



# Merrion Pharmaceuticals plc

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# International Management Team



**John Lynch, CEO**

- 20 years at multinational healthcare companies
- Led a \$100m business for Abbott
- Business Development, Commercial Development
- Ernst & Young, Bayer, Abbott



**Hing Kin Chan, PhD CBO**

- 20 years commercial & business development experience in healthcare industry.
- Development of commercial strategies in drug delivery sector
- DBV Technologies, ProBioGen, Eurand



**Jonathan O'Connell, CFO**

- 18 years as a CFO with commercial experience
- Floated Trinity Biotech (Nasdaq & ISEQ)
- Spectel – raised funding (30m) (trade sale for \$105m)



**Thomas Leonard, PhD CSO**

- 23 years pharmaceutical industry experience
- Inventor on 30 drug patents
- Products through approval process
- Product formulation, R & D Management
- Wyeth-Ayerst, aaiPharma, Endeavor



**John Fox, PhD CDO**

- 20 years at multinational/ specialty pharmaceutical companies
- Pharmaceutical development, regulatory affairs
- Portfolio planning
- Hunter Fleming, Shire, Lilly

Board : P O'Sullivan (Chair), H Stratford, P Thornton, M McKenna, M Donnelly, A Carragher, F Maher

# Merrion Pharmaceuticals Plc

**Acquire  
Technology  
from Élan**

**Complete  
IPO**

**Complete two  
Licenses with  
Novo Nordisk**

**Completed  
Orazol Phase II  
and FDA/EMEA  
agreement**



**Build Product  
Portfolio**

**Build product  
development  
capability**

**Purchased  
new facility  
& scaled  
operation**

**Signed agreements  
3 Companies  
6 Compounds**

**2004**

**2011**

# GIPET<sup>®</sup> Technology



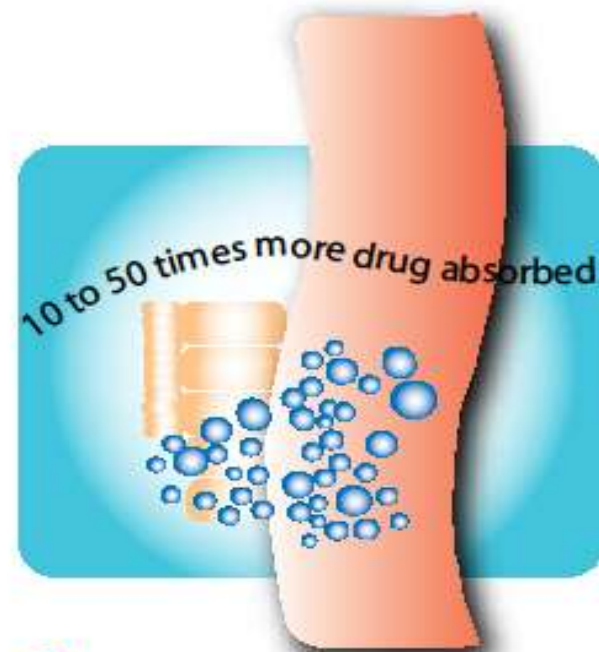
**1**

Enteric coated tablets.  
Targeting the duodenum.  
Facilitating maximum drug delivery  
in this area.



**2**

Dissolution of the tablet results in  
the co-release of the drug and  
absorption enhancer.



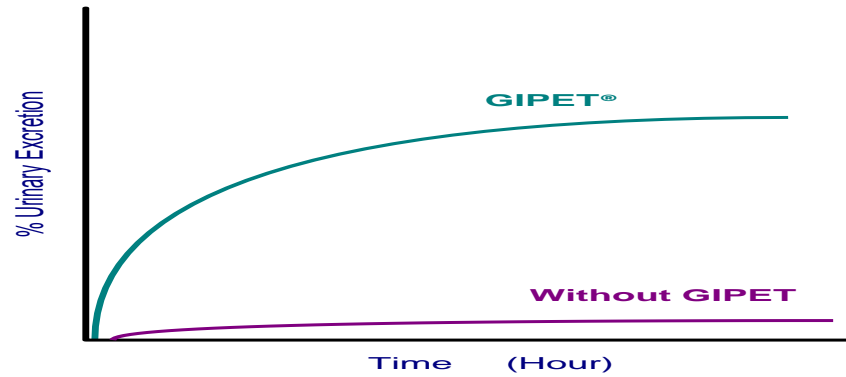
**3**

This physical mix facilitates the  
absorption of the drug across the  
duodenal cell membrane and  
results in increase of  
bioavailability.

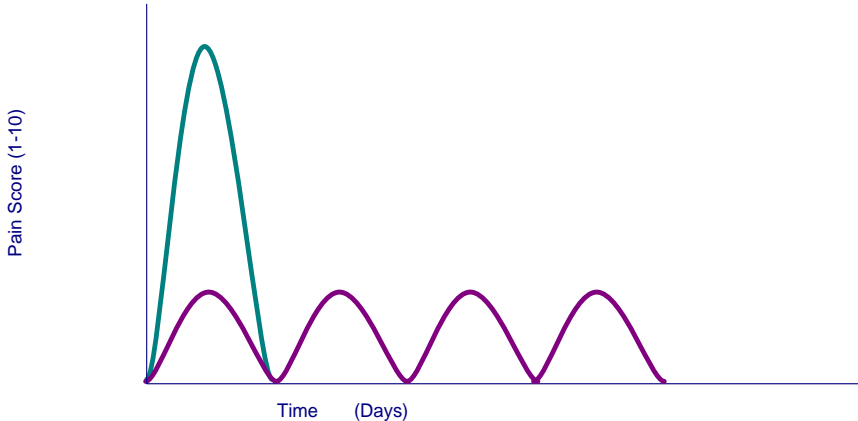
- Up to 50 times more Drug Absorbed in Clinical Trials.
- 20 Clinical Studies. Broad range drug types.
- GRAS status simplifies development.

# Pharmaceutical Industry trends and Merrion Products

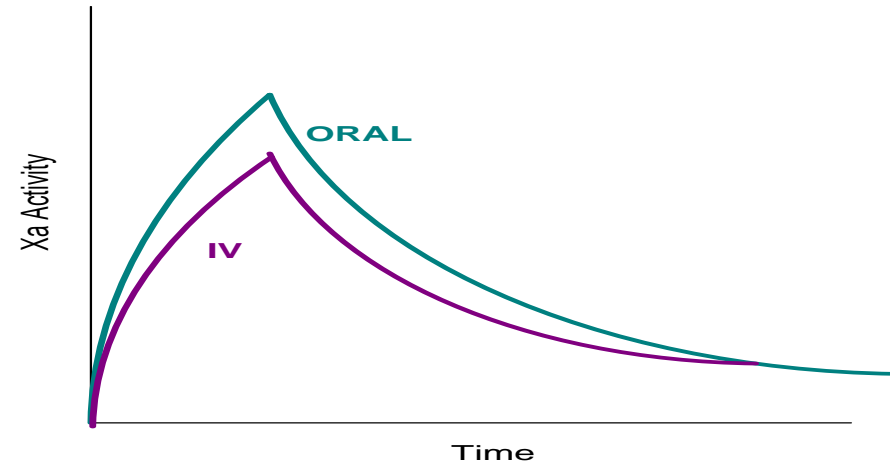
- ✓ Enable oral delivery of peptides  
- Oral insulin, GLP-1
- ✓ Change of Route of administration - Oral product from an acute IV



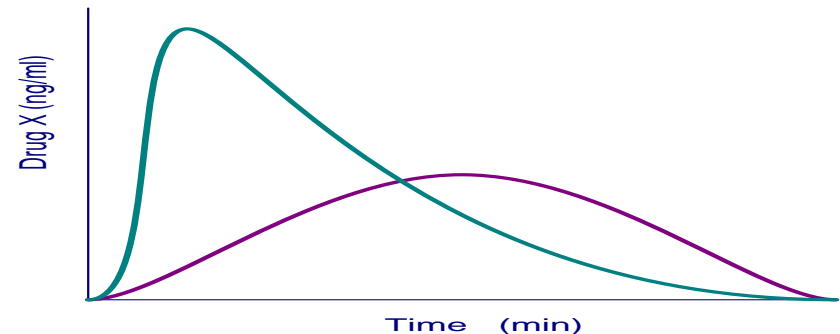
- ✓ Major new indication for product from data generated by injectable - Orazol



- ✓ Lifecycle management of injectables MER 102 – extending patent life



- ✓ Emerging market products - Almerol
- ✓ Improved oral – reduced Tmax, increased Cmax, increasing overall AUC



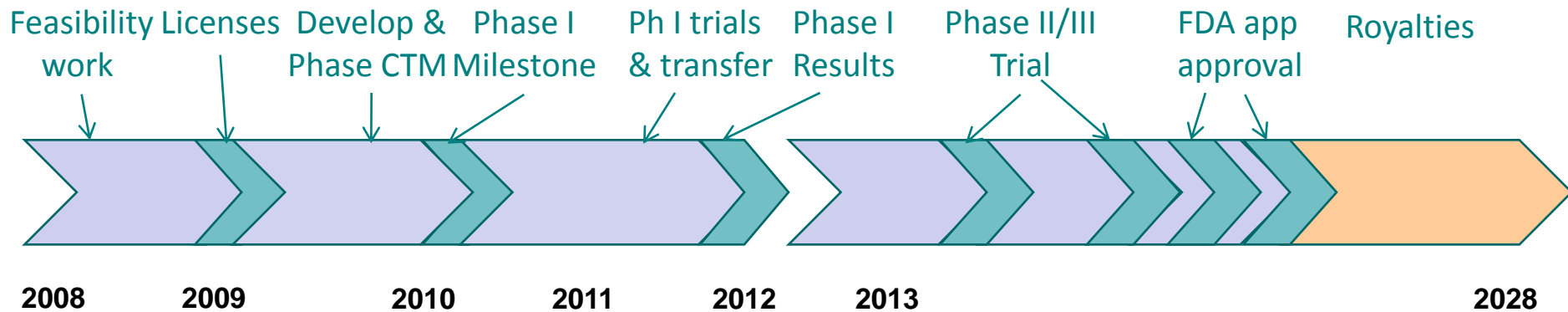
# Merrion Pipeline



# Merrion Partnered Pipeline



# Revenue Model – Novo Nordisk example (>\$20M)



- Feasibility agreement with option fees **€1.3m**
- License agreement – Upfront milestones for Insulin and GLP1 not disclosed
- Development and Phase I Clinical Trial Manufacture (CTM) fees **€6.6m**
- Development Milestone – start Phase I **\$3m** received
- Phase I clinical Trial – ongoing
- Further Milestones – end Phase I, Phase II/III Clinical Trials
- Regulatory Filings/approvals/sales milestones
- Total Milestones received to date **\$9m**
- additional potential milestones \$109m+
- Royalties on very significant sales

# World Class Facilities

- ❑ **Build value by creating products, Speed development & reduce risk**
- ❑ **People**
  - ❖ High quality scientific team, with key expertises
  - ❖ Very positive partner feedback
- ❑ **Facilities**
  - ❖ Highest specification of design, layout and equipment – Low o/head
  - ❖ Highly modular configuration to allow multiple drug development
  - ❖ EU License (previously FDA inspected facilities)



# Managing risk

- **Product**
  - Portfolio of 11 partner programmes
  - Merrion programmes available to partner
- **Regulatory**
  - FDA/EMA Orazol pre-Phase III minutes
- **Safety**
  - Clean clinical database
- **Technology**
  - 50 drugs trialled preclinically, broad range drugs
- **Patent**
  - Continuing important issuances





# Partnerships

# Novo Nordisk Collaboration Injection to Oral



Market Cap	€44Bn
Sales	€8Bn
Employees	30,000

## □ Significant returns to date/blockbuster product opportunities

- ❖ Clinical trials oral insulin, oral GLP-1 2010/2011
- ❖ NN Insulin and GLP-1 Injectable Sales 2010 €5.5Bn
- ❖ Oral products a key to Novo Nordisk medium term strategy
- ❖ Merrion cash receipts >\$20M to date
- ❖ >\$109M potential future milestones
- ❖ Royalty potential – several hundred \$M's

## □ New Agreement – new area December 2010

- ❖ Feasibility study ongoing
- ❖ Upfront plus equity on license

## □ Key Market validating partnership

- ❖ Due diligence for Pharma market
- ❖ Heavy investment in commercialising GIPET technology

## Ferring Pharmaceuticals

- ❑ Injectable to oral collaboration on multiple drugs since 2008
- ❑ Have recommended Merrion technology to other pharma companies

## Rebel Pharmaceuticals

- ❑ Nov 2010 – Feasibility and option agreement **2** compounds
- ❑ US Speciality Pharmaceuticals Company
  - ❖ enhancing approved drugs using proven and patented drug delivery technologies
- ❑ Studies completed, reports being compiled
- ❑ Financial terms agreed
  - ❖ Upfront, Development fees, Milestones, Royalties

# 'Top Ten' Pharma – 3 Compounds

- Feasibility and option agreement
  - ❖ Injectable to oral
  - ❖ 3 compounds
  - ❖ Different Therapeutic areas

## Other Partners/pipeline

- EU biotech company –
  - ❖ improved oral, successfully completed preclinical
- Several potential new partners at different stages of discussion



# Merrion Programmes

# Orazol Product Concept

- ❑ **Provide an ideal product from ‘\$2Bn gold standard’ molecule**
  - ❑ Clinically Improved efficacy
  - ❑ Clinically Improved safety & side effects
  - ❑ Economic benefits of oral delivery
  - ❑ Patient and HCP benefits of oral delivery
- ❑ **Unique oral product**
- ❑ **Build Orazol market beyond current uses and penetration**
  - ❑ Unique new indications
  - ❑ New geographies
  - ❑ Greater penetration of existing markets
- ❑ **>95% Gross margin**
- ❑ **Strong patent fence to late 2020’s**

# What Orazol offers

## ❑ **Key Clinical Benefits**

- ❑ Improved Efficacy in bone pain control
- ❑ Absence of Acute Phase Reactions
- ❑ Designed to reduce renal toxicity
- ❑ Weekly dosing – similar efficacy first week as monthly infusion, decreased variability

## ❑ **Cost Benefits**

- ❑ Modelled cost per QALY v positive

## ❑ **Commercial benefits**

- ❑ Several major new indication opportunities
- ❑ Branded pricing potential, but with pharmacoeconomic benefits

## ❑ **Strategic Benefits**

- ❑ Long patent life – 3 US patents allowed/issued (2020-27, new filings in progress (2030))

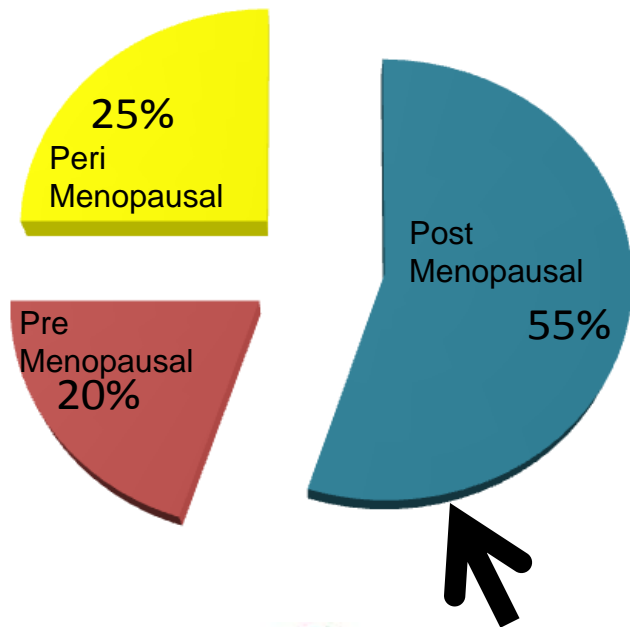
# Orazol Indications

- ❑ **Adjuvant Cancer treatment**
  - ❑ In addition to existing 'standard of care'
  - ❑ Post menopausal breast cancer as initial indication
  - ❑ Multiple myeloma, prostate, lung cancer as further indications
- ❑ **Existing indications**
  - ❑ Bone metastases
  - ❑ Paget's disease
  - ❑ Osteoporosis
- ❑ **Increase use in ROW markets**

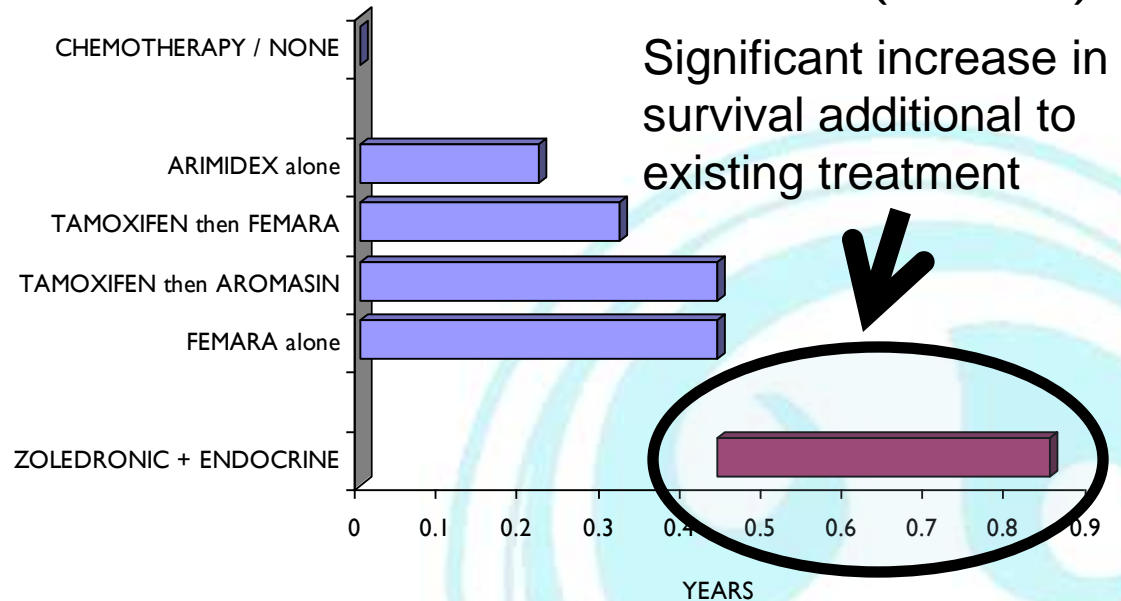
# Large Studies Show Zoledronic Acid Improves Breast Cancer Outcomes

Trial	Drug	Size	Population	Estrogen	Results
<b>AZURE (Coleman) POSTMENOPAUSAL</b>	zoledronic acid	1,101	POSTMENOPAUSAL	ABSENT	29% reduction in the risk of death ( $p=0.017$ ) 21% reduction in the risk of disease or death ( $p<0.05$ )
<b>ABCSG-12 (Gnant)</b>	zoledronic acid	1,803	PREMENOPAUSAL (with hormonal suppression)	ABSENT	36% reduction in the risk of disease progression ( $p=0.01$ ) 35% reduction in the risk of disease recurrence ( $p=0.02$ )
<b>Z-FAST / ZO-FAST</b>	zoledronic acid	1,667	POSTMENOPAUSAL	ABSENT	52% reduction in the risk of disease or death ( $p=0.0396$ ) 56% reduction in the risk of disease ( $p=0.0401$ )
<b>AZURE (Coleman) PREMENOPAUSAL</b>	zoledronic acid	2,258	PREMENOPAUSAL	PRESENT	No effect

## Breast Cancer Population<sup>1</sup>

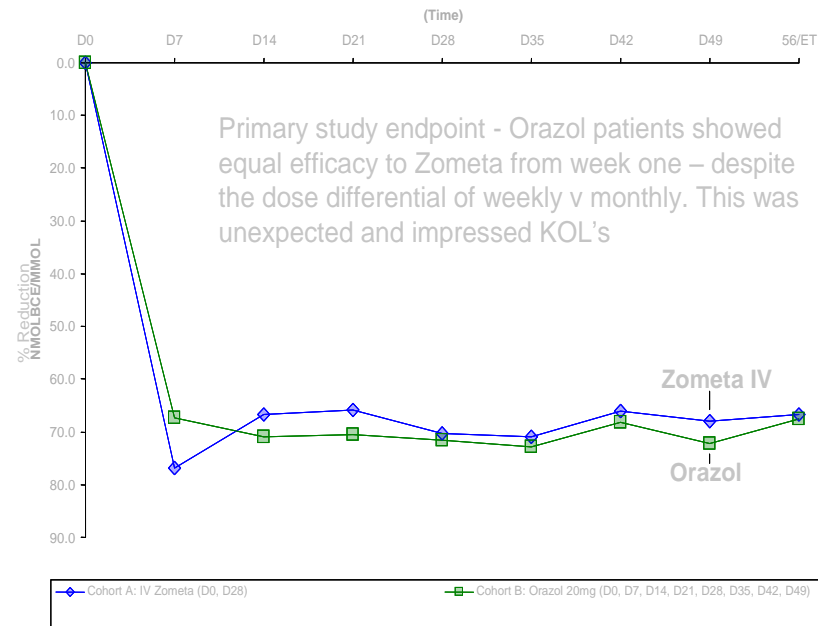


## INCREASE IN OVERALL SURVIVAL (Calculated)



# Orazol – Development Status

NTX, Urine % Reduction from Baseline



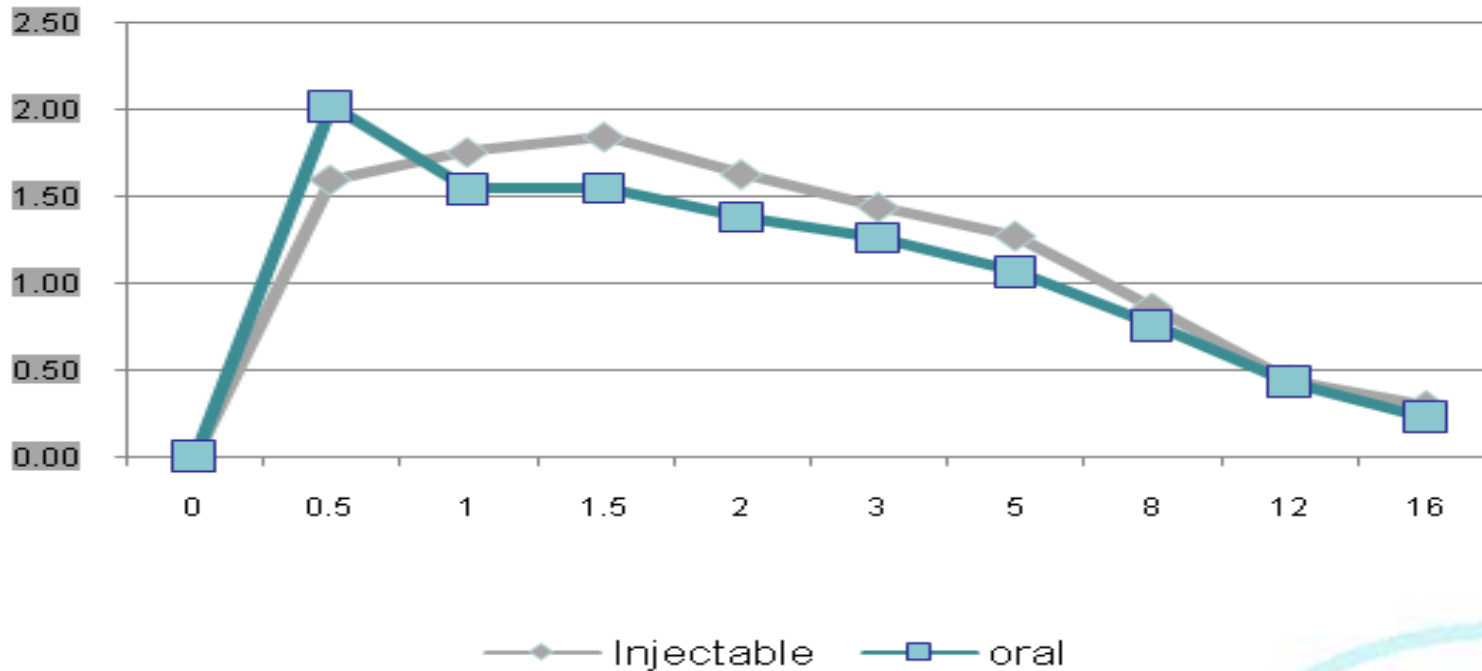
Brief Pain Inventory  
Pain; Worst Severity



## Orazol Phase II Data demonstrated:

- ❑ Similar delivery of Zoledronic Acid to the bone between the two dosage forms (4mg monthly infusion vs. 20mg weekly tablet)
- ❑ Similar efficacy as measured by standard bone turnover biomarkers (CTX, U-NTx)
- ❑ Improved efficacy for bone pain
- ❑ Improved safety and tolerability profile

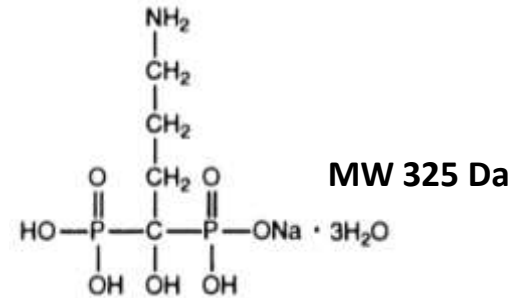
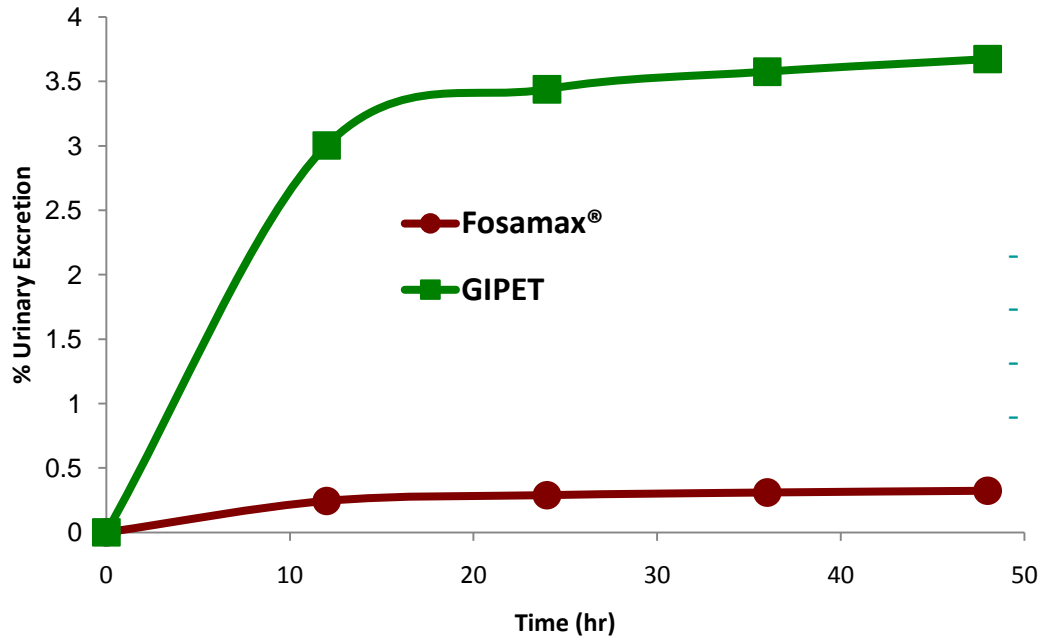
# MER 102 – Anticoagulant



## MER 102

- Patients take daily subcutaneous injections to prevent DVT's
- An oral would provide a series of benefits
  - New indications
  - Additional territories
  - Longer treatment
  - Competitive advantage

# Almerol™



Almerol had 12 fold increased bioavailability  
 Lower variability  
 Release in duodenum, no oesophageal effects  
>92% reduction of drug in GI tract

- Almerol potential in Emerging markets
  - China 90M osteoporosis sufferers
  - Osteoporosis is Chinese govt. health priority
- Almerol offers
  - Patent protected product
  - 92% reduction in API
  - Improved product profile



# Financial Update

## Consolidated P&L - Year to 31 December 2010

	Year ended 31 Dec 2010 €'000	Year ended 31 Dec 2009 €'000	Year ended 31 Dec 2008 €'000
Revenue	4,678	6,335	1,340
Cost of sales	(890)	(1,256)	(448)
Gross profit	3,788	5,079	892
R&D expenses	(5,279)	(5,247)	(3,898)
R&D tax credit	1,117	837	-
Administration expenses	(1,982)	(2,477)	(2,420)
Net Interest income/(exp)	(154)	178	363
Net Loss for the year	(2,510)	(1,629)	(5,062)
Loss per share	(€0.15)	(€0.10)	(€0.30)

## Consolidated Balance Sheet as at 31 December 2010

	31 Dec 2010	31 Dec 2009
	€'000	€'000
Fixed assets	4,730	5,015
Trade and other receivables	2,729	3,029
Cash	3,310	7,218
	10,769	15,262
Trade Creditors and accruals	1,005	1,487
Deferred income	2,912	4,450
Loans & borrowing	2,851	3,258
Retained Loss	(32,868)	(30,358)
Equity	36,869	36,425
	10,769	15,262

# Summary

- ❑ Novo Nordisk - Validation of technology and capability
  - ❑ Oral insulin Q4
  - ❑ GLP1 H1 2012
- ❑ Other potential license deals with partners
  - ❑ New Novo Nordisk deal
  - ❑ Rebel – 2 compounds
  - ❑ Ferring
  - ❑ Top 10 Pharma – 3 compounds to start with
  - ❑ EU Biotech
- ❑ High potential own products for license
  - ❑ Orazol, MER102, Amerol
  - ❑ New product ideas to add to pipeline
- ❑ High quality BD pipeline to generate further feasibility deals
- ❑ Infrastructure
  - ❑ Revenue generation, low overhead
  - ❑ Highest quality facilities for maximum speed/lowest risk
  - ❑ Experienced team
- ❑ Risk diversified approach