



# Merrion Pharmaceuticals plc

## Presentation

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# Management Team



## John Lynch, CEO

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

## John Fox , PhD CDO

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



## Thomas Leonard, PhD CSO

- 23 years pharmaceutical industry experience
- Inventor on 30 drug patents and numerous products through approval process
- Product formulation, R&D Management
- Wyeth-Ayerst, aalPharma, Endeavor Pharmaceuticals

## Jonathan O'Connell, CFO

- 14 years as a CFO with commercial experience
- Floated Trinity Biotech (Nasdaq and ISEQ)
- Spectel - raised funding (30m) (trade sale 2004 for \$105m)



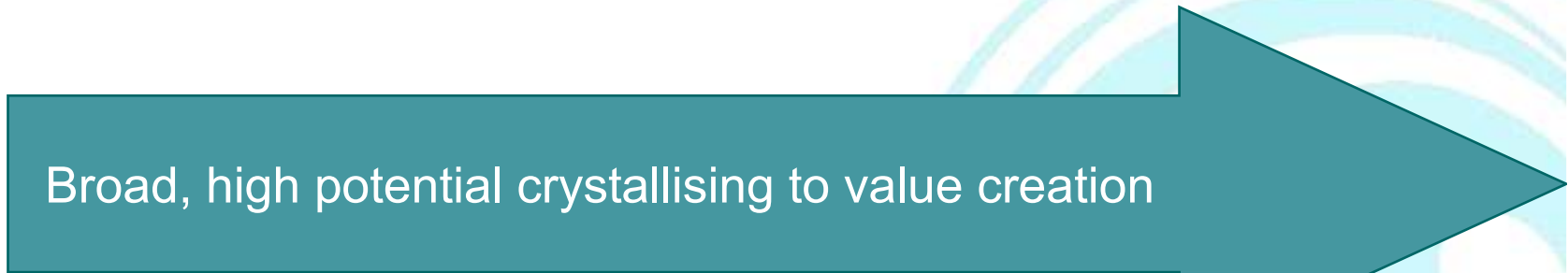
## Board Composition:

P O'Sullivan, H Stratford, P Thornton, M Donnelly, F Maher, A Carragher, M McKenna, J Lynch

42 employees-35 in R&D



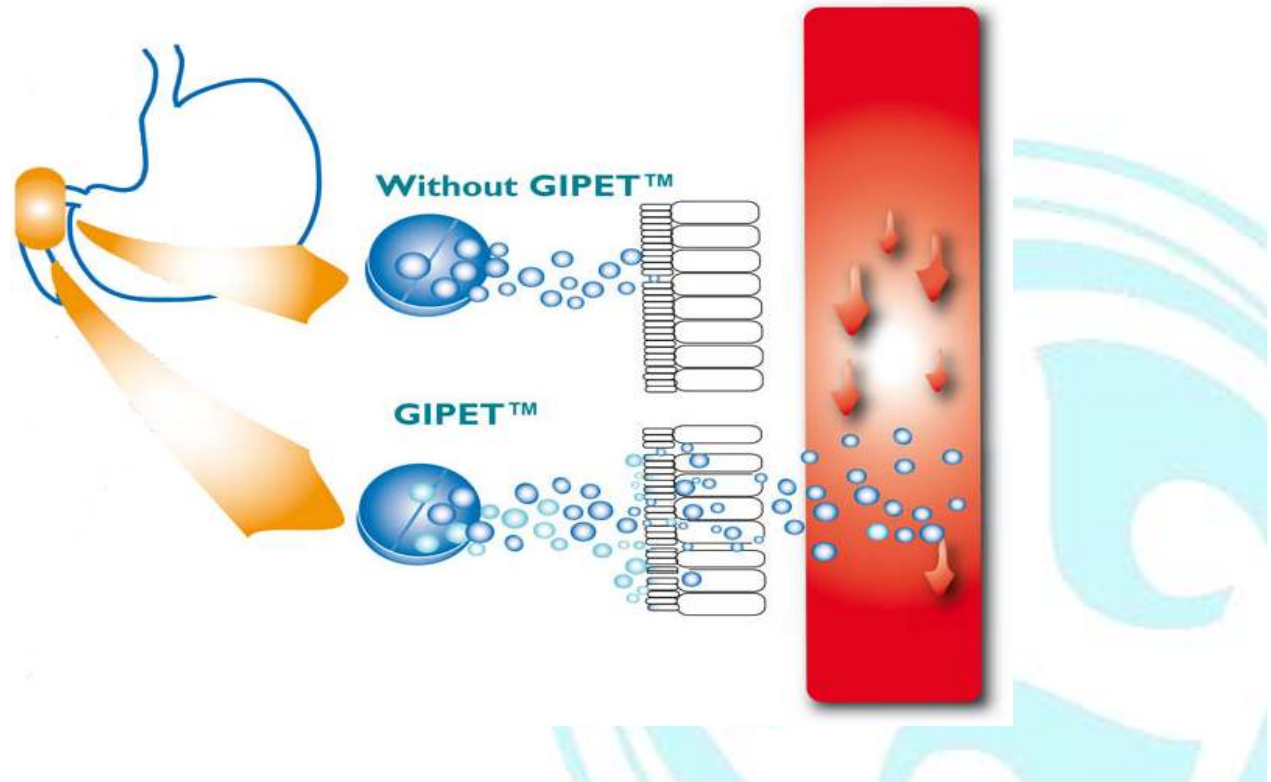
# MERRION PHARMACEUTICALS PLC



Current market cap: \$100M  
Ticker; IEX: Merr

# How does GIPET® work?

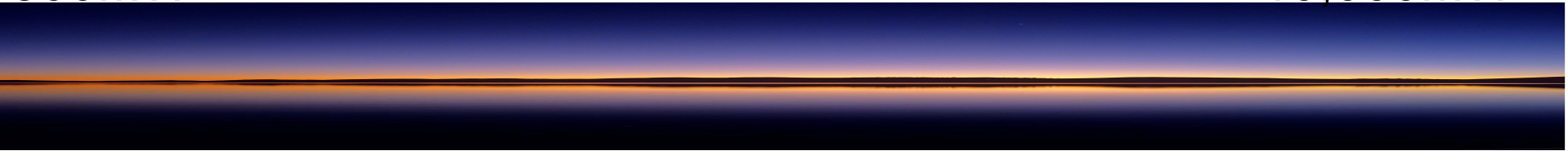
- ❑ Large increases in bioavailability (up to 46 fold)
- ❑ Works in broad range small molecule, peptide compounds
- ❑ Uses GRAS status absorption enhancers
- ❑ Excellent reproducibility (CV%)
- ❑ Abbreviated regulatory pathways e.g. 505(b)2
- ❑ Straightforward manufacture



# GIPET works on a broad horizon of compounds

300MW

10,000MW



Small Molecules

Peptides

Bisphosphonates

HDAC

GLP-1

Insulins

Conventional molecules

Desmopressin

Glycosaminoglycans

Other peptides

GnRH Analogues

Antisense

Platinum

Vancomycin

Demonstration Compounds

Factor Xa Inhibitor

Calcitonin



Clinical Studies



Preclinical compounds

# What Does the Database Tell Us?

## □ GIPET® is:

- ❖ Very versatile technology
  - Has 'worked' on >35 compounds
  - Bisphosphonate (12-15 fold), Peptide (46 fold)
- ❖ Improves absorption of very different drug types
  - Molecular weights
  - Physical/chemical characteristics
- ❖ Clean safety database (as expected with GRAS materials)
- ❖ Provides multiple product opportunities for highly differentiated new products
- ❖ Can demonstrate proof-of-concept quickly and inexpensively to bring product to significant value point

# What product advantages could GIPET Allow?

## ❑ Parenteral (injectable) to oral (single tablet dose)

- ❖ Patient QOL
- ❖ Improved use of healthcare resources
- ❖ Health economics
- ❖ Improved access for patients to drug therapy e.g. Homecare
- ❖ Allow efficacious drugs come to market (e.g. Peptides)
- ❖ New indications for existing drugs



## ❑ Improved Safety Profile

- ❖ Improved dosing regimen (e.g. Renal profile Orazol)

## ❑ Improved side effect profile

- ❖ Less drug exposure
- ❖ Different absorption profile



# What product advantages could GIPET Allow?

## □ Life Cycle Management of products

- ❖ Fast route to clinical studies
- ❖ GRAS status - safety
- ❖ Positive interactions to date with key regulatory bodies (FDA, EMEA)
- ❖ Build patent position fence

## □ NCE's

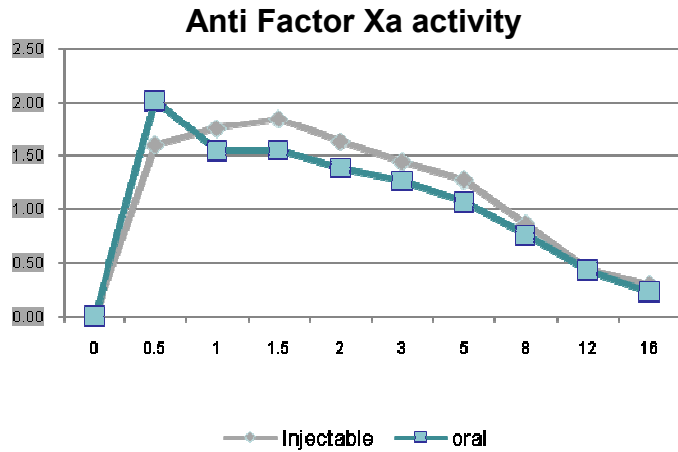
- ❖ Enable bringing to market, without additional complication

## □ Positive variability profile

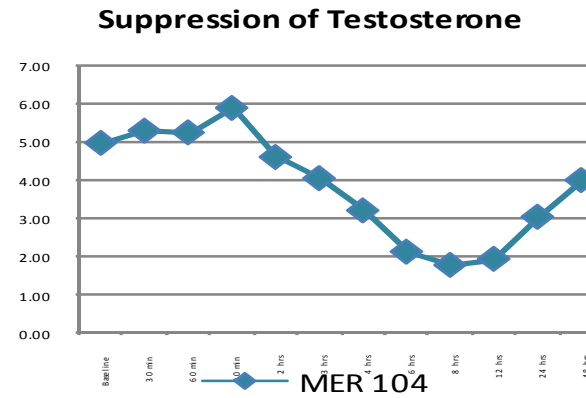
## □ Better efficacy profile?



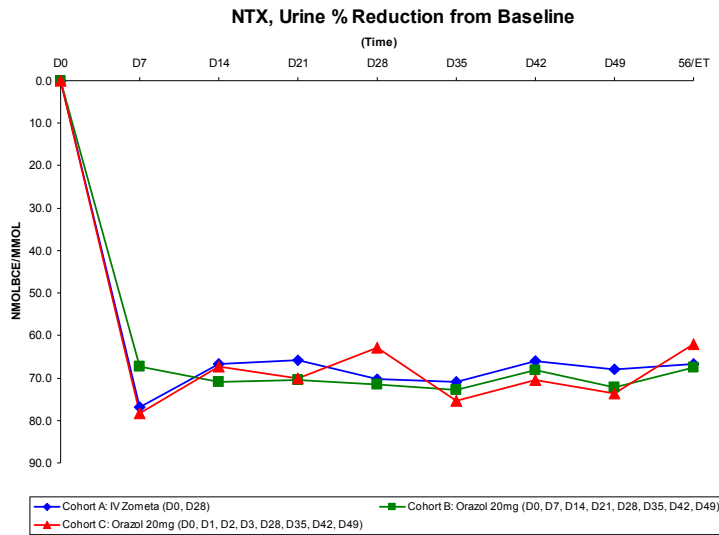
GIPET oral has similar profile to SC, consistent absorption  
Synthetic Glycosaminoglycan



GIPET oral significantly boosts bioavailability, demonstrates  
clinical endpoint - Synthetic Peptide

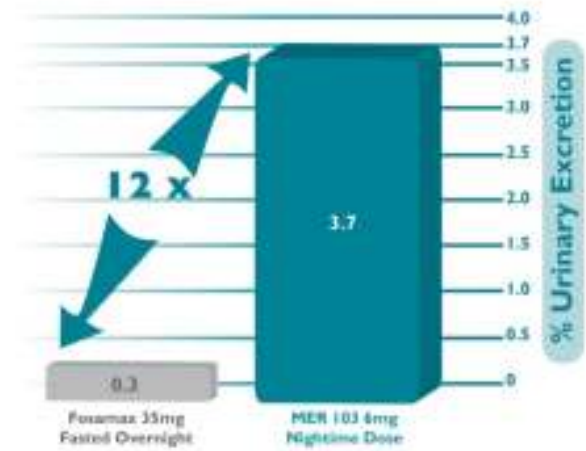


GIPET oral has similar Therapeutic effect  
to IV infusion - Small Molecule



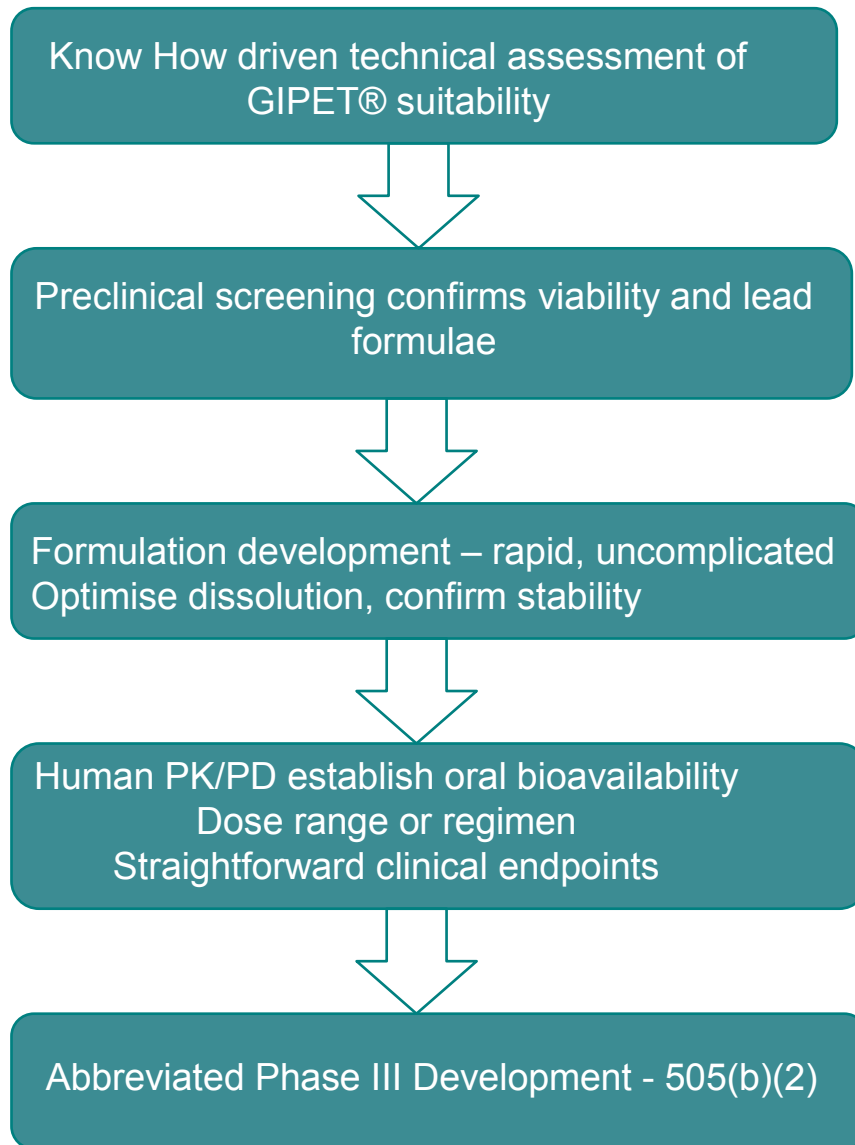
GIPET oral has similar 12 fold increase in bioavailability. As  
well as improved dosing convenience and reduction in fed/  
fasted effect- Small Molecule

Comparative Bioavailability



# GIPET® Development Pathway Marketed Compounds

'it is wasteful and unnecessary to carry out studies to demonstrate what is already known about a drug' FDA



## Business model allows

- Rapid screening
- Rapid tablet formulation
- Rapid human POC
- Phase II to design Ph III
- Straightforward scale up

## Delivering

Highly differentiated products  
brought to licensing (Ph II) rapidly

# Merrion Capabilities

**From idea to final phase II formulation in our own cGMP facilities**

- ❑ **Speed development & reduce risk**
- ❑ **Facilities**
  - ❖ 30,000 sq.ft. purpose built
  - ❖ Highest specification of design, layout and equipment
  - ❖ 21 Processing Rooms - Class D clean room
- ❑ **FDA Audit – Previous pre-approval, EU License**
- ❑ **People**
  - ❖ 40 Employees - 35 highly qualified R&D scientists
  - ❖ Strengthened Board - Harry Stratford, Paddy O’Sullivan (Chairman)
  - ❖ New functional areas – Business Development, Planning, Engineering & Quality



# New Facility – Building Strategic Options

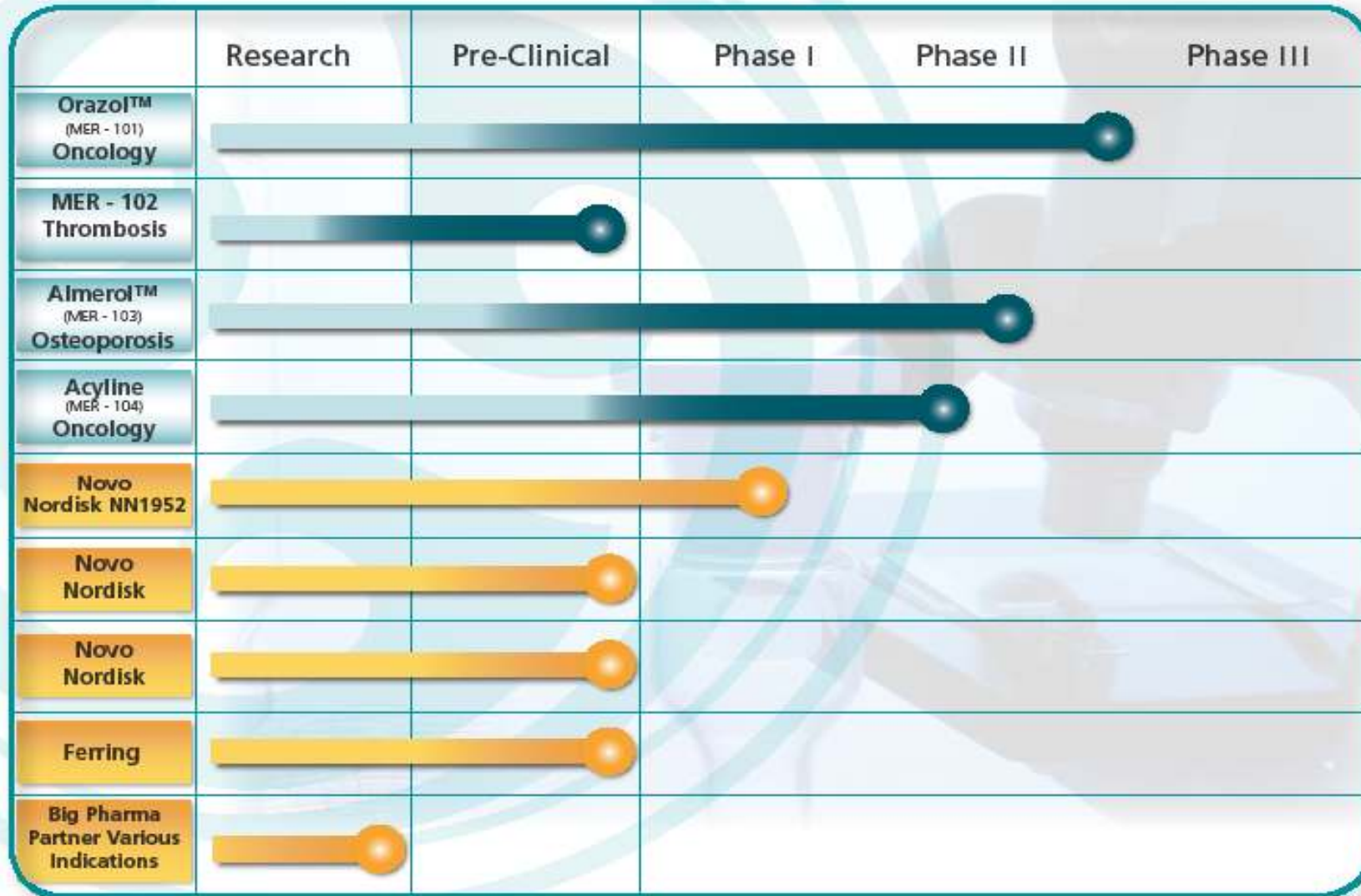
- ❑ **Expands capacity significantly (29,000 sq ft – 5 fold)**
  - ❖ Formulation development and Manufacturing (10 fold)
- ❑ **Purpose built Oral formulation R&D facility**
  - ❖ Designed to support up to Phase III/ small scale commercial
- ❑ **Fully equipped**
  - ❖ Accommodates anticipated capital expenditures for next 4 years
- ❑ **Facility previously successfully passed regulatory reviews:**
  - ❖ FDA Audit –Pre-approval NDA #21-763 and 21-412
  - ❖ IMB Licence Recently re-approved (June 2008)
- ❑ **Allows additional programmes**
  - ❖ Both partner and internal
- ❑ **Commenced initial operations in October 2009**
  - ❖ Transfer from TCD to Q2 2010
- ❑ **Allows for future technology developments**

# Strengthening Patent Position

- ❑ **Conducted Strategic review of patent portfolio**
  - ❖ Engaged US patent litigator with expertise in acting for generic companies
  
- ❑ **Base GIPET Patent - P24,375**
  - ❖ Issued US (09/510,560) with claims directed to bisphosphonates
  - ❖ Issued in EU (00905186.3) and allowable in CA (2363123) with broad claims
  - ❖ Continuation allowable in US (12/172,707) with claims directed towards ZA
  - ❖ Continuation in progress in US (12/553,196) on base patent
  - ❖ Expiry 22 Feb 2020
  
- ❑ **Specific product patent P31,578 on Orazol**
  - ❖ Allowed in US (11/733,007)
  - ❖ Filed WW (EP 07755266.9)
  - ❖ Claims directed to tablet strengths and %Bioavailability
  - ❖ Anticipated expiry 9 Apr 2027
  
- ❑ **Further patent filings to expire in 2030**



# MERRION PIPELINE DRIVING VALUE GROWTH





# Novo Nordisk

# Novo Nordisk Collaboration

- ❑ **NN World leaders in Diabetes health care since 1923**
  - ❖ 52% market share in Insulin
  - ❖ Revenue 2009 \$9.5bn – diabetes 73%
  
- ❑ **License Deals**
  - ❖ Oral Insulin November 2008
  - ❖ Oral GLP-1 January 2009
  - ❖ Total milestones \$116M (first products)
  - ❖ Equity investment €900k in January 2009
  
- ❑ **Milestones received to date - \$8m**
  - ❖ Up front payments
  - ❖ Development Milestone of \$2m for start of first human clinical trial
  
- ❑ **Development fees**
  - ❖ Total received in 2009 €3,950k
  - ❖ Total received to date €5,567k



# Novo Nordisk – Validation

- ❑ **Novo Nordisk excited at opportunity**
  - ❖ **‘Two decisive scientific breakthroughs in the last 24 months’ - CSO**
    - Novo Nordisk success in creating stable versions of insulin/GLP-1 molecule
    - GIPET successfully getting absorption into bloodstream preclinical
  - ❖ **A potential game-changer" in the diabetes field - CEO**
  
- ❑ **Significant due diligence/validation on Merrion/GIPET**
  - ❖ Willing to provide positive references to new partners
  - ❖ Very complimentary at drug Delivery Partnerships Conference–Podium presentation
    - Vacuum cleaned technology space – picked Merrion uniquely
    - ‘like dealing with large pharma company – not like small pharma co’
    - ‘High quality scientists - Expert in oral drug delivery technology’
    - ‘Team Players - Overcommunicated’ – ‘trust built quickly’
  
- ❑ **NN Funding multiple clinical trials using GIPET**
  
- ❑ **NN assisting in scaling up process of manufacturing GIPET**

# Merrion Delivery

- ❑ **Merrion have delivered in this collaboration**
  - ❖ Formulation development
  - ❖ Analytical method development
  - ❖ Clinical trial manufacturing
  - ❖ Passed all QA audits
  - ❖ Project management
  - ❖ Troubleshooting
  - ❖ Additional requests
  
- ❑ **Met all key milestones and timelines**
  - ❖ 'Achieved acceleration plan to beat deadlines' – DDP





# Orazol™

## Improving the Standard of Care in Bone Metastases

# WHAT IS ORAZOL™?

- ❑ Orazol™ is a weekly oral tablet form of zoledronic acid, currently monthly infusion (Zometa®).
- ❑ Orazol™ is formulated in Merrion's proprietary **GIPET®** drug delivery technology.
  - ❖ Large increase in bioavailability with good CV%
  - ❖ Low residual drug = low GI tract exposure = low side effect
  - ❖ Duodenal release = no oesophageal risk
- ❑ Safety & tolerability profile is excellent
- ❑ Orazol is the only oral zoledronic acid product in development

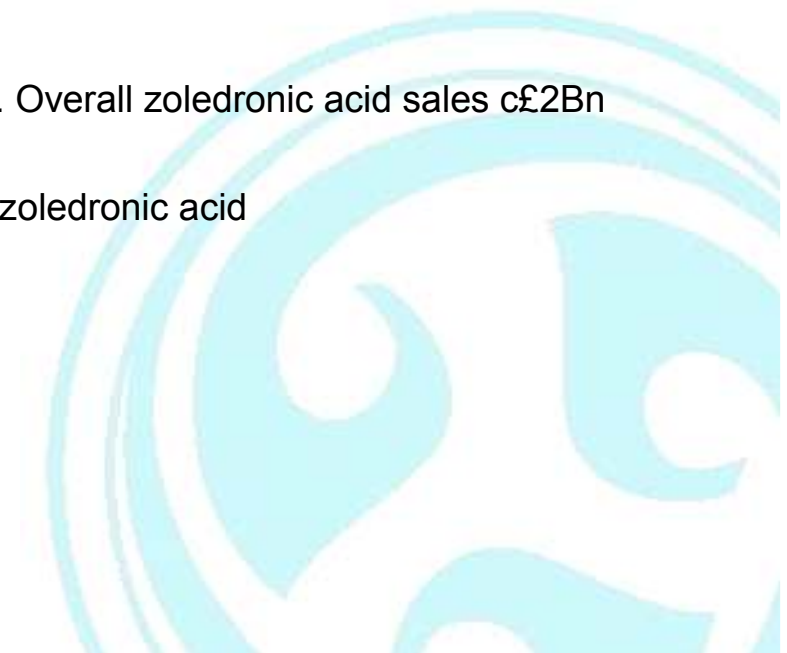


# ORAZOL™ - A New Branded product

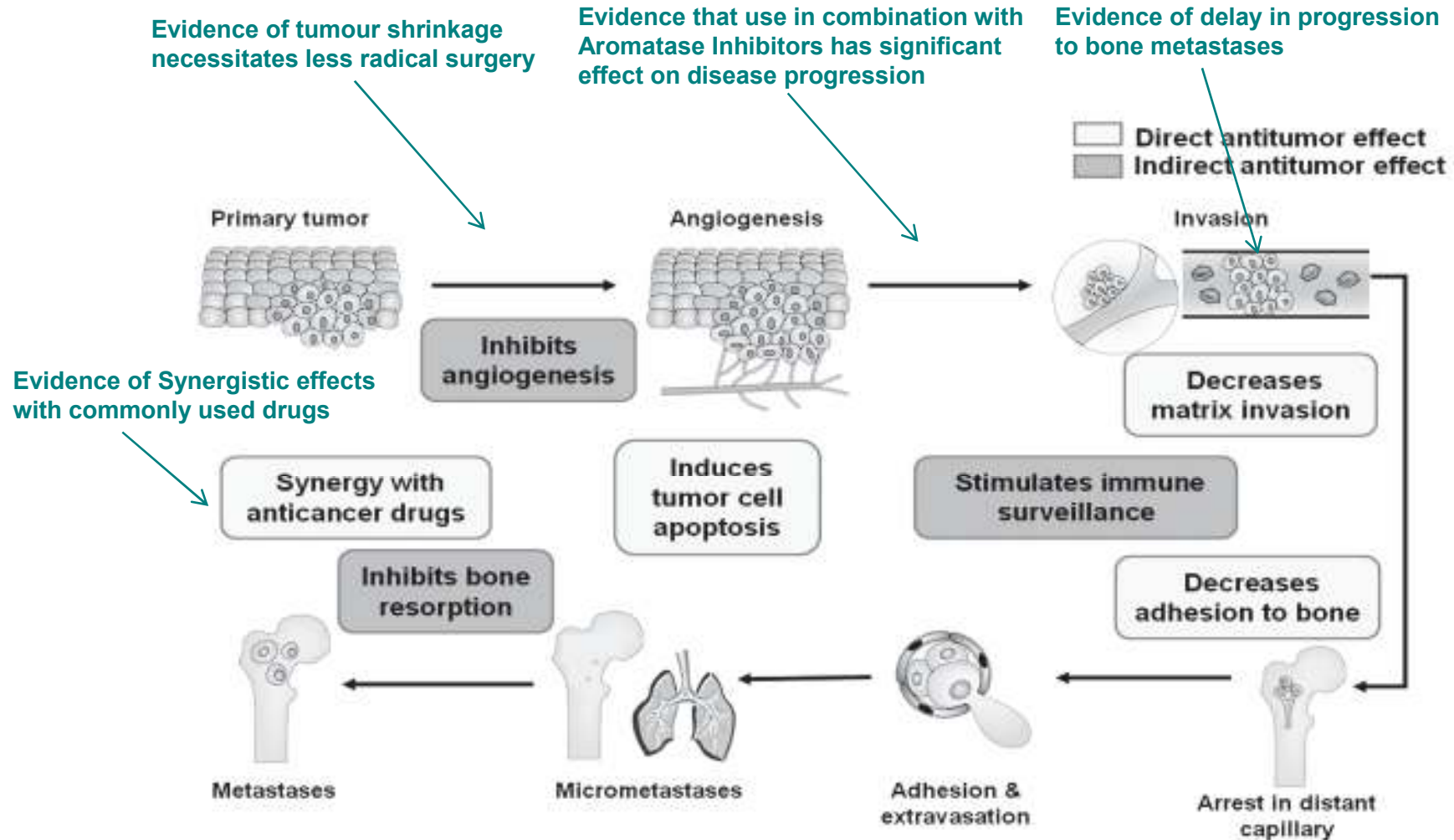
- ❑ **Long patent life**
  - ❖ 3 US patents allowed/issued (2020-2027), new filings in progress (2030)
  - ❖ Strong positive opinion from 'generic litigator' patent lawyer (NYC)
- ❑ **Excellent pricing potential**
  - ❖ Research indicates parity/premium to Zometa (>\$800 per month)
- ❑ **Based on gold standard drug (3 million treated)**
  - ❖ Zoledronic acid is the drug oncologists want to prescribe, safety profile established
- ❑ **Key patient advantages Quality of life & bone pain**
  - ❖ Research shows patients are currently making unnecessary clinic visits
  - ❖ Phase II data showed very strong trend to improved pain control
- ❑ **Key safety & side effect advantages**
  - ❖ Renal deterioration – Orazol 25% cmax Zometa
  - ❖ APR seen commonly in Infusion leg Phase II (50%) V Orazol weekly none (0%)
- ❑ **Significant economic advantages**
  - ❖ US study \$370 administration cost per Zometa infusion
  - ❖ Economic cost of pain, renal damage, APR, QOL
- ❑ **Use of healthcare infrastructure**
  - ❖ Allow significantly better utilisation of infusion clinics
- ❑ **Significant market expansion opportunity**
  - ❖ Orazol only product profile with realistic potential for use at each stage from diagnosis
  - ❖ Zoledronic acid highly efficacious

# BONE METASTASES – EXISTING MARKET OPPORTUNITY

- Estimated 1.5 million patients worldwide.
  - ❖ Associated with extensive osteolytic bone destruction.
  - ❖ Bone pain, pathological fractures, spinal cord compression have a major impact on quality of life.
  - ❖ Breast, prostate, multiple myeloma, lung, renal cancer patients are key target groups.
  - ❖ Estimated US only cost of managing bone metastases is \$12.6 billion.
  
- Zometa®
  - ❖ 2009 positive growth worldwide sales \$1.5 billion. Overall zoledronic acid sales c£2Bn
  - ❖ current standard of care in bone metastases.
  - ❖ Ongoing publications show additional benefits of zoledronic acid
  - ❖ US patent expiry March 2013



# Orazol Anti-Tumor Summary



Antitumor effects of zoledronic acid that may contribute to improved disease-free survival in the adjuvant therapy setting.

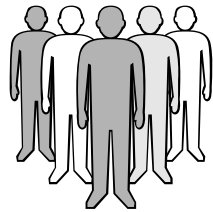
Mundy GR, et al. *Nat Rev Cancer*. 2002

# Market Expansion – Breast Cancer

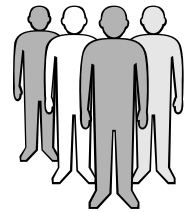
At diagnosis  
Tumour shrinkage  
Means less radical  
surgery

Post surgery in combination  
With aromatase inhibitors  
/chemotherapy

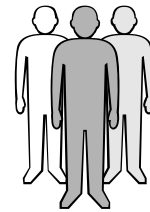
Delay in progression to  
Bone metastases



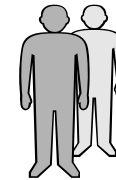
Stage I



Stage II



Stage III

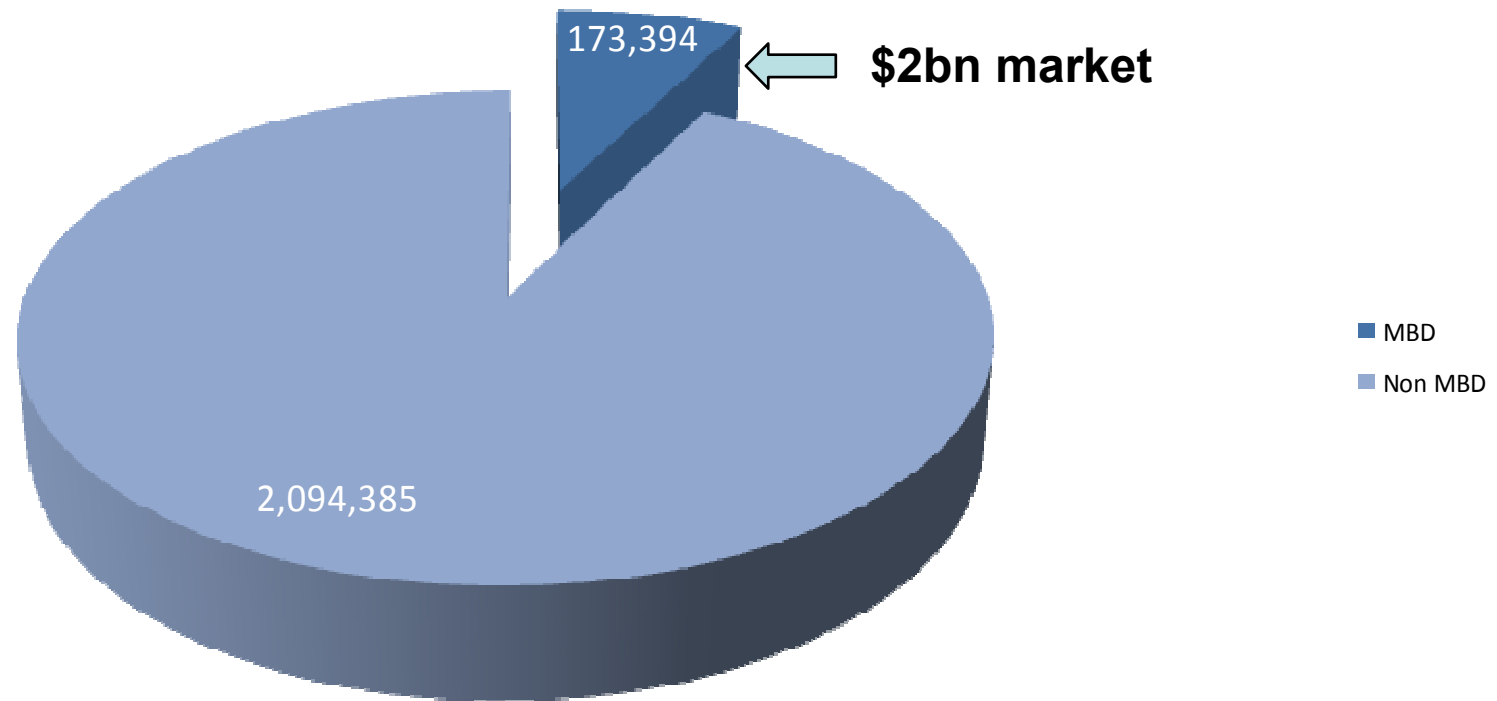


Stage IV

Total US patient population 892,000  
Only 66,000 with MBD

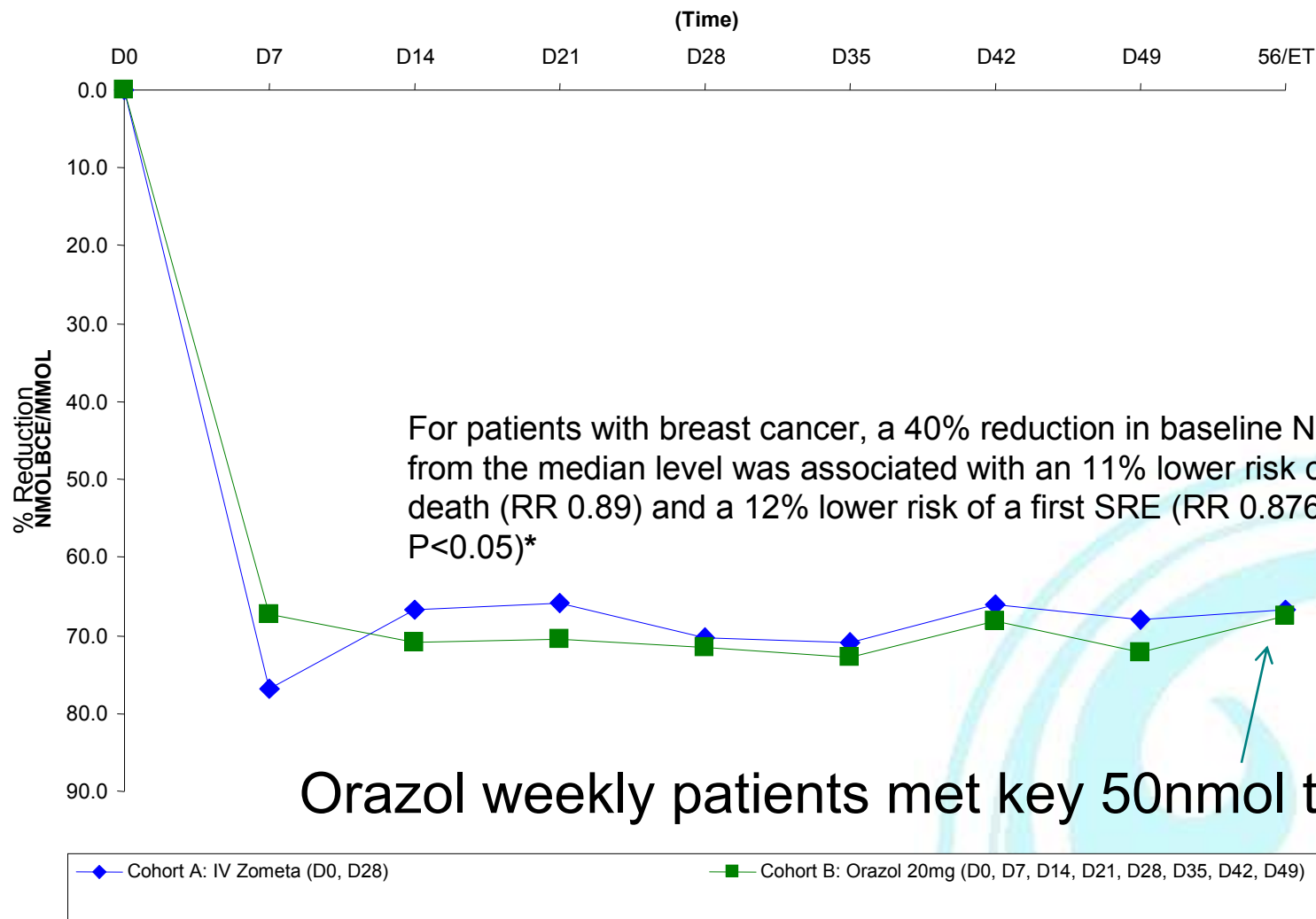
# Market Expansion Opportunity

Prevalence of Breast, Prostate, MM, Lung Cancer



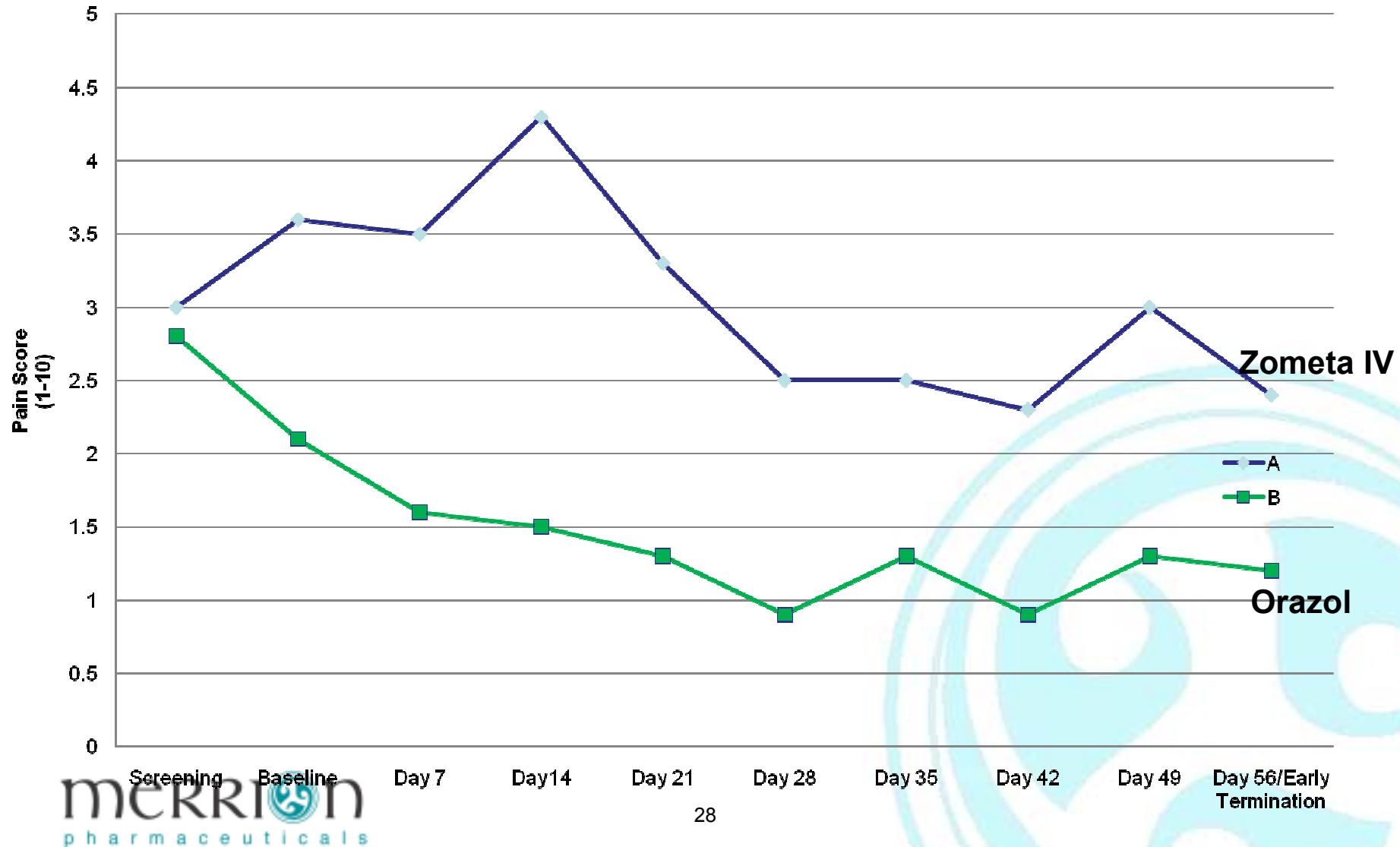
# Orazol™ (MER 101-03) Data

## NTX, Urine % Reduction from Baseline



# MER 101-03

## Brief Pain Inventory Pain; Worst Severity



# Orazol™, Zometa®, Prolia® Comparison

Factor	Orazol™	Zometa®	Prolia®
<b>Efficacy</b>			
Reduce/delay Skeletal Related Events	++	++	+++
Activity on bone pain	++	+	+
Direct/synergistic anti-tumour effect	+	+	-
Potential for early use in cancer patients <ul style="list-style-type: none"> <li>• Access</li> <li>• Known risk/benefit</li> <li>• Compliance</li> <li>• Patient convenience/QoL</li> <li>• Health economics</li> </ul>	++	-	-
Use in late stage 'at risk' patients <ul style="list-style-type: none"> <li>• SRE</li> <li>• Pain</li> </ul>	++	+	++
<b>Safety</b>			
SAE	+	+	+
Potential for life threatening SADR	++	+	-
<b>Clinical use</b>			
Cost effectiveness	+	+/-	-
Patient convenience	++	-	+/-
Clinical experience	++	++	-

## ORAZOL™ to date

- ❑ Orazol™ 20mg tablet once weekly dosage regime yielded a rapid & continuous depression of metabolic bone markers equal to IV Zometa®.
- ❑ Clinical trials with Orazol™ have demonstrated therapeutic equivalence with IV Zometa® & support Orazol's use outside hospital/clinic setting.
- ❑ Positive trend of impacts on bone pain
- ❑ Trends towards Orazol in other secondary endpoints
- ❑ No clinically significant changes in renal function has been observed with Orazol™.
- ❑ Acute phase reaction seen with IV Zometa® has not been observed with a once a week dose regime of Orazol™.
- ❑ Clinical trials with Orazol™ confirmed it is well tolerated.
- ❑ Favourable regulatory advice CHMP (EMA), in discussions FDA
- ❑ Licensing process under way
- ❑ Discussions with multiple pharma players





# Financial Update

## Consolidated P&L - year to 31 December 2009

	Year ended 31 Dec 2009 €'000	Year ended 31 Dec 2008 €'000	Year ended 31 Dec 2007 €'000	Increase (Decrease) 2008-2009
Revenue	6,335	1,340	469	373%
Cost of sales	(1,256)	(448)	(153)	180%
Gross profit	5,079	892	316	469%
R&D expenses	(5,247)	(3,898)	(3,331)	35%
R&D tax credit	837	-	-	
Administration expenses	(2,477)	(2,420)	(2,844)	2%
Net Interest income/(exp)	178	363	(6,217)	(104%)
Net Loss for the year	(1,629)	(5,062)	(12,076)	(210%)
Loss per share	(€0.10)	(€0.30)	(€1.60)	

## Revenue analysis - year to 31 December 2009

	Year ended 31 December 2009 €'000		Year ended 31 December 2008 €'000	
	Revenue	Margin	Revenue	Margin
Revenue				
Milestone amortisation	1,049	842	99	(117)
Development milestone	1,207	1,069	-	-
Development fees	4,079	3,168	1,241	1,009
<b>Total</b>	<b>6,335</b>	<b>5,079</b>	<b>1,340</b>	<b>892</b>
Deferred Revenue	4,450		2,416	

## Consolidated Balance Sheet as at 31 December 2009

	31 Dec 2009	31 Dec 2008
	€'000	€'000
Fixed assets	5,015	788
Trade and other receivables	3,029*	753
Cash	7,218	8,140
	15,262	9,680
Trade Creditors and accruals	1,487	1,593
Deferred income	4,450	2,416
Loans & borrowing	3,258	-
Retained Loss	(30,358)	(28,733)
Equity	36,425	34,404
	15,262	9,680

## Consolidated cash flow - year to 31 December 2009

	Year ended 31 Dec 2009 €'000	Year ended 31 Dec 2008 €'000
Net loss	(1,629)	(5,062)
Non cash items	(17)	759
Change in working capital	1,247	1,396
Net interest	215	299
Cash used in operations	(860)	(2,608)
Acquisition of Fixed assets	(4,816)	(135)
Share issue	1,452	11
Loans	3,258	-
Decrease in cash	(916)	(2,732)