



COLAL-PRED[®] LICENSING DEAL WITH PROMETHEUS



PROMETHEUS[®]
Therapeutics & Diagnostics

Presentation Team

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- Product:** Colon targeted delivery formulation of prednisolone metasulfobenzoate sodium (PMSBS) (prednisolone ester)
- Clinical profile:** Ulcerative colitis
- Benefits:** Equivalent efficacy to prednisolone; elimination of systemic steroidal side effects; treatment of the entire colon; oral administration once-daily
- Status:** EU Phase III study underway



- ◆ Gelatin capsule containing COLAL® coated PMSBS pellets
- ◆ Vary dose by altering capsule fill-weight
- ◆ Produced with conventional manufacturing equipment/plant

- ◆ **2 component film coating system**
 - ◆ **glassy amylose**
 - ◆ **ethylcellulose**

- ◆ **Not digested by human amylases**

- ◆ **Coating digested by microbial enzymes (amylases) in colon**

- ◆ **Release independent of gastrointestinal pH change or time**

- ◆ **Microbial digestion “concept” validated by 5-ASA pro-drugs**

- ◆ **Exclusive licence for COLAL-PRED® in North America**
- ◆ **Up-front payment and development milestones of \$17.5m**
 - \$2.5 million - payable immediately
 - \$15.0 million - payable on future development milestones
- ◆ **Prometheus will be primarily responsible for clinical development costs for the licensed territory**
- ◆ **Royalty rates which increase with higher annual net sales levels**

- ◆ **Currently around 2 million people in major territories suffer from UC**
 - **Estimated 700,000 people in the US**

- ◆ **Market dominated by anti-inflammatory steroids and 5-ASA products**
 - **Safety and/or efficacy issues**

- ◆ **Unique profile of COLAL-PRED[®] allows effective treatment of UC with anti-inflammatory steroid**
 - **No debilitating side effects**

- ◆ **Current projections of sales of COLAL-PRED[®] in major territories**
 - **> \$250 million p.a.**

- ◆ **A US based specialty pharmaceutical company**
- ◆ **Leader in the provision of GI therapeutics and diagnostics to GI specialists throughout the US**
- ◆ **Key products include:**
 - **ENTOCORT® EC (Licensed from Astra-Zeneca) for the treatment of Crohn's disease**
 - **Lotronex® (acquired from GSK) for the treatment of diarrhoea-predominant IBS**



- ◆ **www.prometheuslabs.com**

- ◆ **Net sales grew from \$90 million in 2004, to \$139 million in 2005 and to \$187 million in 2006**
 - pharmaceutical products \$119 million in 2006
 - clinical diagnostic services \$68 million in 2006
- ◆ **ENTOCORT® EC (budesonide) Capsules**
 - net sales increased almost three-fold from approximately \$30 million under AstraZeneca in 2004 to \$85 million in 2006
- ◆ **Net income of \$33 million in 2006**
- ◆ **Cash position of \$78 million at the end of 2006**
- ◆ **Positive operating cash flow in each of the last five years**

European development (Alizyme)

- ◆ **Phase III study ongoing**
- ◆ **Patient recruitment expected to complete by end 2007**
- ◆ **Headline results expected Q2 2008**
- ◆ **MAA submission in H2 2008**
- ◆ **Launch in H2 2009**

North American development (Prometheus)

- ◆ **Phase II study to commence in H1 2008**
- ◆ **Anticipated filing of NDA with FDA in 2011**

Late Stage Development Pipeline

Current Development

PHASE II	PRE-PHASE III	PHASE III
Cetilistat obesity (Japan)	Cetilistat obesity	Renzapride IBS-C (USA)
ATL-104 mucositis	Cetilistat obese diabetics	COLAL-PRED® active UC (EU)

Future Potential Development

Renzapride chronic constipation gastroparesis dyspepsia GERD	Renzapride IBS-M	
COLAL-PRED® Crohn's colitis steroid dependent UC	COLAL-PRED® remission of UC	
		Metabolic
		Gastrointestinal
		Supportive Care

Near term R&D milestones

Cetilistat	- start of Phase III development
Renzapride	- results of 1st Phase III study in US - start of 2nd Phase III study in US
COLAL-PRED®	- results of registration Phase III study in EU - start of Phase II study in North America
ATL-104	- start of 2nd Phase II study

Completion of commercial deals

- ◆ **A deal with a leading GI and diagnostics specialty pharma company**
- ◆ **Financial rewards geared heavily towards product sales**
- ◆ **Further deals for COLAL-PRED® to be concluded in Europe and ROW**
- ◆ **Continued focus on delivering further commercialisation deals across the product portfolio**