



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 Development
- Ernst & Young, Bayer, Abbott



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 & numerous
- Products through approval process
- Product formulation, R & D Management
- Wyeth- Ayerst, aal Pharma, Endeavor



John Fox, PhD CDO

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

Board Composition

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

MERRION PHARMACEUTICALS PLC

90's/00's

2004

Q2 2010

Development of drug delivery technologies in Elan

Merrion opens for business - plan to build own/partner portfolio

Develops in house portfolio of 4 products
Signs major partner programs

IPO December 2007
Further clinical trials

First NN licence agreement November 2008

Second NN licence agreement January 2009

Orazol Phase II results
Acquire new Facility

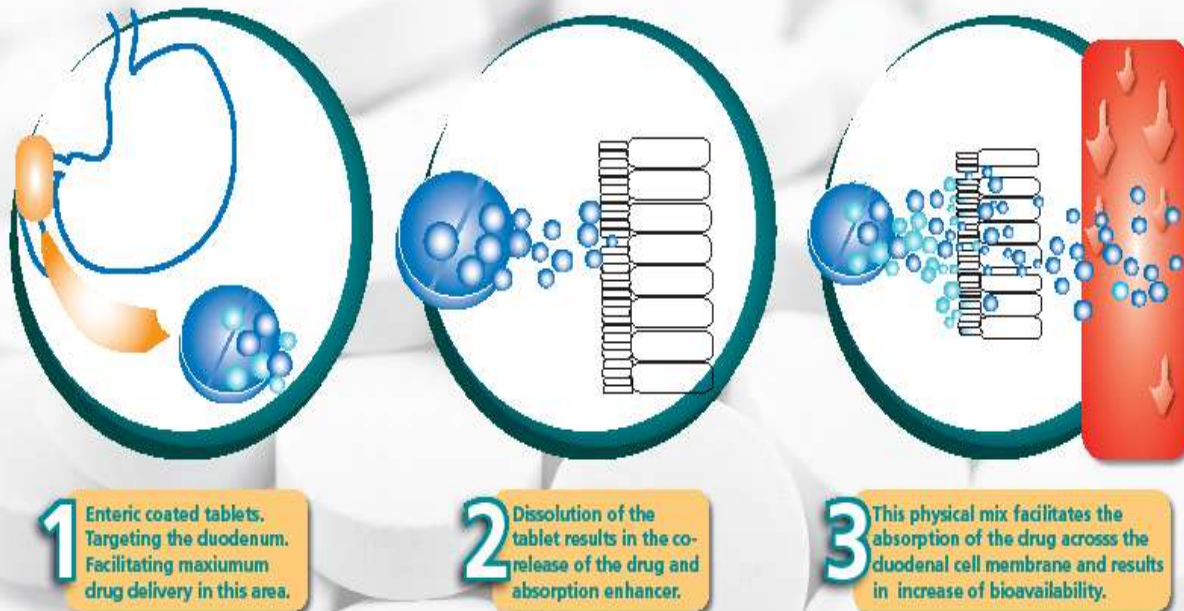
Orazol Anti-cancer indications
Patent issuance US

Broad, high potential crystallising to value creation

Current market cap: €68m
Ticker: ESM: Merr

Orazol™ in GIPET® Technology

HOW DOES GIPET® WORK?



- 10 to 50 fold increase in bioavailability
- GRAS status simplifies development
- 505(b)2 regulatory pathway
- Excellent reproducibility
- No interaction between the API and absorption enhancer
- Straightforward tablet press manufacture
- Robust technology extensive database

MERRION
pharmaceuticals

MERRION
pharmaceuticals

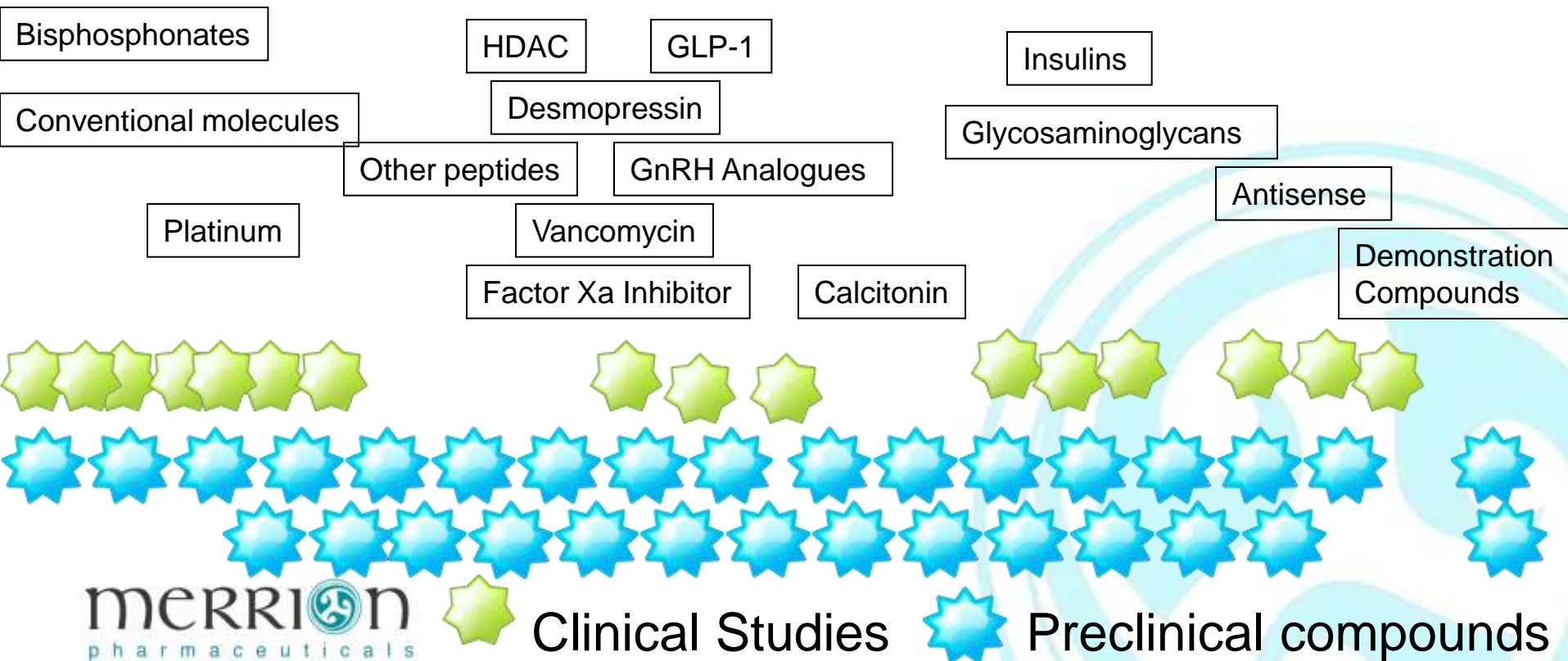
GIPET works on a broad horizon of compounds

300MW

10,000MW

Small Molecules

Peptides



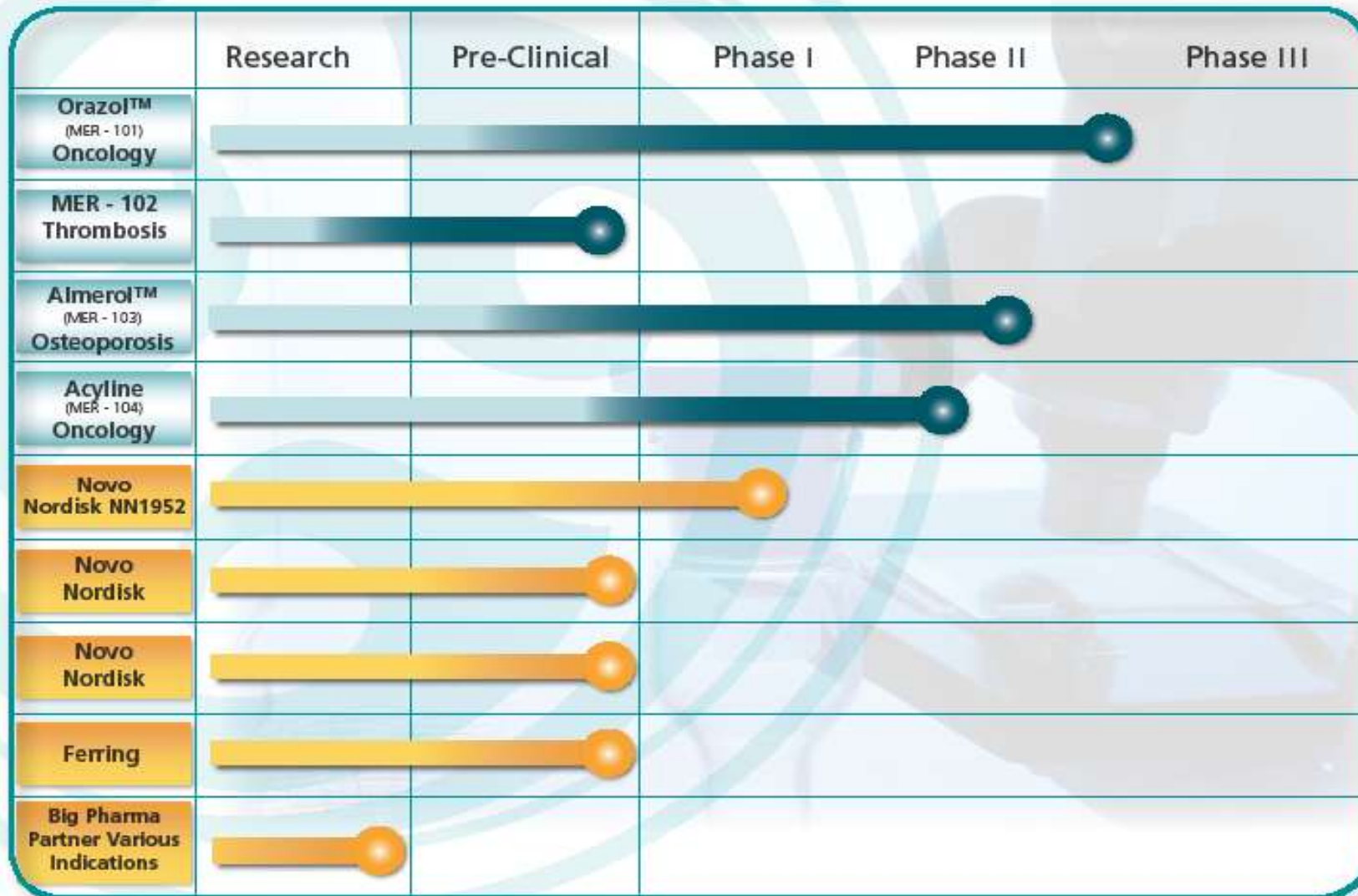
Clinical Studies



Preclinical compounds

MERRION PIPELINE

DRIVING VALUE GROWTH



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 - 34 highly qualified R&D scientists





Novo Nordisk

Novo Nordisk Collaboration

❑ **NN World leaders in Diabetes health care since 1923**

- ❖ 2009 Revenue \$9.5bn – diabetes 73%
- ❖ Diabetes Mkt \$17bn – Insulin \$9bn
- ❖ 52% market share in Insulin

❑ **License Deals**

- ❖ Oral Insulin November 2008
- ❖ Oral GLP-1 January 2009
- ❖ Combined milestones \$116M (first products) / Royalty on sales
- ❖ Equity investment €900k in January 2009 (1.8%)

❑ **Fees / Milestones received to date**

- ❖ Up front payments
- ❖ Development Milestone of \$2m for start of first human clinical trial
- ❖ Total received in 2009 €4,079k
- ❖ Total received to end 2009 €5,567k

❑ **Status**

- ❖ Oral Insulin analogue 'First Human Dose' in Phase I/II trial - November 2009
- ❖ Oral GLP-1 analogue 'First Human Dose' in Phase I/II trial – April 2010
- ❖ Novo are funding additional programmes currently at Pre-clinical stage

Novo Nordisk – Validation

- ❑ **Novo Nordisk Press comments on the Merrion Programmes**
 - ❖ ‘A potential game-changer’ in the diabetes field - CEO
 - ❖ ‘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

- ❑ **Novo Nordisk – Presentation at Delivery Partnerships Conference**
 - ❖ Vacuum cleaned technology space – picked Merrion uniquely for oral insulin
 - ❖ ‘like dealing with large pharma company – not like small pharma company’
 - ❖ ‘High quality scientists - Expert in oral drug delivery technology’
 - ❖ ‘Team Players - Overcommunicated’ – ‘trust built quickly’
 - ❖ ‘Achieved acceleration plan to beat deadlines’

- ❑ **Novo Nordisk are willing to provide positive references to new partners**

- ❑ **Collaborating on scale up of GIPET manufacturing process**

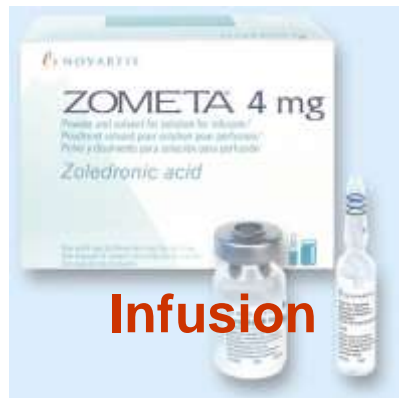


Orazol™

Improving the Standard of Care in Bone Metastases

Orazol™

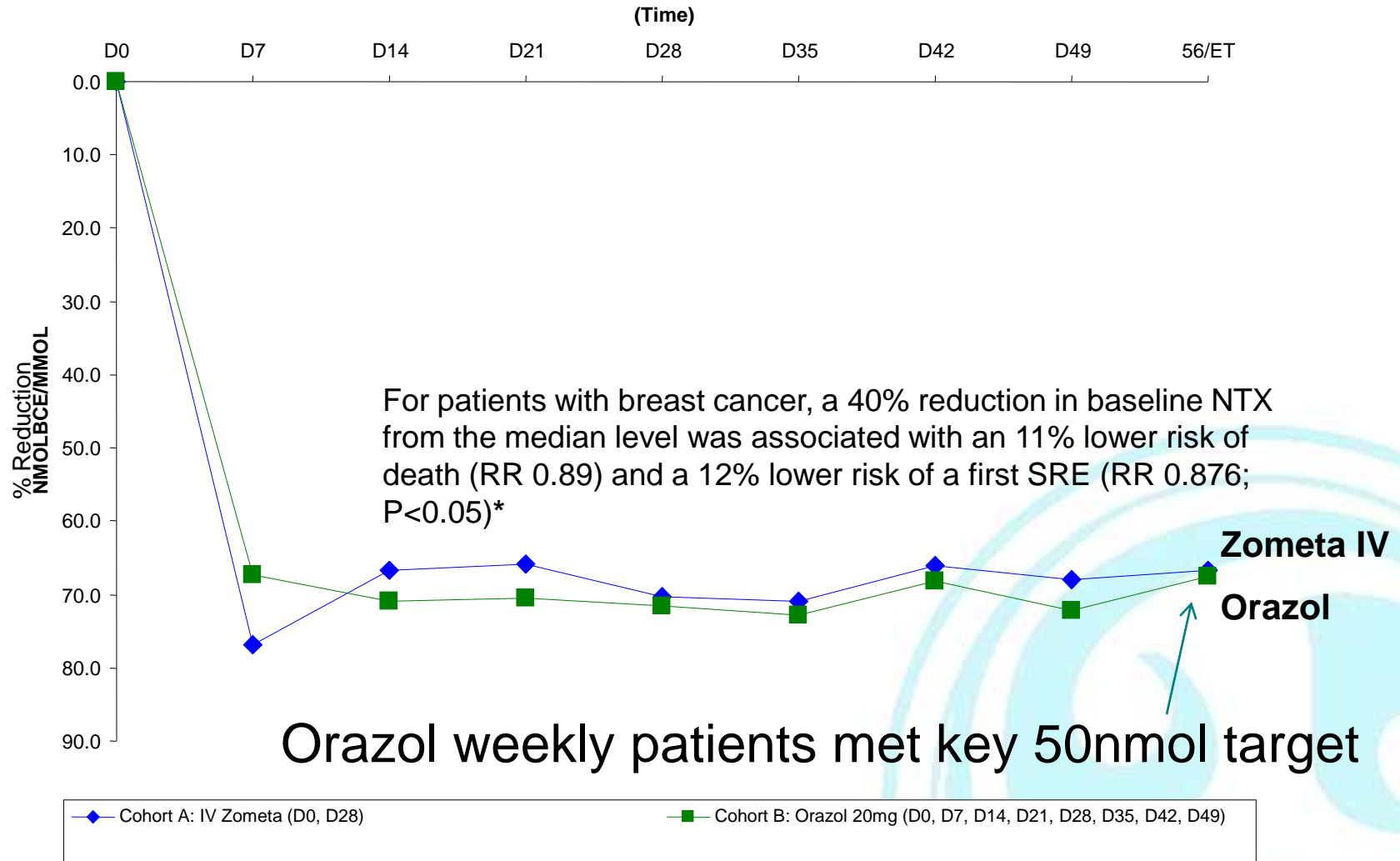
- ❑ Orazol™ is a weekly oral tablet form of zoledronic acid, currently marketed as Zometa® infusion (monthly)



- ❑ Indicated for bone metastases - Bone pain, pathological fractures, spinal cord compression – breast, prostate, MM, lung
- ❑ Zometa® in 2009 had worldwide sales \$1.5 billion - current standard of care in bone metastases
- ❑ US patent expiry March 2013
- ❑ Orazol™ is formulated in Merrion's proprietary **GIPET®** technology.
 - ❖ Large increase in bioavailability with good CV% (low variability)
 - ❖ Excellent Safety & tolerability profile

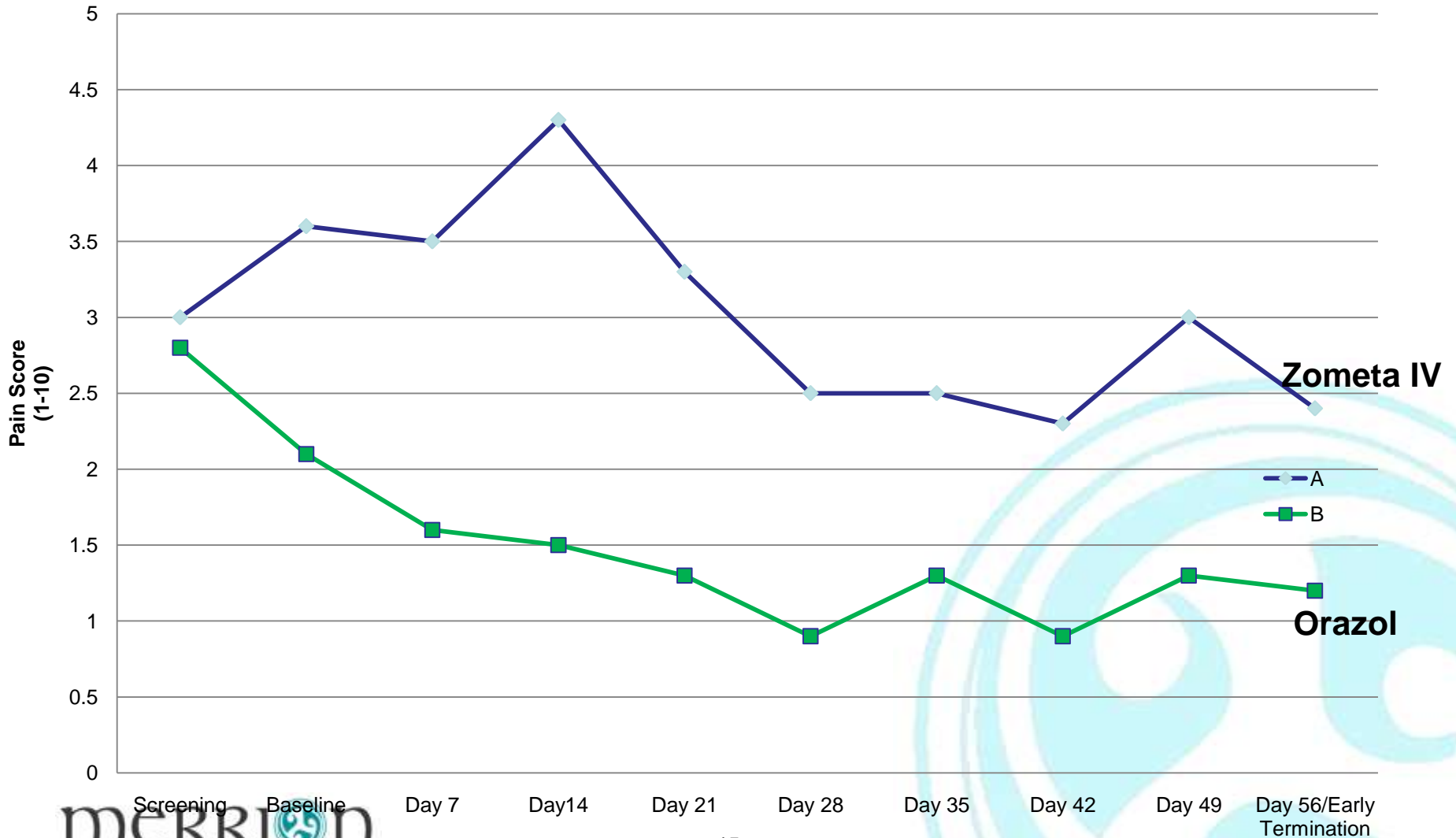
Orazol™ (MER 101-03) Data

NTX, Urine % Reduction from Baseline



MER 101-03

Brief Pain Inventory Pain; Worst Severity

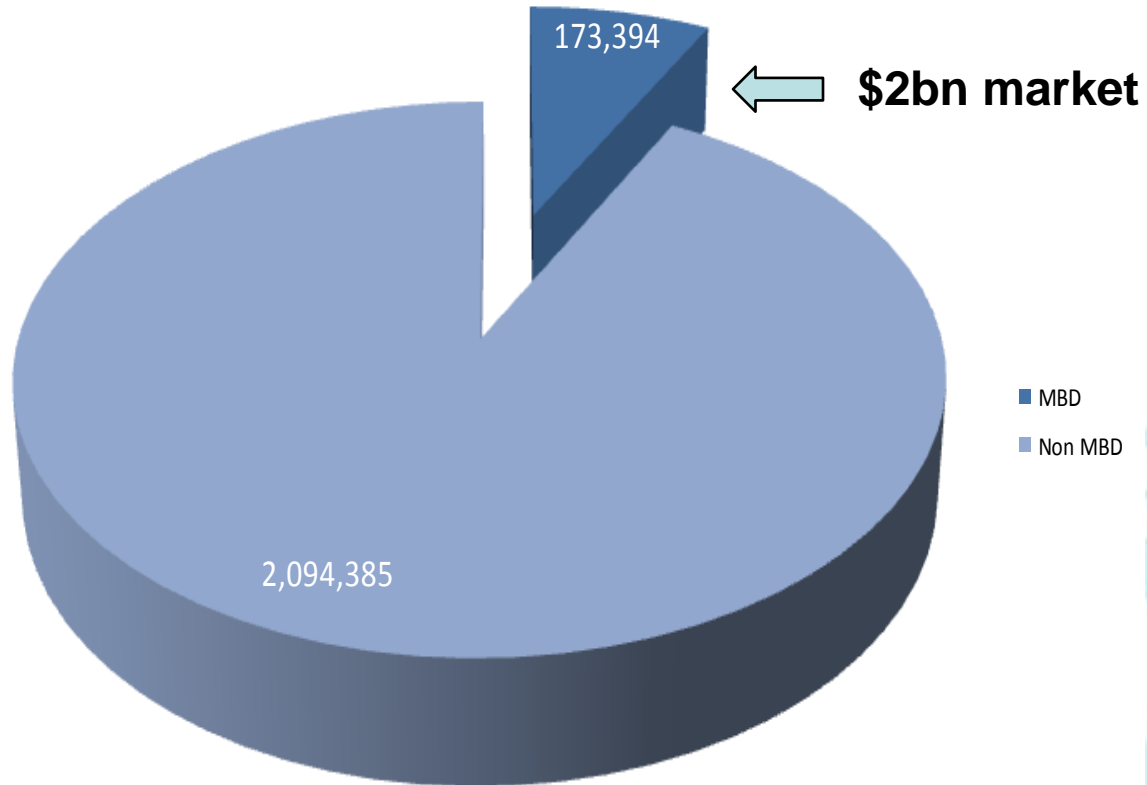


ORAZOL™ - A New Branded product

- ❑ **Long patent life**
 - ❖ 3 US patents allowed/issued (2020-2027), new filings in progress (2030)
 - ❖ Strong positive opinion from 'generic litigator' patent lawyer (NYC)
- ❑ **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 (QOL) & 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
 - ❖ Acute Phase Reaction (Flu) common in Infusion leg Phase II (50%) Vs Orazol weekly 0%
- ❑ **Significant economic advantages**
 - ❖ US study \$370 administration cost per Zometa infusion
 - ❖ Economic cost of pain, renal damage, Acute Phase Reaction, QOL
- ❑ **Use of healthcare infrastructure**
 - ❖ Allow significantly better utilisation of infusion clinics
- ❑ **Excellent pricing potential**
 - ❖ Research indicates parity/premium to Zometa (>\$800 per month)
- ❑ **Significant market expansion opportunity**
 - ❖ Orazol only product profile with realistic potential for use at each stage from diagnosis
 - ❖ Zoledronic acid highly efficacious

Market Expansion Opportunity

Prevalence of Breast, Prostate, MM, Lung Cancer



Orazol™, Zometa®, Prolia® Comparison

Factor	Orazol™	Zometa®	Prolia®
Efficacy			
Reduce/delay Skeletal Related Events (SRE)	++	++	+++
Activity on bone pain	++	+	+
Direct/synergistic anti-tumour effect	+	+	–
Potential for early use in cancer patients <ul style="list-style-type: none"> • Access • Known risk/benefit • Compliance • Patient convenience/Quality of Life • Health economics 	++	–	–
Use in late stage ‘at risk’ patients <ul style="list-style-type: none"> • Skeletal related events • Pain 	++	+	++
Safety			
Serious Adverse Events (SAEs)	+	+	+
Potential for life threatening SADR	++	+	–
Clinical use			
Cost effectiveness	+	+/-	–
Patient convenience	++	–	+/-
Clinical experience	++	++	–

Strengthening Patent Position

❑ **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**

❑ **Conducted Strategic review of patent portfolio**

- ❖ Engaged US patent litigator with expertise in acting for generic companies

ORAZOL™ status

- ❑ Favourable regulatory advice CHMP (EMA),
- ❑ Final discussions with 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
Total	6,335	5,079	1,340	892
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

* January receipts €1,883,000

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)

Summary and Newsflow

- Good cash position - No Immediate funding requirement
 - Low overhead base
- Novo Nordisk deals
 - Validating/reference deal with major industry player
 - \$116m in milestones, royalties on 2 potential blockbusters
 - Results on clinical trials in 2010/2011
- Improved capability and capacity in new facility – IMB License
- Strengthened patent position – further IP to be issued this year
- High value internal development projects – Orazol
 - Positive phase 2 results - license potential this year
- Other partner programs in progress - Potential license deals this year
- New partner programs and new pipeline products



Question & Answers