



Merrion Pharmaceuticals

BIO Chicago

May 2010

MERRION PHARMACEUTICALS PLC

90's/00's

2004

Q1 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

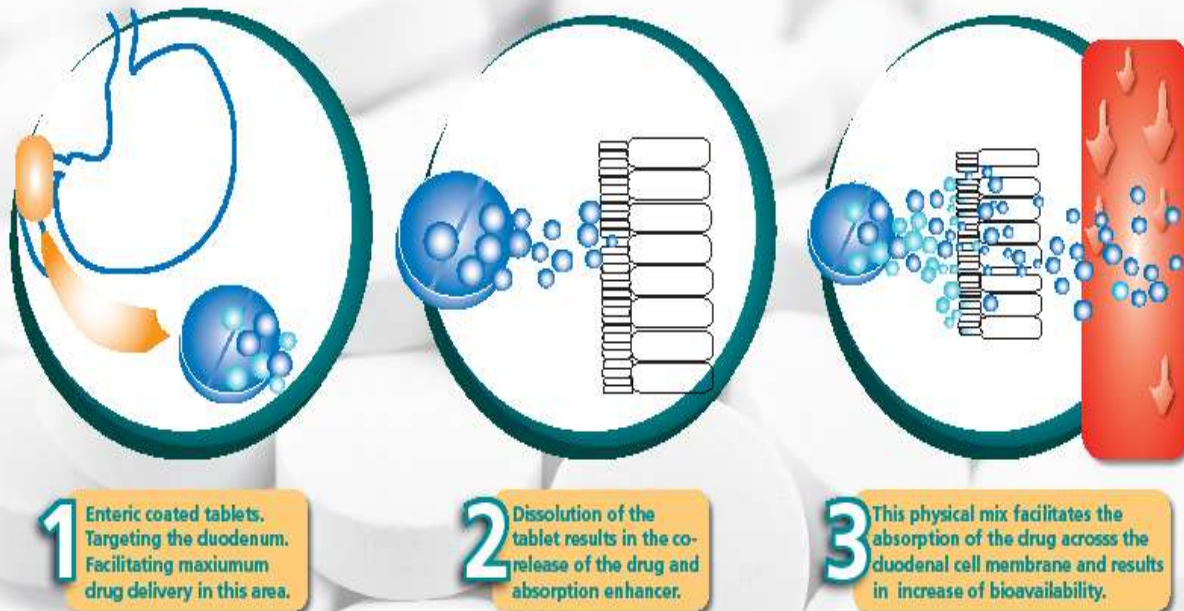
Orazol Anti-cancer indications
Patent issuance US

Broad, high potential crystallising to value creation

Current market cap: €68m
Ticker: IEX: 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

Small molecules
<1000MW

Bisphosphonates RGD Peptide
Thrombin inhibitor
ACE Inhibitor Calcein Platinum

7 clinical trials
5 pre-clinical trials

Peptides
1000 – 5000
MW

HDAC GLP-1 Desmopressin
Vancomycin
Leuprolide Factor Xa Inhibitor
LMW Heparin GnRH Analogues

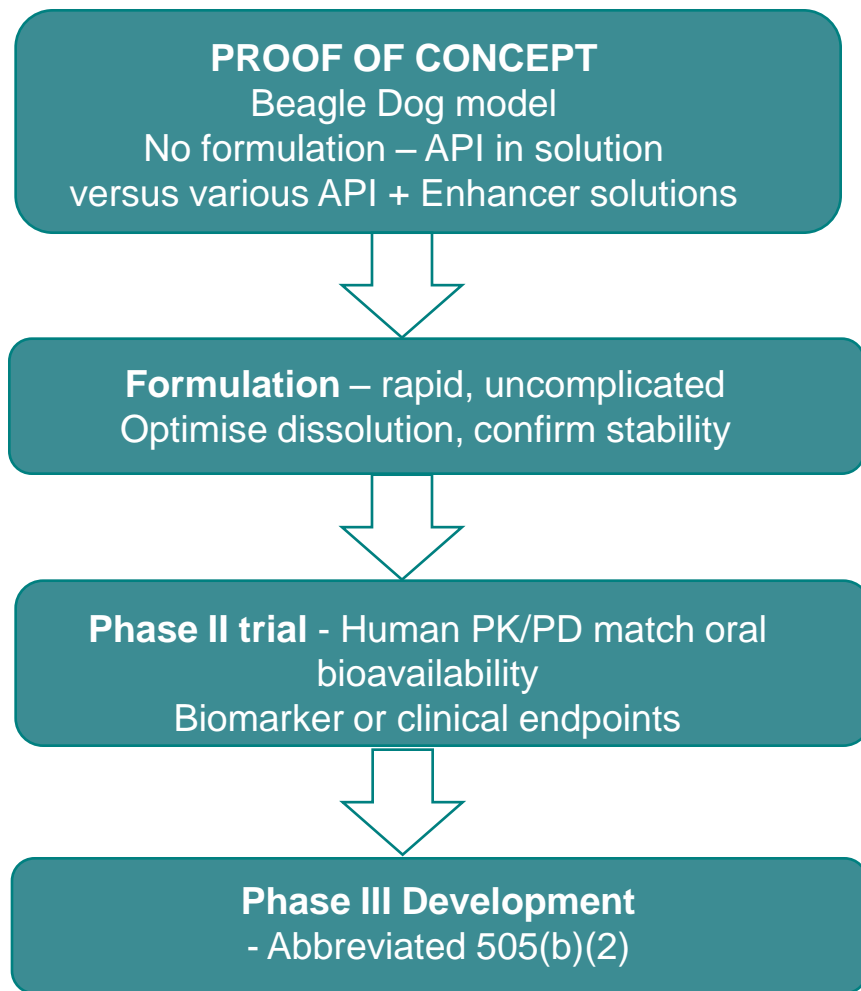
3 clinical trials
15 pre-clinical trials

Proteins
>5,000MW

Insulins Antisense
Dextran Glycosaminoglycans
Antisense

6 clinical trials
11 pre-clinical trials

SIMPLE DEVELOPMENT PATHWAY



Business model allows

- Simple proof of concept
- Rapid tablet formulation
- Straight to Phase II
- Phase II trials design Ph III
- Standard scale up
- POC animal data
 - 3 months
 - Low cost

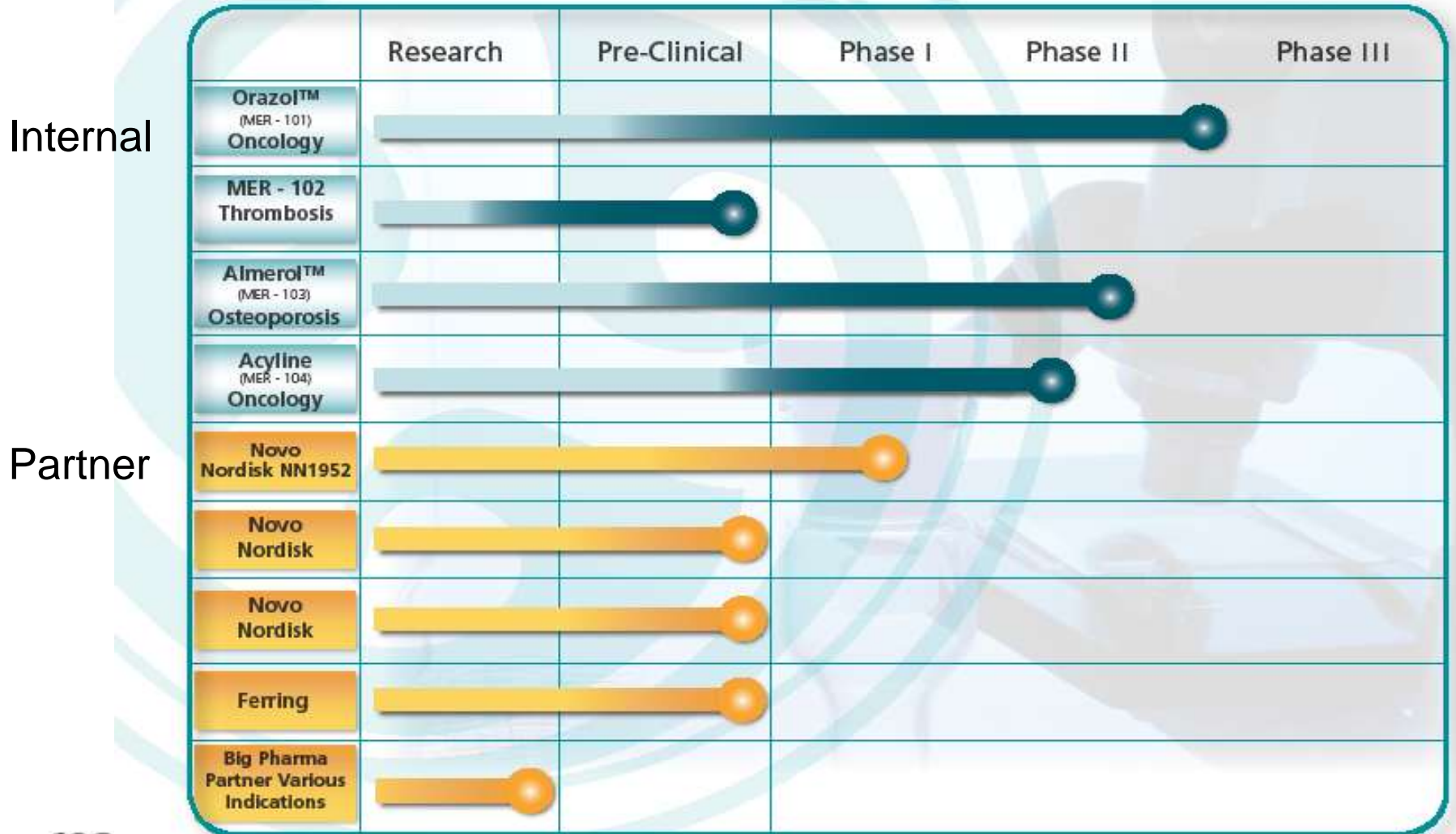
Merrion Capabilities

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



MERRION PIPELINE DRIVING VALUE GROWTH





Novo Nordisk

Novo Nordisk Collaboration

□ 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%)
- ❖ Up-front and development milestones received to date



□ 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

□ Development fees

- ❖ Fees received in 2009 \$5.3M, Fees to date \$7.3M

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**

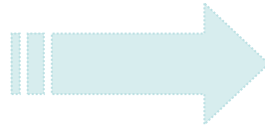
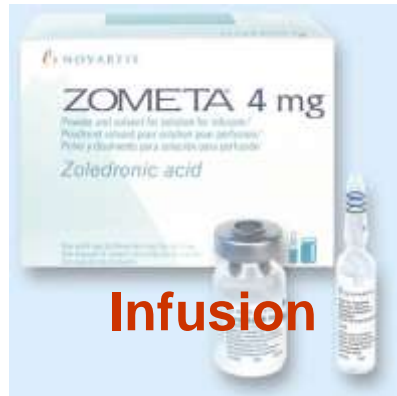


Orazol™

Improving the Standard of Care in Bone Metastases

Orazol™

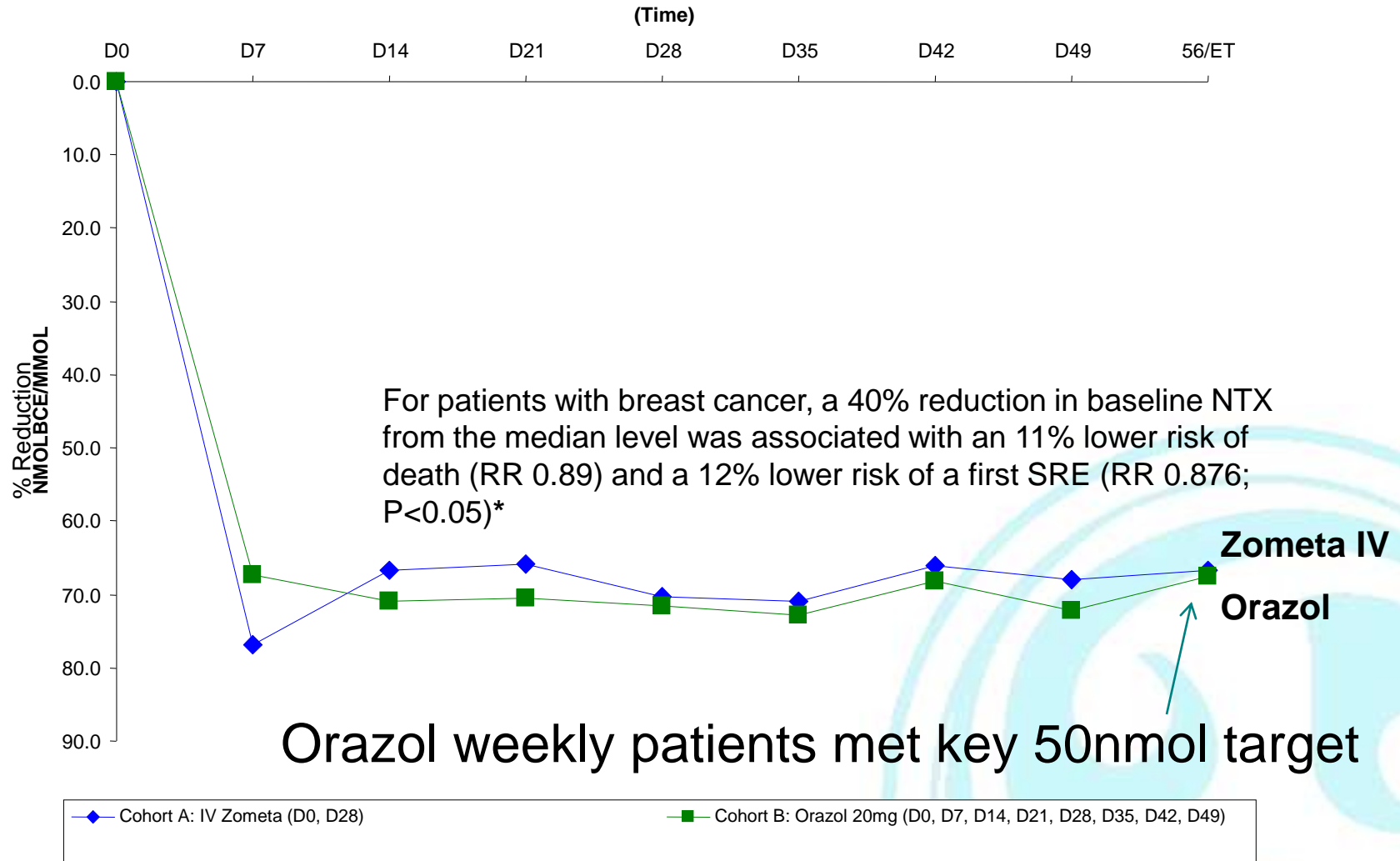
- ❑ Orazol™ is an oral tablet form of zoledronic acid, currently marketed as Zometa® infusion



- ❑ 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
- ❑ **PH IIs completed - shows bioequivalence in AUC between**
 - ❖ **Monthly 4mg IV dose & Weekly 20mg GIPET tablet formulation**

Orazol™ Phase II Data

NTX, Urine % Reduction from Baseline



Advantages IV to GIPET® oral

□ Expected

- ❖ Patient / Physician preference
- ❖ Savings – cost and time (\$370 administration cost per Zometa infusion)
- ❖ Capacity freed – better utilization of infusion clinics

□ Less obvious

- ❖ Market expansion
 - Novartis has filed NDA supplement for adjuvant early stage breast cancer
 - First lesions / treatment cycles / Urologists
- ❖ Acute Phase reactions – common in Infusion leg in Phase II(50%) vs Orazol weekly none (0%)
- ❖ Renal toxicity – Orazol 25% cmax Zometa
- ❖ Bone Pain – Phase II showed very strong trend to improved pain control

□ Strategic

- ❖ Long patent life – 3 US patents allowed/issued (2020-27, new filings in progress (2030))
- ❖ Pricing potential – research indicates parity/premium to Zometa (>\$800/month)

ORAZOL™ status

- ❑ Favourable regulatory advice CHMP (EMA),
- ❑ Final discussions with FDA
- ❑ Licensing process under way
- ❑ Discussions with multiple pharma players



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

Summary

Strong foundations – significant potential

- Novo Nordisk deals
 - Validating/reference deal with major industry player
 - \$116m in milestones, royalties on 2 potential blockbusters
- Improved capability and capacity in new facility
- Strengthened patent position
- High value internal development projects – Orazol
 - Positive phase 2 results
- Other partner programs in progress
- New partner programs and new pipeline products
- Good cash position - No Immediate funding requirement