



# Merrion Pharmaceuticals plc

## Orazol Opportunity

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# THE MERRION APPROACH

## INJECTABLE TO ORAL TECHNOLOGY

### STRATEGY

- ④ Use unique patented technology ...to develop high potential (blockbuster) products...by meeting pipeline needs of pharmaceutical companies.

### HIGH POTENTIAL

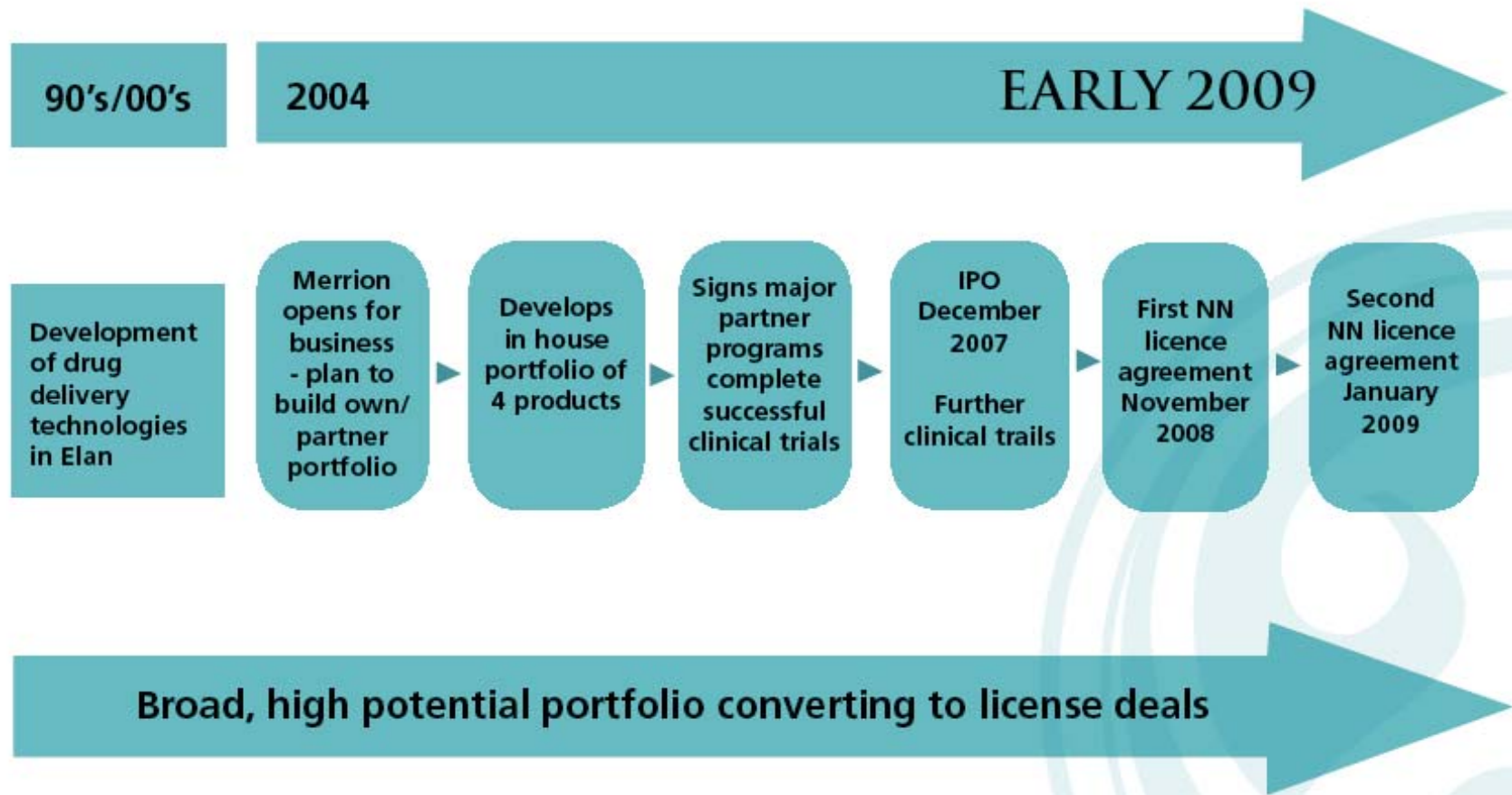
- ④ Several high potential products in development
- ④ Return potential demonstrated by 2 license deals
- ④ Near term license opportunities

### RISK MITIGATED

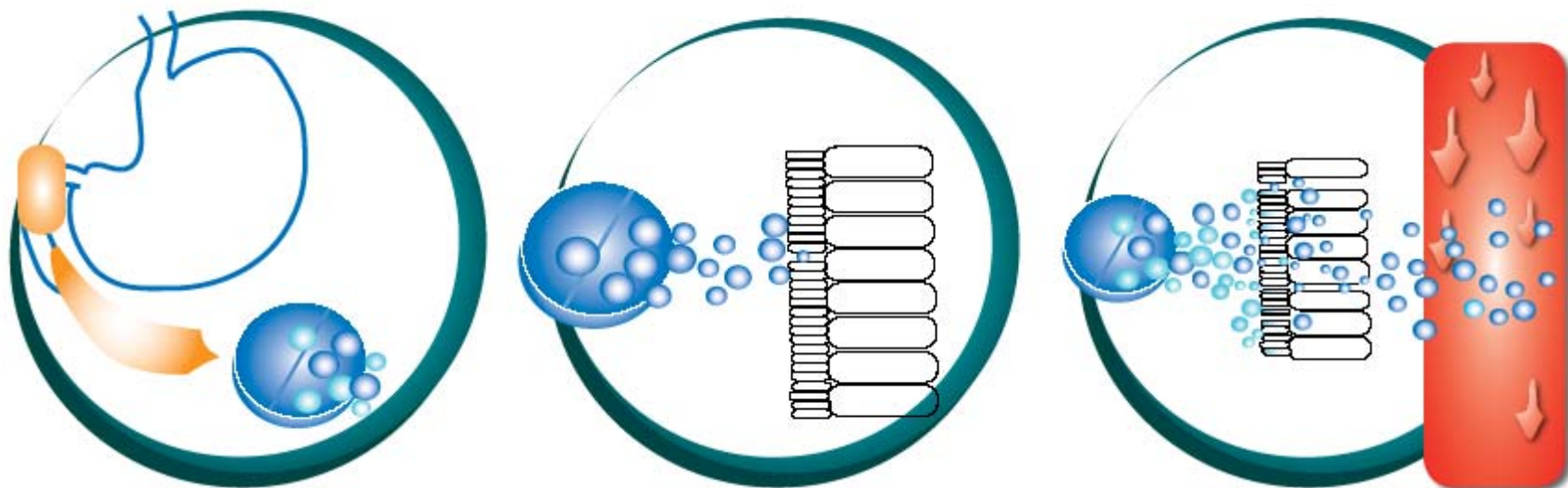
- ④ Balance between own/partner programmes
- ④ Life cycle management v NCE
- ④ License own products at Phase II, lower cost development



# FROM POTENTIAL TO VALUE CRYSTALLISATION



# HOW DOES GIPET® WORK?



**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 46 Times more Drug Absorbed in Clinical Trials
- 20 Clinical Studies - Broad range drug types
- GRAS status simplifies development
- 505(b)2 regulatory pathway
- Excellent reproducibility

# GIPET™ - COMMERCIAL OPPORTUNITIES

By making drugs **orally available**, the **patients' preferred** route of administration, you can open up the commercial potential of a drug and meet previously unmet needs:

Gain **New Indications**

Change the **competitive dynamic**

Reach a **greater number of patients**

Provide key **pharmacoeconomic benefits**

**Additional prescribing options**, e.g. dose titration.

More favourable **absorption profile** than injectable, with safety **benefits**.

Avoid **infection risks** of injectable products

Meet the needs of the significant numbers of patients who want **oral alternative to injections**

# ORAZOL (MER 101)

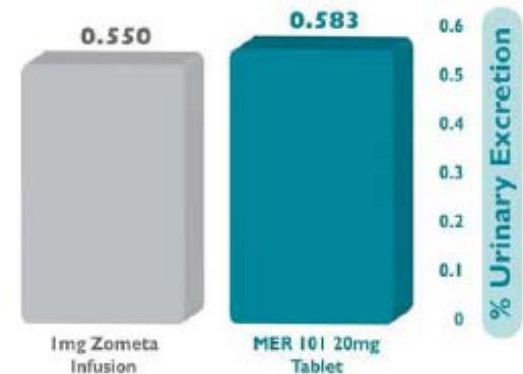
## PRODUCT CONCEPT

- Tablet version of Blockbuster IV drug (Zometa, Novartis)
- For the treatment of bone metastases
- Patented GIPET® product

## MARKET

- Bone metastases - IV version sells \$1.4Bn (Market \$2Bn)
- Osteoporosis (approved in US 2007) – IV sells \$254M
- Early stage breast cancer -
  - New trials show 'anti-tumour' and disease free survival benefit.
  - Potential to be blockbuster indication (>\$1Bn).
  - ASCO major cancer advance 2008

Orazol tablet -  
same bioavailability  
as zometa infusion



## PHASE I/II

- Demonstrated that Orazol can deliver equivalent bioavailability orally to marketed IV (Zometa®)
- No AE's

## PHASE IIB

- Completed enrolment of hormone refractory prostate cancer patients (11 Sites US/EU)
- Data Q2 2009

## DOSING STUDY

- Dosing commences Feb 27th 2009

## REGULATORY

- US 505b(2)
- EU Hybrid application

# ORAZOL

## ORAZOL BENEFITS

- Weekly tablet instead of monthly infusion
- Tablet at home instead of hospital/clinic infusion
- Key quality of life benefits
- Major pharmacoeconomic benefits
  - Costs of infusion limit patient access (insurance, reimbursement)
  - Impact on hospital/clinic resources
- Potential safety benefits
  - Weekly tablet has lower absorbed dose than IV – Kidney function
- Potential efficacy benefits
  - More regular exposure to drug expected to be better

 **PLAN** License Orazol following completion of Phase 11b study

## PRICING

- Orazol price comparator is Zometa (\$750/month)
- Movement to oral cancer medicine for reimbursement
- Manufacturing cost low – margin potential >90%

## PATENT POSITION

- Multiple patents (20 years) have been filed covering Orazol

## DEVELOPMENT PLAN

- 505 (b)(2) allows Merrion to use much Zometa data
- GRAS status of GIPET® reduces development work
- Manufacturing is straight forward & scale up has been assessed

## DATAMONITOR:

‘MER-101 has the potential to be the most potent, orally available bishosphonate’

# ORAZOL MARKET POSITION\*

Datamonitor believe that.....“ORAZOL has the potential to be the most potent, orally available bisphosphonate”

- ③ “ORAZOL has the potential to significantly exceed what has currently been achieved with orally available bisphosphonates in bone metastases patients”
- ③ “I think the [bisphosphonates] available are quite good but obviously the disease takes its toll...newer agents which are more conveniently dosed would be critical.” US Opinion Leader
- ③ “Results from the Phase II trial will help evaluate whether by incorporating GIPET, ORAZOL can significantly improve the efficacy of orally administered zoledronic acid therapy to potentially produce a safer and more convenient alternative to intravenous bisphosphonates”

# PARTNERING STRATEGY



- ③ License to marketing partner to complete Phase III & bring to market
- ③ Key quality of life, pharmacoeconomics and safety data to be generated at Phase III.
- ③ Typical industry deal structure type – upfront, milestones & royalties
  - Structured to account for upside opportunities in early stage cancer and osteoporosis

# SUMMARY

- ④ **ORAZOL major new oral product based on 'gold standard'**
  - Quality of life/convenience
  - Pharmacoeconomics
  - Long patent position
  - Safety
  - Efficacy
- ④ **Phase III ready Q2 2009**
- ④ **Existing indications represent major opportunity**
- ④ **Offers significant potential to penetrate new indications**
- ④ **High margin potential**
- ④ **High return potential for limited outlay**