

# **Company Overview**

January 2015

Robert Joseph

PRESIDENT & CHIEF EXECUTIVE OFFICER



### **Cautionary Note Regarding Forward-Looking Statements**

This presentation contains forward-looking statements and information within the meaning of the U.S. Private Securities Reform Act of 1995. Words such as "may," "anticipate," "estimate," "expects," "projects," "intends," "plans," "develops," "believes," and words and terms of similar substance used in connection with any discussion of future operating or financial performance identify forward-looking statements. Forward-looking statements represent management's present judgment regarding future events and are subject to a number of risk and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks include, but are not limited to, risks and uncertainties regarding Parnell's research and development activities, its ability to conduct clinical trials of product candidates and the results of such trials, as well as risks and uncertainties relating to litigation, government regulation, economic conditions, markets, products, competition, intellectual property, services and prices, key employees, future capital needs, dependence on third parties, and other factors, including those described in Parnell's Annual Report on Form 20-F filed with the Securities and Exchange Commission, or SEC, on September 15, 2014, along with our other reports filed with the SEC. In light of these assumptions, risks, and uncertainties, the results and events discussed in the forward-looking statements contained in this presentation might not occur. Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this presentation. Parnell is under no obligation, and expressly disclaims any obligation, to update or alter any forwardlooking statements, whether as a result of new information, future events, or otherwise.



### The Parnell Opportunity in Animal Healthcare:

Established Commercial Presence & Valuable Product Pipeline

**Five Marketed Products; US Market Expansion Underway** 

**Robust Pipeline with Seven Products in Development** 

Integrated Development, Manufacturing & Commercial Capabilities

**Unique Commercialization Model Utilizing Digital Technologies** 

**Experienced Leadership in Global Animal Healthcare with Track Record** 



## **Our People**



Robert Joseph
Director, President and CEO
9 years
(ex-marketing executive at Eli Lilly
& finance executive at Allergan)



Brad McCarthy
Director and Chief Financial Officer
5 years
(ex-CFO for Allied Pickfords Europe
and finance executive at Volkswagen)



Matthew Musselman
Chief Commercial Officer
(ex-Director of Companion Animal
at Boehringer Ingelheim, Director
of Dairy at Farmland Industries)



Dr Edward Robb Chief Scientific Officer (ex-V.P of R&D at Pharmacia, Pfizer, Boehringer Ingelheim & Ceva)



# Our Business Strategy

- Parnell's strategy and advantages
  - Track-record of successful in-house drug development and commercialization in major markets
  - Existing revenues provide market experience and supplement the funding of drug development and commercial expansion
  - Impressive pipeline of unique drugs that will bring innovation to large, existing markets with unmet needs
  - Low cost drug development through in-house capabilities including manufacturing
  - History of astute capital management coupled with real-world experience in animal healthcare and proven customer insights





### Strategy execution in 2015:

- Bringing Zydax<sup>®</sup> & Glyde<sup>®</sup> to Large Markets
  - Successful large-scale pilot efficacy study; pivotal study commenced
  - FDA approved safety section
  - CMC section nearing completion; successful manufacturing scale-up
  - Establish US Canine sale team and launch Glyde
- Strong Revenue growth in Dairy and Companion
  - US Dairy presence increasing to 7 territories; triple digit sales growth
  - Double digit Canine sales growth in AU & establish US sales team
  - Opportunity to increase revenue growth through mySYNCH® & iKAM®
  - Expand geographic presence through marketing partner appointments
- Advancing 7 Proprietary Pipeline Programs
  - Multiple clinical and preclinical studies with quick read-outs
  - Pipeline additions through in-house development and licensing







# Product Pipeline





# Our Products & Pipeline

	Pilot Studies	Pivotal Studies	Anticipated Approval	Market Size
GONAbreed® & estroPLAN® (Fertility) – Cattle			Marketed (12 Countries)	\$200m
ZYDAX® (Osteoarthritis) – Dogs & Horses			Marketed (5 Countries; US/EU 2016)	\$400m
GLYDE™ (Osteoarthritis) – Dogs & Horses			Marketed (5 Countries)	\$500m
TERGIVE™ (Osteoarthritis) - Dogs			Marketed (1 Country)	\$400m
PAR121 (Orthopedics) – Dogs, Cats & Horses			2018	~\$200m
PAR122 (Dermatology) – Dogs			2018	~\$300m
PAR081 (Anesthesia) – Dogs & Cats			2017	\$120m
PAR101 (Diabetes & Laminitis) – Dogs & Horses			2017	~\$100m
GONADOPRO™ (Fertility) – Cattle			2017	\$200m
PAR061 (Mastitis) - Cattle			2019	\$400m





# Zydax®

"the best OA drug I have used in my 30 years of veterinary practice"

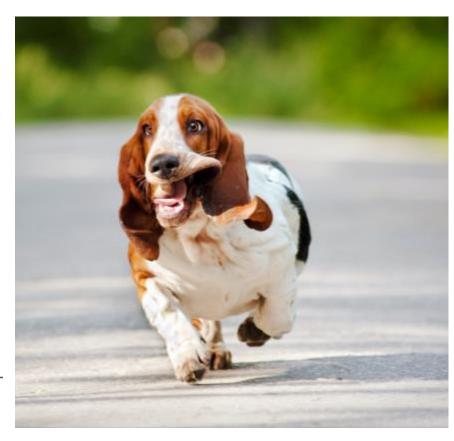
Leading Australian Veterinary Surgeon

#### Need

 All current and potential drugs are ostensibly anti-inflammatories which fail to target the primary cause of OA – cartilage degradation

#### Solution

- Zydax is a highly sulfated polymeric drug with a proven bi-modal action
  - stimulates proteoglycan synthesis
  - inhibits Aggrecanase-1
- Only drug to have successfully completed FDA required "owner assessed, clinical endpoint" efficacy trials



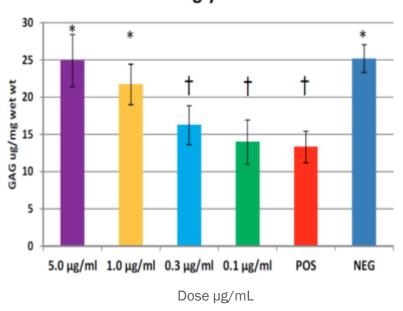


# Zydax

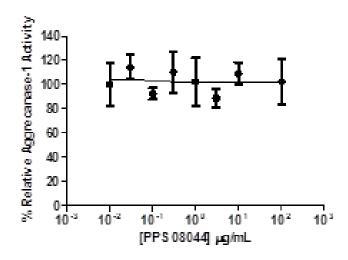
Mode of Action Studies

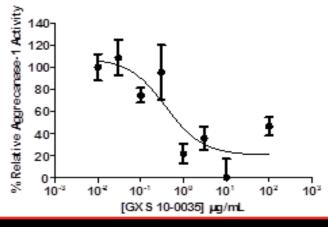
#### <u>Anabolism</u>

### **Tissue Proteoglycan Content**



### **Catabolism**

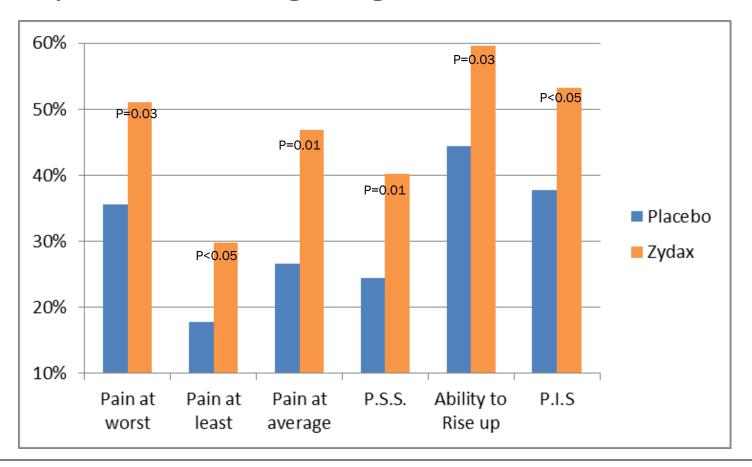






# Zydax

Efficacy trial results: Percentage of Dogs that Reached <u>Individual Clinical End Points</u>

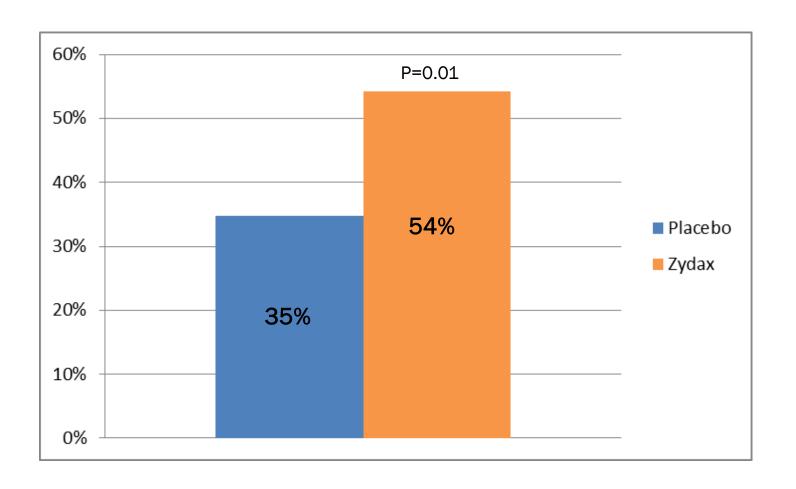


54% of Zydax treated dogs improved their total mobility score by more than 40%



# Zydax

Efficacy trial results: Percentage of dogs that <u>TOTAL Clinical End Point</u>





### Milestones & Summary

		2014	2015	2016	2017
ZYDAX® (Osteoarthritis)	Dogs	Commence Pivotal Efficacy Trial, Q4	Submit All Data	Launch 1H: US & Europe	<b>Launch 1H:</b> Asia & Canada
	Horses		TAS	Efficacy	<b>Launch 1H:</b> EU & US , Asia

- Successful M.O.A. studies and more planned
- Safety section and label language FDA approved
- Pilot efficacy studies successful
- Pivotal efficacy study running in 24 trial sites in AU & USA; complete Q2, '15
- Lonza successfully scaled up commercial manufacture of API
- Long patent remaining (2028) with opportunities for further IP
- Significant market success in comparable markets against NSAIDS, DMOADs and Nutraceuticals
- Final EU and US submissions Q2, 2015 with launch expected in 1H, 2016
- Equine approvals will be pursued in 2015/16
- Potential to add feline indications in 2015.



### PAR121 – Orthopedics

#### **Market Need**

- Dogs, and especially horses, do not tolerate casts or prolonged immobilization
- Multi-billion dollar canine orthpedic surgery market; in majority of equine cases, animal is euthanized

#### Solution

 PAR121 stimulates osteoblast differentiation to rapidly speed bone healing 1-week after fracture or orthopedic surgery

- 2015: Formulation development
- 2016: Pilot efficacy read out





### PAR122 - Dermatology

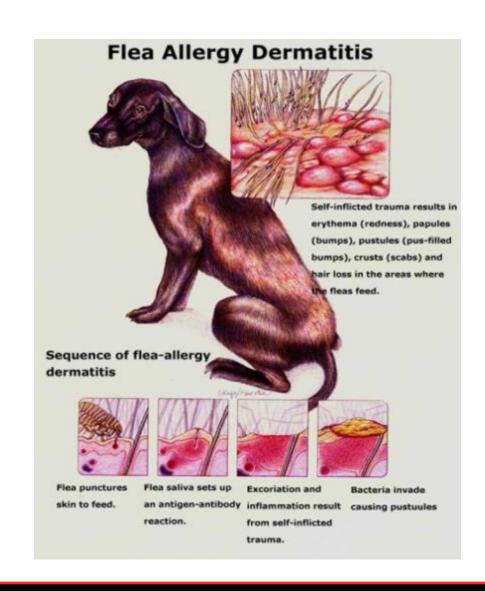
#### **Market Need**

- Flea Allergy Dermatitis ("FAD") is the biggest cause of atopic dermatitis
- New Anti-pruritic medications will reduce itching but there is no effective treatment for the secondary problem of bacterial skin infection

#### Solution

 PAR122 is a first-in-class product that stimulates rapid epithelial cell differentiation to speed skin healing

- 2015: Formulation development
- 2016: Pilot efficacy read out





### PARO61 - Mastitis

#### **Market Need**

- Current dry cow mastitis therapies require infusion of antibiotic paste directly into the teats of the udder
  - Process is cumbersome and laborious

#### Solution

- PARO61 is a pro-drug that crosses the blood-milk barrier and remains active for a prolonged period using an ion trap via a simple subcutaneous injection
- Revolutionizes dry cow therapy

- 2015: Formulation development
- 2016: Pilot efficacy read out



### PAR081 - Anesthesia

#### **Market Need**

- Propofol is the most commonly used anesthetic; current propofol-based products have significant shortcomings
  - Emulsions are difficult to sterilize introducing high risk of bacterial infection

#### Solution

- PARO81 is a water soluble formulation
  - No risk of bacterial infection
  - More predictable anesthetic induction

- 2015: Formulation development
- 2016: Pivotal efficacy & TAS





Move from this

To this



### PAR101 - Laminitis

#### **Market Need**

 No effective therapy to prevent or reverse laminitis; emphasis on symptomatic treatments, diet restrictions and exercise

#### Solution

- PAR101 is a daily oral therapeutic utilizing pioglitazone (insulin-sensitizer for type 2 diabetes in humans)
- Only known product candidate in development targeting one of the major causes of laminitis, metabolic syndrome

- 2015: Pilot efficacy
- 2016: Pivotal efficacy & TAS



### **GONADOPRO – Cattle Reproduction**

### **Market Opportunity**

- Reproduction is the single biggest driver of economic gain on a dairy farm
- Options to improve conception rates involve long duration and complex breeding programs

#### Solution

- Combination formulation of GnRH and Progesterone enables 10 day breeding program
- 30% improvement in conception rates
- overcomes challenges associated with intravaginal progesterone devices

- 2015: In-vivo hormone profiles
- 2016: Pivotal efficacy



## Opportunities for Expanding our Product Pipeline

- Our goal is to bring at least one new product to market each year commencing in 2015 through:
  - In-house drug development
  - Active in-licensing activities
- We expect to enhance our pipeline through quality:
  - large, established markets;
  - with significant un-met needs;
  - preferably an "improvement archetype";
  - which provides; lower risk, lower cost of development, faster path to market and lower cost of commercialization.

- Therapeutic Targets
  - Osteoarthritis
  - Orthopedics
  - Laminitis
  - Skin diseases (Atopic dermatitis)
  - Wound healing
  - Cancer
  - Obesity
  - Reproduction
  - Protein production efficiency



### **Product Portfolio Milestones**

### multiple value inflections in 2015

	2014	2015	2016	2017
GONAbreed® & estroPLAN® (Fertility) - Cow	mySYNCH® PROCEPT®	EU Launch Q4	China Launch Q4	
Dogs ZVDAV® (Octoborthyitio)	Commence Pivotal Efficacy Trial, Q3	Submit All Data	Launch 1H: US & Europe in 1H	Launch 1H: Asia and Canada
ZYDAX® (Osteoarthritis)  Horse	S	TAS	Efficacy	<b>Launch 1H:</b> EU & US , Asia
GLYDE® (Osteoarthritis) – Dogs & Horses	Glyde Chews Launch Q4	Launch 2H: US		
TERGIVE® (Osteoarthritis) – Dogs		Submit U.S dossier	Launch 2H: US	
PAR121 (Orthopedics) - Dogs, Cats, Horses	6	MOA & CMC	Pilot Efficacy	TAS & Efficacy
PAR122 (Dermatology) - Dogs		MOA & CMC	Pilot Efficacy	TAS & Efficacy
PAR081 (Anesthesia) – Dogs & Cats		CMC	TAS & Efficacy	Launch
PAR101 (Diabetes & Laminitis) - Horses		Pilot Efficacy	TAS & Efficacy	Launch
GONADOPRO® (Fertility) - Cattle		In vivo hormone trials	Pivotal Efficacy	Launch
PAR061 (Mastitis) - Cattle		CMC	Pilot Efficacy	Toxicology



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