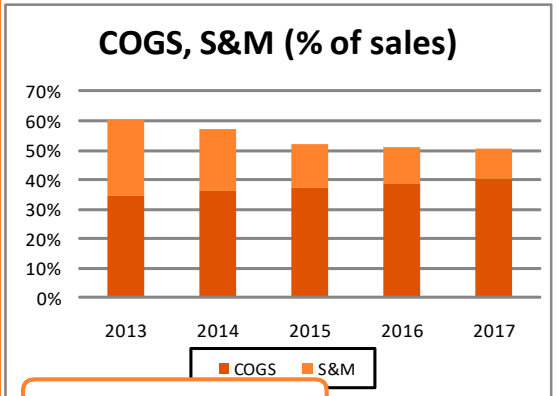
Status 19 October 2011 (PC Meeting for approval)

Financial valuation ('000 EUR) **C (1/4)** **A (5/6)**

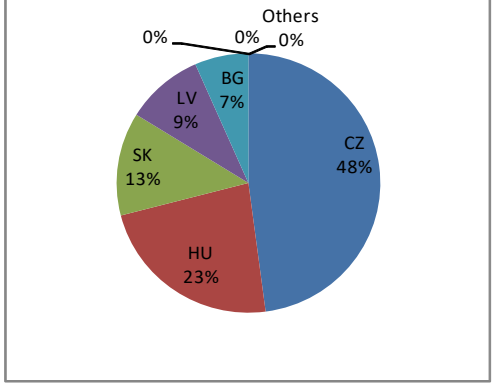
Project name	**Rilmenidine**			
First launch	Hungar Jun 2013	Project NPV		1 836
Start of investment	2011	Peak sales (in year)	(2017)	2 694
Expected investment	98	Present value of		
Sales total	10 824	final working capital		135



	2013	2014	2015	2016	2017
Sales	1 199,9	1 877,1	2 364,1	2 689,7	2 693,6
COGS	413,4	683,4	878,1	1 041,4	1 079,2



Quantitative evaluation



Strategic fit / opportunity 1 ☐ 2 ■ 3 ☐

Market access: No unusual complications

Competition (Low/Med/High): Low/Moderate

Therapeutic / pharmaceutical relevance: At a dose of 1 mg given as a single daily administration during controlled trials, the incidence of side effects was comparable to that observed with

Risk assessment 1 ☐ 2 ☐ 3 ■

R&D risks: No

IP risks: Low (to be re-confirmed by IP after project approval)

Commercial risks: Low

Qualitative evaluation

Overall score B

Recommendation from PoM Go for IL

Explanation

A niche local opportunity, which is a good fit to the cardio portfolio of the selected markets.
Limitted competition and low price erosion are expected.

Financial assessment for Rilmenidine

Status 19 October 2011 (PC Meeting for approval)

EUR '000	2011	2012	2013	2014	2015	2016	2017	2018	Total
Total Sales	-	-	1 199,9	1 877,1	2 364,1	2 689,7	2 693,6	-	10 824,4
% growth				36%	21%	12%	0%		
CoGS	-	-	413,4	683,4	878,1	1 041,4	1 079,2	-	4 095,5
Gross Margin	**-**	**-**	**786,5**	**1 193,7**	**1 486,0**	**1 648,3**	**1 614,4**	**-**	**6 728,9**
% sales			66%	64%	63%	61%	60%		62%
Selling & Marketing (S&M)	-	-	310,4	389,4	358,3	333,0	288,1	-	1 679,3
EBITDA	**-**	**-**	**476,1**	**804,2**	**1 127,6**	**1 315,3**	**1 326,3**	**-**	**5 049,6**
% sales			40%	43%	48%	49%	49%		47%
Working capital	-	-	354,7	558,7	708,3	816,0	828,8	483,5	
Increase in working capital	-	-	354,7	204,0	149,6	107,7	12,9	-345,3	483,5
CAPEX	40,0	20,0	20,0	-	-	-	-	-	80,0
Capitalised registrations	18,4	-	-	-	-	-	-	-	18,4
Free cash flow	**-58,4**	**-20,0**	**101,4**	**600,2**	**978,1**	**1 207,6**	**1 313,4**	**345,3**	**4 467,7**
PV of Cash Flows	**-58,4**	**-16,7**	**70,4**	**347,3**	**471,7**	**485,3**	**439,9**	**96,4**	**1 835,9**

Sum of PV of Cash Flows / NPV	**1 835,9**
Present value of final working capital	**134,9**
IRR	**181%**

Excluding any tax implications

Overview sales and NPVs by country for Rilmenidine

Status 19 October 2011 (PC Meeting for approval)

Sales per year and NPV (in T EUR)

Country	2013	2014	2015	2016	2017	Total	NPV	Market Size YBL (EUR)	PoM Recommendation
Total	1 200	1 877	2 364	2 690	2 694	**10 824**	**1 836**	28 213	
Hungary	186	423	584	661	642	**2 747**	**475**	7 192	Go
Czech Republic	698	925	1 096	1 213	1 255	**5 724**	**1 017**	11 319	Go
Latvia	63	127	208	312	327	**1 230**	**199**	3 338	Go
Bulgaria	55	138	168	189	164	**782**	**161**	778	Go
Slovakia (Slovak Republic)	197	264	309	315	306	**1 513**	**190**	5 585	Go
Austria									Rejacted by Market
Portugal									Rejacted by Market
Turkey									Rejacted by Market
Romania									Rejacted by Market

Note: DPs are not included in NPV calculation by country

Potential Deal Structure for Rilmenidine

Status 19 October 2011 (PC Meeting for approval)

Originator market development, market entry & launch situation

Servier has a relatively smooth market development without much investment. The market is almost flat, with small growth (3% over the last 2 years). Teva has launched in April 2011 in CZ, as a first generic company, no other company has MA.

Rilmenidine, an oxazoline compound with antihypertensive properties, acts on both medullary and peripheral vasomotor structures. It shows greater selectivity for imidazoline receptors than for cerebral alpha2-adrenergic receptors, distinguishing it from reference alpha2-agonists.

Gx market formation and Actavis positioning

The molecule is of regional importance, thus only a few competitors are expected, Teva launched this year.
Due to the limitted competition, the price erosion will be about 20-30% of the originatory.

Potential Deal Structure for Rilmenidine

Status 19 October 2011 (PC Meeting for approval)

actavis
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IL terms

Stendard IL from Delpharm/IDL - a French sub-contracting manufacturer and Business development CRO has developed and registered in France a Rilmenidine; MRP out of our exisitng MA in France
The cost of the sale of this registration file is 80 K EUR for Czech Republic, Latvia, Bulgaria, Slovakia and Hungary.
Actavis is already selling the product in France since 19th of May, 2010.
Down payment 80 K EUR payable as follows:
1/3 at signature; 1/3 at MRP day 90; 1/3 at first launch
Supply price:
1,48 euro box of 30 tabs
4,33 euro box of 90 tabs

Regulatory and IP

The registration file has been updated recently;
French MA being delivered in 2005;
The registration file is in eCTD format and in English version.

Based on RA experience in FR would take from 12 – 18 month to start MRP.
Then MRP 3 months and national phase from 1 to 6 months.

Project opportunity for Perindopril+Indapamide

Status 19 October 2011 (PC Meeting for approval)

actavis
think smart medicine

Project ID:	Perindopril+Indapamide

Suggestion from PoM: Go Go

Product information

INN	Perindopril+Indapamide
Dosage form	tablets
Dosage strengths	2mg/0,625mg, 4mg/1,25mg
Indication(s)	Essential hypertension
Brand name	Pretanix combi; Noliprel
Originator	Servier

Product information (in 000s)

NPV (start of project)	€ 1.336,6
IRR (start of project)	163%
Peak sales	€ 1.859,2
Peak year	2016
IP Costs	
Registration	57,5
Total investments	€ 177,5
Development costs	
2011	€ 40,0
2012	€ 20,0
2013+	€ 60,0

Summary of opportunities (in 000s)

Countries (Top10 by sales)	Sales (2010)[1]	Growth (09/10)[1]	Data exclusivity	Market exclusivity
France	72.079	-20%	Open	TBC
Australia	26.549	19%	Open	TBC
Russia	24.123	11%	Open	TBC
Italy	19.067	-106%	Open	TBC
Turkey	18.699	-31%	Open	TBC
Germany	14.637	-14%	Open	TBC
Hungary	13.366	27%	Open	TBC
Portugal	12.391	8%	Open	TBC
Romania	8.320	24%	Open	TBC
Slovakia	6.961	6%	Open	TBC
Belgium	6.736	-26%	Open	TBC
Spain	6.160	-19%	Open	TBC
	229.088	-13%		

Brief Project Description & Target

Local exclusive IL opportunity for Hungary (from Galex (SL)), was already approved. MA transfer expected by the end of the year.

PoM evaluated the interest from other markets, too.

MA transfer for Poland and Slovakia and MRP for the other markets.

Timeline

Project start	Q2 2011
Dossier ready	available
1st MA	available
1st Launch (Hungary	Q1 2012

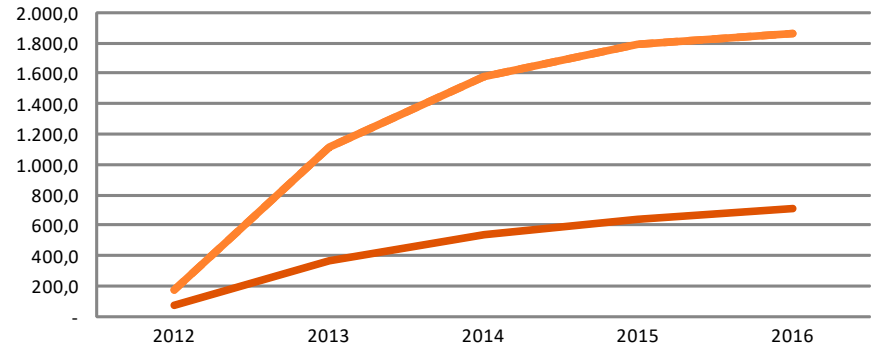
1 Current molecule/form expectation based upon 2010; in '000 EUR

Overview project evaluation for Perindopril+Indapamide

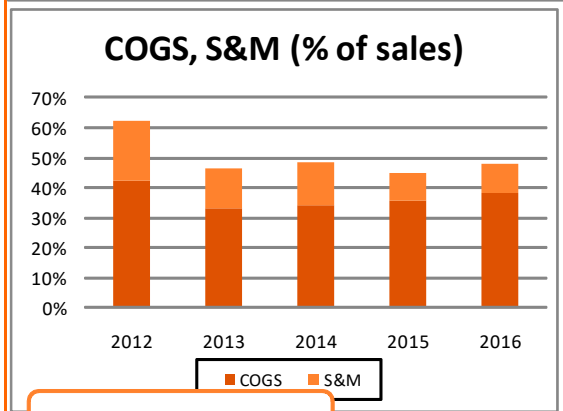
Status 19 October 2011 (PC Meeting for approval)

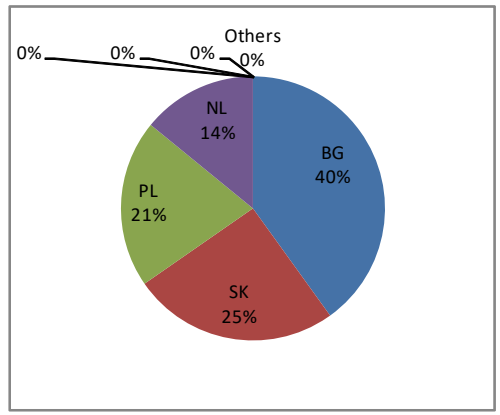
Financial valuation ('000 EUR) **C (1/4)** **B (4/6)**

Project name	**Perindopril+Indapamide**				
First launch	Hungar	Jan 2012	Project NPV		1.337
Start of investment		2011	Peak sales (in year)	(2016)	1.859
Expected investment		177	Present value of		
Sales total		6.516	final working capital		160



	2012	2013	2014	2015	2016
Sales	171,5	1.114,6	1.578,0	1.793,2	1.859,2
COGS	72,4	371,1	540,3	643,4	713,0





Quantitative evaluation

Strategic fit / opportunity 1 ☐ 2 ■ 3 ☐

Market access: No unusual limitations

Competition (Low/Med/High): Medium.
Originator (Srevier) is on the market its own generic (EGIS), Krka entered in 2007

Therapeutic / pharmaceutical relevance: Perindopril/Indapamid has a predictable and sustained blood pressure effect giving a 24-h cover without excessive peak effect or poor trough effect.

Risk assessment 1 ☐ 2 ■ 3 ☐

R&D risks: No

IP risks: IP to make detailed evaluation, when the project is approved

Commercial risks: Some of the Gx have already launched, Servier is trying to switch the market to Perindopril Arginine.

Qualitative evaluation

Overall score C

Recommendation from PoM

Explanation
Local Cardio portfolio fit

Financial assessment for Perindopril+Indapamide

Status 19 October 2011 (PC Meeting for approval)

EUR '000	2011	2012	2013	2014	2015	2016	2017	Total
Total Sales	-	171,5	1.114,6	1.578,0	1.793,2	1.859,2	-	6.516,5
% growth		100%		29%	12%	4%		
CoGS	-	72,4	371,1	540,3	643,4	713,0	-	2.340,2
Gross Margin	**-**	**99,1**	**743,5**	**1.037,7**	**1.149,8**	**1.146,2**	**-**	**4.176,3**
% sales		58%	67%	66%	64%	62%		64%
Selling & Marketing (S&M)	-	34,4	146,7	222,1	164,6	180,1	-	747,8
EBITDA	**-**	**64,7**	**596,8**	**815,6**	**985,2**	**966,1**	**-**	**3.428,5**
% sales		38%	54%	52%	55%	52%		53%
Working capital	-	93,7	278,4	389,8	448,3	479,0	479,0	
Increase in working capital	-	93,7	184,8	111,4	58,4	30,7	-	479,0
CAPEX	40,0	20,0	60,0	-	-	-	-	120,0
Capitalised registrations	57,5	-	-	-	-	-	-	57,5
Free cash flow	**-97,5**	**-49,0**	**352,0**	**704,2**	**926,8**	**935,5**	**-**	**2.772,0**
PV of Cash Flows	**-97,5**	**-40,8**	**244,4**	**407,5**	**446,9**	**375,9**	**-**	**1.336,6**

Sum of PV of Cash Flows / NPV	**1.336,6**
Present value of final working capital	**160,4**
IRR	**163%**

Excluding any tax implications

Overview sales and NPVs by country for Perindopril+Indapamide

Status 19 October 2011 (PC Meeting for approval)

Sales per year and NPV (in T EUR)

Country	2012	2013	2014	2015	2016	Total	NPV	Market Size YBL (EUR)	PoM Recommendation
Total	172	1.115	1.578	1.793	1.859	**6.516**	**1.337**	32.668	
Bulgaria	-	357	643	769	769	**2.538**	**810**	2.750	Go
Netherlands	-	220	222	224	227	**893**	**297**	4.827	Go
Slovakia (Slovak Republic)	130	302	371	396	403	**1.602**	**333**	6.265	Go
Italy	-	37	43	49	51	**180**	**54**	15.254	Go
Poland	41	198	298	355	410	**1.303**	**102**	3.573	Go
France									Rejected by Market
Russia									Rejected by Market
Turkey									Rejected by Market
Germany									Rejected by Market
Portugal									Rejected by Market
Romania									Rejected by Market
Spain									Rejected by Market
Switzerland									Rejected by Market
Ireland									Rejected by Market
UK									Rejected by Market

Note: DPs are not included in NPV calculation by country

Potential Deal Structure for Perindopril+Indapamide

Status 19 October 2011 (PC Meeting for approval)

Originator market development, market entry & launch situation

Perindopril/Indapamide is a combination therapy for the treatment of Essential hypertension, developed by Servier.

Originator switched to a diferent salt (arginine) in order to block the entrance of Gx.

Gx market formation and Actavis positioning

Competitors already on the market, dispite IP.

One of leading molecule in the segment for CEE. On the marke is already established with a few Gx competitors.

Potential Deal Structure for Perindopril+Indapamide

Status 19 October 2011 (PC Meeting for approval)

Development

Standard IL from Galex (Slovenia). Producer is in Germany

Down payment 120 K EUR payable as follows:

1/3 at signature

1/3 at first MA grant

1/3 at launch

Supply price:

2mg/0,625 x 30 tabs - 1,11 EUR

4mg/1,25 x 30 tabs - 1,36 EUR EXW Germany

Regulatory and IP

The therapeutic indications for original product and some generics are "Treatment of essential hypertension in patients whose blood pressure is not adequately controlled on perindopril alone. The Public Assessment Reports are claiming "Each of the active ingredients reduces blood pressure and they work together to control your blood pressure".

As the "essential hypertension" (controlling blood pressure) arises out of "arteriolo-capillary microcirculatory disorders", the generic combination of Perindopril/Indapamide should not infringe the patent EP1032414 -WO-09925374. The generic combination does not treat "arteriolo-capillary microcirculatory disorders".

The patent that regard the generics is the already revoked for AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE TR AL LT LV MK RO SI, patent EP1296947 for alpha crystalline form of Perindopril. There are valid patents and pending application that are analogue to EP1296947. The equivalent patent EA005008 is valid in AM, AZ, BY, KG, KZ, MD, RU, TJ and TM. The expiry date is 6-Jul-2021.

Project opportunity for Candesartan+HCTZ 32/12,5mg and 32/25mg

Status 19 October 2011 (PC Meeting for approval)

Current overview includes costs associated with registration on all Actavis Candesartan markets and DP to Siegfred

actavis
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Project ID:	Candesartan+HCTZ Higher Strengths Only

Suggestion from PoM: Go

Product information

INN	Candesartan+HCTZ
Dosage form	tablets
Dosage strengths	32/12,5mg and 32/25mg
Indication(s)	CVS
Brand name	Atacand
Originator	AZ

Product information (in 000s)

NPV (start of project)	-
IRR (start of project)	-
Peak sales	€ 717,2
Peak year	2017
IP Costs	
Registration	**€ 243**
Total investments	**€ 343**
Dossier Fee	
2011	**€ 33**
2012	**€ 33**
2013+	**€ 34**

Summary of opportunities (in 000s)

Countries (Top10 by sales)	Sales (2010)[1]	Growth (09/10)[1]	Data exclusivity	Market exclusivity
Germany	21 409	>100%	Open	Apr.2011
Spain	7 551	>100%	Open	Apr.2011
Italy	6 857	>100%	Open	Apr.2011
Australia	3 252	>100%	Open	Apr.2011
Switzerland	1 382	>100%	Open	Apr.2011
Austria	1 135	>100%	Open	Apr.2011
Sweden	960	>100%	Open	Apr.2011
Greece	904	>100%	Open	Apr.2011
Turkey	888	>100%	Open	Apr.2011
Finland	708	>100%	Open	Apr.2011
Denmark	229	>100%	Open	Apr.2011
Norway	54	>100%	Open	Apr.2011
	45 331	**650%**		

- Candesartan/HTCZ is one of the key launched for 2012 and all markets on which the higher strengths were launched, see them as crutial for the project

- The therapeutic guidelines are moving to the higher strengths

- We would like to have approval for registration on all Candesartan markets - FI; SE; NO; IS; PT; IT; FR; DE; AT; CH; BG; LT; EE; LV and NL; DK; IE; UK; ES; HU; PL; SK.

- The total regulatory cost for the above markets is expected to be 243k EUR.

Brief Project Description & Target

We already have the other strengths from Siegfred - to launched in Q2 2012.

The higher strengths 32/12,5mg and 32/25mg were launched in late 2009, early 2010 and grew very fast.

We would like to sign additional agreement with Siegfred and secure the higher strengths, too. Start registration, as soon as the current procedure is over (Q1 2012) and launch the line extensions as soon as possible.

Timeline

Project start	2011
Dossier ready	available
1st MA	Q1 2013
1st Launch (Germany)	2013

1 *IMS data includes only 32/12,5mg and 32/25mg strengths. First EU launch is 01.5.2009 in Sweden. (IMS 2010)

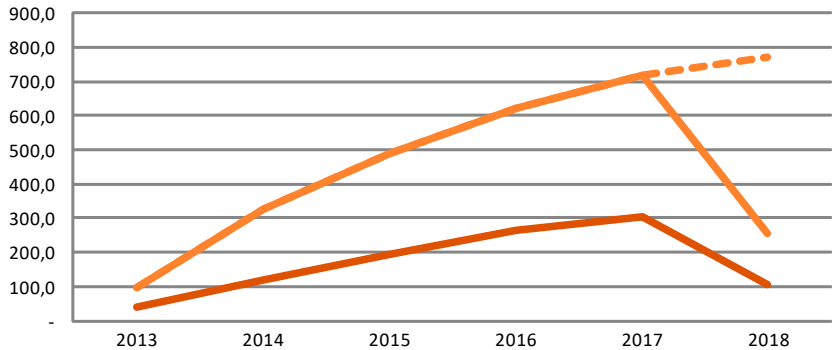
Overview project evaluation for Candesartan+HCTZ

32/12,5mg and 32/25mg

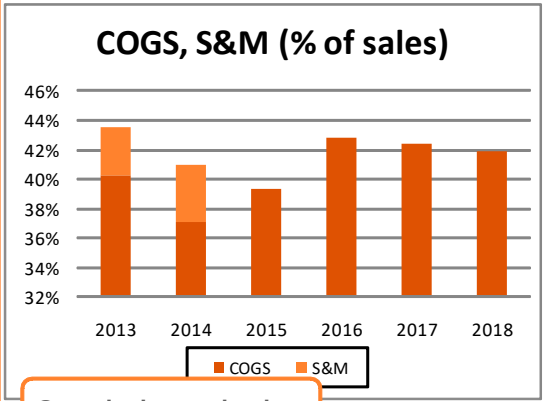
Status 19 October 2011 (PC Meeting for approval)

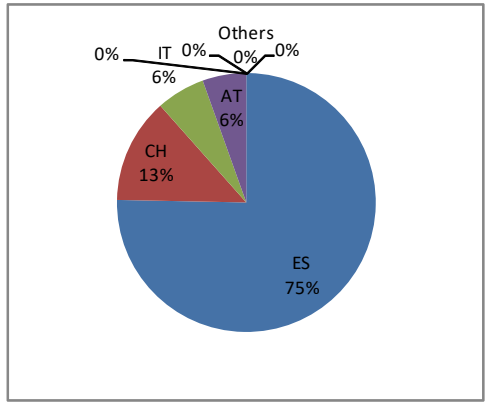
Financial valuation ('000 EUR) **C (0/4)**

Project name	**Candesartan+HCTZ Higher Strengths Only**			
First launch	Spain May 2013	Project NPV		334
Start of investment	2011	Peak sales (in year)	(2017)	717
Expected investment	192	Present value of		
Sales total	2 504	final working capital		65



	2013	2014	2015	2016	2017	2018
Sales	95,8	324,9	490,4	619,3	717,2	256,8
COGS	38,6	120,6	192,8	265,2	304,3	107,5





Quantitative evaluation

Strategic fit / opportunity 1 ☐ 2 ■ 3 ☐

Market access: no unusual limitations

Competition (Low/Med/High): High

Therapeutic / pharmaceutical relevance: The recommended starting dosage for congestive heart failure is 4mg/day. Every 2 weeks, the dose may be increased to a target dose of 32mg/day. If side effects occur, a lower dose may be recommended.

Risk assessment 1 ☐ 2 ■ 3 ☐

R&D risks: no

IP risks: no

Commercial risks: the other competotors to have the higher strengths before us.

Qualitative evaluation

Overall score C

Recommendation from PoM Go

Explanation

We will have the basic strengths launched in April next year, and these strengths will complete the portfolio.

BC including only core markets currently selling 32mg combination

Financial assessment for Candesartan+HCTZ 32/12,5mg and 32/25mg

Status 19 October 2011 (PC Meeting for approval)

EUR '000	2011	2012	2013	2014	2015	2016	2017	2018	Total
Total Sales	-	-	95,8	324,9	490,4	619,3	717,2	256,8	2 504,4
% growth				71%	34%	21%	14%		
CoGS	-	-	38,6	120,6	192,8	265,2	304,3	107,5	1 029,0
Gross Margin	**-**	**-**	**57,2**	**204,2**	**297,6**	**354,1**	**413,0**	**149,3**	**1 475,4**
% sales			60%	63%	61%	57%	58%	58%	59%
Selling & Marketing (S&M)	-	-	3,1	12,5	-	-	-	-	15,6
EBITDA	**-**	**-**	**54,1**	**191,7**	**297,6**	**354,1**	**413,0**	**149,3**	**1 459,8**
% sales			56%	59%	61%	57%	58%	58%	58%
Working capital	-	-	44,5	105,6	152,7	198,3	229,1	234,5	
Increase in working capital	-	-	44,5	61,1	47,1	45,5	30,9	5,4	234,5
CAPEX	33,3	33,3	33,3	-	-	-	-	-	100,0
Capitalised registrations	-	91,8	-	-	-	-	-	-	91,8
Free cash flow	**-33,3**	**-125,1**	**-23,7**	**130,6**	**250,4**	**308,6**	**382,1**	**143,9**	**1 033,5**
PV of Cash Flows	**-33,3**	**-104,2**	**-16,4**	**75,6**	**120,8**	**124,0**	**128,0**	**40,2**	**334,5**

Sum of PV of Cash Flows / NPV	**334,5**
Present value of final working capital	**65,4**
IRR	**62%**

BC including only core markets currently selling 32mg combination

Excluding any tax implications

Overview sales and NPVs by country for Candesartan+HCTZ

32/12,5mg and 32/25mg

Status 19 October 2011 (PC Meeting for approval)

Sales per year and NPV (in T EUR)

Country	2013	2014	2015	2016	2017	2018	Total	NPV	Market Size YBL (EUR)	PoM Recommendation
Total	96	325	490	619	717	257	**2 504**	**334**	48 262	
Austria	5	11	20	33	41	20	**130**	**25**	2 202	Go
Switzerland	-	16	51	88	110	46	**310**	**54**	3 213	Go
Germany	4	9	14	17	21	9	**74**	**- 7**	18 222	Go
Italy	12	24	28	32	35	12	**144**	**10**	12 290	Go
Sweden	12	16	14	12	11	3	**67**	**- 20**	1 927	Go
Spain	62	250	364	437	500	167	**1 780**	**355**	10 408	Go

PoM recommendation is to registries Candesartan+HCTZ 32/12,5mg and 32/25mg on all markets Actavis plans to sell Candesartan: FI; SE; NO; IS; PT; IT; FR; DE; AT; CH; BG; LT; EE; LV and NL; DK; IE; UK; ES; HU; PL; SK.

Note: DPs are not included in NPV calculation by country

BC including only core markets currently selling 32mg combination

Potential Deal Structure for Candesartan+HCTZ

32/12,5mg and 32/25mg

Status 19 October 2011 (PC Meeting for approval)

Originator market development, market entry & launch situation

32/12,5mg and 32/25mg were launched in mid 2009. The market is rapidly growing.

The MS of both strengths is increasing to 10% in 2010.

Gx market formation and Actavis positioning

All major Gx companies are expected to have the product, but for the higher strengths we expect to be among the first.

Potential Deal Structure for Candesartan+HCTZ

32/12,5mg and 32/25mg

Status 19 October 2011 (PC Meeting for approval)

actavis
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IL terms

Line extention of the deal with Siegfried.

Down payment 100 K EUR payable as follows:
1/3 at signature
1/3 at MRP day 90
1/3 at first launch

Territory is Geographical Europe (w/o Russia). MOQ of 500 packs

Regulatory and IP

Regulatory timeline:
We would on average estimate 6 months to start MRP, 3 months to run MRP and then in addition 1 to 6 months to finalise national phase.
So MAs could be granted 10 – 16 months from request of MRP.

Project opportunity for Tianeptine

Status 19 October 2011 (PC Meeting for approval)

Project ID: Tianeptine 12,5mg tablets

Suggestion from PoM: No Go

Product information

INN	Tianeptine
Dosage form	tablets
Dosage strengths	12,5mg
Indication(s)	major depressive episodes
Brand name	Stablon; Coaxil
Originator	Servier

Product information (in 000s)

NPV (start of project)	€ 321,6
IRR (start of project)	64%
Peak sales	€ 915,4
Peak year	2016
IP Costs	
Registration	23,0
Total investments	€ 223,0
Development costs	
2011	€ 40,0
2012	€ 80,0
2013+	€ 80,0

Summary of opportunities (in 000s)

Countries (Top10 by sales)	Sales (2010)[1]	Growth (09/10)[1]	Data exclusivity	Market exclusivity
France	35 742	-3%	Open	Open
Poland	6 251	6%	Open	Open
Turkey	3 964	22%	Open	Open
Romania	2 283	23%	Open	Open
Russia	1 695	-21%	Open	Open
Hungary	1 632	-4%	Open	Open
Slovakia	1 394	3%	Open	Open
Portugal (Retail	1 008	-13%	Open	Open
Slovenia	649	-12%	Open	Open
Czech	579	-3%	Open	Open
Saudi Arabia (R	306	-4%	Open	Open
Lithuania	274	-6%	Open	Open
	55 777	-1%		

Brief Project Description & Target

Tianeptine is niche product, not heavily promoted by Servier, but with stabel market. There are still no generics on most markets.

MA acquisition from Lupin. If project is approved we can launch in France by Q2 2012.

Timeline

Project start	Q4 2011
Dossier ready	available
1st MA	Oct. 2011
1st Launch (France)	2012

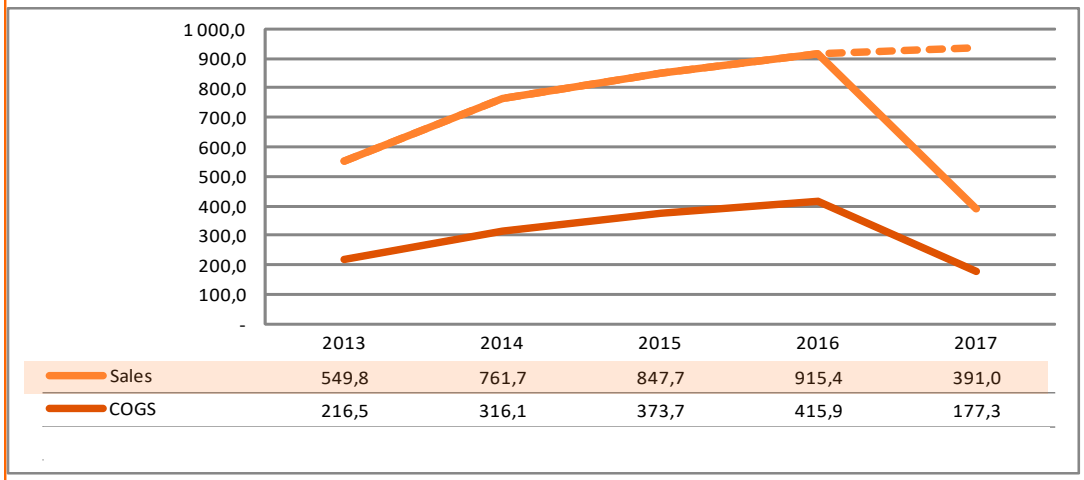
1 Current molecule/form expectation based upon 2010; in '000 EUR

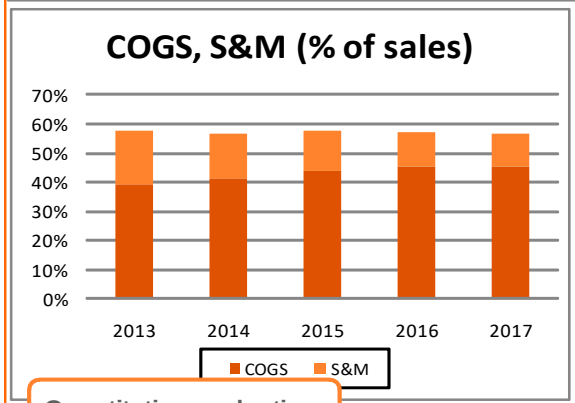
Overview project evaluation for Tianeptine

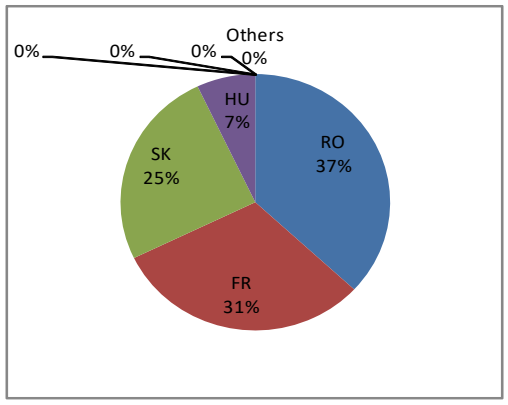
Status 19 October 2011 (PC Meeting for approval)

Financial valuation ('000 EUR) **C (0/4)**

Project name	**Tianeptine 12,5mg tablets**				
First launch	France	Jun 2012	Project NPV		322
Start of investment		2011	Peak sales (in year)	(2016)	915
Expected investment		223	Present value of		
Sales total		3 576	final working capital		142







Quantitative evaluation

B (3/6)

Strategic fit / opportunity 1 ☐ 2 ■ 3 ☐

Market access: no unusual limitations

Competition (Low/Med/High): Low

Therapeutic / pharmaceutical relevance: Tianeptine shows efficacy against serious depressive episodes (major depression), comparable to amitriptyline, imipramine and fluoxetine, but with far fewer side effects.

Risk assessment 1 ☐ 2 ■ 3 ☐

R&D risks: None

IP risks: Detailed IP evaluation to be done if the project is approved

Commercial risks: To have more competitors then expected

Qualitative evaluation

Overall score C

Recommendation from PoM No Go

Explanation
Weak financial parameters

35

Financial assessment for Tianeptine

Status 19 October 2011 (PC Meeting for approval)

EUR '000	2011	2012	2013	2014	2015	2016	2017	Total
Total Sales	-	110,5	549,8	761,7	847,7	915,4	391,0	3 576,1
% growth		100%		28%	10%	7%	-134%	
CoGS	-	38,5	216,5	316,1	373,7	415,9	177,3	1 538,2
Gross Margin	**-**	**72,0**	**333,3**	**445,6**	**474,0**	**499,4**	**213,6**	**2 037,9**
% sales		65%	61%	58%	56%	55%	55%	57%
Selling & Marketing (S&M)	-	29,3	100,6	116,1	115,2	106,2	44,6	512,0
EBITDA	**-**	**42,7**	**232,6**	**329,4**	**358,8**	**393,3**	**169,0**	**1 525,9**
% sales		39%	42%	43%	42%	43%	43%	43%
Working capital	-	77,7	226,5	324,3	376,6	416,5	424,6	
Increase in working capital	-	77,7	148,8	97,8	52,2	39,9	8,1	424,6
CAPEX	40,0	80,0	80,0	-	-	-	-	200,0
Capitalised registrations	23,0	-	-	-	-	-	-	23,0
Free cash flow	**-63,0**	**-115,0**	**3,8**	**231,6**	**306,6**	**353,3**	**161,0**	**878,3**
PV of Cash Flows	**-63,0**	**-95,8**	**2,7**	**134,1**	**147,8**	**142,0**	**53,9**	**321,6**

Sum of PV of Cash Flows / NPV	**321,6**
Present value of final working capital	**142,2**
IRR	**64%**

Excluding any tax implications

Overview sales and NPVs by country for Tianeptine

Status 19 October 2011 (PC Meeting for approval)

Sales per year and NPV (in T EUR)

Country	2012	2013	2014	2015	2016	2017	Total	NPV	Market Size YBL (EUR)	PoM Recommendation
Total	111	550	762	848	915	391	**3 576**	**322**	36 229	
France	57	157	239	254	272	109	**1 088**	**192**	30 513	No Go
Hungary	8	57	64	59	48	13	**248**	**- 36**	1 652	No Go
Lithuania	1	6	11	15	17	9	**59**	**8**	554	No Go
Romania	13	166	252	317	375	175	**1 298**	**138**	2 283	No Go
Slovakia (Slovak Republic)	32	164	196	202	204	85	**883**	**179**	1 227	No Go
Poland										Rejected by Market
Turkey										Rejected by Market
Russia										Rejected by Market
Portugal										Rejected by Market
Czech										Rejected by Market
Bulgaria										Rejected by Market

Note: DPs are not included in NPV calculation by country

Potential Deal Structure for Tianeptine

Status 19 October 2011 (PC Meeting for approval)

actavis
think smart medicine

Originator market development, market entry & launch situation

Tianeptine is used for treating major depressive episodes (mild, moderate, or severe). It has structural similarities to the tricyclic antidepressants, but it has different pharmacological properties. Until recently, it has been assumed that tianeptine is a selective serotonin reuptake enhancer (SSRE). Tianeptine enhances the extracellular concentration of dopamine in the nucleus accumbens and modulates the D2 and D3 dopamine receptors, but this effect is modest and almost certainly indirect. There is also action on the NMDA and AMPA receptors. Recent reviews point to this pathway as a hypothesized mechanism of action, based on tianeptine's effect of promoting stress-associated impaired neuroplasticity.

Market is slowly declining, no Gx on most of the markets.

Gx market formation and Actavis positioning

No Gx competition yet.

Potential Deal Structure for Tianeptine

Status 19 October 2011 (PC Meeting for approval)

Development

Deal Type: MA acquisition. IL territory: FR, RO, PL, HU, CZ, SK, SI, Baltics

DP: EUR 200K: - 40K upon signature; - 40K upon MA transfer in FR; - 40K upon MA transfers in rest of territory; - 40K upon launch; - 40K upon 1 year after launch.

CoGs: 30% of Actavis NSP, not less than floor price of EUR 1,25/30s

As an alternative we can have a duplicate of the French MA (already acquired via a national procedure). Lupin have the only Gx registration presently in FR and with a time frame for the duplicate of 3-4 months, Actavis could potentially be the second Gx player on the market from the start of 2012. Lupin would be ready to go for a semi-exclusive arrangement. The downpayment would be in the range of EUR 100K (France being by far the most interesting market, so Lupin are assigning it 40% of the originally offered DP).

Regulatory and IP

DCP by Lupin with D210 in September 2011 + national application in France

Project opportunity for Cilostazol

Status 19 October 2011 (PC Meeting for approval)

Project ID: Cilostazol

Suggestion from PoM: No Go

Product information

INN	Cilostazol
Dosage form	tablets
Dosage strengths	50mg; 100mg
Indication(s)	intermittent claudication in individuals with peripheral vascular disease
Brand name	Pletal
Originator	Otsuka Pharmaceuticals

Product information (in 000s)

NPV (start of project)	€ 462,8
IRR (start of project)	50%
Peak sales	€ 1 536,8
Peak year	2017
IP Costs	
Registration	229,9
Total investments	€ 449,9
Development costs	
2011	€ 55,0
2012	€ 0,0
2013+	€ 165,0

Summary of opportunities (in 000s)

Countries (Top10 by sales)	Sales (2010)[1]	Growth (09/10)[1]	Data exclusivity	Market exclusivity
Germany	10 310	22%	Open	Open
Spain	10 149	256%	Open	Open
China	6 571	33%	Open	Open
Taiwan	6 108	33%	Open	Open
Thailand	5 581	29%	Open	Open
Philippines	4 989	17%	Open	Open
Turkey	3 503	38%	Open	Open
Indonesia	3 026	47%	Open	Open
India	2 883	39%	Open	Open
UK	2 811	12%	Open	Open
Italy	2 616	141%	Open	Open
Egypt	1 051	23%	Open	Open
	59 600	47%		

Brief Project Description & Target

In late 2009 Cilostazol tablets 50mg and 100mg was evaluated for transfer from US. At that time the decision was not to cancel the project (very limitted interest from Actavis markets)

Now we have an IL option from Adamed. Markets' forecasts/interest was updated.

Timeline

Project start	2009
Dossier ready	Q2 2012
1st MA	Q4 2013
1st Launch (TBC)	Q4 2013

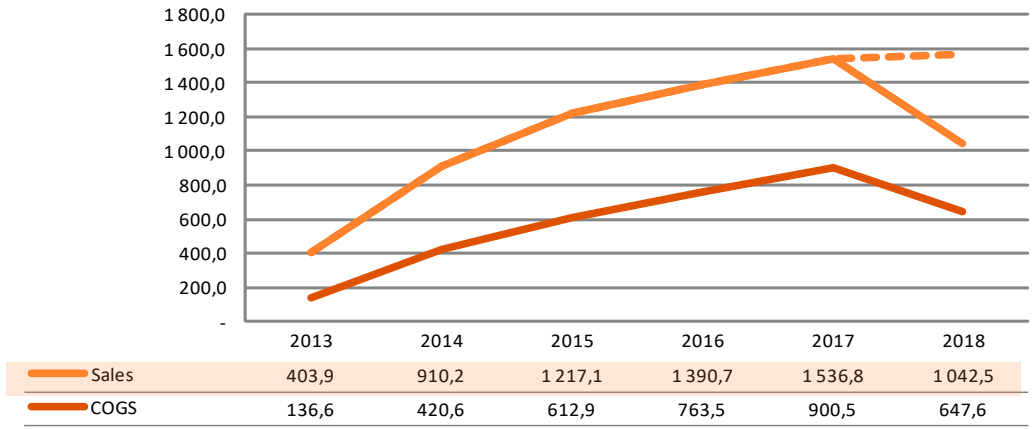
1 Current molecule/form expectation based upon 2010; in '000 EUR

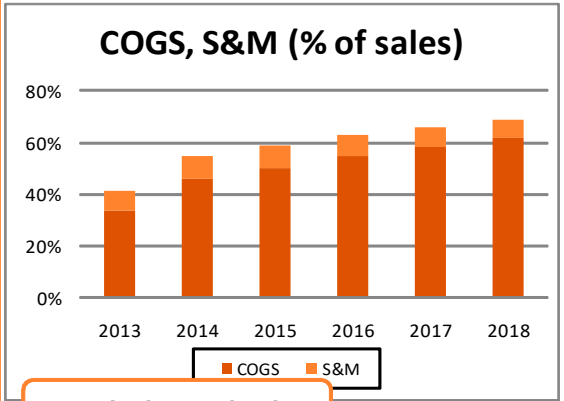
Overview project evaluation for Cilostazol

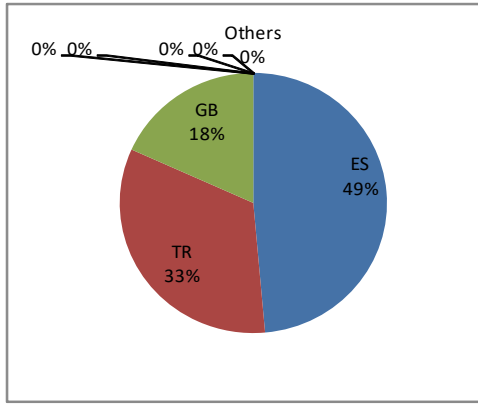
Status 19 October 2011 (PC Meeting for approval)

Financial valuation ('000 EUR) **C (0/4)**

Project name	**Cilostazol**				
First launch	TBC	Sep 2013	Project NPV		463
Start of investment		2011	Peak sales (in year)	(2017)	1 537
Expected investment		450	Present value of		
Sales total		6 501	final working capital		141







Quantitative evaluation

B (4/6)

Strategic fit / opportunity 1 ☐ 2 ■ 3 ☐

Market access: no unusual limitations

Competition (Low/Med/High): Medium

Therapeutic / pharmaceutical relevance: it is indicated for the improvement of the maximal and pain-free walking distances in patients with intermittent claudication. The only alternative treatment available for intermittent claudication is Pentoxifylline.

Risk assessment 1 ☐ 2 ■ 3 ☐

R&D risks: No If we go with the IL option

IP risks: No

Commercial risks: Niche product, with limited competion and indication. There is a risk of being too late on the market.

Qualitative evaluation

Overall score C

Recommendation from PoM No Go

Explanation

Low financial parameters of the BC. Project was not approved in 2009 and now we are late for makret formation.

This a niche product (with very cheap alternative treatment).

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Financial assessment for Cilostazol

Status 19 October 2011 (PC Meeting for approval)

EUR '000	2011	2012	2013	2014	2015	2016	2017	2018	Total
Total Sales	-	-	403,9	910,2	1 217,1	1 390,7	1 536,8	1 042,5	6 501,2
% growth				56%	25%	12%	10%		
CoGS	-	-	136,6	420,6	612,9	763,5	900,5	647,6	3 481,7
Gross Margin	**-**	**-**	**267,3**	**489,5**	**604,2**	**627,3**	**636,3**	**394,9**	**3 019,5**
% sales			66%	54%	50%	45%	41%	38%	46%
Selling & Marketing (S&M)	-	-	30,9	79,9	101,3	115,7	108,7	71,8	508,4
EBITDA	**-**	**-**	**236,4**	**409,6**	**502,8**	**511,5**	**527,6**	**323,1**	**2 511,1**
% sales			59%	45%	41%	37%	34%	31%	39%
Working capital	-	-	176,3	274,8	377,0	441,9	498,4	506,0	
Increase in working capital	-	-	176,3	98,5	102,3	64,8	56,5	7,6	506,0
CAPEX	55,0	-	165,0	-	-	-	-	-	220,0
Capitalised registrations	98,1	131,8	-	-	-	-	-	-	229,9
Free cash flow	**-153,1**	**-131,8**	**-105,0**	**311,2**	**400,6**	**446,7**	**471,1**	**315,5**	**1 555,3**
PV of Cash Flows	**-153,1**	**-109,8**	**-72,9**	**180,1**	**193,2**	**179,5**	**157,8**	**88,1**	**462,8**

Sum of PV of Cash Flows / NPV	**462,8**
Present value of final working capital	**141,2**
IRR	**50%**

Excluding any tax implications

Overview sales and NPVs by country for Cilostazol

Status 19 October 2011 (PC Meeting for approval)

Sales per year and NPV (in T EUR)

Country	2012	2013	2014	2015	2016	2017	Total	NPV	Market Size YBL (EUR)	PoM Recommendation
Total	-	404	910	1 217	1 391	1 537	6 501	463	31 630	
Italy	-	6	21	26	31	35	145	14	2 397	No Go
Spain	-	83	421	586	649	684	2 812	435	10 774	No Go
Turkey	-	20	200	324	433	517	1 917	- 109	4 653	No Go
Hong Kong	-	-	-	40	74	106	306	53	1 531	No Go
Germany	-	42	49	50	45	49	266	50	9 144	No Go
United Kingdom	-	252	219	190	158	147	1 056	188	3 131	Not in Territory
Australia										Rejacted by Market
APRO										Rejacted by Market
Baltics										Rejacted by Market
France										Rejacted by Market
China										Rejacted by Market
Ireland										Rejacted by Market
Poland										Rejacted by Market
MEA										Rejacted by Market
Sweden										Rejacted by Market

Note: DPs are not included in NPV calculation by country

Potential Deal Structure for Cilostazol

Status 19 October 2011 (PC Meeting for approval)

Originator market development, market entry & launch situation

Cilostazil is an antithrombotic agents, platelet aggregation inhibitor excl. heparin. (ATC code: B01A C)
It is indicated for the improvement of the maximal and pain-free walking distances in patients with intermittent claudication, who do not have rest pain and who do not have evidence of peripheral tissue necrosis (peripheral arterial disease Fontaine stage II).
The only other treatment available for intermittent claudication is Pentoxifylline (Sanofi-Aventis).

Gx market formation and Actavis positioning

For Turkey, we need to either go through GMP Audit of the plant manufacturing the product or transfer manufacturing to a local toll manufacturer in Turkey. In the latter case, the supplier should be able to do the technology transfer as well.

Potential Deal Structure for Cilostazol

Status 19 October 2011 (PC Meeting for approval)

IL Terms

IL - Dossier completion Q2 2012. PL and UK not included in IL deal with Adamed. Zone 4 stability available.
Country of Manufacture is Poland
OD - Transfer from US, to be finalized by Q4 2012. Estimated cost is 310k EUR.
IL territory: Spain, Italy, Germany, Hong Kong, Turkey

Down payment 220 K EUR payable as follows: 1/4 upon procedure start; 1/4 upon launch;
1/2 upon successful launch in Turkey (100k EUR est. for transfer in TR)
Supply price: 50mg x 60 tabs - 3,35 EUR; 100mg x 60 - 5,60 EUR
Rev Share : 30%

Regulatory and IP

According to preliminary IP report there is no patent and DE has expired in March.2010.

Oxycodone PR tablets

5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg

- Previously decided by PCM to go for IL agreement with Acino to be able to launch on patent expiry and then later switch to a new matrix formulation which also included additional strengths (5 mg, 15 mg, 30 mg and 60 mg in addition to the current 10 mg, 20 mg, 40 mg and 80 mg)

- After further discussions with Acino it seems that they are not very advanced with the new formulation and that the best option would be to go into co-development with them on the new formulation, using the formulation that was already in development at Actavis.

- Negotiations with Acino on the possible co-development are on-going and a new strategy for this project will be brought to the Pipeline Committee shortly for approval.

LOCAL OPPORTUNITIES

	Glucosamine (RU) • 1500 mg **→ NEW PROJECT APPROVAL**
	Isotretinoin tablets (SA) • 1500 mg **→ NEW PROJECT APPROVAL**

Project opportunity for Glucosamine Russia

Status 19 October 2011 (PC Meeting for approval)

Project ID:	Glucosamine sachets

Suggestion from PoM: Go

Product information

INN	Glucosamine
Dosage form	Sachets
Dosage strengths	1,5 g
Indication(s)	Ostheoarthritis
Brand name	Dona
Originator	Rottapharm

Product information (in 000s)

NPV (start of project)	€ 223,2
IRR (start of project)	71%
Peak sales	€ 735,0
Peak year	2015
IP Costs	
Registration	19,0
Total investments	€ 69,0
Downpayment	
2011	€ 20,0
2012	€ 0,0
2013+	€ 30,0

Summary of opportunities (in 000s)

Countries (Top10 by sales)	Sales (2010)ₕ	Growth (09/10)ₕ	Data exclusivity	Patent expiry
Russia	5.873	4%	Expired	Expired

Brief Project Description & Target

To extend license-in agreement on glucosamine sachets with Genenpharm for Russian market.

Timeline

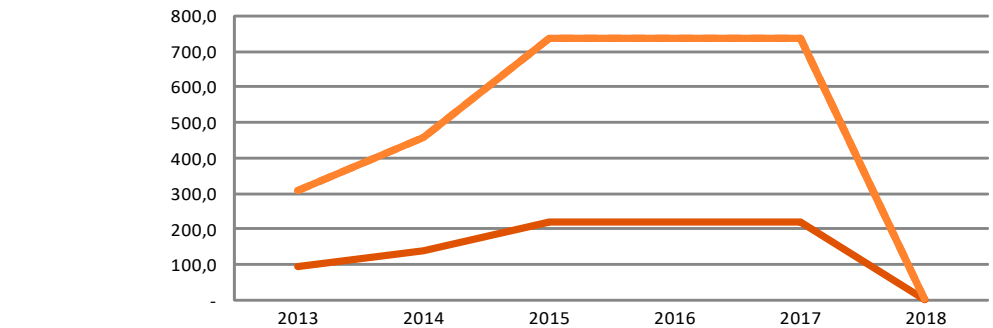
Project start	October 2011
Dossier ready	Available
1st MA	Q1 2013
1st Launch ()	Apr 2013

Overview project evaluation for Glucosamine Russia

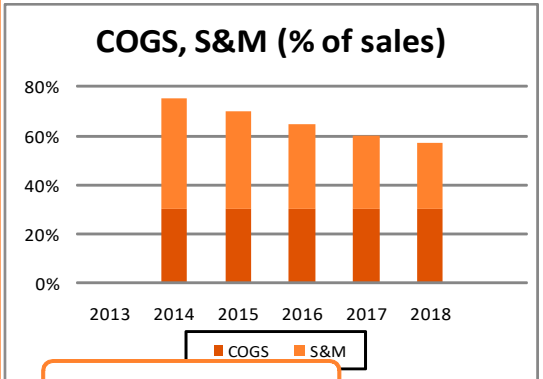
Status 19 October 2011 (PC Meeting for approval)

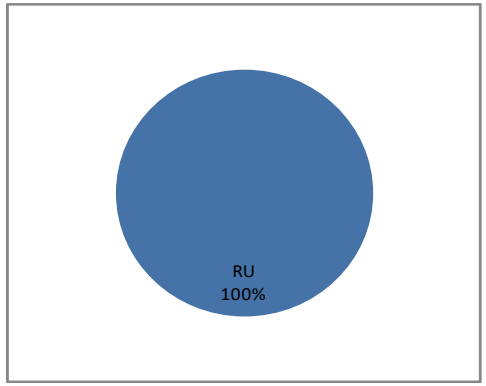
Financial valuation ('000 EUR) — **C (0/4)**

Project name	**Glucosamine sachets**				
First launch	- €	Apr 2013	Project NPV		223
Start of investment		2011	Peak sales (in year)	(2015)	735
Expected investment		69	Present value of		
Sales total		2.971	final working capital		97



	2013	2014	2015	2016	2017	2018
Sales	309,0	457,3	735,0	735,0	735,0	-
COGS	92,7	137,2	220,5	220,5	220,5	-





Quantitative evaluation

B (4/6)

Strategic fit / opportunity — 1 ☐ 2 ■ 3 ☐

Market access:

Use of established channels

Competition (Low/Med/High):

Apart from Dona no strong competitors

Therapeutic / pharmaceutical relevance:

Risk assessment — 1 ☐ 2 ■ 3 ☐

R&D risks:

No

IP risks:

No

Commercial risks:

Medium risk

Qualitative evaluation

Overall score

Recommendation from PoM: Go

Explanation

Nice financials and good fit with female care (supportive products)

Financial assessment for Glucosamine Russia

Status 19 October 2011 (PC Meeting for approval)

EUR '000	2011	2012	2013	2014	2015	2016	2017	2018	Total
Total Sales	-	-	309,0	457,3	735,0	735,0	735,0	-	2.971,3
% growth			#DIV/0!	48%	61%	0%	0%		
CoGS	-	-	92,7	137,2	220,5	220,5	220,5	-	891,4
Gross Margin	**-**	**-**	**216,3**	**320,1**	**514,5**	**514,5**	**514,5**	**-**	**2.079,9**
% sales			70%	70%	70%	70%	70%		70%
Selling & Marketing (S&M)	-	-	139,1	182,9	257,3	220,5	198,5	-	998,2
EBITDA	**-**	**-**	**77,3**	**137,2**	**257,3**	**294,0**	**316,1**	**-**	**1.081,8**
% sales			25%	30%	35%	40%	43%		36%
Working capital	-	-	145,5	215,3	346,1	346,1	346,1	346,1	
Increase in working capital	-	-	145,5	69,8	130,8	-	-	-	346,1
CAPEX	20,0	-	10,0	10,0	10,0	-	-	-	50,0
Capitalised registrations	-	19,0	-	-	-	-	-	-	19,0
Free cash flow	**-20,0**	**-19,0**	**-78,3**	**57,4**	**116,5**	**294,0**	**316,1**	**-**	**666,6**
PV of Cash Flows	**-20,0**	**-15,8**	**-54,4**	**33,2**	**56,2**	**118,2**	**105,8**	**-**	**223,2**

Sum of PV of Cash Flows / NPV	**223,2**
Present value of final working capital	**96,6**
IRR	**71%**

Excluding any tax implications

Potential Deal Structure for Glucosamine Russia

Status 19 October 2011 (PC Meeting for approval)

actavis
think smart medicine

Deal structure

50 kEuro down-payment. 10k at signature, 10 upon submission, 10k on MA, 10k 1y after MA, 10k 2 years after MA

Supply prices 30% of selling prices subject to floor prices
Territory extension of already signed deal for Hungary with Genepharm.

Regulatory and IP

Dona is registred as Rx medicine and therefore we will follow the same strategy. Need for local clinical trials to be clarified with Russian authorities.

No IP risk

Overview project evaluation for Isotretinoin for KSA

Status 19 October 2011 (PC Meeting for approval)

actavis
think smart medicine

Project ID:	Isotretinoin Caps

Suggestion from PoM: Go

Product information

INN	Isotretinoin
Dosage form	Capsules
Dosage strengths	10mg and 20mg
Indication(s)	Severe Acne
Brand name	Roaccutane
Originator	Roche

Product information (in 000s)

NPV (start of project)	€ 774.5
IRR (start of project)	135%
Peak sales	€ 1,232.6
Peak year	2016
IP Costs	
Registration	0.0
Total investments	€ 110.0
Downpayment	
2011	€ 110.0
2012	€ 0.0
2013+	€ 0.0

Summary of opportunities (in 000s)

Countries (Top10 by sales)	Sales (2010)[1]	Growth (09/10)	Data exclusivity	Patent expiry
Saudi Arabia	6,817	10%	NO	NO

Brief Project Description & Target

A co-marketing agreement to introduce isotretinoin faster to the market as the 1st generic is about to launch. Current IL product from Douglas is not suitable for Saudi market due to a complex SC and RA issues. Isotretinoin has a strategic importance for our Derma TA and is an essential product to build a franchise around Neotigason

Timeline

Project start	October 2011
Dossier ready	Available
1st MA	June-12
1st Launch ()	Sep 2012

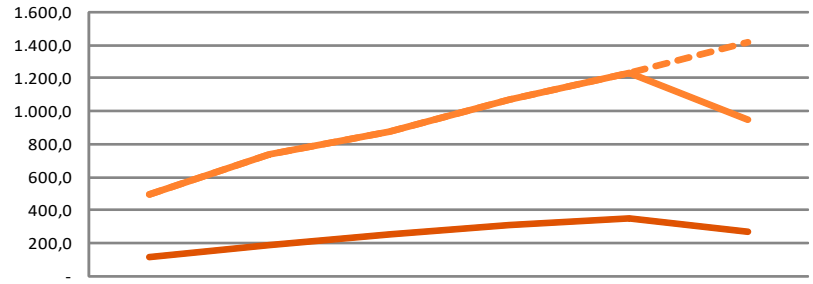
1 Current molecule/form expectation based upon 2010; in '000 EUR

Overview project evaluation for Isotretinoin for KSA

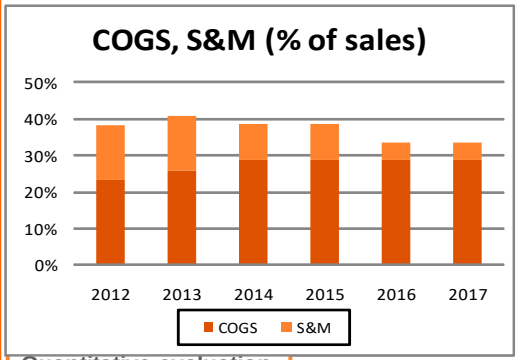
Status 19 October 2011 (PC Meeting for approval)

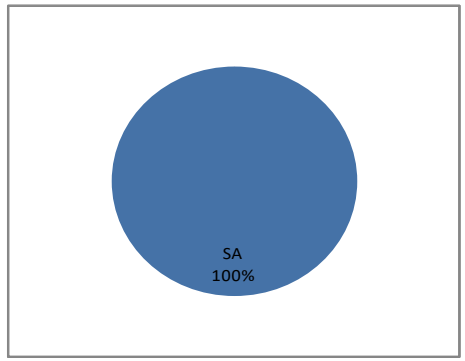
Financial valuation ('000 EUR) — **C (0/4)**

Project name	**Isotretinoin Caps**				
First launch	- €	Sep 2012	Project NPV		775
Start of investment		2011	Peak sales (in year)	(2016)	1.233
Expected investment		110	Present value of		
Sales total		5.350	final working capital		130



	2012	2013	2014	2015	2016	2017
Sales	494,9	735,0	873,2	1.067,2	1.232,6	947,0
COGS	114,8	189,4	250,1	305,6	353,0	271,2





Quantitative evaluation

Strategic fit / opportunity — 1 ☐ 2 ■ 3 ☐

Market access:

Co-marketing is faster way to the market as the product is already in late stage registration with GCCDR

Competition (Low/Med/High):

LOW

Therapeutic / pharmaceutical relevance:

An important product to build our Derma franchise

Risk assessment — 1 ☐ 2 ■ 3 ☐

R&D risks:

No

IP risks:

No

Commercial risks:

MA will not be in Actavis' name.

Qualitative evaluation

Overall score C

Recommendation from PoM: Go

Explanation

Important product, needed to expand derma segment , and with solid financials

Financial assessment for Isotretinoin for KSA

Status 19 October 2011 (PC Meeting for approval)

EUR '000	2011	2012	2013	2014	2015	2016	2017	Total
Total Sales	-	494,9	735,0	873,2	1.067,2	1.232,6	947,0	5.349,8
% growth			49%	19%	22%	16%	-23%	
CoGS	-	114,8	189,4	250,1	305,6	353,0	271,2	1.484,2
Gross Margin	**-**	**380,1**	**545,5**	**623,1**	**761,6**	**879,6**	**675,8**	**3.865,6**
% sales		77%	74%	71%	71%	71%	71%	72%
Selling & Marketing (S&M)	-	74,2	110,2	87,3	106,7	61,6	47,3	487,5
Commission		74,2	110,2	131,0	160,1	184,9	142,0	
% sales		15,0%	15,0%	15,0%	15,0%	15,0%	15,0%	
Royalty		32,2	47,8	56,8	69,4	80,1	61,6	347,7
% sales		6,5%	6,5%	6,5%	6,5%	6,5%	6,5%	7,%
EBITDA	**-**	**199,5**	**277,3**	**348,0**	**425,4**	**553,0**	**424,8**	**3.378,1**
% sales		40%	38%	40%	40%	45%	45%	63%
Working capital	-	135,5	205,7	250,2	305,8	353,2	389,1	
Increase in working capital	-	135,5	70,2	44,5	55,6	47,4	35,9	389,1
CAPEX	110,0	-	-	-	-	-	-	110,0
Capitalised registrations	-	-	-	-	-	-	-	-
Free cash flow	**-110,0**	**64,0**	**207,1**	**303,5**	**369,8**	**505,6**	**388,9**	**2.879,0**
PV of Cash Flows	**-110,0**	**53,3**	**143,8**	**175,6**	**178,3**	**203,2**	**130,3**	**774,5**

Sum of PV of Cash Flows / NPV	**774,5**
Present value of final working capital	**130,3**
IRR	**135%**

Excluding any tax implications

Development and Regulatory for Isotretinoin for KSA

Status 19 October 2011 (PC Meeting for approval)

actavis
think smart medicine

Deal structure

A co-marketing agreement between GA Pharmaceuticals and Actavis ME for 5 yrs. Actavis will buy at a fixed price and will pay the GA Pharmaceuticals ME master agent a royalty of 6.5% on sales in addition to

Regulatory and IP

The product is at the last stage of registration with GCCDR and will be registered by GAP with SFDA as soo as it get the GCCDR registration.

Excluding any tax implications

Assumptions on key drivers of sales for Isotretinoin for KSA

Status 19 October 2011 (PC Meeting for approval)

actavis
think smart medicine

Originator market development, market entry & launch situation

Roaccutane ® is well trenched and it dominates the market. Tender market was resistant to a generic isotretinoin is expected to continue to be so for the first year of launch

Gx market formation and Actavis positioning

Jazeera Pharmaceuticals (Al Hikma Group) is expecting to launch the 1st generic this year. Actavis/ GAP product is expected to be the 2nd generic. Reducar ® will be positioned as European quality alternative to Roaccutane® of Roche but at a competitive price

Excluding any tax implications

US OWN DEVELOPMENT & IN-LICENSING PROJECTS

Agenda

US Portfolio – Discontinuations

1.	**Risedronate Tablets** → Discontinue development with Orchid
2.	**Aspririn; Diypridamole ER Capsules** → Discontinue development with Orchid, move internal

US Portfolio – In House Development Starts

1.	**Asprin; Dipyridamole ER Capsules** → New Project Approval
2.	**Hydrocodone ER Tablets** → New Project Approval

US Portfolio – In-Licensing

1.	**Potassium Chloride ER Capsules** → License marketing rights from Tris
2.	**Evoclin Foam** → Proceed with negotiations to acquire brand from GSK, launch own AG
3.	**NAB Paclitaxel Injection** → License product rights from Biovectra
4.	**Scopolomine Patch** → License product rights from Dermapharm
5.	**Project Vertigo** → Details Strictly Confidential
6.	**Tadalafil Tablets (Adcirca)** → License marketing rights from Synthon

US Portfolio Overview
Discontinuations & Own Development

Discontinuations

- Orchid Risedronate Tablets
  - NPV: (€ 932) k
  - Rationale:
    - Orchid not agreeable to develop all strengths for original development fee
    - COGs not reasonable
    - Orchid missed deadline putting Actavis launch at MF at risk
    - Have negotiated to withdraw from contract with no further payments or penalty
- Orchid Aspirin; Dipyridamole ER Capsules
  - NPV: € 790 k, IRR: 29%
  - Rationale:
    - Orchid has continually missed deadlines for technically challenging product, Actavis expects to be more successful with internal program
    - Have negotiated to withdraw from contract with no further payments or penalty

Own Development

- Aspirin; Dipyridamole ER Capsules
  - Limited competition, Earliest launch: Jan-16, Cost: € 1,653 k
  - NPV: € 4,394 k, IRR: 70%
- Hydrocodone ER Capsules
  - FTF opportunity, Earliest launch: Mar-16, Cost: € 3,625 k
  - NPV: € 3,266 k, IRR: 46%

US Portfolio Overview
In-Licensing Opportunities

Near-term revenue, Limited Competition

- Tris Potassium Chloride ER Capsules
  - ANDA filed, Earliest launch: Jul-12, Cost: € 2,948 k
  - NPV: € 954 k, IRR: 33%
- Stiefel Evoclin (Actavis to launch AG)
  - Currently Marketed, Cost: € 8,138 k
  - NPV: € 10,720 k, IRR: 307%

Very good strategic fit & high value; More risk &revenue further out

- Biovectra NAB Paclitaxel Injection
  - FTF opportunity, In development, Earliest launch: Aug-15, Cost: € 1,440 k
  - NPV: € 9,124 k, IRR: 127%
- Dermapharm Scopolomine Patch
  - FTM opportunity, In development, Earliest launch: Jan-15, Cost: € 1,168 k
  - NPV: € 6,137 k, IRR: 95%
- Project Vertigo
  - Details not to be discussed, STRICTLY CONFIDENTIAL

Other

- Synthon Tadalafil Tablets (RLD: Adcirca)
  - Confirmed FTF, ANDA filed, Earliest launch: Nov-17, Cost: € 3,099 k
  - NPV: € 713 k, IRR: 25%

Orchid Risedronate Tablets Discontinue

Project ID:	Risedronate - Orchid

Suggestion from PoM:	Discontinue Project

Product information

INN	Risedronate Sodium
Dosage form	Tablet
Dosage strengths	30mg, 35mg & 150mg
Indication(s)	Osteoporosis
Brand name	Actonel
Originator	Warner Chilcott

Product information (in 000s)

NPV (start of project)	€ 0.0
IRR (start of project)	n/a
Peak sales	€ 0.0
Peak year	2011
Total project investments	#DIV/0!
Development costs	
2011	#DIV/0!
2012	#DIV/0!
2013+	#DIV/0!

Summary of opportunities (in 000s)

Trailing sales[1] :	#DIV/0!	Unit growth[1] :	#DIV/0!
Expected peak[2] :	#DIV/0!	Earliest Gx mkt :	Jun-14

Patents & Exclusivities

"122 patent	10-Jun-14
'342 patent	22-May-12 (30mg & 35mg)
'513 patent	10-Dec-18
M-61 exclusivity	10-Dec-18
'443 patent	14-Feb-19 (35mg)
'329, '932 & '801 patents	17-Jan-19 (35mg)
'634 & '938 patents	6-Nov-23 (150mg)
NS exclusivity	22-Oct-11 (150mg)

Type of product

- ☐ Gx blockbuster
- ☐ Added-vale Gx
- ☐ OTC
- ☑ Rx
- ☐ Hospital
- ☐ Gx niche

Source

- ☐ Own development
- ☐ Co-development
- ☑ In-licensing Orchid

Timeline

Project start	
ANDA filing	October-11
ANDA approval	December-14
Launch (earliest case)	December-14

Other information

Based on the latest information, Orchid will not meet the required file date. A notification letter will go out Nov-11 removing this product from further contractual obligation. Project to be discontinued with Orchid.

[1] Based on FY 2010 IMS

Orchid Aspirin; Dipyridamole ER Capsules Discontinue

Project ID:	Aspirin; dipyridamole - Orchid
Suggestion from PoM:	Discontinue Project

Product information

INN	Aspirin & Dipyridamole
Dosage form	Capsule, ER
Dosage strengths	25mg/200mg
Indication(s)	Reduce the risk of stroke in patients who have had ischemia
Brand name	Aggrenox
Originator	Boehringer Ingelheim

Product information (in 000s)

NPV (start of project)	€ 0.0
IRR (start of project)	n/a
Peak sales	€ 0.0
Peak year	2011
Total project investments	#DIV/0!
Development costs	
2011	#DIV/0!
2012	#DIV/0!
2013+	#DIV/0!

Summary of opportunities (in 000s)

Trailing sales[1] :	#DIV/0!	Unit growth[1] :	#DIV/0!
Expected peak[2] :	#DIV/0!	Earliest Gx mkt :	Jul-15

Patents & Exclusivities

"577 patent	18-Jan-17

Type of product

- ☐ Gx blockbuster
- ☐ Added-vale Gx
- ☐ OTC
- ☑ Rx
- ☐ Hospital
- ☐ Gx niche

Source

- ☐ Own development
- ☐ Co-development
- ☑ In-licensing — Orchid

Timeline

Project start	
ANDA filing	September-11
ANDA approval	September-14
Launch (earliest case)	January-16

Other information

This project had been discontinued in 2009, but then re-instated with revised milestones. An Addendum for revised timelines was approved. Based on the latest information, Orchid did not meet the required file date of Sep-11.

Upon approval of this event form, a notification letter will go out Oct-11 removing this product from further contractual obligation. Project to be discontinued with Orchid and development will be moved internally.

[1] Based on FY 2010 IMS

Aspirin; Dipyridamole ER Capsules Start

Project ID:	Aspirin; dipyridamole
Suggestion from PoM:	Add to ELIZ development pipeline

Product information

INN	Aspirin; dipyridamole
Dosage form	Capsule, ER
Dosage strengths	25mg;250mg
Indication(s)	Reduce risk of stroke
Brand name	Aggrenox
Originator	Boehringer Ingelheim

Product information (in 000s)

NPV (start of project)	€ 4,394.1
IRR (start of project)	70%
Peak sales	€ 7,818.8
Peak year	2016
Total project investments	€ 1,653.4
Development costs	
2012	€ 791.4
2013	€ 215.5
2014+	€ 646.6

Summary of opportunities (in 000s)

Trailing sales[1] :	€ 295,513	Unit growth[1] :	-5%
Expected peak[2] :	€ 315,505	Earliest Gx mkt :	Jul-15

Patents & Exclusivities

6015577 (U)	1/18/2017

Type of product

- ☐ Gx blockbuster
- ☐ Added-vale Gx
- ☐ OTC
- ☑ Rx
- ☐ Hospital
- ☐ Gx niche

Source

- ☑ Own development
- ☐ Co-development
- ☐ In-licensing

Timeline

Project start	January-12
ANDA filing	Apr-13
ANDA approval	Jan-16
Launch (earliest case)	Jan-16

Other information

Para IV, not FTF. Teva filed an ANDA and was sued July 2007. No other filers are known. Teva settled and will launch a generic 7/1/15.

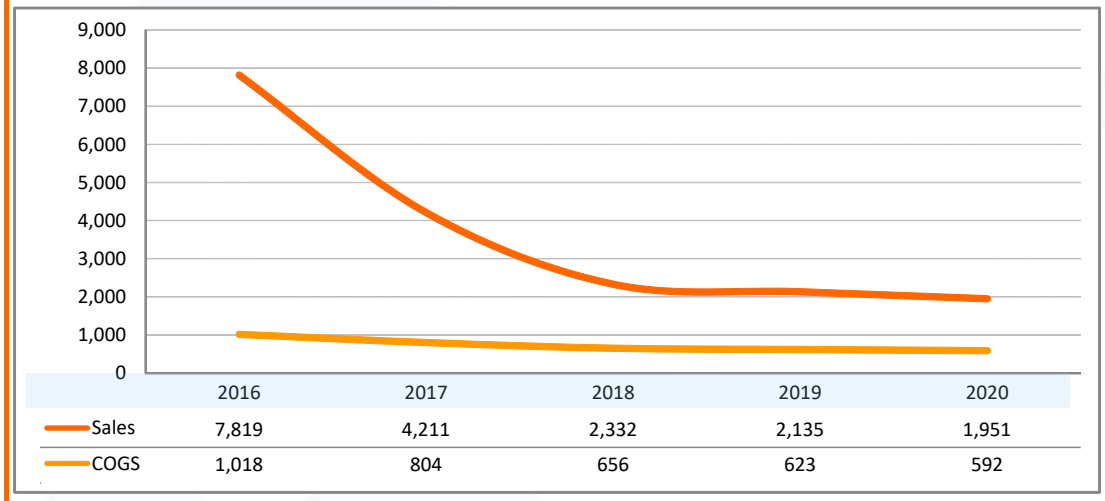
Currently in development under Orchid contract. Actavis has negotiated to remove this from contractual obligation due to continued delays in development.

[1] Based on FY 2010 IMS

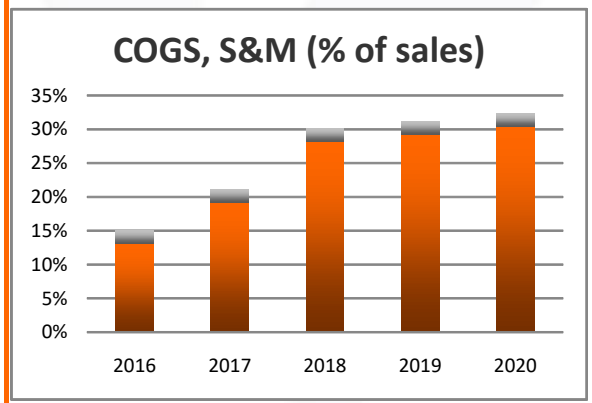
Aspirin; Dipyridamole ER Capsules Start

Financial valuation ('000 EUR)

Project name	Aspirin; dipyridamole				
First launch	US	Jan-2016	Project NPV		4,394
Start of investment		2012	Peak sales (in year)	(2016)	7,819
Expected investment		1,653	Present value of		
Sales total		20,227	final working capital		87



	2016	2017	2018	2019	2020
Sales	7,819	4,211	2,332	2,135	1,951
COGS	1,018	804	656	623	592



NPV - Best (excl final WC)	€ 12,780
Non-US NPV (not incl above)	
Peak Sales - Best	€ 17,489
Non-US Peak Sales	
Sales Total - Best	€ 44,170
Non-US Sales Total	
Prob Weighting - Best	35%
Prob Weighting - Base	50%

Strategic fit / opportunity 1 ☐ 2 ☐ 3 ■

Market access:

Standard Rx

Competition (Low/Med/High):

Low based on technical challenges.

Therapeutic / pharmaceutical relevance:

Established generic distribution channel, no incremental S&M needs

Risk assessment 1 ☐ 2 ☐ 3 ■

Medium risk -

Qualitative evaluation

Overall score

[type here]

Aspirin; Dipyridamole ER Capsules Start

EUR '000	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Total Sales	-	-	-	-	7,818.8	4,210.5	2,331.9	2,134.5	1,951.1	1,780.6
% growth		0%	0%	0%	0%	-46%	-45%	-8%	-9%	-9%
CoGS	-	-	-	-	1,018.2	804.1	655.7	622.9	591.7	562.2
Gross Margin	**-**	**-**	**-**	**-**	**6,800.5**	**3,406.4**	**1,676.2**	**1,511.6**	**1,359.3**	**1,218.5**
% sales					87%	81%	72%	71%	70%	68%
Selling & Marketing	-	-	-	-	156.4	84.2	46.6	42.7	39.0	35.6
Profit Split Payment	-	-	-	-	-	-	-	-	-	-
EBITDA	**-**	**-**	**-**	**-**	**6,644.2**	**3,322.2**	**1,629.5**	**1,468.9**	**1,320.3**	**1,182.9**
% sales					85%	79%	70%	69%	68%	66%
Working capital	-	-	-	-	1,388.0	768.8	443.3	407.7	374.5	343.6
Increase in working capital	-	-	-	-	1,388.0	-619.2	-325.5	-35.6	-33.2	-30.9
Investment (prob wtd)	791.4	215.5	215.5	215.5	215.5	-	-	-	-	-
Capitalised registrations										
Free cash flow	**-791.4**	**-215.5**	**-215.5**	**-215.5**	**5,040.7**	**3,941.4**	**1,955.0**	**1,504.6**	**1,353.5**	**1,213.7**
PV of Cash Flows	**-791.4**	**-179.6**	**-149.7**	**-124.7**	**2,430.9**	**1,584.0**	**654.7**	**419.9**	**314.8**	**235.2**

Sum of PV of Cash Flows / NPV	**4,394.1**
Present value of final working capital	**87.1**
IRR	**70%**

Aspirin; Dipyridamole ER Capsules Start

Originator market development, market entry & launch situation	
IMS/ market data - year	2010
Actual market size (gross ex-manufacturer) - mio EUR	295.5
Actual market size - mio units	175.6
Annual growth until first launch - CAGR	-5%

The brand product was approved in November 1999 and launched the following month.

Competition	
Gx market formation - best case	July 1, 2015
Number of competitors - at launch	5-6
Number of competitors - peak sales year	5-6

Competition is expected to be low due to technical barriers.
There is only one known filer, Teva via Barr acquisition.

Price erosion	
Current unit originator price (gross ex-manufacturer) - EUR/Unit	1.68
Proj unit originator price @ MF (gross ex-manufacturer) - EUR/Unit	2.36
Actavis net price (% of originator price) - at launch	11 - 34%
Actavis net price (% of originator price) - peak sales year	11 - 34%

Pricing is based on standard GPI for 3 competitors (best case) and 5 competitors (base case).
Additional competitive launches result in 30% erosion of estimated generic price.

Market share (Gx & Actavis)	
Gx market share - at launch	84%
Gx market share - peak sales year	84%
Actavis share in Gx - at launch	12 - 20%
Actavis share in Gx - peak sales year	12 - 20%

Actavis market share is expected to range from 12% (base case with 5 total competitors) to 20% (best case with 3 total competitors). This is 60% of fair share. Some decline in share is expected as additional competitors enter market, especially upon expiry of the OB-listed patent in 2017.

Hydrocodone ER Tablets Start

Project ID:	Hydrocodone ER

Suggestion from PoM:	Add to ASA/ELIZ development pipeline

Product information

INN	Hydrocodone
Dosage form	oral, ER
Dosage strengths	10mg, 20mg, 30mg, 40mg, 50mg
Indication(s)	Moderate to severe pain
Brand name	Zohydro
Originator	Zogenix

Product information (in 000s)

NPV (start of project)	€ 3,265.8
IRR (start of project)	46%
Peak sales	€ 5,498.9
Peak year	2016
Total project investments	€ 3,624.9
Development costs	
2012	€ 617.9
2013	€ 1,308.7
2014+	€ 1,698.3

Summary of opportunities (in 000s)

Trailing sales[1] :	€ 0	Unit growth[1] :	#DIV/0!
Expected peak[2] :	€ 132,280	Earliest Gx mkt :	Mar-16

Patents & Exclusivities

TBD

Type of product

- ☐ Gx blockbuster
- ☐ Added-vale Gx
- ☐ OTC
- ☑ Rx
- ☐ Hospital
- ☐ Gx niche

Source

- ☑ Own development
- ☐ Co-development
- ☐ In-licensing

Timeline

Project start	1Q12
ANDA filing	Oct-13
ANDA approval	Mar-16
Launch (earliest case)	Mar-16

Other information

Brand is not yet approved, but assume a Para IV, FTF opportunity.

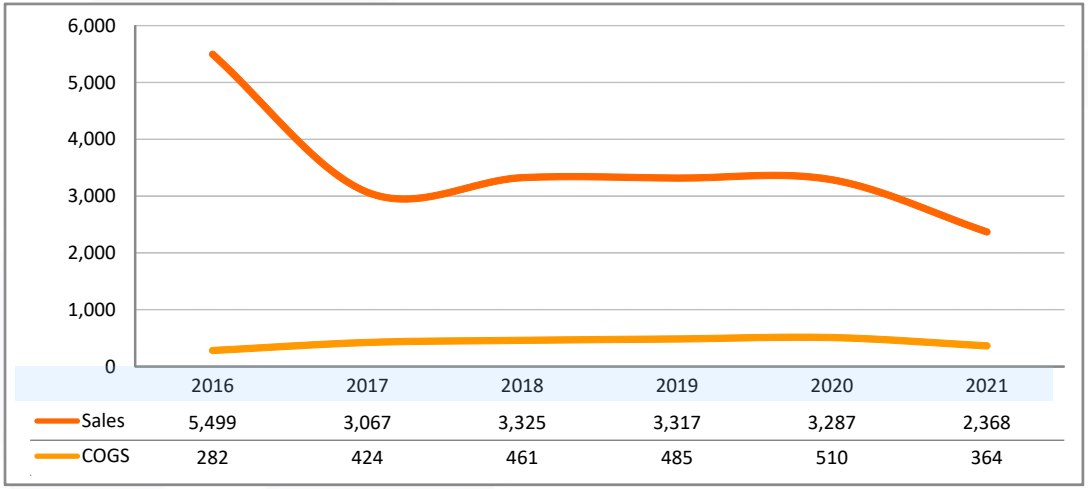
Positive phase III data has been announced and the NDA filing is expected early 2012. Brand launch assumption is Jan-13 with Actavis filing Mar-13.

[1] Based on FY 2010 IMS

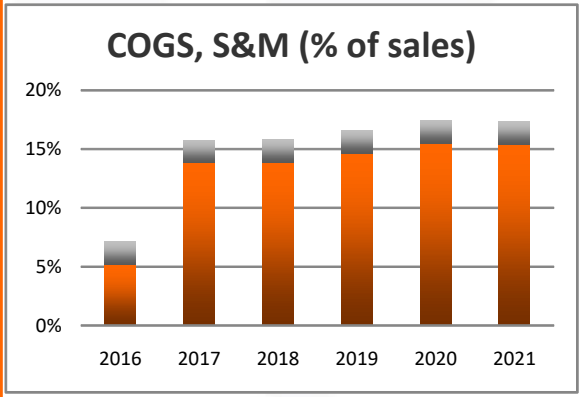
Hydrocodone ER Tablets
Start

Financial valuation ('000 EUR)

Project name	Hydrocodone ER				
First launch	US	Mar-2016	Project NPV		3,266
Start of investment		2012	Peak sales (in year)	(2016)	5,499
Expected investment		3,625	Present value of		
Sales total		20,863	final working capital		82



	2016	2017	2018	2019	2020	2021
Sales	5,499	3,067	3,325	3,317	3,287	2,368
COGS	282	424	461	485	510	364



NPV - Best (excl final WC)	€ 11,005
Non-US NPV (not incl above)	
Peak Sales - Best	€ 15,239
Non-US Peak Sales	
Sales Total - Best	€ 50,627
Non-US Sales Total	
Prob Weighting - Best	35%
Prob Weighting - Base	50%

Strategic fit / opportunity 1 ☐ 2 ☐ 3 ■

Market access:

Standard Rx

Competition (Low/Med/High):

Medium - based on ER technology and DEA schedule rating.

Therapeutic / pharmaceutical relevance:

Established generic distribution channel, no incremental S&M needs

Risk assessment 1 ☐ 2 ☐ 3 ■

Medium risk -

Qualitative evaluation

Overall score

[type here]

Hydrocodone ER Tablets
Start

EUR '000	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Total Sales	-	-	-	-	5,498.9	3,067.0	3,324.7	3,317.3	3,287.3	2,368.2
% growth		0%	0%	0%	0%	-44%	8%	0%	-1%	-28%
CoGS	-	-	-	-	282.1	423.6	460.6	485.4	509.7	363.9
Gross Margin	**-**	**-**	**-**	**-**	**5,216.8**	**2,643.4**	**2,864.1**	**2,831.9**	**2,777.6**	**2,004.3**
% sales					95%	86%	86%	85%	84%	85%
Selling & Marketing	-	-	-	-	110.0	61.3	66.5	66.3	65.7	47.4
Profit Split Payment	-	-	-	-	-	-	-	-	-	-
EBITDA	**-**	**-**	**-**	**-**	**5,106.9**	**2,582.1**	**2,797.7**	**2,765.6**	**2,711.9**	**1,956.9**
% sales					93%	84%	84%	83%	82%	83%
Working capital	-	-	-	-	940.0	546.5	592.5	593.3	590.4	425.0
Increase in working capital	-	-	-	-	940.0	-393.5	46.0	0.8	-3.0	-165.3
Investment (prob wtd)	617.9	1,308.7	517.3	517.2	517.2	146.6	-	-	-	-
Capitalised registrations										
Free cash flow	**-617.9**	**-1,308.7**	**-517.3**	**-517.2**	**3,649.6**	**2,829.1**	**2,751.6**	**2,764.8**	**2,714.9**	**2,122.3**
PV of Cash Flows	**-617.9**	**-1,090.6**	**-359.2**	**-299.3**	**1,760.0**	**1,136.9**	**921.5**	**771.6**	**631.4**	**411.3**

Sum of PV of Cash Flows / NPV	**3,265.8**
Present value of final working capital	**82.4**
IRR	**46%**

Hydrocodone ER Tablets
Start

Originator market development, market entry & launch situation	
IMS/ market data - year	2013
Actual market size (gross ex-manufacturer) - mio EUR	0.0
Actual market size - mio units	0.0
Annual growth until first launch - CAGR	#N/A

Brand is currently in phase III and expected to file the NDA early 2012. Projected brand launch date is January 2013 provided that there are not CRLs or PDUFA date extensions.
Zogenix licensed the product from Elan. It uses Elan's SODAS® technology.
This will be the first mono hydrocodone ER product available.

Competition	
Gx market formation - best case	March-16
Number of competitors - at launch	2
Number of competitors - peak sales year	2

Competition is expected to be limited due to the DEA handling requirements and ER technology.

Price erosion	
Current unit originator price (gross ex-manufacturer) - EUR/Unit	N/A
Proj unit originator price @ MF (gross ex-manufacturer) - EUR/Unit	5.36
Actavis net price (% of originator price) - at launch	7 - 42%
Actavis net price (% of originator price) - peak sales year	7 - 42%

The broad range of GPI is based on whether Actavis can achieve FTF status and enjoy higher price points during the first 6 months.

Market share (Gx & Actavis)	
Gx market share - at launch	63%
Gx market share - peak sales year	63%
Actavis share in Gx - at launch	10 - 50%
Actavis share in Gx - peak sales year	10 - 50%

Actavis market share is expected to range from 10% (base case with 6 total competitors) to 50% (best case with Actavis and AG at launch). In the best case, it is forecasted that Actavis' share will drop to 32% when additional competitors enter the market.

Potassium Chloride ER Capsules Start

Project ID:	Potassium Cl ER Caps

Suggestion from PoM:	Approve offer for product

Product information

INN	Potassium Chloride
Dosage form	Capsule, ER
Dosage strengths	8meq, 10meq
Indication(s)	Hypokalemia
Brand name	Micro-K
Originator	Ther-Rx (KV)

Product information (in 000s)

NPV (start of project)	€ 954.3
IRR (start of project)	33%
Peak sales	€ 6,449.9
Peak year	2013
Total project investments	€ 3,103.4
Development costs	
2012	€ 3,103.4
2013	€ 0.0
2014+	€ 0.0

Summary of opportunities (in 000s)

Trailing sales[1] :	€ 106,277	Unit growth[1] :	-7%
Expected peak[2] :	€ 106,277	Earliest Gx mkt :	Jan-04

Patents & Exclusivities

No unexpired OB patents or exclusivities

Type of product

- ☐ Gx blockbuster
- ☐ Added-vale Gx
- ☐ OTC
- ☑ Rx
- ☐ Hospital
- ☐ Gx niche

Source

- ☐ Own development
- ☐ Co-development
- ☑ In-licensing Tris

Timeline

Project start	Past
ANDA filing	May-10
ANDA approval	Jul-12
Launch (earliest case)	Jul-12

Other information

Actavis has previously partnered with Tris on Ibuprofen Drops and Fexofenadine Suspension (FTF). Tris has offered Actavis the first rights to a filed ANDA for Potassium Chloride ER Caps (Brand: Micro-K).

Actavis proposed counter offer: € 1.7 mill at signing and € 1.4 mill at launch, 60% profit to Tris.

COGs: €4.41/90 for 8meq, €5.24/90 for 10meq. In 2013, €0.69/bottle cheaper due to more efficient equipment purchase.

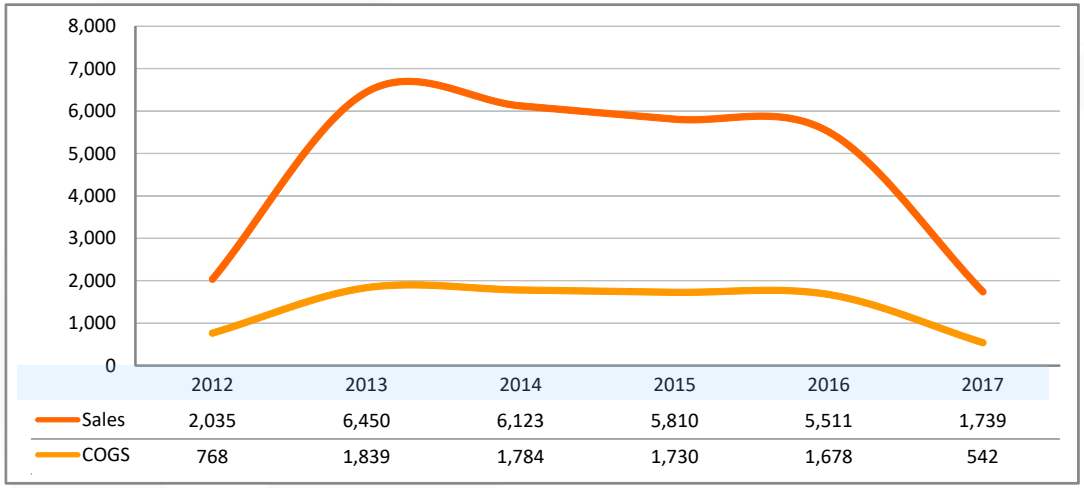
[1] Based on FY 2010 IMS

Potassium Chloride ER Capsules
Start

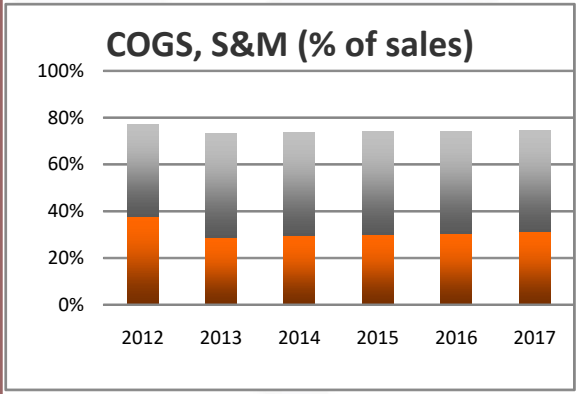
actavis
think smart medicine

Financial valuation ('000 EUR)

Project name	Potassium Cl ER Caps				
First launch	US	Jul-2012	Project NPV		954
Start of investment		2012	Peak sales (in year)	(2013)	6,450
Expected investment		3,103	Present value of		
Sales total		7,249	final working capital		135



	2012	2013	2014	2015	2016	2017
Sales	2,035	6,450	6,123	5,810	5,511	1,739
COGS	768	1,839	1,784	1,730	1,678	542



NPV - Best (excl final WC)	€ 986
Non-US NPV (not incl above)	
Peak Sales - Best	€ 6,450
Non-US Peak Sales	
Sales Total - Best	€ 29,679
Non-US Sales Total	
Prob Weighting - Best	50%
Prob Weighting - Base	50%

Strategic fit / opportunity 1 ☐ 2 ☐ 3 ■

Market access:

Standard Rx

Competition (Low/Med/High):

Low. Due to technical challenges, the generic competition has been very limited and is expected to remain low with Tris being the 4th, and possibly, last competitor in many years.

Therapeutic / pharmaceutical relevance:

Established generic distribution channel, no incremental S&M needs anticipated.

Risk assessment 1 ☐ 2 ☐ 3 ■

Medium risk since ANDA was filed and accepted for review in 2010. However, quality / compliance issues need to be evaluated during due diligence phase.

Qualitative evaluation

Overall score

Potassium Chloride ER Capsules Start

EUR '000	2012	2013	2014	2015	2016	2017
Total Sales	2,035.1	6,449.9	6,123.2	5,810.3	5,510.6	1,738.9
% growth		217%	-5%	-5%	-5%	-68%
CoGS	767.6	1,839.0	1,783.8	1,730.3	1,678.4	541.9
Gross Margin	**1,267.5**	**4,611.0**	**4,339.4**	**4,080.0**	**3,832.2**	**1,196.9**
% sales	62%	71%	71%	70%	70%	69%
Selling & Marketing	40.7	129.0	122.5	116.2	110.2	34.8
Profit Split Payment	760.5	2,766.6	2,603.6	2,448.0	2,299.3	718.2
EBITDA	**466.3**	**1,715.4**	**1,613.3**	**1,515.8**	**1,422.7**	**443.9**
% sales	23%	27%	26%	26%	26%	26%
Working capital	403.1	1,228.2	1,169.2	1,112.6	1,058.3	335.0
Increase in working capital	403.1	825.1	-59.1	-56.6	-54.3	-723.3
Investment (prob wtd)	3,103.4	-	-	-	-	-
Capitalised registrations						
Free cash flow	**-3,040.3**	**890.3**	**1,672.4**	**1,572.4**	**1,477.0**	**1,167.3**
PV of Cash Flows	**-3,040.3**	**741.9**	**1,161.4**	**910.0**	**712.3**	**469.1**

Sum of PV of Cash Flows / NPV	**954.3**
Present value of final working capital	**134.6**
IRR	**33%**

Potassium Chloride ER Capsules Start

Originator market development, market entry & launch situation	
IMS/ market data - year	2010
Actual market size (gross ex-manufacturer) - mio EUR	106.3
Actual market size - mio units	280.2
Annual growth until first launch - CAGR	#DIV/0!

The brand, Micro-K, was originally approved in October 1980. In recent years, KV (the originator) received an extensive warning letter for multiple GMP violations. This resulted in the brand being withdrawn from the market to complete remediation efforts. Watson became the resultant RLD.

KV, now Nesher Pharmaceuticals, has relaunched both the brand and AG products.

Competition	
Gx market formation - best case	January-04
Number of competitors - at launch	4
Number of competitors - peak sales year	4

Generic competition includes Watson (now the RLD), Nesher, and recently Perrigo (via Paddock acquisition).

Additional competition, while possible, is not expected.

Price erosion	
Current unit originator price (gross ex-manufacturer) - EUR/Unit	0.35
Proj unit originator price @ MF (gross ex-manufacturer) - EUR/Unit	0.35
Actavis net price (% of originator price) - at launch	48%
Actavis net price (% of originator price) - peak sales year	47%

With the limited competition and recent supply issues, competitors have taken advantage with significant price increases in 2008 and 2009. The reintroduction of Nesher and the Perrigo/Paddock product has resulted in some decline, but not significant. Actavis is expecting a 30% average decrease upon launch to obtain the target share.

Market share (Gx & Actavis)	
Gx market share - at launch	100%
Gx market share - peak sales year	100%
Actavis share in Gx - at launch	15%
Actavis share in Gx - peak sales year	15%

Actavis is expected to obtain and maintain 60% of fair share with a total of 4 players.

GSK (Stiefel) Evoclin Foam Start

Project ID:	Clindamycin foam

Suggestion from PoM:	Submit bid to acquire rights to Evoclin® asset

Product information

INN	Clindamycin
Dosage form	topical, aerosol
Dosage strengths	1%, 50 gm & 100 gm
Indication(s)	Acne
Brand name	Evoclin
Originator	GSK (via Stiefel acquisition)

Product information (in 000s)

NPV (start of project)	€ 10,720.4
IRR (start of project)	307%
Peak sales	€ 5,849.3
Peak year	2012
Total project investments	€ 8,137.9
Development costs	
2012	€ 5,517.2
2013	€ 2,620.7
2014+	€ 0.0

Summary of opportunities (in 000s)

Trailing sales[1] :	€ 26,746	Unit growth[1] :	0%
Expected peak[2] :	€ 26,746	Earliest Gx mkt :	Mar-10

Patents & Exclusivities

7141237	1/23/24
7374747 (U)	8/9/26

Type of product

- ☐ Gx blockbuster
- ☐ Added-vale Gx
- ☐ OTC
- ☑ Rx
- ☐ Hospital
- ☐ Gx niche

Source

- ☐ Own development
- ☐ Co-development
- ☑ In-licensing GSK

Timeline

Project start	Past
ANDA filing	N/A
ANDA approval	N/A
Launch (earliest case)	Feb-12

Other information

GSK has several brand products for sale from the Stiefel acquisition. Once brand, Evoclin® is of potential value to Actavis. The generic market formed in 2010 with the approval and launch of Perrigo's ANDA. There has not been an AG or additional approval.

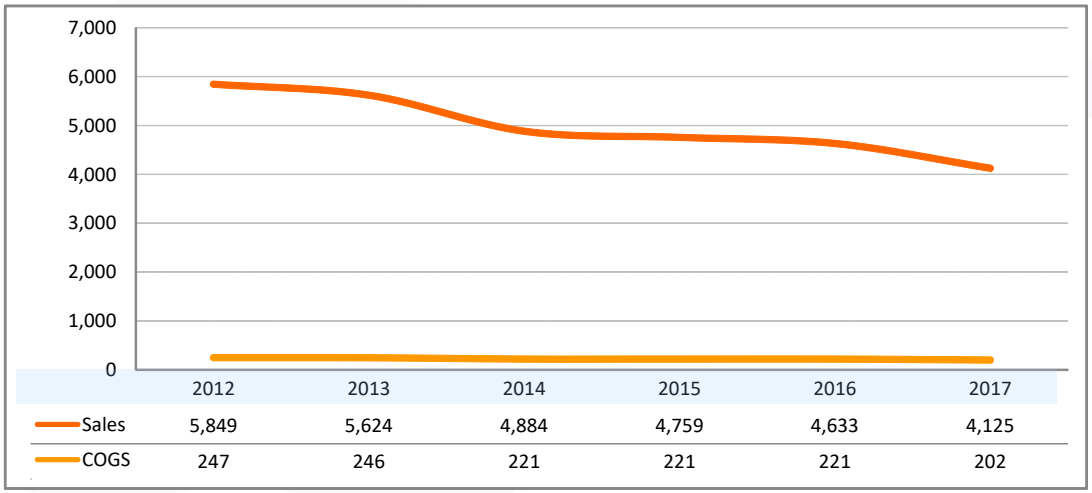
In addition to the residual brand sales expected (no detail efforts to be expended), Actavis plans to launch an AG to greatly increase the asset value.

[1] Based on FY 2010 IMS

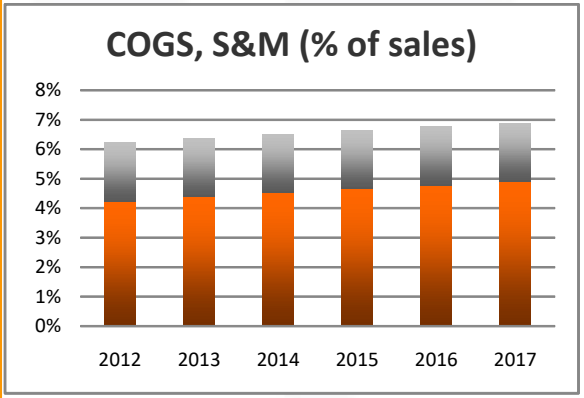
GSK (Stiefel) Evoclin Foam Start

Financial valuation ('000 EUR)

Project name	Clindamycin foam				
First launch	US	Feb-2012	Project NPV		10,720
Start of investment		2012	Peak sales (in year)	(2012)	5,849
Expected investment		8,138	Present value of		
Sales total		8,758	final working capital		283



	2012	2013	2014	2015	2016	2017
Sales	5,849	5,624	4,884	4,759	4,633	4,125
COGS	247	246	221	221	221	202



NPV - Best (excl final WC)	€ 12,667
Non-US NPV (not incl above)	
Peak Sales - Best	€ 6,157
Non-US Peak Sales	
Sales Total - Best	€ 33,772
Non-US Sales Total	
Prob Weighting - Best	55%
Prob Weighting - Base	40%

Strategic fit / opportunity 1 ☐ 2 ☐ 3 ■

Market access:

Standard Rx

Competition (Low/Med/High):

Low based on specialized aerosol foam technology.

Therapeutic / pharmaceutical relevance:

Established generic distribution channel, no incremental S&M needs

Risk assessment 1 ☐ 2 ☐ 3 ■

Low Risk

Qualitative evaluation

Overall score

[type here]

GSK (Stiefel) Evoclin Foam Start

EUR '000	2012	2013	2014	2015	2016	2017
Total Sales	5,849.3	5,624.5	4,884.1	4,758.6	4,633.1	4,124.7
% growth		-4%	-13%	-3%	-3%	-11%
CoGS	247.4	245.8	220.7	220.7	220.7	201.9
Gross Margin	**5,601.9**	**5,378.7**	**4,663.5**	**4,538.0**	**4,412.4**	**3,922.8**
% sales	96%	96%	95%	95%	95%	95%
Selling & Marketing	117.0	112.5	97.7	95.2	92.7	82.5
Profit Split Payment	-	-	-	-	-	-
EBITDA	**5,484.9**	**5,266.2**	**4,565.8**	**4,442.8**	**4,319.8**	**3,840.3**
% sales	94%	94%	93%	93%	93%	93%
Working capital	995.5	957.9	832.4	811.5	790.6	704.3
Increase in working capital	995.5	-37.6	-125.5	-20.9	-20.9	-86.3
Investment (prob wtd)	5,517.2	2,620.7	-	-	-	-
Capitalised registrations						
Free cash flow	**-1,027.8**	**2,683.1**	**4,691.3**	**4,463.7**	**4,340.7**	**3,926.6**
PV of Cash Flows	**-1,027.8**	**2,235.9**	**3,257.8**	**2,583.2**	**2,093.3**	**1,578.0**

Sum of PV of Cash Flows / NPV	**10,720.4**
Present value of final working capital	**283.0**
IRR	**307%**

GSK (Stiefel) Evoclin Foam Start

Originator market development, market entry & launch situation	
IMS/ market data - year	2010
Actual market size (gross ex-manufacturer) - mio EUR	26.7
Actual market size - mio units	0.2
Annual growth until first launch - CAGR	#DIV/0!

The originator of this product (Connetics) received FDA approval for Evoclin® Foam in October 2004 with a launch in December. Steifel acquired the company and associated products in 2006. GSK then acquired Stiefel in 2009. The first generic approved was Perrigo (via Cobrek development partnership) and settled with GSK to launch at ANDA approval. Since that approval, brand sales have steeply declined prompting GSK to include this in a basket of derm brands being divested.

Competition	
Gx market formation - best case	March-10
Number of competitors - at launch	2
Number of competitors - peak sales year	2

Perrigo is the only known competitor. Due to the unique equipment needs, this is expected to remain very limited. GSK has not partnered with anyone to launch an AG and Actavis would look to do this immediately upon acquiring the brand.

Price erosion	
Current unit originator price (gross ex-manufac-turer) - EUR/Unit	€ 154.38
Proj unit originator price @ MF (gross ex-manufac-turer) - EUR/Unit	€ 154.38
Actavis net price (% of originator price) - at launch	42%
Actavis net price (% of originator price) - peak sales year	42%

As the second generic, some price erosion is expected. The average GPI is forecasted to be 42%. Year over year erosion is expected as on-going bids for business may result in pressure to lower prices.

Market share (Gx & Actavis)	
Gx market share - at launch	90%
Gx market share - peak sales year	90%
Actavis share in Gx - at launch	30%
Actavis share in Gx - peak sales year	30%

Since Perrigo has an established presence in the generic market, Actavis is forecasted to target and obtain 60% of fair share, which is 30%.

NAB Paclitaxel Injection Start

actavis
think smart medicine

Project ID:	nab-paclitaxel

Suggestion from PoM:	Approve in-licensing deal with Biovectra

Product information

INN	Paclitaxel
Dosage form	Injectable
Dosage strengths	100 mg
Indication(s)	Antineoplastic
Brand name	Abraxane®
Originator	Abraxis Oncology (Celgene)

Product information (in 000s)

NPV (start of project)	€ 9,124.3
IRR (start of project)	127%
Peak sales	€ 12,919.9
Peak year	2015
Total project investments	€ 1,440.1
Development costs	
2011	€ 0.0
2012	€ 503.7
2013+	€ 936.4

Summary of opportunities (in 000s)

Trailing sales[1] :	€ 237,997	Unit growth[1] :	5%
Expected peak[2] :	€ 291,729	Earliest Gx mkt :	Aug-15

Patents & Exclusivities

Currently 10 OB listed patents; 7 expire in 2013 1 expires in 2016 (RE41884.) 1 expires in 2023 (7,923,536) 1 expires in 2024 (7,820,788)	There is a constraining "quasi" product patent in Italy (EP-0961612/ WO-09814174) with granted SPC, expiring Sep-2022. This patent is under opposition at EPO – oral hearing Nov-2011 No valid patents listed in RO

Type of product

- ☐ Gx blockbuster
- ☐ Added-vale Gx
- ☐ OTC
- ☐ Rx
- ☑ Hospital
- ☐ Gx niche

Source

- ☐ Own development
- ☐ Co-development
- ☑ In-licensing

Timeline

Project start	Not yet started
ANDA filing	January-13
ANDA approval	August-15
Launch (earliest case)	August-15

Other information

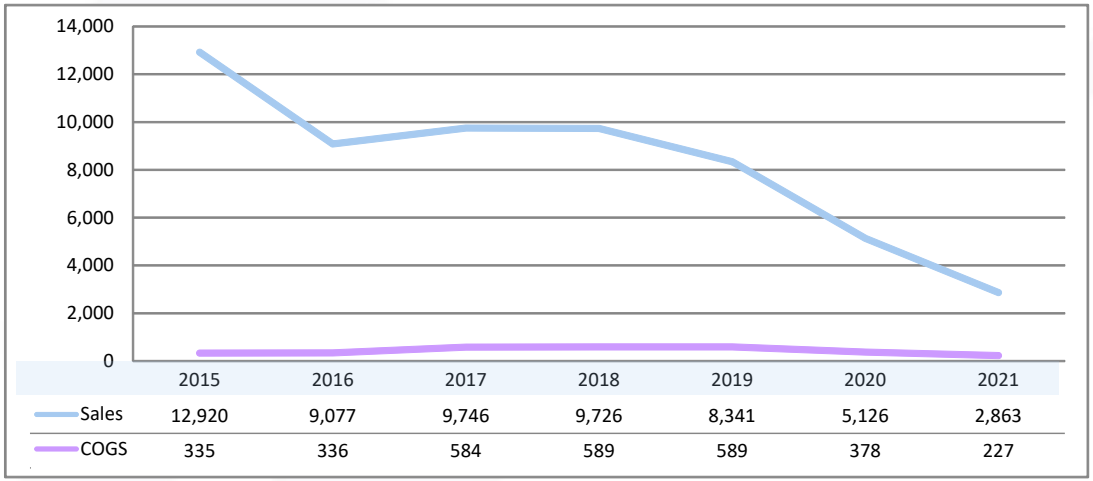
This is a FTF PIV opportunity for nab-paclitaxel (ABRAXANE®), a novel solvent-free formulation of paclitaxel in which the drug substance is complexed with albumin to form stable nano-particles. The potential partner, BioVectra is a Canadian-based pharma/biotech company with a proven record in taxane formulation. While BioVectra has 3 FDA-inspected facilities, this product would be manufactured at Sindan/Nerviano or a CMO. Terms: all development, IP costs and profit to be shared 60% Actavis, 40% BioVectra. Actavis' share of development exp estimated at €656K and IP exp at €1,035K-2,069K.

[1] Based on FY 2010 IMS

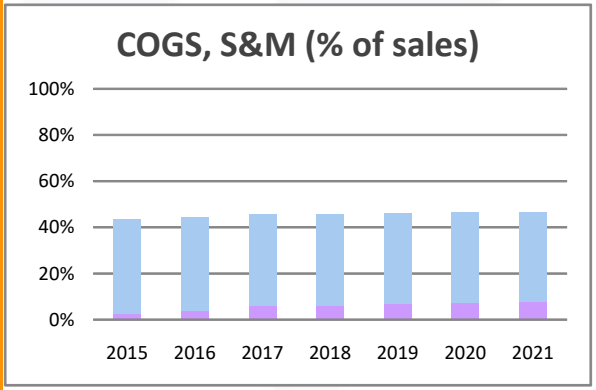
NAB Paclitaxel Injection
Start

Financial valuation ('000 EUR)

Project name	nab-paclitaxel				
First launch	US	Aug-2015	Project NPV		9,124
Start of investment		2011	Peak sales (in year)	(2015)	12,920
Expected investment		1,440	Present value of		
Sales total		60,617	final working capital		80



	2015	2016	2017	2018	2019	2020	2021
Sales	12,920	9,077	9,746	9,726	8,341	5,126	2,863
COGS	335	336	584	589	589	378	227



NPV - Best (excl final WC)	€ 88,975
Non-US NPV (not incl above)	
Peak Sales - Best	€ 51,679
Non-US Peak Sales	
Sales Total - Best	€ 172,492
Non-US Sales Total	
Prob Weighting - Best	25%
Prob Weighting - Base	55%

Strategic fit / opportunity 1 ☐ 2 ■ 3 ☐

Market access:

Market access primarily through oncology distributors; product could be marketed by current US partner, Sagent or via Actavis sales team

Competition (Low/Med/High):

Medium - moderate degree of difficulty to reproduce physicial charactersitics (i.e.particle size) of RLD. Clinical study requirment and assoicated cost may reduce number of generic comps

Therapeutic / pharmaceutical relevance:

Risk assessment 1 ☐ 2 ■ 3 ☐

Medium risk

Qualitative evaluation

Overall score

[type here]

NAB Paclitaxel Injection Start

EUR '000	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Total Sales	-	-	-	12,919.9	9,077.4	9,745.6	9,726.4	8,340.5	5,126.1	2,862.8	2,818.6
% growth	0%	0%	0%	0%	-30%	7%	0%	-14%	-39%	-44%	-2%
CoGS	-	-	-	334.9	336.1	583.6	588.9	589.0	378.0	227.4	226.8
Gross Margin	**-**	**-**	**-**	**12,585.0**	**8,741.3**	**9,162.0**	**9,137.5**	**7,751.5**	**4,748.1**	**2,635.4**	**2,591.8**
% sales				97%	96%	94%	94%	93%	93%	92%	92%
Selling & Marketing	-	-	-	258.4	181.5	194.9	194.5	166.8	102.5	57.3	56.4
Profit Split Payment	-	-	-	5,034.0	3,496.5	3,664.8	3,655.0	3,100.6	1,899.2	1,054.2	1,036.7
EBITDA	**-**	**-**	**-**	**7,292.6**	**5,063.2**	**5,302.3**	**5,288.0**	**4,484.1**	**2,746.4**	**1,524.0**	**1,498.8**
% sales				56%	56%	54%	54%	54%	54%	53%	53%
Working capital	-	-	-	2,181.2	1,540.9	1,672.9	1,670.1	1,439.2	885.8	496.1	488.7
Increase in working capital	-	-	-	2,181.2	-640.3	132.0	-2.8	-231.0	-553.3	-389.8	-7.4
Investment (prob wtd)	584.3	257.6	366.2	314.5	147.9	-	-	-	-	-	-
Capitalised registrations											
Free cash flow	**-584.3**	**-257.6**	**-366.2**	**4,796.9**	**5,555.6**	**5,170.3**	**5,290.8**	**4,715.1**	**3,299.7**	**1,913.8**	**1,506.2**
PV of Cash Flows	**-486.9**	**-178.9**	**-211.9**	**2,313.3**	**2,232.7**	**1,731.5**	**1,476.6**	**1,096.6**	**639.5**	**309.1**	**202.7**

Sum of PV of Cash Flows / NPV	**9,124.3**
Present value of final working capital	**80.1**
IRR	**127%**

NAB Paclitaxel Injection Start

Originator market development, market entry & launch situation	
IMS/ market data - year	2010
Actual market size (gross ex-manufacturer) - mio EUR	238.0
Actual market size - mio units	0.39
Annual growth until first launch - CAGR	1.2%

Approved by FDA in 2005, ABRAXANE® (paclitaxel protein-bound particles for injectable suspension) is indicated for the treatment of breast cancer. Conventional paclitaxel has multiple indications: advanced carcinoma of the ovary, breast cancer, NSCL cancer, and AIDS-related Kaposi's sarcoma. Abraxane is Cremaphor-free and addresses some of the serious side-effects and limitiations associated with this solvent/standard paclitaxel therapy. Advantages include: less toxicity; higher doses possible; higher tumor tissue selectivity; reduced neutropenia. Abraxane unit growth has averaged 21% since 2005 while the conventional pacli mkt has remained relatively flat. This suggests that there are distinct markets for the two versions. Use of Abraxane may increse as indications are added and/or outside indication use grows.

Competition	
nab-paclitaxel	August-15
Number of competitors - at launch	1-7
Number of competitors - peak sales year	1-7

There are 9 generic approvals for conventional paclitaxel. Protein-bound paclitaxel is technically more challenging and, according to Biovectra, significant effort is required to produce stable 130nm nanoparticles consistently. For this reason, the number of competitors reflected in the business case has been reduced versus conventional paclitaxel from nine to seven.

Price erosion	
Current unit originator price (gross ex-manufacturer) - EUR/Unit	650.00
Proj unit originator price @ MF (gross ex-manufacturer) - EUR/Unit	687.40
Actavis net price (% of originator price) - at launch	21-60%
Actavis net price (% of originator price) - peak sales year	21-60%

Price erosion adjusted from standard erosion assumption to reflect staggered entyr of market competitors.

Market share (Gx & Actavis)	
Gx market share - at launch	35-95%
Gx market share - peak sales year	35-95%
Actavis share in Gx - at launch	10-100%
Actavis share in Gx - peak sales year	10-100%

Base case assumes unsuccessful PIV FTF position and delayed market entry. As one of 7 competitors, 10% is less than fair share.

Dermapharm Scopolomine Patch Start

Project ID:	Scopolamine Patch
Suggestion from PoM:	Pursue partnership for final development

Product information

INN	Scopolamine
Dosage form	transdermal film, ER
Dosage strengths	1mg/72 hrs
Indication(s)	Prevention of nausea & vomiting
Brand name	Transderm-Scop
Originator	Novartis/ Baxter

Product information (in 000s)

NPV (start of project)	€ 6,137
IRR (start of project)	95%
Peak sales	€ 6,998
Peak year	2016
Total project investments	€ 1,168
Development costs	
2012	€ 393
2013	€ 774
2014+	€ 0

Summary of opportunities (in 000s)

Trailing sales[1] :	€ 48,946	Unit growth[1] :	9%
Expected peak[2] :	€ 53,007	Earliest Gx mkt :	Jan-15

Patents & Exclusivities

No unexpired OB patents or exclusivities

Type of product

- ☐ Gx blockbuster
- ☐ Added-vale Gx
- ☐ OTC
- ☑ Rx
- ☐ Hospital
- ☐ Gx niche

Source

- ☐ Own development
- ☐ Co-development
- ☑ In-licensing DermaPharm

Timeline

Project start	Past
ANDA filing	July-12
ANDA approval	January-15
Launch (earliest case)	January-15

Other information

Dermapharm is near completing development of scopolamine patch. The product was originally developed using the Amarin transdermal facility in Argentina. The activity has since been transferred to LTS in Germany.

Terms: Actavis to fund remaining development work (~€ 375k), € 69k due to Dermapharm at signing for use of old data, Actavis to fund biopharm activity (€ 731k).
5% royalty on net sales to LTS, 35% profits to Dermapharm
COGs: € 0.34 / patch

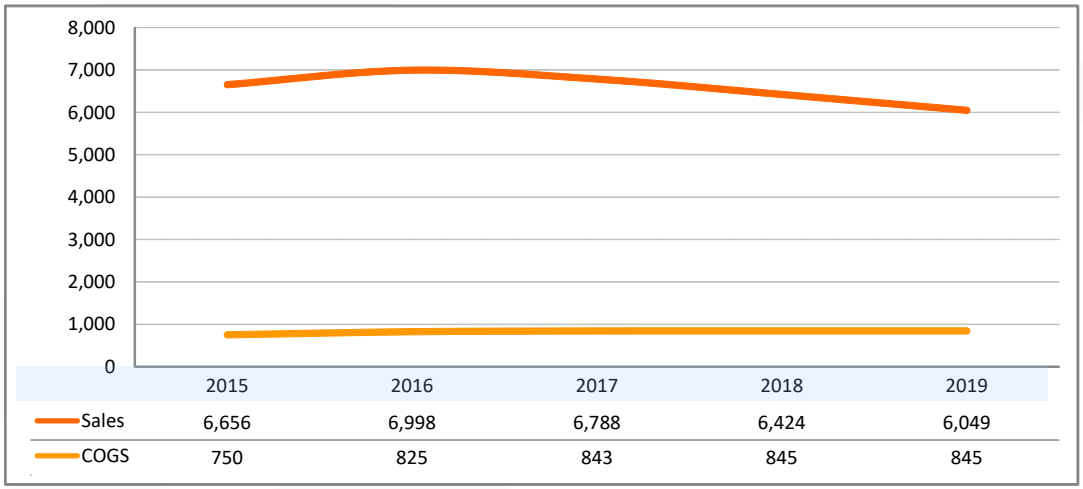
[1] 2010 IMS market sales

[2] Expected peak market sales

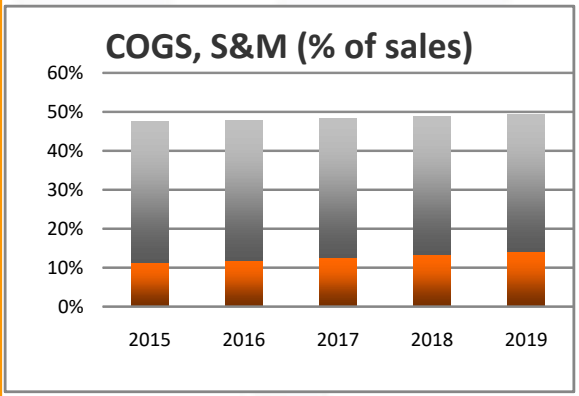
Dermapharm Scopolomine Patch Start

Financial valuation ('000 EUR)

Project name	Scopolamine Patch				
First launch	US	Jan-2015	Project NPV		6,137
Start of investment		2012	Peak sales (in year)	(2016)	6,998
Expected investment		1,168	Present value of		
Sales total		31,919	final working capital		301



	2015	2016	2017	2018	2019
Sales	6,656	6,998	6,788	6,424	6,049
COGS	750	825	843	845	845



NPV - Best (excl final WC)	€ 9,733
Non-US NPV (not incl above)	
Peak Sales - Best	€ 10,415
Non-US Peak Sales	
Sales Total - Best	€ 57,588
Non-US Sales Total	
Prob Weighting - Best	55%
Prob Weighting - Base	40%

Strategic fit / opportunity 1 ☐ 2 ☐ 3 ■

Market access:

Standard Rx

Competition (Low/Med/High):

Low. FTM opportunity on old established brand product.

Therapeutic / pharmaceutical relevance:

Established generic distribution channel, no incremental S&M needs anticipated.

Risk assessment 1 ☐ 2 ☐ 3 ■

Medium risk based on biodata reviewed, but formulation strategy with LTS is established.

Qualitative evaluation

Overall score

Dermapharm Scopolomine Patch Start

EUR '000	2012	2013	2014	2015	2016	2017	2018	2019	2020
Total Sales	-	-	-	6,655.6	6,998.2	6,788.1	6,424.0	6,049.5	5,659.4
% growth		0%	0%	0%	5%	-3%	-5%	-6%	-6%
CoGS	-	-	-	750.4	825.3	843.5	844.7	844.7	842.4
Gross Margin	**-**	**-**	**-**	**5,905.1**	**6,172.8**	**5,944.7**	**5,579.3**	**5,204.8**	**4,817.0**
% sales				89%	88%	88%	87%	86%	85%
Selling & Marketing	-	-	-	126.5	133.0	129.0	122.1	114.9	107.5
Profit Split Payment	-	-	-	2,283.1	2,387.9	2,301.2	2,161.5	2,018.3	1,869.9
EBITDA	**-**	**-**	**-**	**3,495.6**	**3,652.0**	**3,514.5**	**3,295.7**	**3,071.5**	**2,839.6**
% sales				53%	52%	52%	51%	51%	50%
Working capital	-	-	-	1,171.8	1,235.1	1,201.6	1,141.1	1,078.6	1,013.4
Increase in working capital	-	-	-	1,171.8	63.3	-33.5	-60.6	-62.4	-65.2
Investment (prob wtd)	393.1	774.4	-	-	-	-	-	-	-
Capitalised registrations									
Free cash flow	**-393.1**	**-774.4**	**0.0**	**2,323.8**	**3,588.6**	**3,548.0**	**3,356.3**	**3,133.9**	**2,904.8**
PV of Cash Flows	**-393.1**	**-645.3**	**0.0**	**1,344.8**	**1,730.6**	**1,425.8**	**1,124.0**	**874.6**	**675.6**

Sum of PV of Cash Flows / NPV	**6,137.0**
Present value of final working capital	**301.0**
IRR	**95%**

Dermapharm Scopolomine Patch Start

Originator market development, market entry & launch situation	
IMS/ market data - year	2010
Actual market size (gross ex-manufacturer) - mio EUR	48.9
Actual market size - mio units	7.7
Annual growth until first launch - CAGR	0%

This is a very old brand which launched in 1980. It is indicated for prevention of nausea and vomiting due to motion sickness and recovery from anesthesia. This is also a control substance with known addictive properties.
Novartis, the innovator markets the product to physicians for the motion sickness indication. Baxter co-markets the product to the hospital segment for the anesthesia indication.

Competition	
Gx market formation - best case	January-15
Number of competitors - at launch	4 - 5
Number of competitors - peak sales year	4 - 5

Although this product is very old, there are no generic approvals or competitors. This is a FTM opportunity.
Due to the technical challenges, especially as it relates to comparative clinical requirements, competition is also expected to remain low.
Dermapharm has also approached Actavis with an OTC switch opportunity. This will remain an opportunity to monitor and possibly pursue in the future, but focus on the FTM ANDA is priority for both companies.
As Dermapharm does not have internal patch capability, they have recently partnered with LTS out of Germany to finalize development activity and commercial production. Previously they were using Amarin out of Argentina.

Price erosion	
Current unit originator price (gross ex-manufac-turer) - EUR/Unit	€ 6.55
Proj unit originator price @ MF (gross ex-manufac-turer) - EUR/Unit	€ 7.67
Actavis net price (% of originator price) - at launch	34%- 42%
Actavis net price (% of originator price) - peak sales year	34%- 42%

The price point is expected to remain high due to the limited competition and cost of utilizing a CMO (as most generic companies do not have internal capability for patches).

Market share (Gx & Actavis)	
Gx market share - at launch	77% - 90%
Gx market share - peak sales year	77% - 90%
Actavis share in Gx - at launch	20% - 50%
Actavis share in Gx - peak sales year	20% - 50%

As a FTM opportunity, Actavis is expected to obtain fair share at launch assuming an AG also launches. This is expected as Sandoz is the generic division of Novartis. In the late to market scenario, Actavis is forecasted to obtain 60% of fair share, which is 20% for the 3rd entry.

Synthon Tadalafil Tablets Start

Project ID:	Tadalafil

Suggestion from PoM:	Proceed with IL opportunity

Product information

INN	Tadalafil
Dosage form	Tablet
Dosage strengths	20mg
Indication(s)	Hypertension
Brand name	Adcirca
Originator	Lilly

Product information (in 000s)

NPV (start of project)	€ 713.1
IRR (start of project)	25%
Peak sales	€ 6,960.6
Peak year	2018
Total project investments	€ 3,262.1
Development costs	
2012	€ 1,317.2
2013	€ 627.6
2014+	€ 1,317.2

Summary of opportunities (in 000s)

Trailing sales[1] :	€ 15,613	Unit growth[1] :	558%
Expected peak[2] :	€ 103,934	Earliest Gx mkt :	Nov-17

Patents & Exclusivities

5859006 (U)	11/21/17
6821975	11/19/20
7182958	4/26/20
NP exlcusivity	5/22/12

Type of product

- ☐ Gx blockbuster
- ☐ Added-vale Gx
- ☐ OTC
- ☑ Rx
- ☑ Hospital
- ☐ Gx niche

Source

- ☐ Own development
- ☐ Co-development
- ☑ In-licensing Synthon

Timeline

Project start	Past
ANDA filing	Oct-09
ANDA approval	Nov-17
Launch (earliest case)	Nov-17

Other information

Synthon filed an ANDA vs the Adcirca RLD with Para IV certification 15-Oct-09. Lilly sued Synthon 15-Mar-10. The case has been stayed effective 18-Feb-11. Synthon and/or partner will be responsible for reactivating the suit to achieve market formation at the expiry of the 2017 patent (Synthon certified PIII vs this patent).

Proposed terms: € 1.4 mill paid across 4 milestones (signing, TA, litigation resolution, launch), 30% Profits, Actavis to fund remaining litigation.

COGs: € 0.05 / tablet

[1] Based on FY 2010 IMS

Synthon Tadalafil Tablets
Start

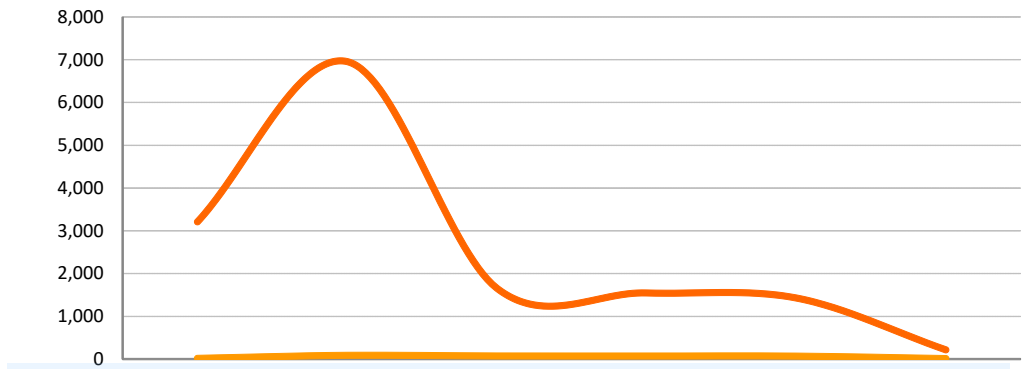
NPV Sensitivity Analysis

Discount Rate	NPV (€ 000)
10%	2,948
15%	1,637
20%	713
25%	53

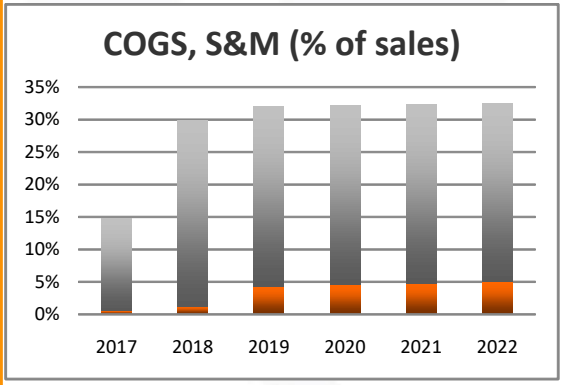
Synthon Tadalafil Tablets Start

Financial valuation ('000 EUR)

Project name	Tadalafil				
First launch	US	Nov-2017	Project NPV		713
Start of investment		2012	Peak sales (in year)	(2018)	6,961
Expected investment		3,262	Present value of		
Sales total		15,030	final working capital		6



	2017	2018	2019	2020	2021	2022
Sales	3,212	6,961	1,660	1,548	1,431	217
COGS	16	87	72	70	68	11



NPV - Best (excl final WC)	€ 1,674
Non-US NPV (not incl above)	
Peak Sales - Best	€ 8,861
Non-US Peak Sales	
Sales Total - Best	€ 20,463
Non-US Sales Total	
Prob Weighting - Best	50%
Prob Weighting - Base	50%

Strategic fit / opportunity 1 ☐ 2 ☐ 3 ■

Market access:

Standard Rx

Competition (Low/Med/High):

Medium - Due to smaller brand market and projected IP spend. 4 (best case) - 5 (base case).

Therapeutic / pharmaceutical relevance:

Established generic distribution channel, no incremental S&M needs anticipated.

Risk assessment 1 ☐ 2 ☐ 3 ■

Low, ANDA filed. Synthon FTF. Litigation stayed based on timing.

Qualitative evaluation

Overall score

[type here]

Synthon Tadalafil Tablets Start

EUR '000	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Total Sales	-	-	-	-	-	3,212.4	6,960.6	1,660.1	1,548.5	1,431.0	216.9
% growth		0%	0%	0%	0%	0%	117%	-76%	-7%	-8%	-85%
CoGS	-	-	-	-	-	16.5	86.6	71.8	70.1	68.0	10.8
Gross Margin	**-**	**-**	**-**	**-**	**-**	**3,196.0**	**6,874.0**	**1,588.4**	**1,478.4**	**1,363.0**	**206.0**
% sales						99%	99%	96%	95%	95%	95%
Selling & Marketing	-	-	-	-	-	64.2	139.2	33.2	31.0	28.6	4.3
Profit Split Payment	-	-	-	-	-	394.0	1,853.4	426.7	397.1	366.0	55.3
EBITDA	**-**	**-**	**-**	**-**	**-**	**2,737.7**	**4,881.4**	**1,128.5**	**1,050.3**	**968.4**	**146.4**
% sales						85%	70%	68%	68%	68%	67%
Working capital	-	-	-	-	-	536.8	1,167.3	282.7	263.9	244.2	37.0
Increase in working capital	-	-	-	-	-	536.8	630.5	-884.6	-18.7	-19.8	-207.1
Investment (prob wtd)	1,317.2	627.6	972.4	-	-	344.8	-	-	-	-	-
Capitalised registrations											
Free cash flow	**-1,317.2**	**-627.6**	**-972.4**	**0.0**	**0.0**	**1,856.1**	**4,250.9**	**2,013.1**	**1,069.1**	**988.2**	**353.5**
PV of Cash Flows	**-1,317.2**	**-523.0**	**-675.3**	**0.0**	**0.0**	**745.9**	**1,423.6**	**561.8**	**248.6**	**191.5**	**57.1**

Sum of PV of Cash Flows / NPV	**713.1**
Present value of final working capital	**6.0**
IRR	**25%**

Synthon Tadalafil Tablets Start

Originator market development, market entry & launch situation	
IMS/ market data - year	2010
Actual market size (gross ex-manufacturer) - mio EUR	15.6
Actual market size - mio units	1.4
Annual growth until first launch - CAGR	20%

Brand product was approved Jul-09. Peak sales are estimated to grow to 400 mil EUR

Competition	
Gx market formation - best case	November-17
Number of competitors - at launch	5-6
Number of competitors - peak sales year	5-6

Competition is expected to be average for a generic product. The large brand market will attract many competitors, however the difficulty of obtaining passing biostudy results will likely keep this from becoming a bloodbath.

Price erosion	
Current unit originator price (gross ex-manufacturer) - EUR/Unit	2.45
Proj unit originator price @ MF (gross ex-manufacturer) - EUR/Unit	3.22
Actavis net price (% of originator price) - at launch	7 - 11%
Actavis net price (% of originator price) - peak sales year	7 - 10%

Percent of originator price is based off the standard business case model assumption for 5 - 6 competitors.

Market share (Gx & Actavis)	
Gx market share - at launch	77%
Gx market share - peak sales year	84%
Actavis share in Gx - at launch	17 - 20%
Actavis share in Gx - peak sales year	17 - 20%

Actavis market share is expected to range from 17% (base case with 6 total competitors) to 20% (best case with 5 total competitors).

Other decisions

- Confirm Crown Jewel status
  - List of projects from second discussion
  - CJ status for Iceland
- Caspofungin – confirmed development cost
- Ropnirole PR – additional biostudy
- Entacapone Combi – additional biostudy
- Rivastigmine capsules – eraly launch UK
- Amlodipine/Atorvastatin – litigation strategy
- RA: Registration strategy
- CPM: Launch status and deviations

Crown Jewels – meeting September 20th

INN	Dosage form/Strengths	Countries	Reason	Request	Revenue [000 EUR]	Decisions/Actions to be taken
Acetylsalicylic acid	EC tablets 150 mg, 160 mg and 75 mg	DK, SE	Only one on the markets today with EC tablets.	CJ status to DK and SE.		The disadvantage of Medis not having these 2 countries in the agreement is less than the opportunity for OB. **Decision:** Agreed to grant CJ status to DK and SE, if there are changes to the situation then to be discussed again.
Amlodipine/Valsartan	Film-coated tablets 5/80 mg, 5/160 mg and 10/160 mg	FI	Early launch	CJ status for FI		Early launch opportunity to be evaluated further, need more information from IP (Bert) - PoM will set up separate meeting for early launches in FI
Bosentan	Tablets 62.5 mg and 125 mg	FI	Early launch	CJ status for FI		Early launch opportunity to be evaluated further, need more information from IP (Bert) - PoM will set up separate meeting for early launches in FI
Buprenorphine	Sublingual tablets 0.4 mg, 1 m, 2 mg, 4 mg and 8 mg	FI, DK, SE	Limited competition, class A product. Only one with the 6 mg strength. Will be number 2 or 3 on the market. If the same dossier is brought in then there will be direct competition	CJ status for FI, DK and SE		Medis is in negotiations with 2 clients, want to be able to pursue pan European agreements. Medis forecasts are at the moment not outweighing the OB opportunity, but negotiations are very advanced. **Decision:** CJ status not granted. If there is a change in plans from Medis side, they will bring it back to the CJ forum. Markets will be made aware that there will be some competition.
Duloxetine	Capsules 30 mg and 60 mg, 20 mg and 40 mg	FI	Early launch	CJ status for FI		Early launch opportunity to be evaluated further, need more information from IP (Bert) - PoM will set up separate meeting for early launches in FI
Entacapone/Carbidopa/ Levodopa	Tablets 50/12.5/200mg, 100/25/200mg, 150/37.5/200mg, 75/18.75/200mg, 125/31.25/200mg, 200/50/200mg	FI	Data exclusivity launch	CJ status for FI		Medis wants to have rights for multi national and/or pan-European agreements. **Decision:** This is a run for the market, no CJ status granted.
Finasteride	Tablets 1 mg	DK	Niche market	CJ status for DK		Small niche market. Medis has already several EU agreements. This was a co-development with Tiefenbacher so they could sell the dossier. **Decision:** No CJ status

Crown Jewels

Folic acid	Tablets 5 mg	DK	Limited competition expected	CJ status for DK	Small CJ value (280 k EUR). Medis is in negotiations with companies for Europe. Downpayment alone would offset the CJ value. **Decision:** No CJ status
Lercanidipine	Tablets 10 mg and 20 mg	DK		CJ status for DK	Small CJ value (299 k EUR). Medis has already signed 3 pan European agreements. **Decision:** No CJ status.
Levetiracetam	Tablets 250 mg, 500 mg and 1000 mg	SE	Unique in dose-dispensing and there is no substitution. If the same dossier is available to others there will be direct substituion.	CJ status for SE	Medis does not expect any pan European agreements, will not match the OB opportunity. **Decision:** Agreed to grant CJ status for Sweden.
Levetiracetam	Oral solution 100 mg/ml	SE	Limited competition, non-substitutable	CJ status for SE	**Decision:** Agreed to grant CJ status for Sweden
Levothyroxine	Tablets	UK, FI, NL, SE	Limited competition.	CJ status for UK, FI, NL, SE	2-3 dossiers available, quality of the dossiers unknown. **Actions:** Wolter to discuss with Silvester the IL opportunities to evaluate the possible competition for this product. Marketing to evaluate and bring in for discussion other markets that are requesting CJ status (PL, IT, FR), to be discussed in the next meeting. **Decision:** Agreed to have CJ status for UK, FI, NL, SE.
Nebivolol	Tablets 5 mg	DK	Limited competition		Small CJ value. Medis does not have available MA's in Denmark and does not expect to sell this. However downpayment for any deal would offset the CJ value. **Decision:** No CJ status to be granted
Paracetamol	Oral solution 24 mg/ml	FI, DK, SE	Part of the Pinex portfolio in DK and NO. In SE we will be the only one with the oral solution. The solution is not big but it is a door opener, deals with pharmacy chains, unique selling point.	CJ status for FI, DK and SE	Medis is supplying another pharmacy chain, that Actavis is not in business with. Medis has a few interested clients, but would not match the CJ value from OB. **Decision:** Medis does not do further agreements for these markets, CJ status agreed for FI, DK and SE.

Crown Jewels

Pemetrexed	Concentrate for solution for infusion 100 mg/4 ml	FI	Early launch	CJ status for FI	Early launch opportunity to be evaluated further, need more information from IP (Bert) - PoM will set up separate meeting for early launches in FI
Pramipexole	Prolonged release tablets 0.26mg, 0.52mg, 1.05mg, 2.1mg, 3.15mg	FI	First to market	CJ status for FI	This is not a unique opportunity as such. This is a big moelcule, a lot of developers will be coming to the market. **Decision:** No CJ status
Pregabalin	Capsules 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg & 300 mg	FI	Early launch	CJ status for FI	Early launch opportunity to be evaluated further, need more information from IP (Bert) - PoM will set up separate meeting for early launches in FI
Quetiapine	Tablets 25 mg, 100 mg, 200 mg and 300 mg	NO	Early launch	CJ status for NO	Medis has no licences and no clients in Norway. There are a number of generic companies that have MA´s in Norway. **Decision:** No CJ status
Sertraline	Capsules 25 mg	SE	25 mg strength is new, we are the only on with this strength	CJ status for SE	Medis only has agreements in France, onoly have licenses in France. **Decision:** CJ status agreed for SE
Solifenacin	Tablets 5 mg and 10 mg	FI	Early launch	CJ status for FI	Early launch opportunity to be evaluated further, need more information from IP (Bert) - PoM will set up separate meeting for early launches in FI
Topiramate	Tablets	SE	Dose dispensing, niche market and non-substitutable in SE	CJ status for SE	**Decision:** Agreed to grant CJ status for Sweden

Crown Jewel status - Iceland

- There has been no Crown Jewel status requested for products in Iceland, the understanding has been that Iceland automatically has this status for all products

- Confirm that Iceland should by default have CJ status

Financial assessment for Caspofungine – updated*

Status 19 October 2011 (PC Meeting for project approval)

EUR '000	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	Total
Total Sales	-	-	-	-	1.699,5	7.737,9	7.696,7	6.849,6	6.464,5	6.736,6	1.755,4	38.940,2
% growth						355%	-1%	-11%	-6%	4%	-74%	
CoGS	-	-	-	-	307,4	3.316,6	3.591,1	3.358,8	3.505,8	3.735,2	968,0	18.782,8
Gross Margin	**-**	**-**	**-**	**-**	**1.392,2**	**4.421,3**	**4.105,6**	**3.490,8**	**2.958,7**	**3.001,4**	**787,4**	**20.157,4**
% sales					82%	57%	53%	51%	46%	45%	45%	52%
Selling & Marketing (S&M)	-	-	-	-	43,5	173,1	151,6	87,6	55,7	63,4	17,3	592,1
EBITDA	**-**	**-**	**-**	**-**	**1.348,7**	**4.248,2**	**3.954,0**	**3.403,2**	**2.903,1**	**2.938,0**	**770,1**	**19.565,3**
% sales					79%	55%	51%	50%	45%	44%	44%	50%
Working capital	-	-	-	-	680,4	2.515,7	2.392,3	2.167,1	2.136,7	2.276,3	2.306,7	
Increase in working capital	-	-	-	-	680,4	1.835,3	-123,4	-225,3	-30,4	139,6	30,4	2.306,7
CAPEX	330,0	1.360,0	-	-	-	-	-	-	-	-	-	1.690,0
Capitalised registrations	-	-	156,7	156,7	-	-	-	-	-	-	-	313,4
Free cash flow	**-330,0**	**-1.360,0**	**-156,7**	**-156,7**	**668,3**	**2.412,9**	**4.077,3**	**3.628,5**	**2.933,5**	**2.798,4**	**739,7**	**15.255,2**
PV of Cash Flows	**-275,0**	**-944,4**	**-90,7**	**-75,6**	**268,6**	**808,1**	**1.137,9**	**843,9**	**568,5**	**452,0**	**99,6**	**2.792,8**

Sum of PV of Cash Flows / NPV	**2.792,8**
Present value of final working capital	**310,5**
IRR	**47%**

*** Based on updated development cost**

Excluding any tax implications

Development cost for Caspofungine

Status 19 October 2011 (PC Meeting for project approval)

Development

Updated development budget is Euro 1.690k (API 1.150k, internal cost 400k, other 140k)

API cost calculation:					
Formulation dev	No. Of Batches	Batch Size(Lt)	Batch Size Vials	API per vial(mg)	Total API (g)
50mg/vial	1		250	50	12,5
70mg/vial	1		250	70	17,5
					30
Production trials	No. Of Batches	Batch Size(Lt)	Batch Size Vials	API per vial(mg)	Total API (g)
50mg/vial	1		750	50	37,5
70mg/vial	1		750	70	52,5
					90
Submission batches	No. Of Batches	Batch Size(Lt)	Batch Size Vials	API per vial(mg)	Total API (g)
50mg/vial	1		5000	50	250
70mg/vial	1		3000	70	210
					460
Validation batches at subr	No. Of Batches	Batch Size(Lt)	Batch Size Vials	API per vial(mg)	Total API (g)
50mg/vial	2		17500	50	1750
70mg/vial	1		12000	70	840
					2590
				Total API (g)	**3170**
			API Price(USD/g)	$500	**$1.585.000**

Ropinirole PR – additional biostudy

ACTAVIS

CAPITAL EXPENDITURE REQUEST (CER)

Setment / Operating Unit		Budgeted / 3YP	No	€0	CER Number
Legal entity owner		CER amont in €		€450.000	CER Approval date
Project name		Project start date	Dec	2011	
Project type		Project end date	Mar	2012	
Project purpose		CER Currency / LC/EUR	USD	1,40	

PROJECT DESCRIPTION AND JUSTIFICATION (continue on additional sheets if required)

Project Objectives

The development of Ropinirole Prolonged Release Tablets (2mg, 3mg, 4mg, 6mg, 8mg, 10mg & 12mg) was completed in Malta in November 2010. A DCP started the same month supported with 2mg single dose fed, fasted & steady state studies and a 4mg single dose fasted study . We agreed with the Reference Member State (DK) that we could waive up to the 8mg strength from 2mg (on ethical grounds based on 8mg being a high dose) but since they have now received an 8mg study from another applicant they strongly recommend that we conduct the 8mg study. Although DK will still support our argument for waiving from 2mg through to 8mg they are expecting that other countries (CMS) will request this study. Despite the positive opinion of the Danes the worst case scenario from the CMS countries is that the absence of an approved 8mg study could well result in a failure to gain Marketing Authorisations for the 4mg, 6mg & 8mg strengths. Comments from CMS countries are expected at the end of November 2011 will ultimately determine the need for this study.Our strategy is to design the necessary protocol, acquire the necessary import license and have a slot in Canada ready to start a study in November/December 2011 if needed .

Justification

The risk of not conducting the study is that a number of CMS countries may deny us not only an MA for the 8mg strength but also possibly for the 4mg & 6mg strengths. If our underpowered 4mg study is also deemed inadequate then we could potentially be left with an approval for the 2mg only. A successful 8mg study would justify approval of all registered strengths. Sales data clearly indicates that the 8mg tablet is the key strength. Accumulated sales data from Germany, France, Italy, Spain, UK, Poland, Netherlands & Sweden clearly reflects this (see below).

Ropinirole	Sum of EUR MNF MAT Q2 2009	Sum of EUR MNF MAT Q2 2010	Sum of EUR MNF MAT Q2 2011
Total	114.727.040	125.699.446	129.827.710
Retard tablets	60.011.848	101.320.991	113.270.715
8 mg	38.120.874	65.947.811	73.582.296
4 mg	14.564.504	24.155.640	27.500.342
2 mg	7.326.470	11.217.540	12.188.077

Ropinirole PR – additional biostudy

How we get there:
The study will be run in Canada. It is not possible to run at Lotus because of the high dosage ethical issue. Preparations will be put in place and will be ready for the outcome of the CMS comments end November 2011.

Efficiencies: Gained
See Justification above

Cost Avoidance:
Not Applicable

Cost Savings:
Not Applicable

Capitalised	EUR amontus	2011	2012	2013	2014	2015	Total
Steady State Study (8mg)	450	450.000	0	0	0	0	**450.000**
		0	0	0	0	0	**0**
		0	0	0	0	0	**0**
		0	0	0	0	0	**0**
		0	0	0	0	0	**0**
	CAPITAL SUBTOTAL	**450.000**	**0**	**0**	**0**	**0**	**450.000**

Entacapone Combi – additional biostudy

ACTAVIS

CAPITAL EXPENDITURE REQUEST (CER)

Setment / Operating Unit		Budgeted / 3YP	No	€0	CER Number
Legal entity owner		CER amont in €		€560.000	CER Approval date
Project name		Project start date	Dec	2011	
Project type		Project end date	Mar	2012	
Project purpose		CER Currency / LC/EUR	USD	1,40	

PROJECT DESCRIPTION AND JUSTIFICATION (continue on additional sheets if required)

Project Objectives

The development of Entacapone/Levodopa/Carbidopa Tablets will be completed in Iceland in October 2011. The strategy was to challenge the validity of the Originators data exclusivity on the basis that the originator had not provided any additional clinical or tox data. In line with this strategy, we conducted our BE studies against the Originator combination product. It was planned to submit the dossier both as a CP for own brand and as DCPs for Medis.

It has since transpired, that although we can file a Central Application the EMA has been unwilling to commit beforehand on the outcome of such a challenge and also the timelines involved may be significantly longer than anticipated. Furthermore, the DCP RMS states have denied our application, because we used the Originator combination product in the BE studies. Medis is totally reliant on the DCP procedure and our own brand timelines are also at risk because the CP procedure can be lengthy, as the EMA may take a long time to address the DE challenge itself, before starting the procedure.

In view of this we propose to pursue an additional regulatory pathway, namely , to register a hybrid application based on the mono reference products (Comtess (Entacapone) and Sinemet (levodopa/carbidopa)). The DCP RMS have indicated that they will accept application based on different legal basis. However, detailed content of the dossier and clinical development plan has not been discussed with the RMS. By using this pathway, we would be circumventing the data exclusivity of Stalevo. We would however have to run new BE studies using the appropriate reference products, which will cost approximately 560.000€.

Justification

If we don't run the new biostudies and a hybrid application we could significantly compromise the registration of this product.

Entacapone Combi – additional biostudy

Medis sales budget:

	TOTAL	0	646.933	3.136.299	3.378.395	0	6.062	33.257	41.241
Market	*Client*	*2011-EUR*	*2012-EUR*	*2013-EUR*	*2014-EUR*	*2011-K-units*	*2012-K-Units*	*2013-K-Units*	*2014-K-Units*
FRANCE			601.190	1.803.570	1.893.749		5.616	16.847	17.690
PORTUGAL			45.743	48.030	50.431		446	468	492
POLAND			0	288.915	346.698		0	9.009	10.810
SPAIN			0	706.858	777.543			3.600	3.960
GREECE			0	156.917	164.763			1.133	1.189
AUSTRIA			0	132.009	145.210			1.000	1.100
CZECH REPUBLIC			0	0	0			400	2.000
HUNGARY			0	0	0			400	2.000
ROMANIA			0	0	0			400	2.000

World wide sales (5EU):

	Sum of EUR MNF MAT Q2 2011	Growth 10/11
Germany	60.227.161	7%
France	28.989.695	10%
Spain	28.980.691	7%
Italy	16.904.928	6%
UK	14.879.064	10%

How we get there:

The studies will be run at Lotus and will take approximately 3 months per study. Although the mono refernce products are BE to the originators formulation we would need to run dissolution tests against our formulation before commencing the biostudies. Furthermore, we need to confirm that no further clinical trials (safety/efficacy) are needed for hybrid application.

Efficiencies: Gained
See Justification above

Cost Avoidance & Cost Savings
Not Applicable

Early launch of Rivastigmin capsules in UK

Objective:

- To evaluate early launch of rivastigmin capsules in UK

Rational:

- Basic patent for Rivastigmine (s-enantiomer) has recently been invalidated in UK (SPC on it would have expired on 30.07.2012)
- UK market is open now for launch at risk – decision might be open for appeal
- The reasoning for the decision to invalidate the patent is very sound and we are expecting that this will withstand appeal
- Early launch makes impact only on sales in 2012
- Only capsules (8,2 m, +6%) are relevant because we are late with liquid
- Assumption is that we launch in March 2012
- Sales would be higher for Euro 360k, EBITDA 308k and NPV for 250k in “launch at risk” scenario

Recommendation:

- Go for early launch

Financial assessment for Rivastigmin capsules *difference*

EUR '000	2011	2012	2013	2014	Total
Total Sales	-	358,9	-	-	358,9
% growth		100%	-100%	#DIV/0!	
CoGS	-	51,3	-	-	51,3
Gross Margin	**-**	**307,6**	**-**	**-**	**307,6**
% sales		86%			86%
Selling & Marketing (S&M)	-	-	-	-	-
EBITDA	**-**	**307,6**	**-**	**-**	**307,6**
% sales		86%			86%
Working capital	-	72,8	-	-	
Increase in working capital	-	72,8	-72,8	-	-
CAPEX	-	-	-	-	-
Capitalised registrations	-	-	-	-	-
Free cash flow	**-**	**234,8**	**72,8**	**-**	**307,6**
PV of Cash Flows	**-**	**195,7**	**50,6**	**-**	**246,3**

Sum of PV of Cash Flows / NPV	**246,3**
Present value of final working capital	**0,0**
IRR	**n/a**

Excluding any tax implications

Project opportunity for Atorvastatin+Amlodipine (IP costs)

Status 19 October 2011 (PC Meeting for approval)

actavis
think smart medicine

Project ID: Atorvastatin+Amlodipine

Suggestion from PoM: Approve litigation

Product information

INN	Atorvastatin+Amlodipine
Dosage form	tablets
Dosage strengths	5/10 mg and 10/10 mg
Indication(s)	CVS
Brand name	Caudet
Originator	Pfizer

Product information (in 000s)

NPV (start of project)	€ 762,7
IRR (start of project)	84%
Peak sales	€ 2 440,2
Peak year	2017
IP Costs	
Registration	€ 37,8
Total investments	€ 111,9
RA and IP costs	
2011	€ 21,9
2012	€ 90,0
2013+	€ 0,0

Summary of opportunities (in 000s)

Countries (Top10 by sales)	Sales (2010)1	Growth (09/10)1	Data Exclusivity	IP Data Combinatio
France	7 132	1%	-	-
Czech	2 975	10%	-	-
Hungary	2 464	17%	-	-
Romania	1 523	62%	-	-
Latvia	728	-8%	-	-
Bulgaria	599	77%	-	-
Slovakia	460	27%	-	-
Russia	335	74%	-	-
	16 215	**15%**		

IP status

	Combination	Data exclusivity
DE	Opposition at EPO	07-Jul-2015
RO	Opposition at EPO	07-Jul-2011
RS	In force	07-Jul-2011
HU	Pending	07-Jul-2011
CZ	In force	07-Jul-2011
ES	Opposition at EPO	07-Jul-2011
FR	Opposition at EPO	07-Jul-2015
LT	Opposition at EPO	07-Jul-2011
BG	In force	07-Jul-2011
IE	Opposition at EPO	07-Jul-2011
KW	No data	No data
SA	No data	No data
UAE	No data	No data

Brief Project Description & Target

From markets launching the product, there are 3 countries where the combination patent is in force as a national patent CZ, BG and RS. The combination patent is also pending in Hungary so it might potentially be of relevance there.

All four markets have updated their forecast and confirmed interest in the product and launch as soon as possible.

We would like to have approval of the IP costs for the 4 markets.

The BC is very possitive (assuming it will be successful, which acording to IP is the likely outcome!).

Timeline

Project start	2009
Dossier ready	October 2011
1st MA	November 2012
1st Launch (France)	Q1 2013

1 Current molecule/form expectation based upon 2010; in '000 EUR

Financial assessment for Atorvastatin+Amlodipine (IP costs)

Status 19 October 2011 (PC Meeting for approval)

EUR '000	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total
Total Sales	-	-	-	1 291,8	1 899,2	2 238,3	2 440,2	2 432,2	-	10 301,7
% growth				100%	32%	15%	8%			
CoGS	-	-	-	570,2	895,5	1 084,0	1 225,5	1 248,5	-	5 023,7
Gross Margin	**-**	**-**	**-**	**721,6**	**1 003,7**	**1 154,3**	**1 214,7**	**1 183,6**	**-**	**5 278,0**
% sales				56%	53%	52%	50%	49%		51%
Selling & Marketing (S&M)	-	-	-	287,4	330,8	308,1	287,3	226,4	-	1 440,0
EBITDA	**-**	**-**	**-**	**434,2**	**672,9**	**846,3**	**927,4**	**957,3**	**-**	**3 838,0**
% sales				34%	35%	38%	38%	39%		37%
Working capital	-	-	-	561,9	888,7	1 122,5	1 312,9	1 289,8	1 289,8	
Increase in working capital	-	-	-	561,9	326,9	233,8	190,4	-23,1	-	1 289,8
CAPEX	-	-	-	-	-	-	-	-	-	-
Capitalised registrations	21,9	90,0	-	-	-	-	-	-	-	111,9
Free cash flow	**-21,9**	**-90,0**	**-**	**-127,7**	**346,1**	**612,4**	**737,0**	**980,3**	**-**	**2 436,3**
PV of Cash Flows	**-21,9**	**-75,0**	**-**	**-73,9**	**166,9**	**246,1**	**246,8**	**273,6**	**-**	**762,7**

Sum of PV of Cash Flows / NPV	**762,7**
Present value of final working capital	**300,0**
IRR	**84%**

Excluding any tax implications

Overview sales and NPVs by country for Atorvastatin+Amlodipine (IP costs)

Status 19 October 2011 (PC Meeting for approval)

Sales per year and NPV (in T EUR)

Country	2014	2015	2016	2017	2018	Total	NPV*	Market Size YBL (EUR)	PoM Recommendation
Total	1 292	1 899	2 238	2 440	2 432	**10 302**	**763**	11 356	
Hungary	136	319	460	525	523	**1 963**	**258**	3 608	Go
Bulgaria	500	629	524	527	551	**2 730**	**350**	1 045	Go
Czech Republic	426	571	748	748	748	**3 242**	**436**	5 245	Go
Serbia	229	381	506	641	610	**2 367**	**19**	1 458	Go

**NPV includes litigations costs, assuming possitive outcome!*

Approved countries for Atorvastatin+Amlodipine are LV; LT; EE; BG; CZ; DE; ES; FR; HU; IE; KW, SA, UAE; RO; RS; FI

PoM recommendation is to approve litigation costs and timeline in the presented markets. Total cost for the four markets is about 75k EUR.

Litigation costs 1st instance		
	Cost (EUR)	*Time (years)*
Hungary*	<30.000	1,5
Czech	~30.000	1,5
Bulgaria	~10.000	1-2
Serbia	~4.000	0,5-1

* Combinatinon patent is still pending

Note: DPs are not included in NPV calculation by country

Potential Deal Structure for Atorvastatin+Amlodipine (IP costs)

Status 19 October 2011 (PC Meeting for approval)

Development

OD crystalline Atorvastatine Ca API is used. Pfizer has a granted patent (expiry 2016) for it in HU, CZ, BG but oppositions are running.

The plan is to launch the amorphus in CEE markets. We should have the dossier ready by April 2012.

Regulatory and IP

	1 st instance	
	Cost (EUR)	Time (years)
Hungary*	<30.000	1,5
Czech	~30.000	1,5
Bulgaria	~10.000	1-2
Serbia	~4.000	0,5-1

* Combinatinon patent is still pending

	Combination	Data exclusivity	Crystal
DE	Opposition at EPO	07-Jul-2015	Open
RO	Opposition at EPO	07-Jul-2011	In force
RS	In force	07-Jul-2011	Open
HU	Pending	07-Jul-2011	In force
CZ	In force	07-Jul-2011	In force
ES	Opposition at EPO	07-Jul-2011	Open
FR	Opposition at EPO	07-Jul-2015	Open
LT	Opposition at EPO	07-Jul-2011	Open
BG	In force	07-Jul-2011	In force
IE	Opposition at EPO	07-Jul-2011	Open
KW	No data	No data	No data
SA	No data	No data	No data
UAE	No data	No data	No data

Registration Strategy

PCM October 2011

Imatinib capsules

- 1 CP for Actavis brand
  - 1 Marketing authorisation valid in EU + NO, IS
- Submission in November
- Pat Ex in WE 2016 but markets in CEE open
- Can only include limited number of indications as orphan status applies
  - Pre submission meeting with EMA scheduled to clarify
- Cost 130.000EUR

Imatinib tablets

- 1 CP for Actavis brand
  - 1 Marketing authorisation valid in EU + NO, IS
- Submission in November
- Pat Ex in WE 2023 but opposition pending
- Can only include limited number of indications as orphan status applies
  - Pre submission meeting with EMA scheduled to clarify
- Cost 130.000EUR

Imatinib capsules - Medis

Request for 4 MA at RISK into Portugal

- Medis requests 4 MA's in Portugal for Imatinib capsules 50 mg and 100 mg
  - 2 local MA´s in Portugal with MRP start for running MRP into CEE 9.500 EUR each
  - 2 local MA's in Portugal for later applying for MRP into CEE 3.500 EUR each
  - Total cost 26.000 EUR
  - Additional cost for each CMS country estimated at 5.000 EUR and cost for running MRP on national MA 6.500 EUR

*IMS Data 2Q11

Imatinib capsules - Medis

- The MA´s are intended for running MRP into CEE and other open countries
  - The total market in open countries listed in IMS (Poland, Hungary, Romania, Slovakia, Croatia, Bulgaria, Slovenia, Lithuania, Estonia, and Latvia) is 115,3 m EUR (+4,2%)
  - 100 mg capsules 1,7 m (-11,9%), 28,8 m EUR (-8,9%)
  - 100 mg tablets 701k (-8,3%), 11,7 m EUR (-10,2%)
  - 400 mg tablets 1,1 m (+12,9%), 74,7 m EUR (+13,4%)
  - Down payment estimated at 50-70.000 EUR and all registration cost to be paid by the client
  - The new 3 year plan forecasts sales into Poland for 107k EUR in 2013 and 323k EUR in 2014
- Competition
  - Medis has not signed with any costumer for CEE
  - Negotiating for Back-up for CEE for one client – will be using the DCP – not at RISK
  - We expect the competition to be intense and many of our clients have signed with other companies already offering 400 mg capsules and tablets

Amlodipine/Atorvastatin

- DCP from PT
- PoM recommends to register into following Actavis markets;
  - LV; LT; EE; ES; IE; FI – Can use current dossier
    - Total reg cost 48.000EUR
  - HU; RO; CZ – Need to add in new API because of patent restrictions
    - Total reg cost 26.000EUR
  - DE; FR – Need to wait to 2015 until data exclusivity expires

Amlodipine/Atorvastatin - Medis

- DCP from PT
  - 1 national MA
  - 3 submissions to ES at risk
  - Total cost 70.000EUR

Montelucast granules

- MRP from DK
- Countries to be included *ES*, *FR*, *IT*, *UK*, *SE*, *RO*, *DK*, *NO*, *HU*, *AT*, *CZ*, *NL*
- Submission in November
- Pat Ex 08-2012
- Cost 133.000EUR

Azythromycine tablets

- MRP from NL
- Countries to be included; *PL, UK, PT, SK, HU, BG, RO, AT, IE, SE, LV, LT, EE, CY, IS, MT, CZ*
- Open markets
- Submission in december
- Total RA cost 120.000EUR

Entacapone combination

- 1 CP for Actavis brand
  - 1 Marketing authorisation valid in EU + NO, IS
- Challenge Data Exclusivity!
  - Pre Submission meetings with EMA have been held
  - EMA understands Actavis' position but they require guidance from the Commission before they can accept such an application
  - Application from Actavis would trigger EMA to consult the Commission in Brussel
  - Legal basis – Generic application 10.1
- Total cost 130.000EUR

Entacapone combination

- Back up strategy
- DCP for Medis/Actavis
  - DCP to into 3 countries
  - Legal basis – Hybrid application
- Risks?
  - Rejection
  - Additional BE studies might be requested
- Cost of registration ca. 50.000EUR

Corporate Project Management

Oct 2011

Olanzapine FCT & ODT- Launched End Sept

Background

- OD, Supplier: Malta
- Market Formation: Sept 26th and 27th 2011
- Patent expiry in CH is in June 2012

	UK	DE	FR	IT	NL	ES	PT	SE	DK	NO	FI	IS	IE	AT	CH	PL	RO	HU	BG	CZ	SK	Baltics
Olanzapine	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Market Formation dates	26.09.11	27.09.11	27.09.11	27.09.11	26.09.11	24.04.11	22.04.17	26.09.11	27.09.11	27.09.11	29.09.11	Open	26.09.11	27.09.11	27.06.12	Open	27.09.11	24.04.11	24.04.11	24.04.11	24.04.11	Open
Planned launch dates	L	L	L	L	L	L		L	L		L	L	L	L		L	L	L	L	L		L
Olanzapine ODT	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Market Formation dates	26.09.11	27.09.11	27.09.11	06.03.12	26.09.11	24.04.11	22.04.17	26.09.11	27.09.11	27.09.11	29.09.11	Open	26.09.11	27.09.11	27.06.12	Open	27.09.11	24.04.11	24.04.11	24.04.11	24.04.11	Open
Planned launch dates	L	L	L		L	L		L	L		L			L		L	L	L			L	

- Market Decision not to launch: SK is not launching FCT. NL, IS, BG and Baltics are not launching ODT.
- Actavis launched into 12 markets on day 1
- Medis launched to 18 customers on day 1
- Medis sales figures for 2011 €12M (€9,6M in budget)
- Actavis sales figures for 2011 €6,2M (€7,8M in budget)

Olanzapine FCT & ODT

- Actavis Launches 10 Preparations of Olanzapine on Day 1 Patent Expiry

I am pleased to announce the successful launch on Tuesday 27th September of Olanzapine Tablets and Olanzapine Orodispersible Tablets supplied on the first day of patent expiry. Olanzapine is used for the treatment of Schizophrenia and Bio-polar disorder.

Competition within the market place was challenging on day one, with thirteen companies competing for business. The professionalism and determination from our sales teams resulted in first day invoiced sales of **£441,450.19** which exceeded our expectations.

Olanzapine and Olanzapine Orodispersible is our 7th day one patent expiry launch this year, patent expiry launches are key to driving our business forward in expanding our product portfolio to benefit pharmacists and patients.

I would like to thank everyone who contributed to these successful launches.

Olanzapine FCT & ODT

News of Olanzapine

- **Posted on 11/10/2011 in Pharmacy Supplier News**
- Teva has announced the UK launch of a range of generic Olanzapine products for the treatment of schizophrenia.

  Off-patent Olanzapine film-coated tablets and orodispersible tablets are being introduced bearing the Teva 360 livery in a variety of different strength specifications.

  The product is a generic version of the branded product Zyprexa from Lilly, which is clinically proven to maintain improvement during continuation therapy for schizophrenia patients who have shown an initial response.

  It is also indicated for the treatment of moderate to severe manic episodes and for the prevention of recurrence in patients with bipolar disorder.

  Kim Innes, commercial director at Teva UK, said: "We are delighted to be bringing a generic version of this product to the UK market and at the same time further broaden our portfolio, which is the widest of any UK generics supplier."

  This comes after fellow generics specialist Actavis also released an off-label version of Olanzapine at the end of last month

Valsartan/Valsartan HCT

Background

- OD, Supplier: Malta→transfer to Dubnitza
- Market formation: Nov 2011

	UK	DE	FR	IT	NL	ES	PT	SE	DK	NO	FI	IS	IE	AT	CH	PL	RO	HU	BG	CZ	SK	Baltics
Valsartan	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Market Formation dates	12.11.11	13.11.11	13.11.11	13.11.11	12.11.11	12.02.11	23.03.14	12.11.11	14.11.11	Open	Open	Open	12.11.11	13.11.11	27.08.11	EXU	12.02.11	18.02.11	Open	Open	Open	Open
Planned launch dates						L				L	L	L			L	L		01.01.12	L			L
Valsartan HCT	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Market Formation dates	12.11.11	13.11.11	13.11.11	25.09.12	24.09.12	12.02.11	02.02.15	12.11.11	13.11.11	Open	Open	Open	12.11.11	13.11.11	27.08.11	EXU	EXU	18.02.11	Open	Open	Open	Open
Planned launch dates						L				L	L	L			L			01.01.12	L			L

- Market Decision not to launch: CZ, RO, SK
- HU decided to launch Irbestratan and Irbesartan HCT first and then Valsartan and Valsartan HCT
- Valsartan HCT Patent Expiry in IT and NL in Sept 2012

Production and Packing

Market	SFP	AW	Packed
Actavis AT	v	v	3/4 Packed
Actavis DE	v	v	0/10Packed
Actavis DK	v	v	10/15Packed
Actavis GB	v	v	4/4Packed
Actavis IE	v	v	0/6Packed
Actavis IT	v	v	12/12Packed
Actavis LT	v	v	0/2Packed
Actavis NL	v	v	1/2Packed
Actavis PL	v	v	0/2Packed
Actavis SE	v	v	4/7Packed
Actavis SI	v	v	5/5Packed

Atorvastatin 10, 20, 40 mg

	UK	DE	FR	IT	NL	ES	PT	SE	DK	NO	FI	IS	IE	AT	CH	PL	RO	HU	BG	CZ	SK	Baltics
Atorvastatin	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Market Formation dates	06.05.12	07.05.12	07.05.12	08.05.12	06.05.12	Open	10.01.12	06.05.12	07.05.12	Open	Open	Open	06.05.12	07.05.12	28.05.12	Open	26.02.11	Open	Open	Open	Open	Open
Planned launch dates						L					01.03.12	L				L	03.01.12	L	L	L	L	L

Background

- OD – Manufacturing Site: Iceland
- Market formation Nov 2011 but due to PIP May 2012
- IMS €2695M EUR MNF MAT Q3 2010

Issues

- PIP granted in : AT, BE, DK, FR, IE, IT, LU, NL, SE, UK, DE
- Variations needed before launch
- Ator Ca NF Amorphous 40 mg : will not be delivered in Duma bottles only blisters. Has failed on impurities at 25C, being evaluated. Impact on markets minor (Medis FI, Actavis DK and SE)
- Ator 80 mg : special equipment needed for production, not available at site now – launch pending Q4 2012

Atorvastatin 10, 20, 40mg cont.

Actions

- Two procedures to meet the launch of different markets (1413 for amorphous API and 1404 for Crystalform1 API)

Expected Result

- All markets on time (excluding RO and NO) :
- UK : will not go to market in Dec, but in May 2012. Teva case has been settled out of court. Production in Iceland had not started.
- NO needs to have 80 mg Amorphous to be able to launch other strengths – looking into IL possibilities
- Estimated 80M tablets for launch in May
- Medis : 7 customers as of now, high interest

Levetiracetam Tablets

Background

- OD – Manufacturing site : Iceland
- Product Status : Regulatory
- Regulatory stratetgy :
  - DCP-SE : (BG,CY,HU,MT,PL) : Day 210 13.09.2011 *
  - CP-EU : Day 277 26.09.2011 MA right after
- Data Exclusivity ended Sept 29th 2010

Competitors already with MA in DE

Desitin, USB and Winthrop
Teva and Ratiopharm got positive opinion 2 months earlier than Actavis

* No market using the DCP

Levetiracetam Tablets

Registration :

		WE																		ME A& AP		CE									No n EU			
Levetirac. tablets	**Target Date**	BE	NL	LU	DK	FI	SE	NO	IS	IE	UK	PT	ES	IT	FR	DE	AT	CH	EL	MT	CY	BG	CZ	HU	PL	RO	SK	SI	LT	EE	LV	RS	RU	TR	UA
DCP	11/12 2012						X													X	X			X	X									
CP	10 2011	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X			
National																	X	X															X	X

	Launched
	Budget/Go
	Confirmed No Go
X	Registration

Target Date = Closing of Procedure

Expected Results :

Launch in UK was aimed for Oct 3rd 2011 but launched Oct 10th due to EMA

Launch goods available for: DK, IS, PL, DE, NL, AT this week (17-21 of Oct)

Other launches: IS, FI, FR Dec 2011
SE, RO Jan 2012, IT May 2012
PT,CZ,ES,HU 2012

Gemcitabine non-etoh solution

Background

- OD – Nerviano
- IMS EU (MAT Q3 2010): 222M

Status

- 2 batches of the new formulation was manufactured in Nerviano (38mg/ml)
- Variation to switch back to etoh solution will be submitted on 21st of October (Up to 6 month timeline)
- HBU managing demand in the gap until we get the variation approved

Actions

- Due to marketing reason, HBU will go for 40mg/ml. Samples are being provided to have a better look at the formulation and try to minimize possible complications later on. Three batches will then have to be produced and put on stability before we can do a variation to market the 40mg/ml

Key Molecules 2012

	UK	DE	FR	IT	NL	ES	PT	SE	DK	NO	FI	IS	IE	AT	CH	PL	RO	HU	BG	CZ	SK	Baltics
Latanoprost	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		x	x	x	x	x
Market Formation dates	17.01.12	18.01.12	18.01.12	Open	17.01.12	Open	26.05.13	17.01.12	18.01.12	Open	17.01.12	Open	17.01.12	18.07.11	17.09.11	Open		Open	Open	Open	Open	Open
Planned launch dates				L		L						L			L	L		L	L	L		15.03.12
Donepezil conv	x	x	x	x		x		x	x					x	x							
Market Formation dates	13.02.12	14.02.12	14.02.12	13.02.12		14.02.12		13.02.12	14.02.12					14.02.12	15.05.12							
Planned launch dates																						
Telmisartan	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Market Formation dates	10.12.13	11.12.13	11.12.13	11.12.13	10.12.13	11.12.13	01.09.14	10.12.13	10.12.13	11.12.13	11.12.13	Open	10.12.13	10.12.13	17.12.13	05.02.12	Open	04.02.12	31.01.12	04.02.12	04.02.12	Open
Planned launch dates																	L					
Quetiapine IR	x	x		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Market Formation dates	23.03.12	24.03.12		24.03.12	23.03.12	24.03.12	27.03.12	23.03.12	27.03.12	25.03.12	Process	Open	15.03.12	24.03.12	23.03.12	Open	24.03.12	Open	Open	Open	Open	Open
Planned launch dates						L						L		L		L		L	L	L	L	L
Quetiapine SR	x	x		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		x		x
Market Formation dates	23.03.12	24.03.12		24.03.12	23.03.12	24.03.12	27.03.12	23.03.12	27.03.12	25.03.12	15.03.12	Open	15.03.12	24.03.12	23.03.12	Open	24.03.12	Open		Open		Open
Planned launch dates					13.08.12	16.09.12	02.08.12			01.01.13	19.04.12		16.04.12	11.11.12	15.01.13		01.11.12					15.12.12
Candesartan	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		x	x			x
Market Formation dates	28.04.12	29.04.12	29.04.12	29.04.12	28.04.12	29.04.12	24.10.12	28.04.12	29.04.12	29.04.12	29.04.12	Open	28.04.12	29.04.12	25.08.12	25.10.11		22.04.11	Open			23.04.11
Planned launch dates												01.12.11							15.11.11			
Candesartan+HCT		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		x	x		x	x
Market Formation dates		29.04.12	29.04.12	29.04.12	28.04.12	29.04.12	24.10.12	28.04.12	29.04.12	29.04.12	29.04.12	Open	28.04.12	29.04.12	25.08.12	25.10.11		22.04.11	Open		25.10.11	23.04.11
Planned launch dates				28.07.12		10.12.12						01.12.11	25.06.12						15.11.11		29.04.12	
Atorvastatin	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Market Formation dates	06.05.12	07.05.12	07.05.12	08.05.12	06.05.12	Open	10.01.12	06.05.12	07.05.12	Open	Open	Open	06.05.12	07.05.12	28.05.12	Open	26.02.11	Open	Open	Open	Open	Open
Planned launch dates						L					01.03.12	L				L	03.01.12	L	L	L	L	L
Montelukast conv	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		x	x	x
Market Formation dates	24.08.12	25.08.12	25.08.12	25.08.12	24.08.12	25.08.12	18.04.14	24.08.12	25.08.12	25.08.12	11.10.11	Open	24.08.12	25.08.12	28.06.13	Open	11.10.11	11.10.11		11.10.11	11.10.11	Open
Planned launch dates								25.02.13			L	L					L	L		L		
Montelukast chew	x	x	x	x	x	x	x	x	x	x	x	x	x	x		x	x	x	x	x	x	x
Market Formation dates	24.08.12	25.08.12	25.08.12	25.08.12	24.08.12	25.08.12	18.04.14	24.08.12	24.08.12	25.08.12	11.10.11	Open	24.08.12	25.08.12		Open	11.10.11	11.10.11	Open	11.10.11	11.10.11	Open
Planned launch dates								25.02.13			L						L	L	L	L		
Irbesartan	x	x	x	x	x	x	x	x	x	x		x	x		x	x	x	x	x	x	x	x
Market Formation dates	14.08.12	15.08.12	15.08.12	15.08.12	26.08.12	Open	Open	14.08.12	15.08.12	Process		Open	14.08.12		14.08.12	Open	Open	Open	Open	Open	Open	Open
Planned launch dates						L	L		16.10.13							L	L	L		L		
Rabeprazol	x	x	x	x	x	x	x					x	x	x		x	x	x	x	x		x
Market Formation dates	12.11.12	13.11.12	12.11.12	13.11.12	12.11.12	13.11.12	Open					Open	Open	13.11.12		Open	Open	Open	Open	Open		Open
Planned launch dates							L					L	L					L				

Explanation of deviations
(markets in red)

Latonoprost

- IL, Supplier: Siegfried
- IMS Europe sales 2010: €380M
- Market decision not to launch: NO, AT, SK, SI
- PL late due to late supply from Jadran, Baltics late due to late orders placement

Donepezil conv. Tablets

- OD Malta
- Market formation: 13th Feb 2012
- IMS MAT Q2 2011 Europe – 467.8 mln Euro
- The following markets to launch on time for patent expiry: DK, SE, UK, ES, IT, FR, DE, AT, CH.
- Launch critical variation needed – update on Dr Reddys DMF – submission in November (IB)

Explanation of deviations
(markets in red)

Telmisartan

- OD manufactured in Iceland
- IMS €320M EUR MNF MAT Q3 2010
- Market Decision not to launch: AT,BE,CZ,EE,EL,IS,LT,SE

Quetiapine IR

- OD, Supplier: Malta
- IMS MNF MAT Q3 2010 : €601M
- Market Decision not to launch: FI

Explanation of deviations (markets in red)

Quetiapine SR

Background

- IL , IP Torrent, release in Dupnitza
- Market formation: 15th March 2012
- IMS MAT Q2 2011 Europe – 423.7 mln Euro

Deviation

- Dossier submitted late due to switch to IL source. Prolonged clock stop until 8th September.

Actions

- Discussions with Torrent to commit to shortening the lead times.
- Close monitoring of the issue around small batch manufacturing area – potential capacity consideration for launch. (increased batch size variation not planned ahead)
- Separate RA Duplicate strategy ongoing for DE with potential to launch on patex. Also planned is late MRP add on RA strategy for NL & AT.

Expected Results

- Artwork completed at risk after Day 160 which will be 4th Nov
- We have commitment to comply with challenging timelines from Torrent
- Potential to launch in **UK, DE** and DK, SE, IS for patent expiry.

Explanation of deviations
(markets in red)

Quetiapine SR cont.
Expected results

- IT, MT – decided not to launch the product due to local reasons
- AT, NL planned to be added only now to the MRP strategy resulting in earliest launch timelines in November and August respectively.
- NO could potentially launch between April and July however decided due to local market reasons to postpone the launch until 2013.
- ES, FI, IE, PT, RO – unable to launch on time due to national timings vs the late DCP start.
- CH – late national submission pushing the earliest launch date into Q1 2013.
- LT, LV, EE – local MA expected only Dec 2012, local strategy will be identified mid 2012.

Explanation of deviations
(markets in red)

Candesartan

- IL, Supplier: Siegfried
- IMS Europe sales 2010: €676M
- Market decision not to launch: PL, HU, Baltics
- IS late due to missing informatiom from authorities (PIL). AT launching 6 months after PE

Candesartan HCT

- IL, Supplier: Siegfried
- IMS Europe sales 2010: €440M
- Market decision not to launch: DK, HU, PL, Baltics, IS late due to missing information from authorities (PIL)
- MRP to start in October/November including NL,SE,IE,ES,IT,DE,AT,SK. Based on standard timelines for price reimbursement it's foreseen that at least IT,ES,IE, SK will be late

Explanation of deviations
(markets in red)

Atorvastatin

- OD manufactured in Iceland
- IMS €2695M EUR MNF MAT Q3 2010
- Market Decision not to launch: BE, EL, MT, CY
- RO late : Actavis sold their license and no MA yet
- FI : has delayed their launch, lot of competitors already on market
- NO : Cancelled orders, need 80 mg as well

Montelukast FCT

- OD, Supplier: Malta
- IMS: €462M EUR (MNF MAT Q3 2010)
- Market Decision not to launch: EL, MT, PL, MT, SI, SK, Baltics
- Market decision to launch later in: SE and AT

Montelukast Chewable

- OD, Supplier: Malta
- IMS: €196M EUR (MNF MAT Q3 2010)
- Market Decision not to launch: IS, PL, SK, Baltics
- Market decision to launch later in: SE and AT

Explanation of deviations
(markets in red)

Irbesartan

- OD manufactured in Iceland
- IMS €467M EUR MAT Q3 2010
- Countries not launching: BE, IS, IE, EL, MT, Baltics
- NO had to go off market, court case
- BG, SK : cancelled orders, strategic decision
- DK : low sales, market condition have changed

Rabeprazole

- OD manufactured in Iceland
- IMS €323M EUR MAT Q3 2010
- Market Decision not to launch: AT,BG,CZ,EE,EL,ES,IT,LT, MT,PL,RO

Other Day 1 Launches 2012

	UK	DE	FR	IT	NL	ES	PT	SE	DK	NO	FI	IS	IE	AT	CH	PL	RO	HU	BG	CZ	SK	Baltics
Latanoprost Timolol	x			x		x	x	x	x		x		x	x				x	x			x
Market Formation dates	17.01.12			Open		Open	26.05.13	17.01.12	18.01.12		17.01.12		17.01.12	18.07.11				Open	Open			Open
Planned launch dates	17.03.12			14.08.12				01.12.12										15.03.12	15.02.12			15.03.12
Donepezil ODT	x	x	x			x	x	x		x				x	x							
Market Formation dates	13.02.12	14.02.12	14.02.12			14.02.12	15.02.12	13.02.12		14.02.12				14.02.12	15.05.12							
Planned launch dates						18.09.12	04.08.12															
Zolmitriptan conv	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		x	x	x	x	x
Market Formation dates	06.03.12	07.03.12	07.03.12	07.03.12	06.03.12	07.03.12	23.06.14	06.03.12	07.03.12	07.03.12	06.03.12	Open	06.03.12	07.03.12	18.12.12	Open		Open	Open	22.09.14	07.03.12	15.03.13
Planned launch dates																						
Zolmitriptan ODT	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Market Formation dates	06.03.12	07.03.12	07.03.12	07.03.12	06.03.12	07.03.12	23.06.14	06.03.12	07.03.12	07.03.12	06.03.12	Open	06.03.12	07.03.12	18.12.12	Open	Open	Open	Open	22.09.14	07.03.12	15.03.13
Planned launch dates																						
Naratriptan	x	x	x		x																	
Market Formation dates	09.03.12	10.03.12	10.03.12		09.03.12																	
Planned launch dates	02.04.12	02.04.12	01.08.12		02.04.12																	
Rivastigmin patch	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Market Formation dates	30.07.12	Appl. Pen	31.07.12	04.03.13	03.03.11	04.03.13	01.08.12	04.03.11	31.07.12	Open	Open	Open	30.07.12	31.07.12	30.07.12	Open	Open	Open	Open	Open	Open	Open
Planned launch dates	24.07.13	24.07.13	24.07.13	24.07.13	24.07.13	24.07.13	24.07.13	24.07.13	24.07.13	24.07.13	24.07.13	24.07.13	24.07.13	24.07.13	24.07.13	24.07.13	24.07.13	24.07.13	24.07.13	24.07.13	24.07.13	24.07.13
Rivastigmin caps	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Market Formation dates	30.07.12	31.07.12	31.07.12	04.03.13	03.03.11	04.03.13	01.08.12	04.03.11	31.07.12	Open	Open	Open	30.07.12	31.07.12	30.07.12	Open	Open	Open	Open	Open	Open	Open
Planned launch dates					10.02.12			04.03.12			01.08.12						01.03.12					
Tolterodine XL caps	x*				x*	x*		x*	x*	x	x	x	x			x						x
Market Formation dates	04.09.12				04.09.12	05.09.12		04.09.12	05.09.12	Appl. Pen	Appl. Pen	Open	Open			Open						Open
Planned launch dates	16.11.12				15.12.12	14.05.13		15.12.12	16.11.12	16.12.12	14.01.13	15.12.12	19.11.12			15.12.12						15.12.12
Tolterodine IR tabs	x													x								
Market Formation dates	04.09.12													05.09.12								
Planned launch dates																						
Riluzole	x	x	x	x	x	x	x	x	x	x	x	x	x			x	x	x	x	x	x	x
Market Formation dates	22.10.12	22.10.12	22.10.12	22.10.12	22.10.12	22.10.12	22.10.12	22.10.12	22.10.12	22.10.12	Open	Open	22.10.12			Open	Open	22.10.12	Open	22.10.12	22.10.12	22.10.12
Planned launch dates																						
Zoledronic Acid	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Market Formation dates	16.05.13	16.05.13	15.05.13	19.05.13	15.05.13	25.11.12	20.05.13	16.05.13	20.05.13	25.11.12	25.11.12	25.11.12	19.05.13	25.11.12	20.11.12	25.11.12	25.11.12	25.11.12	25.11.12	25.11.12	25.11.12	25.11.12
Planned launch dates																						
Oxycodone tabs	x	x			x			x														
Market Formation dates	25.11.12	25.11.12			25.11.12			25.11.12														
Planned launch dates																						
Desogestrel		x	x		x		x	x			x			x				x				
Market Formation dates		12.12.12	12.12.12		11.12.12		23.02.15	12.12.11			13.12.13			12.12.11				Open				
Planned launch dates								01.04.12										15.01.12				

* EP 1039882 B1 expiry 26.08.2019 has been opposed. Although the chances to invalidate the patent are very good (> 75%), a 1st instance decision is not to be expected before Q3 2013. Launch at basic patent expiry is a launch at risk

Explanation of deviations
(markets in red)

Latonoprost Timolol

- IL, Supplier: AZAD Pharma
- IMS Europe sales 2010: €110M
- Market decision not to launch: ES, AT
- UK,IT,SE late due ongoing DCP (Target end in Feb-12). HU late due to AW creation and BG late due variations impacting AW, Baltics late due to late orders placement

Donepezil ODT

- IL, Genepharm (EL)
- IMS MAT Q2 2011 Europe: €63M
- Market Decision not to launch: NO, AT
- PT, ES - unable to launch on time due to national timings vs the late DCP finish

Zolmitriptan conv.

- OD, Malta.
- IMS Europe sales total in 2010: €47M
- Market Decision not to launch: DE, NL, ES, IS, IE, AT, CH, BE, EL, PL, HU, BG, SK, EE, UA, MT.

Explanation of deviations (markets in red)

Zolmitriptan ODT

- OD, Malta
- IMS Europe sales total in 2010: €75M
- Market Decision not to launch: DE, IT, ES, IS, AT, CH, BE, EL, HU, BG, SK, EE.

Naratriptan

Background

- IL, Orchid, release Orchid UK.
- Market Formation: Day 1 launch, 9 March 2012
- IMS Europe sales total in 2010: ?
- Markets: UK, DE (OTC), FR & NL

Deviation/not launching on day 1

- The registered release site is Exova in UK, but due to patent we can not use it.
- Another testing site was not found in time, special equipment was required (for one test), that complicated this.
- The registered site of Orchid in UK will be used, and according to plans we will be about 4 weeks late to market.

Explanation of deviations
(markets in red)

Rivastigmine Patches

- Actavis and 3M co-development
- IMS : 267 ME EUR (MAT Q2 2011)
- Market formation: 31.07.2012
- Central procedure submission in February 2012.
- Will miss market formation in all patented markets

Rivastigmine Caps

- OD manufactured in Iceland
- IMS EUR MAT Q3 2010: €120M
- NL and SE : Site not producing until Feb 2012 due to low demand
- Market Decision not to launch: PT,ES HU,BE,BG,CZ,EE,IS,IE,LT,LV,NO,SK,SL

Zoledronic Acid (vials)

- OD - Italy
- IMS EUR MAT Q3 2010 Europe:
- Market Decision not to launch: EL,IS
- Still evaluating which markets will launch

Explanation of deviations (markets in red)

Tolterodine SR capsules

Background

- IL, Pharmathen
- IMS : €129M EUR MNF MAT Q3 2010
- Market formation: 04.09.2012

Status

- Will miss basic patent expiry in all patented markets if clock stop exceeds 3-4 months. Still possible to hit target in few markets if patent is not valid.
- Constraining formulation patent was granted on 10.11.2010 - expiry 26.08.2019. Actavis filed an opposition on 10th August 2011. 1st instance decision is not to be expected before QT3 2013.
- IP strategy has been proposed for Tolterodine SR capsules 2, 4 mg on a country by country basis for the following countries:UK, NL, IE, ES, SE, DK, FI, LT, NO, PL, IS
- BC is needed to evaluate the strategy and evaluate then the urgency of the clock stop

Explanation of deviations (markets in red)

Tolterodine IR Tabl

- **IL, Pharmathen**
- **IMS: €33M EUR MNF MAT Q3 2010**
- **Market Formation: 4 September 2012**
- **UK and AT only markets with MAs**
- **PoM evaluating other markets**

Riluzole

- **OD, Iceland**
- **IMS Europe sales total in 2010: €72M**
- **Market Decision not to launch: FI, IS, IE, BE, EL, PL, RO, HU, BG, LT, EE, MT.**

Explanation of deviations (markets in red)

Oxycodone ER tablets

Background

- IL , IP Acino
- Market formation: 25th November 2012
- IMS MAT Q2 2011 Europe – 268.9 mln Euro
- IL closing discussions ongoing with Acino

Status

- Only 4 markets in discussion for market formation launch vs the BC presented to PCM for 13 markets.
- Launch for pellet formulation: 4 key markets: NL, SE, UK, DE have potential of launching on market formation in November 2012.
- DK, FI, NO and IS will be included it the November DCP run by Acino – launch strategy undefined yet.
- All approved markets will have possibility to participate in DCP run for the Matrix formulation earliest in Q2 2012 without 15mg/30mg/60mg strengths, alternatively procedure will run in Q3/Q4 with all strengths.

Explanation of deviations (markets in red)

Desogestrel

- IL, Supplier: Helm AG
- IMS Europe sales 2010: €112M
- SE waiting new strategy on hormonal products and new guidelines from authorities to be implemented, HU late orders,
- Patent in FI postponed – patent expiry later
- AT not launching

Other Launches 2012

	UK	DE	FR	IT	NL	ES	PT	SE	DK	NO	FI	IS	IE	AT	CH	PL	RO	HU	BG	CZ	SK	Baltics
Buprenorphine	x	x	x			x	x	x	x	x		x		x		x			x	x		
Market Formation dates	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open
Planned launch dates	27.02.12	27.02.12	27.02.12					27.02.12	27.02.12	27.02.12									27.02.12			
Desloratadin	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Market Formation dates	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open
Planned launch dates	02.03.12	02.03.12	15.04.12	05.02.13	02.03.12	01.09.12	01.01.13	02.03.12	02.03.12	13.03.12	29.03.12	02.03.12	10.03.12	10.03.12	01.05.13	15.09.12	31.07.12	15.02.13	01.02.13	01.09.12	15.01.13	15.01.13
Ropinorol SR	x	x	x	x	x	x	x	x	x	x	x	x	x	x		x	x	x	x	x	x	x
Market Formation dates	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open		Open	Open	Open	Open	Open	Open	Open
Planned launch dates	13.04.12	28.05.12	26.08.12		28.05.12	23.01.13	09.11.12	07.06.12	27.06.12	25.09.12	25.09.12			26.08.11		26.08.12	26.08.12	05.09.12		28.01.13	28.05.12	28.05.12
Lymecycline caps	x		x	x				x	x	x	x		x			x					x	
Market Formation dates	Open		Open	Open				Open	Open	Open	Open		Open			Open					Open	
Planned launch dates	01.06.12		26.06.12	26.11.12				23.08.12	12.09.12	11.12.12	11.12.12		24.10.12			11.11.12					13.08.12	
Esomeprasol caps*	x	x	x	x	x					x		x	x	x		x	x		x			
Market Formation dates	27.05.14	27.05.14	27.05.14	27.05.14	27.05.14					27.05.14		05.05.14	27.05.14	27.05.14		Open	Open		Open			
Planned launch dates		02.11.11	02.04.12	11.09.12	29.05.12							01.11.11				27.08.12	27.08.12		12.07.12			

* Patent expiry dates subject to litigation

Litigation and Launch strategy confirmed by PCM

Launch in DE & FR (Litigation, Reg. and Launch), IS (no litigation) in October

Launches 2012: ES, IT, NL (Litigation, Reg. and Launch), RO, BG (no litigation), UK, FI (Reg. and wait clearance)

Launches 2014: PL (Litigation, Reg. and Launch), MT (no litigation), IE (Reg. and wait clearance)

Data Exclusivity Launches:

- **Desloratadin**
- **Ropinorole SR**

Explanation of deviations
(markets in red)

actavis
think smart medicine

Buprenorphine 2 and 8 mg tabl

Background

- OD, Supplier: Iceland
- IMS: €154 EUR MNF MAT Q3 2010
- Market Formation: open

Status

- Validation of analytical method finalized in September 2011. New impurities detected with consequential impact on shelf life.
- 24 months shelf life is supported in alu/alu packaging but not alu/pvdc which the manufacturing site had already ordered
- Two options: 1)file a variation and launch with 18 months shelf life, 2) switch to alu/alu packaging and launch with 24 months shelf lifer

Explanation of deviations
(markets in red)

Buprenorphine 2 and 8 mg tablets Cont.

Status

- The Core Team recommended switching to alu/alu based on the following:
  - New shelf life of 18 months is not considered commercially viable
  - New tooling considered most cost effective way of supporting product launch with regards to cost and timing
- Investment for the alu/alu tooling has been approved
- Launch in all markets February 2012

Explanation of deviations
(markets in red)

Desloratatine tablets

- OD - Malta
- IMS EUR MAT Q3 2010 Europe: 211M
- Market Decision not to launch: EL, SI

Lymecycline

- OD, Iceland
- IMS € MAT Q3 2010 EU: ?
- Crown Jewels in UK and FI and SE
- Issues: Registration, Roller Compactor
- Aiming to launch in Q2-2012 for UK
- Opportunity to push other launch markets to 2012

Explanation of deviations
(markets in red)

Ropinirole SR

- OD - Malta
- IMS EUR MAT Q3 2010 Europe: 141M
- Market Decision not to launch: IT, IS, IE, EL, BG
- All other markets late due to delayed DCP (Target end in Feb-12)
  - Day 105 answers were submitted on 7th of October. This lead to 2 months delay from the original plan
  - If any of the CMS will request a new biostudy, we will go into referal where we will submit the study. This will delay the launch until September 2012 (further three months)
  - 10 and 12 mg have already been pulled out of the DCP

Esomeprazole

- IL, Supplier: Ethypharm
- IMS Europe sales 2Q 2010 – 2Q 2011: €67M
- DE,IS late due to trihydrate issue. Late MA in FR. IT,PL,RO,BG late according to set timelines. UK,IE need clearance from IP when able to launch
- NO not launching – PCM decision
- AT – unclear strategy

2013 Launches

	UK	DE	FR	IT	NL	ES	PT	SE	DK	NO	FI	IS	IE	AT	CH	PL	RO	HU	BG	CZ	SK	Baltics
Rizatriptan	x		x	x	x	x		x	x	x	x	x							x	x		
Market Formation dates	10.02.13		11.02.13	11.02.13	10.02.13	11.02.13		10.02.13	11.02.13	11.02.13	10.02.13	Open							10.02.13	16.02.15		
Planned launch dates																						
Dorzolomid+Timolol	x	x	x	x	x	x	x	x	x	x	x	x	x	x				x				x
Market Formation dates	Open	06.03.13	06.03.13	06.03.13	Open	06.03.13	11.03.13	05.03.13	06.03.13	15.10.13	Open	Open	05.03.13	06.03.13				Open				30.02.13
Planned launch dates	L				15.11.11						01.11.11	01.11.11						11.12.11				
Ziprazidone		x*				x*	x	x*	x*	x		x		x*		x		x	x	x	x	x
Market Formation dates		07.05.13				07.05.13	07.05.13	07.05.13	07.05.13	31.08.13		Open		07.05.13		08.08.13		31.08.13	Open	31.08.13	Open	Open
Planned launch dates												31.03.11										
Memantine	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Market Formation dates	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	13.04.14	Open	Open	Open	Open	Open	Open	Open
Planned launch dates	03.05.13	03.05.13	29.06.13	15.05.13	03.05.13	29.07.13	26.11.13	03.05.13	03.05.13	14.05.13	30.05.13	03.05.13	11.06.13	03.05.13		03.05.13	29.07.13	09.06.13	13.07.13	23.08.13	03.05.13	
Sildenafil tabs	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		x
Market Formation dates	21.06.13	14.09.13	22.06.13	22.06.13	21.06.13	14.09.13	21.01.14	21.06.13	22.06.13	13.05.14	Open	Open	20.06.13	22.06.13	22.06.13	20.06.11	EXU	Open	Open	13.05.14		Open
Planned launch dates						L					L	L				L		L	L	01.12.11		
Pramipexol SR	x	x	x	x	x	x	x	x	x	x	x	x	x	x		x	x	x	x	x	x	x
Market Formation dates	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open	Open		Open	Open	Open	Open	Open	Open	Open
Planned launch dates	14.06.13	29.07.13	27.10.13	11.11.13	29.07.13	26.03.13	10.01.14	08.08.13	28.08.13	26.11.13	26.11.13	29.07.13		27.10.13		27.10.13		06.11.13		31.03.14	29.07.13	
Sildenafil chew tabs				x	x	x				x				x		x		x	x	x		
Market Formation dates				14.09.13	13.09.13	14.09.13				13.05.14				22.06.13		Open		Open	Open	Open		
Planned launch dates																03.10.12		13.10.12	18.08.12	07.03.13		
Irbesartan HCT	x	x	x	x	x	x	x	x	x	x		x	x			x	x	x	x		x	
Market Formation dates	14.10.13	15.10.13	15.10.13	15.10.13	14.10.13	15.10.13	Process	14.10.13	15.10.13	Process		Open	14.10.13			20.03.11	20.03.11	20.03.11			05.02.16	
Planned launch dates						L											L	L				
Capecitabin	x	x	x	x	x	x	x	x	x	x	x	x	x	x		x	x	x	x	x	x	x
Market Formation dates	01.12.13	02.12.13	01.12.13	01.12.13	30.11.13	01.12.13	01.12.13	01.12.13	01.12.13	17.12.13	09.06.13	13.05.23	01.12.13	01.12.13		17.12.13	16.12.13	03.02.16	16.12.13	18.07.16	17.12.13	17.12.13
Planned launch dates									15.03.14										15.01.14			

* EP-01029861 under opposition, if revoked it could change the expiry date to Feb 2013

Explanation of deviations
(markets in red)

Rizatriptan ODT

- OD, Malta
- IMS MAT Q2 2011 Europe: €70M
- Market Decision not to launch: IS, CZ & EL

Dorzolamide Timolol

- IL, GX, Eye drops; Supplier: Pharmathen(EL)
- IMS MAT Q2 2011 Europe: €160M
- General patent expiry in WE March 2013. UK and NL have/will launch 2011, due to revoked patent. Oral hearing in DE on Oct.19th 2011 – if positive outcome, DE can launch asap. FR being explored for potential pre-launch.
- Market decision not to launch: EE small market and big competition

Ziprazidone

- OD , Iceland
- IMS : €96M EUR MNF MAT Q3 2010
- Market formation: 7 May 2013
- Patent EP-01029861 under opposition, if revoked it could change the expiry date to Feb 2013
- IS can not reach MOQ for launch

Explanation of deviations
(markets in red)

Memantine

- OD, Malta
- IMS MAT Q2 2011 Europe: €459M
- CP will be pursued in June 2012 & the following markets will need to be registered however due to local reasons will not launch: LT, EE, LV.
- DCP procedure considered in addition to CP to address INN vs brand issue.

Sildenafil Tabl.

- OD, Malta
- IMS €581M EUR MNF MAT Q3 2010
- Market decision not launch in: RO, Baltics

Explanation of deviations
(markets in red)

Sildenafil Chewables

- IL, Supplier: Genepharm
- DCP: NL, NO, ES, IT, AT, BG, CZ, HU, PL, and national RS
- Market formation: May-Sep 2013 (NO 2014), open in BG, CZ, HU & PL.
- Submitted in June 2011.
- Expected short clock stop and first possible MA in October 2012

Pramipexol PR

- OD, Malta
- IMS MAT Q2 2011 Europe: €153M
- Open market, dossier completion in Dec 2011. Ongoing development issues.
- DCP slot booked for February in Germany
- Market Decision not to be included in the DCP: IE, PL, RO, BG, LT, EE, LV, MT
- EL no corporate strategy to enter Greece

Explanation of deviations
(markets in red)

Irbesartan/HCT

- OD manufactured in Iceland
- IMS €545M EUR MNF MAT Q3 2010
- Market Decision not to launch: IT,FI,EL,EE
- Court case and price issues : NO and PT

Capecitabin

- IL, Cipla
- IMS MAT Q2 2011 Europe: €292M
- RS - late submission will result in launch in Jan 2014 vs market fomation Dec 2013.

Russian OTC

Troxevasin combi - RU

Background

- OD, Supplier: Troyan, Bulgaria

Status

- Module 3 is ready
- Toxology study has been finalised
- Clinical study protocol ready 15 September
- Already submitted the dossier

Next Milestones

- Clinical trial approval 19 November,
- Clinical Study completion in August 2012
- Launch in February 2013

SEDALGIN Brand Russia

Background

- Sedalgin Neo 2010 €10.9M (Actual sales)

Situation

- Russian authority has announced the enforcement of “anti-codeine” law in June 2012. All codeine products are required to switch from OTC to Rx
- Rx status in Russia does not oblige prescribtion however direct to consumer advertisment is forbidden
- Sedalgin Neo will loose the OTC status following the new legislation.
  - Public can continue buying the product in the pharmacy
  - No direct to consumer advertising
  - No promotion to doctors whereas this is not a prescription medicin

Goals

- Keep the OTC status for the SEDALGIN brand in Russia
- Market an effective and safe pain killer in Russia under the brand SEDALGIN
- Keep SEDALGIN brand for Rx as well (Sedalgin Neo)

Sedalgin Brand - Russia

Actions – short term

- Benalgin (Caffeine /Metamizole sodium /Thiamine) will be rebranded as SEDALGIN in Q2 2012
- Variation has been filed to switch Benalgin from Rx to OTC
- Variation is planned to change the name from Benalgin to Sedalgin

Actions – long term

- New formulation will be launched as SEDALGIN in April 2014:
  Paracetamol /Naproxen /Caffeine /Drotaverine hydrochloride /Pheniramine maleate
- Does not contain Metamizole
- The R&D phase is on schedule. Dossier completion planned in June 2012.
- Planned Launch: Q1 2014

Sedalgin Brand - Russia

Risk

- Russian legislation does not allow the usage of the same trade names for two different INNs.
  - SEDALGIN NEO contains Metamizole but the new formulation does not. Hence there is a risk that we will not be able to market the new formulation under the same umbrella
  - However, players on the Russian market have been able to use umbrella brand for different INNs.
  - Russia is confident of being able to use the SEDALGIN brand for the new formulation and will refer to previous examples on the market.

- European markets do not approve of OTC and Rx products being sold under the same brand name.
  - As of now, Russia has not objected the use of the same brand name for OTC and Rx but might follow suit.

Spazmalgon

- Background
  - OD, Bulgaria
  - Market formation: open – on the market
  - Key market: Russia
  - API: Metamizole sodium

- Status
  - Metamizole was banned in many WE countries during the 1970s. Since then, more than 30 countries have followed suit
  - PoM are closely monitoring whether RU would follow the suit

  - ➔ no major issues