

Parnell Investor Day
June 18, 2015

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PRESIDENT AND CHIEF EXECUTIVE OFFICER









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

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### The Parnell Opportunity in Animal Healthcare:

Established Commercial Presence & Valuable Product Pipeline

5 Marketed Products; US Market Expansion Underway

**Robust Pipeline with 7 Products in Development** 

Integrated Development, Manufacturing & Commercial Capabilities

**Unique Commercialization Model Utilizing Digital Technologies** 

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







### Parnell's Business Strategy & Advantages

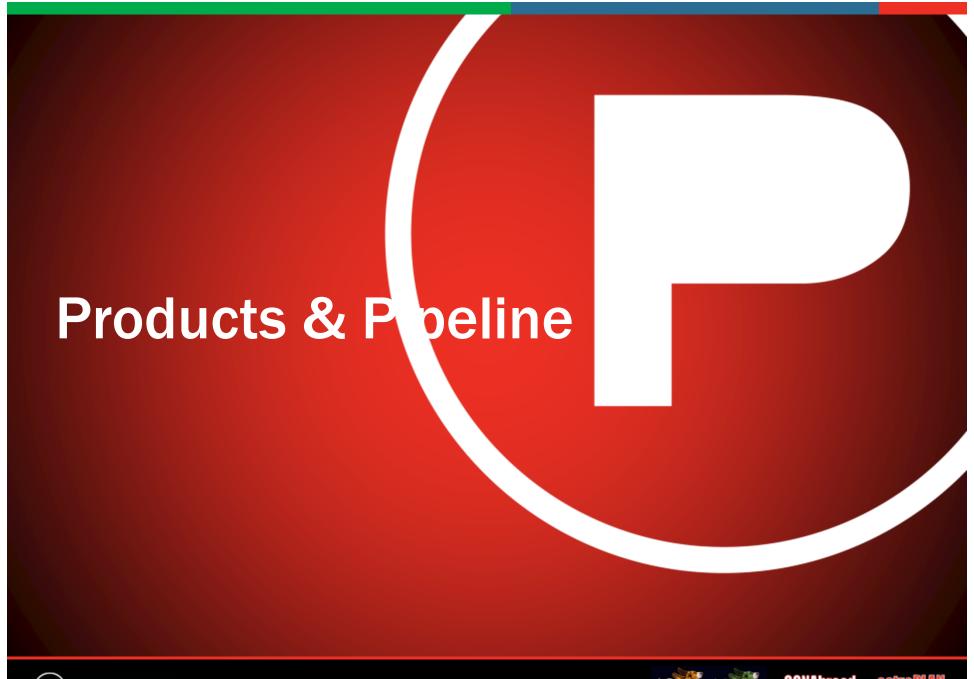
- We have developed, registered, manufactured and commercialized
   Production and Companion Animal drugs in major markets
- We have existing, rapidly growing revenues that demonstrate we can compete against the major multinational incumbents
- We have successfully implemented an innovative commercialization strategy using Digital Technology
- We can develop and commercialise drugs at a much lower cost due to our existing in-house capabilities including manufacturing
- We are using this experience to leverage our fully integrated value chain to progress our pipeline drugs delivering innovation to large, existing markets with unmet needs





















# **Our Products & Pipeline**

	Pilot Studies	Pivotal Studies	Anticipated Approval	Global 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
PARO81 (Anesthesia) - Dogs & Cats			2017	\$120m
PAR101 (Diabetes & Laminitis) – Dogs & Horses			2017	~\$100m
GONADOPRO™ (Fertility) - Cattle			2017	\$200m
PAR061 (Mastitis) - Cattle			2019	\$400m

Production Animal Companion Animal











### **Parnell Investor Day**

June 18, 2015

Dr Edward Robb DVM, MS, DACVN

**CHIEF SCIENTIFIC OFFICER** 



# ZYDAX® - a revolutional y OA togatment -











### **Development History of Zydax®**

- Developed as an enhanced sulfated oligosaccharide
  - Proteoglycans, glycoproteins, and glycolipids contain sulfated carbohydrates.
  - Sulfate groups are negatively charged, playing a role in specific molecular recognition processes
  - Relationships between sulfated oligosaccharides to human hereditary deficiency, cancer, inflammation, and infection
- Sulfated therapeutics modulate the action of Sulfotransferases and Sulfatases which control:
  - Cell Signal Transduction (Cellular degradation)
  - Hormone Regulation
  - Viral Entry
  - Molecular Recognition (drug-receptor binding)











### **Sulfated Oligosaccharides**

- Sulfated Therapeutics
  - Heparin
  - Fondparinux (prevents blood clots)
  - PI-88 (oncolytic)
  - Minoxidil (hair growth)
  - Elmiron (interstitial cystitis treatment)
  - Pentosan Polysulfate Sodium (osteoarthritis treatment....)
- While most therapeutic agents are homogenous species, heparin, PI-88, and PPS are important exceptions to this rule, and are complex mixtures of carbohydrates.









### **Evolution of PPS to GXS**

- PPS initially developed as a Heparin like agent
- Interferes with binding of factorX to thrombin (ATIII independent mechanism)
- PPS approved in interstitial cystitis; oral administration (Elmiron)
- PPS initially developed for OA in humans (in Australia)
  - Discontinued due to issues with thrombocytopenia
  - launched in veterinary market in 1996.
- Mixed success in OA treatment (and Interstitial Cystitis Treatment) due to heterologous nature of the polymer
- Parnell identified enhancement based on significant improvements in low molecular weight heparin

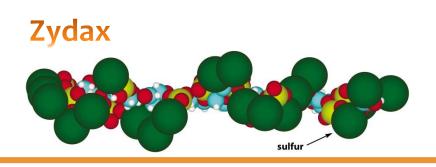








### **Intellectual Property**



- ✓ High sulfation >19.5%
- ✓ Specific tight molecular weight
- ✓ API Manufactured by Lonza AG, Switzerland
- ✓ Formulation Parnell, Sydney, AU



- Development partnership with Lonza has resulted in highly refined proprietary drug substance
- Granted (and filed) patents expiring 2028
  - Granted: EU, AU, NZ
  - Pending: US
- Complex chemistry that provides additional IP coverage
- Additional patent filings planned for 2015



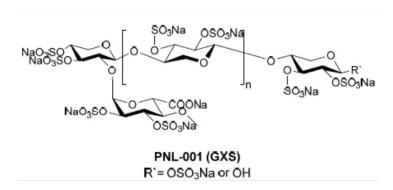






## What makes Zydax® unique?

- 8-10 Xylan units that are each FULLY sulfated
- This leads to a UNIQUE structure that:
  - Inhibits Aggrecanase-1
  - Significantly increases Cartilage Proteoglycan content in 21 days
  - Significantly reduces Prostaglandin (pro-inflammatory) presence
  - Results in HIGHLY significant clinical outcomes
- Long-lasting patent (2028)
- Sold over 1 million doses in Australia





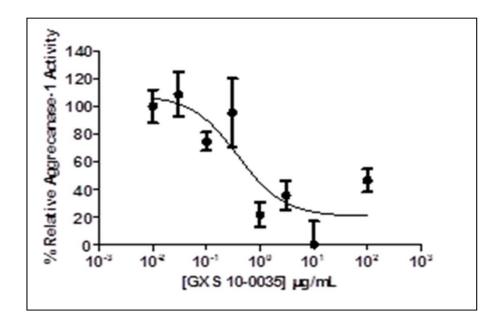


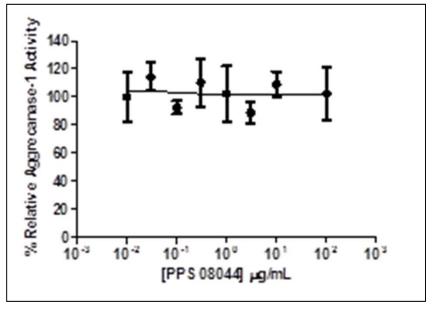




### **Only Zydax Inhibits Aggrecanase-1**

- It is well established the PRIMARY cause of degenerative joint disease is the up-regulation of Aggrecanase-1
- In a head-to-head study against PPS, only ZYDAX was able to substantially reduce the activity of the up-regulated destructive enzymes present in OA







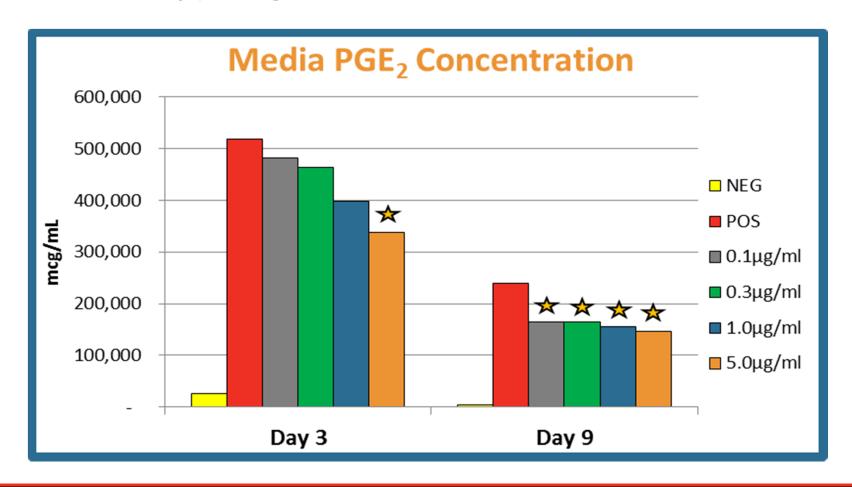






### **Unique Mechanism of Action**

 Displays anti-inflammatory activity by rapidly decreasing proinflammatory prostaglandins

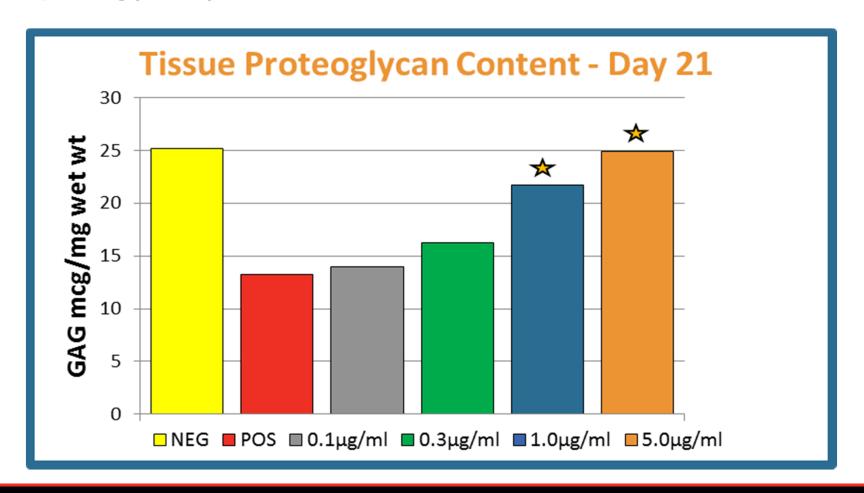






### **Unique Mechanism of Action**

 Restores osteoarthritic cartilage to normal in 21 days by stimulating proteoglycan synthesis







# ZYDAX®

- robust clinical data copports unique market positioning -



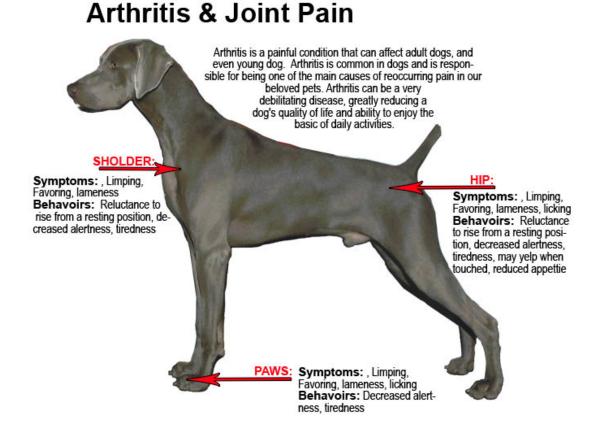








- Clinical Signs
- Physical Exam
- Radiographic Findings
- Synovial Fluid Analysis
- History
- Joint Pain
- Lameness











- Research Methods
  - Force Plate Gate Analysis
    - PVF- Peak Vertical Force
    - VI- Vertical Impulse





Biomechanical force platform with integrated balance. Speed between 1.7 an 2.1 m/s Vertical peak force increased before and after long chain omega-3 fatty acids supplemented diet (p≤0.08).

Comparison of Force Plate Gait Analysis and Owner Assessment of Pain Using the Canine Brief Pain Inventory in Dogs with Osteoarthritis D.C. Brown<sup>1,,</sup> et al, JAN 2013

There was no correlation or concordance between the Pain Severity (PS) or Pain Interference (PI) score changes and change in PVF or VI.









### Veterinary Assessed Lameness

Lameness Score at Trot				
Score	Description			
0	No lameness.			
1	Mild lameness, lameness difficult to observe; not consistently apparent, dog touched foot to floor on all strides.			
2	Moderate lameness, consistently apparent, dog touched foot or toe to floor on all strides.			
3	Severe lameness, marked head nodding, shortened stride, dog touched toe to floor on at least 50% of strides.			
4	Limited weight bearing lameness, dog touched toe to floor on less than 50% of strides.			
5	Non weight bearing lameness, dog does not touch toe to floor at any time, or does not move.			

	Pain Score on Manipulation after Scoring Lameness				
Score	Description				
0	No response to palpation or manipulation.				
1	Mild pain on palpation or manipulation (exhibits muscle tremors and/or slight avoidance movement on palpation or manipulation).				
2	Moderate pain on palpation or manipulation (definite limb withdrawal in response to palpation or manipulation).				
3	Severe pain on palpation or manipulation (marked withdrawal from attempted palpation or manipulation; vocalization; dog may snap or bite). (Note: This should be distinguished from any normal aggressive tendency of the dog.)				

In a study (Quinn MM 2007), three veterinarians with orthopedic training rated lameness utilizing the Numeric Rating Scale and Visual Analog Score before surgery, at 4 weeks and at 8 weeks post surgery.

Inter-reliability was low with no significant relationships between any observer's scores and force plate data except in extreme lameness.









- Owner Assessed Lameness
  - Canine Brief Pain Inventory (CBPI)
  - Modified from (human) Brief Pain Inventory (BPI) by D.C. Brown at U. Penn
  - Two Primary Dimensions
    - Pain Severity: Score 0-10
      - Worst Pain (over last 7 days)
      - Least Pain (over last 7 days)
      - Average Pain (over last 7 days)
      - Pain Right Now
      - PAIN SEVERITY SCORE (average of 4 Scores)
    - Pain Interference: Score 0-10
      - General Activity
      - Enjoyment of Life
      - Ability to Rise Up
      - Ability to Walk
      - Ability to Run
      - Ability to Climb Up
      - PAIN INTERFERENCE SCORE (average of 6 Scores)
    - Quality of Life: 5 point Score
      - Poor, Fair, Good, Very Good, Excellent









## **Zydax PILOT Efficacy Clinical Trial Design**

- **Study Design:** (CP0801 run in 2010)
  - 140 client owned dogs: 94 Zydax, 46 Placebo
  - Multi-site: 9 Trial Sites (USA)
  - Randomized, Double Blinded, Placebo Controlled
  - Dog Owner Assessed Clinical End-Point: Canine Brief Pain Inventory (CBPI)
  - Veterinarian Assessed Clinical End-Point: Lameness and Pain Assessment
  - Treatment: 4 subcutaneous injections given one week apart
  - Measurements taken at:
    - Baseline
    - Day 14 (1 week after 2<sup>nd</sup> injection)
    - Day 28 (1 week after 4<sup>th</sup> injection)
    - Day 70 (11 weeks from baseline), (n= 51 Zydax, 27 Placebo)



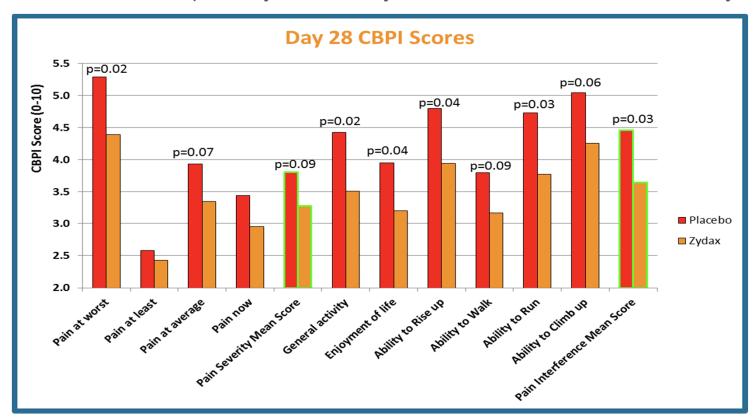






### **Zydax PILOT Efficacy Clinical Trial Outcomes**

- Day 28 CBPI Scores by Category; demonstrates statistical significance across majority of criteria
- 39% improvement in Pain and 46% improvement in Mobility for Zydax Tx'ed Dogs.
- Also demonstrates superiority of "Mobility vs Pain" as a measure of efficacy



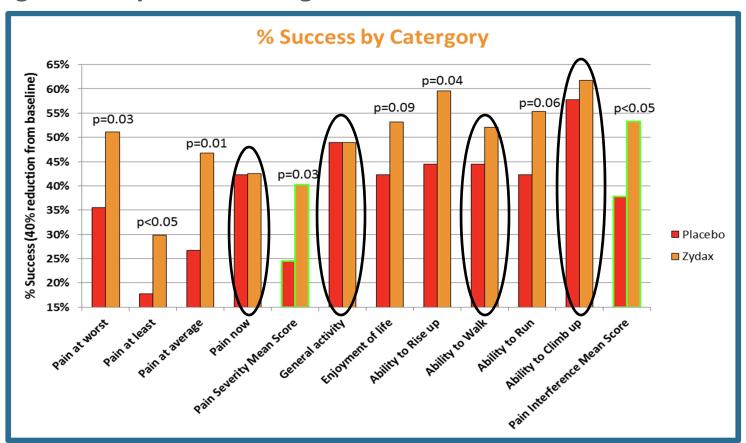






## **Zydax PILOT Efficacy Clinical Trial Outcomes**

- Day 28 % "Successful" by Category; achieved a >2.5 (40%) reduction in CBPI Score
- Demonstrates statistical significance across majority of categories
- Highlights fallibility of certain categories



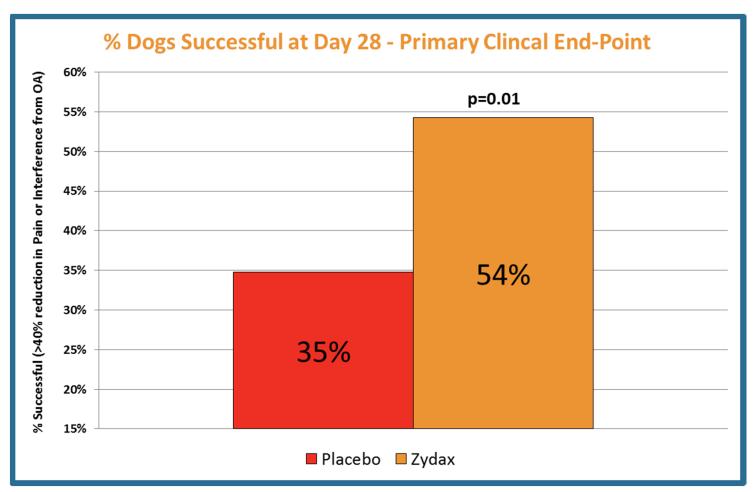






### **Zydax PILOT Efficacy Clinical Trial Outcomes – Day 28**

 Primary Clinical End Point - Percentage of dogs that had a >40% reduction in Pain or Interference caused by OA after 4 injections of Zydax (Day 28)





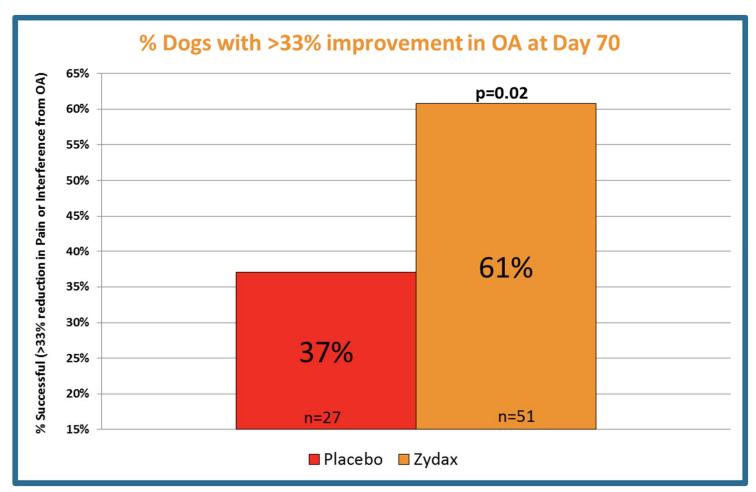






### **Zydax PILOT Efficacy Clinical Trial Outcomes – Day 70**

 <u>Durability of Effect</u>: 61% of Zydax treated dogs still had a >33% improvement in Pain or Interference 6 weeks after treatment with Zydax (Day 70).





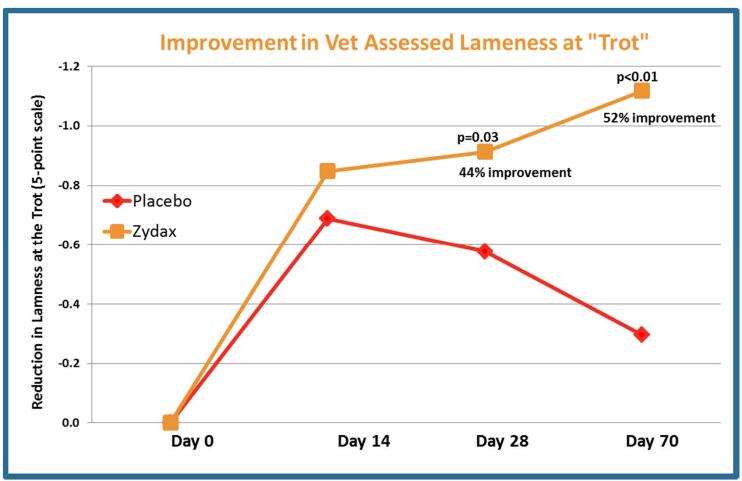






# **Zydax PILOT Efficacy Clinical Trial Outcomes**

 Veterinarian assessed lameness at the "Trot" demonstrating long-lasting benefits of Zydax











### Parnell's experience with CBPI



- Questions not always relevant to all cases/owners
- 11 Point Assessment is Very Difficult for Owners to Scale
- Difficult to Integrate Averages for Past 7 days
- Not all individual measures all have shown efficacy signals for many drugs (including Zydax)
- A simple average for Pain Severity and Pain Interference assumes all questions are equally relevant for all cases







### **CSOM - Client Specific Outcome Measures**

### Trends

- Migration from Lameness → Pain → Mobility outcomes
- Migration from Veterinary Office Evaluations → Clients Home Environment

### CSOM

- Measures the degree of impairment recognized by the owner
- Owner identifies three activities that were impaired compared to when the dog was considered normal
- Owners are asked to be specific and to indicate the places and times the activities were impaired
- Owners at enrollment, rate the degree of impairment associated with these specifically defined activities and evaluate the problem using five categories (translated to a 5 point scale for statistical analysis)
- Results in a more robust analysis of drug vs placebo effect









### **Zydax Pivotal Efficacy Clinical Trial Design**

- Study Design: (CP1402: run Oct '14 Jun '15)
  - 316 client owned dogs: 212 Zydax, 104 Placebo; (2:1)
  - Multi-site: 20 Trial Sites (13 USA, 7 AUS)
  - Randomized, Double Blinded, Placebo Controlled (IACUC approved)
  - No prior participation in OA studies, no OA Tx for prior 2m, no surgery for 6m
  - Radiographic evidence of OA
  - Dog Owner Assessed Clinical End-Point: Client Specific Objective Measures
    - 3 "owner selected, dog specific" measures (not pre-determined)
      - Please describe up to 3 activities that you think are difficult for your dog, or that have changed as a result of your dog's osteoarthritis. Examples of such activities could include:

Walking	Lying down	Moving after activity
Trotting	Getting up	Moving on slippery floors
Running	Going up stairs	Getting into car
Jumping	Going down stairs	Jumping onto furniture
Playing	Moving after resting	Positioning to urinate









### **Examples of Client Specific Outcome Measures**

- 1. Has a difficult time getting up from laying position
- 2. Slower to jump on bed can still do but hesitates
- 3. Gets leg tremors and limps after returning from long walks
- 4. Trouble getting in car and sometimes owner has to assist
- 5. After going on long walks, limps upon returning
- 6. Trouble going up and down stairs
- 7. Sore after playing with other dogs
- 8. Stiff when first gets up
- 9. Hesitates before jumping up and down off things
- 10. Pain difficulties in positioning to urinate
- 11. Jumping up on owner's bed
- 12. Getting on and off the furniture
- 13. Getting comfortable laying down at bedtime
- 14. Shaking the owners hand with the right paw for a treat
- 15. Getting out of the car in the afternoon
- 16. Not bearing weight on left rear leg while walking
- 17. Reduced speed and agility when chasing squirrels and chipmunks in yard
- 18. Difficulty getting down from the bed at night after watching TV with owners
- 19. Difficulty getting up on the sofa during the day at home
- 20. Willingness to play with ball in the morning









### **Zydax Pivotal Efficacy Clinical Trial Design**

### Study Design:

- CSOM measured using categories (converted to 5 point scale for stat analysis)
  - (1) No Problem
  - (2) Mild Problem: Far from extreme (slight, insubstantial, minor, small, weak). You can detect the impairment in your dog; other people who do not know your dog well may not be able to.
  - (3) <u>Moderate Problem</u>: Not excessive or extreme (modest, medium, intermediate, midway). You can easily detect the impairment in your dog and other people can also observe it.
  - (4) <u>Severe Problem</u>: Intensely/extremely bad (serious, highly, great, large). Very obvious to anyone.
  - (5) Impossible
- Three CSOM measures are combined for a Activity Impairment Score (total possible score of 15), minimum score of 7 to be eligible
- Treatment: 4 SC injections, 3mg/kg body weight, given one week apart
- Measurements taken at:
  - Baseline
  - Day 14 (1 week after 2<sup>nd</sup> injection)
  - Day 28 (1 week after 4<sup>th</sup> injection)









# **Zydax Pivotal Efficacy Clinical Trial Design**

Study Activity	Study Day						
	-14-0	0	7±2	14±2	21±2	28±2	35±2
Owner consent form	•						
Case history	•						
Owner Questionnaire	•	•		•		•	
Body weight	•	•	•	•	•	•	
Physical examination	•	•				•	
Lameness assessment	•	•				•	
Pain on manipulation	•	•				•	
Clinical pathology	•					•	
Radiographs <sup>1</sup>	•						
Eligibility assessment	•	•					
Enrolment		•					
Owner observations	Daily on days 0 - 28±2						
Phone call to owner							•
Termination from study							•









### **Study Demographics**

• Study animals were "classic high risk OA": Age (older), Weight (heavier), Breed (certain popular breeds – Labradors, Retrievers etc)

Age						
Treatment	mean	std	min	max		
Placebo	9.5	3.0	2.0	15.0		
Zydax	9.2	3.0	1.0	16.0		

Body Weight, (lbs)						
Treatment	mean	std	min	max		
Placebo	61.8	31.2	8.1	149.6		
Zydax	59.2	28.6	4.8	157.0		

Breed			
Labrador / Retriever	23%		
Large Mixed Breed	16%		
Border Collie	4%		











### **Primary Effectiveness Outcome**

- Definition of Treatment Success at Day 28
  - CSOM assessment 1 week after last Treatment with Zydax or Placebo
  - Reduction in Activity Impairment Score (AIS) between Baseline and Day 28 of 3 or more
  - No Increase in any Individual CSOM Measure between Baseline and Day 28
- Secondary End-Point: Continuum of Effectiveness
  - assess Minimal Clinically Important Difference (MCID) across all responses:
    - AIS Reductions of -2, -3, or -4 at Day 28 compared to Day 0
- Statistical analysis of Primary End-Point
  - Generalized Linear Mixed Model assuming a binomial distribution and using a logit link
  - Treatment as a fixed effect, site and site by treatment interaction as random effects
  - Two Sided alpha=0.05
  - Sites must have 2 Evaluable Cases Zydax Placebo for inclusion



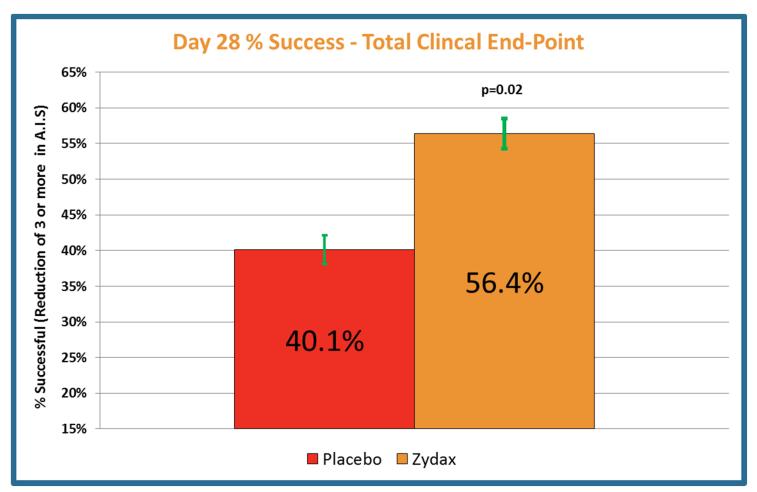






# **Zydax Pivotal Efficacy Clinical Trial Outcomes**

 Significantly more Zydax treated dogs had a reduction of 3 or more in the Activity Impairment Score after 28 days





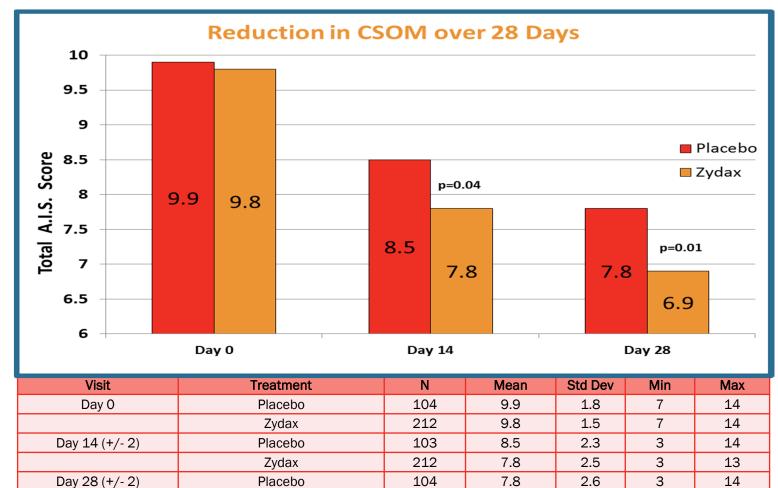






## **Zydax Pivotal Efficacy Clinical Trial Outcomes**

 Zydax Treated Dogs achieved a statistically superior improvement in Activity Impairment Score (AIS); 3 point reduction after 28 days and 2 points after 14 days



212

Zydax

6.9





3

2.6

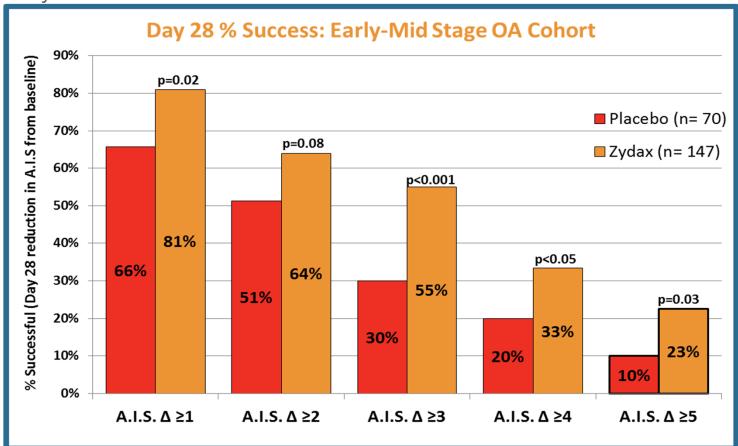


14



## **Zydax Pivotal Efficacy Clinical Trial Outcomes**

 Secondary Outcome: early to mid-stage (mild-moderate) cohort of dogs, Zydax demonstrated a significant improvement in clinical signs of OA; ranging from 81% of dogs showing at least an 11% improvement and 22% showing a 56% improvement at 28 days









## ZYDAX®

- robust clinical data cupports unique market positioning -











## **Parnell Investor Day**

June 18, 2015

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PRESIDENT & CHIEF EXECUTIVE OFFICER









## **2015 Companion Animal Guidance Update**

- Bringing Zydax<sup>®</sup> & Glyde<sup>®</sup> to Large Markets
  - File Zydax in US and Europe in Q3, 2015
  - Launch Glyde and iKAM in USA in Sep, 2015
- Establish US Canine Commercial Team
  - Raised an \$11m non-dilutive debt facility June, 2015
  - Recruited all management positions
  - Recruiting 40 territory managers covering 6,000 clinics
- Final stage of negotiations to appoint a multinational Marketing
   Partner for Zydax and Glyde in Europe (and other major markets)
  - Anticipate multi-million dollar upfront payments and milestones
- Reiterate expectation of significant global sales opportunity
  - Depth of data package and market experience with Zydax provide confidence that Zydax will be uniquely positioned as a revolutionary therapeutic for the management of osteoarthritis in dogs









## **2015 Production Animal Guidance Update**

- Triple digit sales growth in US Production Animal Business
  - 7 territories in place, considering up to 3 more by year-end 2015
  - Market share and sales growing above plan 189% YOY growth Q1, 2015
- mySYNCH<sup>®</sup> launch in September, 2015
  - Expect digital technology assets to create significant differentiation and potential subscription service revenue streams in future
- Expect to appoint Marketing Partner for Europe in 2015 with expected launch in 2H, 2016
- Reiterate expected global peak sales opportunity for reproduction hormones of \$20m - \$30m
- Targeting in-licensing opportunities that can leverage digital technology asset (mySYNCH®)









## **2015** Contract Manufacturing Guidance Update

- Currently negotiating two significant contract manufacturing deals
- One deal could commence end-2015 and the other end-2016 enabling rapid utilization of our current spare capacity (75%)
- Potential to generate multi-million dollar annual revenues with high margin and to commence sooner than previously indicated





















## **Zydax Path to Market - USA**

- Pivotal Efficacy Data Section: met with CVM 22<sup>nd</sup> May
  - Discussed Clinical Data Package that will provide substantial evidence to support approval
  - We remain confident that our Pivotal Efficacy Submission will be robust and complete
- Chemistry & Manufacturing Controls Section: meeting CVM 29<sup>th</sup> June
  - Full review of Chemistry and analytical methods submitted
  - Full review of Drug Master File (VMF) submitted
  - Lonza to file VMF in July, 2015
  - Expect to file CMC's submission July, 2015
- Environmental Assessment Section
  - Filed June, 2015
- Target Animal Safety Section
  - Section Complete received 2014









## **Zydax Path to Market - USA**

- Each dossier Section is reviewed on a 180 day clock
- Three alternative outcomes
  - Section Complete
  - Shortened Reactivation Timeframe
    - After Parnell resubmits clarifications, review is 60 days
  - Section Incomplete (resubmit with review on 180-day clock)
- Virtually all CMC section reviews take more than one 180-day review.
  - We remain confident of the robustness of our file
- Most likely approval time-frame:
  - File Efficacy and CMC's (and VMF) sections in July/Aug 2015
  - Receive first reviews in Jan/Feb 2016
  - If require second submission expect approval September, 2016









## **Zydax Path to Market - EU**

- Additional requirements typically result in approval ~3months after US approval
- EU requires "Expert Opinion Reports"
  - once full dossier is complete, independent "EU Expert" must review file and compile opinion of completeness to accompany file
- EU approves a facility and drug separately, must have the facility approved prior to submitting
  - successful TGA inspection occurred in May, 2015 under mutual recognition for EU
  - expect to have certification from TGA in September 2015
- EU Process has "stop clocks" for questions and typically takes 3 months longer than FDA process
- Expect EU approval in Q4, 2016









## **Zydax Path to Market - Rest of World**

- Expect to use US or EU Dossier to file in:
  - Canada
  - Japan
  - China
  - South Africa
  - Mexico
  - Brazil
- Approvals vary greatly by country; Canada typically similar time frames to EU; expect approval in early 2017 and progressively for other markets







## 12 months to prime the US market for Zydax

- Plans on track to establish Companion Animal Sales team in the USA for September commencement
  - 4 Regional Sales Managers (RECRUITED)
  - 40 Territory Managers (recruiting)
  - 4 Sales Associates; Inside Sales Reps (recruiting)
- Launch Glyde Chews in Sep, 2015
- Launch FETCH (new name for iKAM) in Sep, 2015
- 24,000 Companion Animal Clinics nationally
  - 4,100 clinics account for 50% of sales

















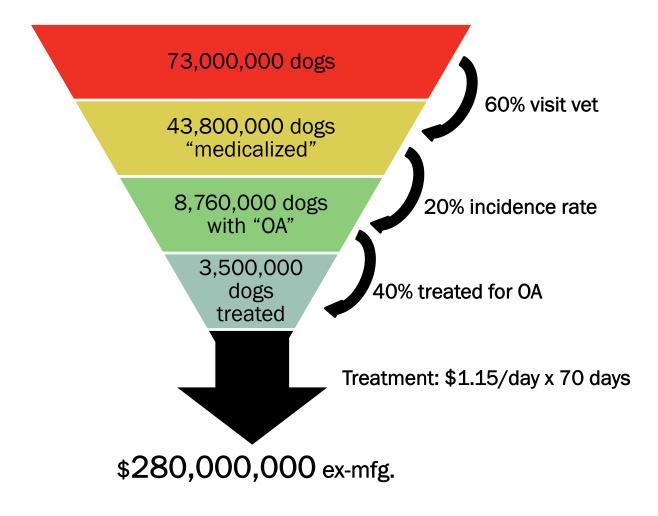








#### **US Canine OA Market Estimate**











#### **US Disease Modifying Osteoarthritis Drug (DMOAD) Market**

VS.



#### \$20M in US: inferior product profile

- Polysulfated Glycosaminoglycan
- 3 to 4 sulfate esters per disaccharide unit
- 2 injections/week for 4 weeks
- **IM** injection
- 51 dogs in one clinical study
- Low/no focus from multi-national sales team



#### Substantial improvement to DMOAD segment

- GlucuranoXylan Sulfate
- 8 to 10 Xylans, each fully sulfated
- 1 injection/week for 4 weeks
- **Subcutaneous injection**
- 600 dogs studied in 39 clinical sites
- **MoA Studies**
- **Durability Studies**
- **Concurrent Use with NSAIDs**
- "Flagship" focus product



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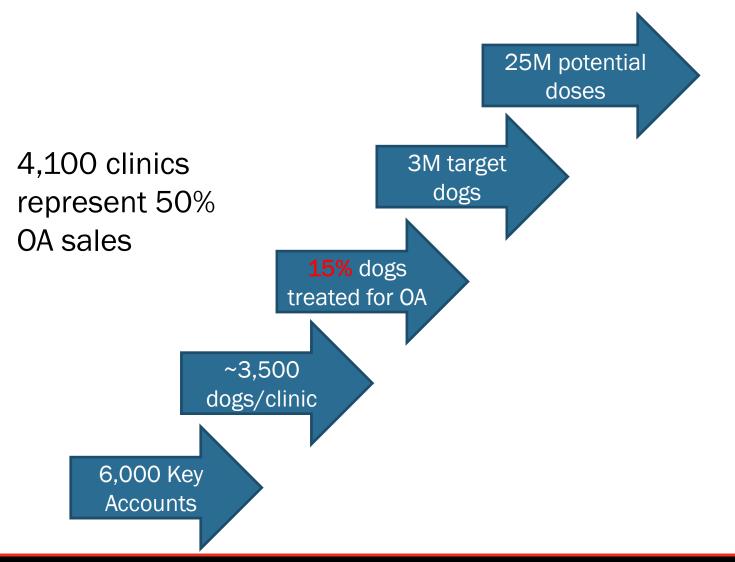








## **Zydax US Sales Potential**



25% of potential doses = \$80m Zydax Sales in USA



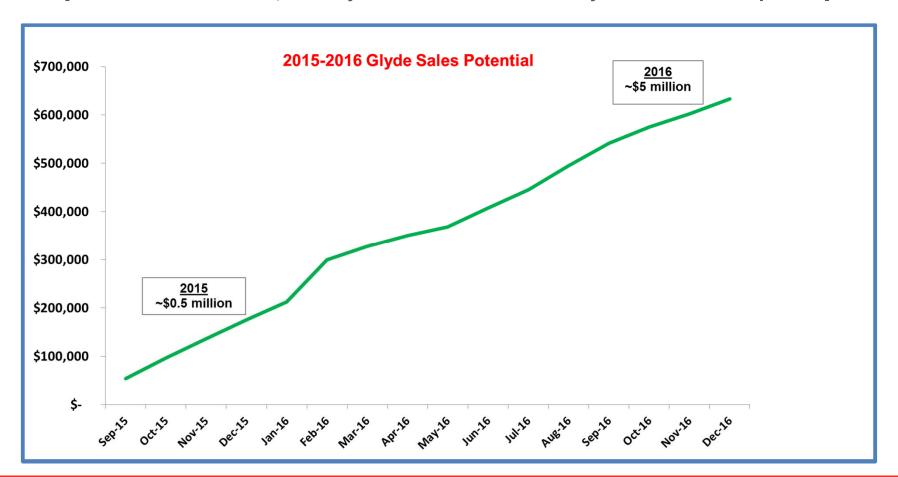






## **GLYDE Sales Forecast**

2015 Glyde Sales Forecast, \$0.5m growing to \$5m in 2016/17
[Assumes 5% SOM in 6,000 Key Accounts with 1 tub of Glyde Chews at \$35 per tub]









## What's our secret weapon?

- Analogous Market Experience: >1 million doses sold in Australia
  - Analogous pet owner population
  - Analogous veterinarian population
  - Analogous vet clinic dynamics
  - Analogous price sensitivity
  - Greater competition (3 generic PPS products, 4X lower price)
- FETCH!









## **History of our Digital Technology Products**

• 2009 - 2012



**Vet Nurse Consultants** 

• 2012



iKAM V1.0

2013



**iKAM PRO** 

• 2014



Dog Monitor









## 65% Conversion









**Vet Clinic** 

Waiting Room

Diagnosis

Treatment

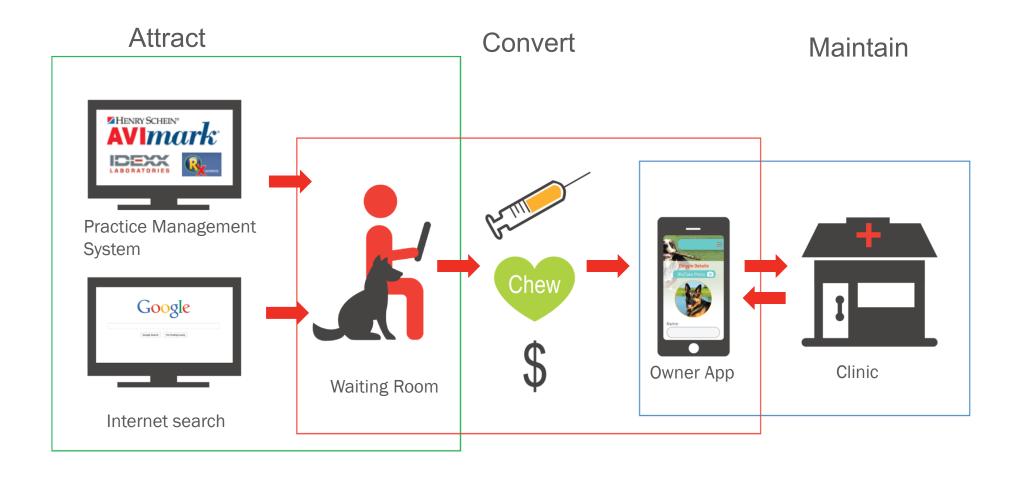








## **How FETCH! Fits together**







## **The Clinic App – Waiting Room**



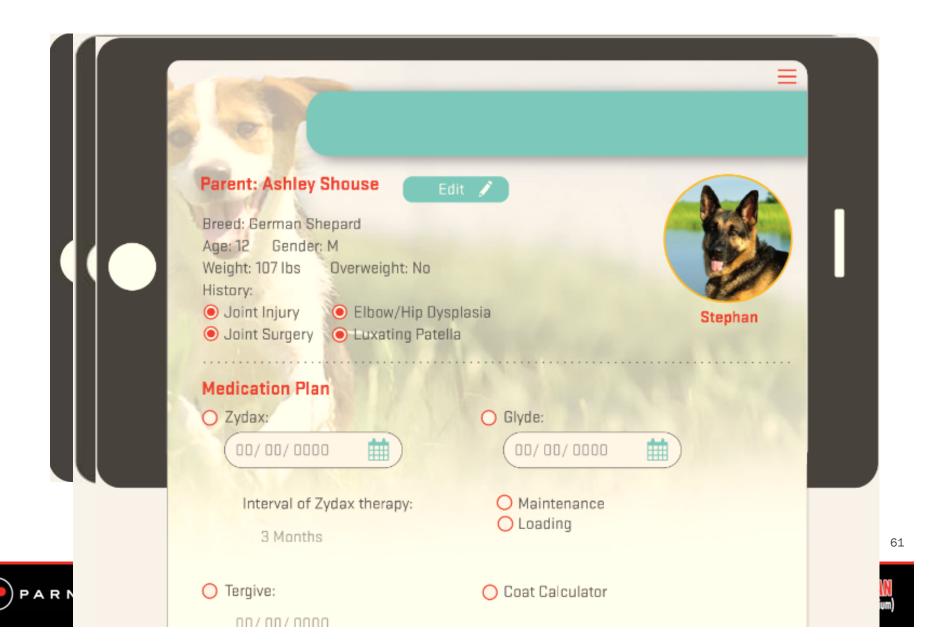








## **The Clinic App - Vet**



## **Clinic to Home**











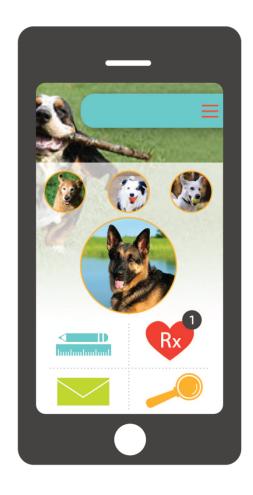
Owner App

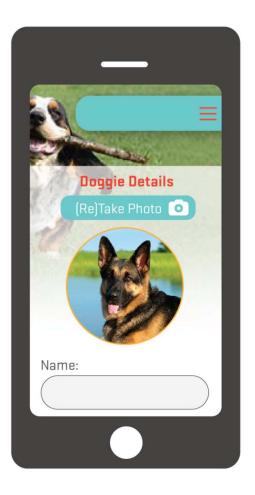


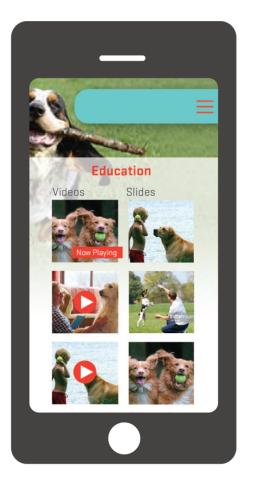




## **Owner App**















## PARNELL













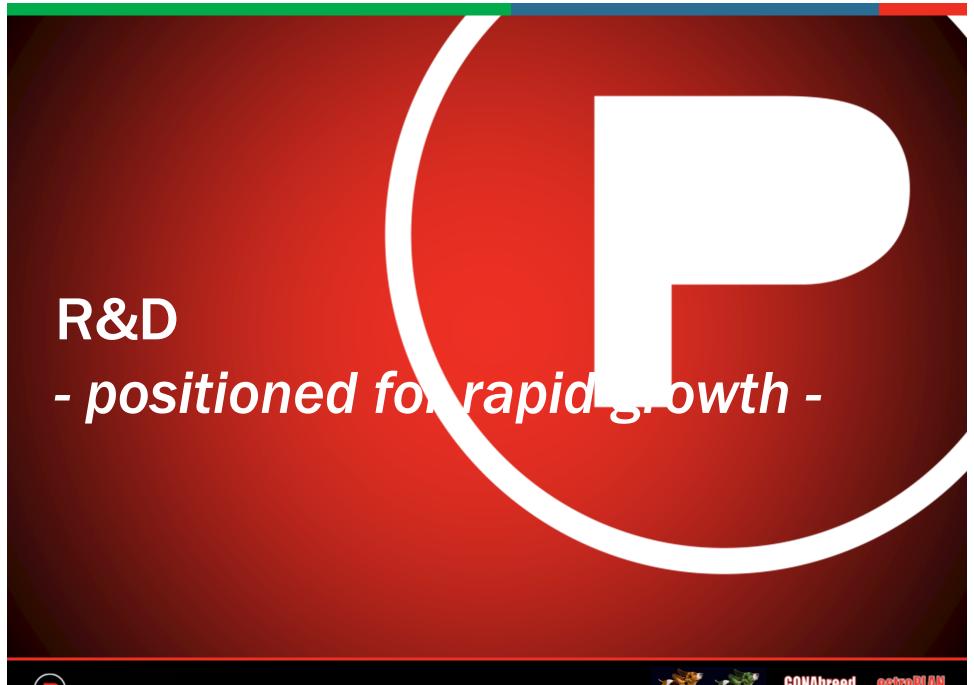
## **Parnell Investor Day**

June 18, 2015

Dr. Edward Robb DVM, MS, DACVN

**CHIEF SCIENTIFIC OFFICER** 















## **2015** R&D Pipeline Update:

- Advancing 7 Proprietary Pipeline Programs
- Significant number of in-licensing opportunities under consideration:
  - Expect to complete at least one in-licensing transaction in 2H, 2015
  - Continue to focus on major companion animal markets:
    - Mobility
    - Dermatology
    - Surgery
  - Drugs/Nutraceuticals/Med-Device
- Progress species expansion opportunities for Zydax in 2015
  - Feline & Equine

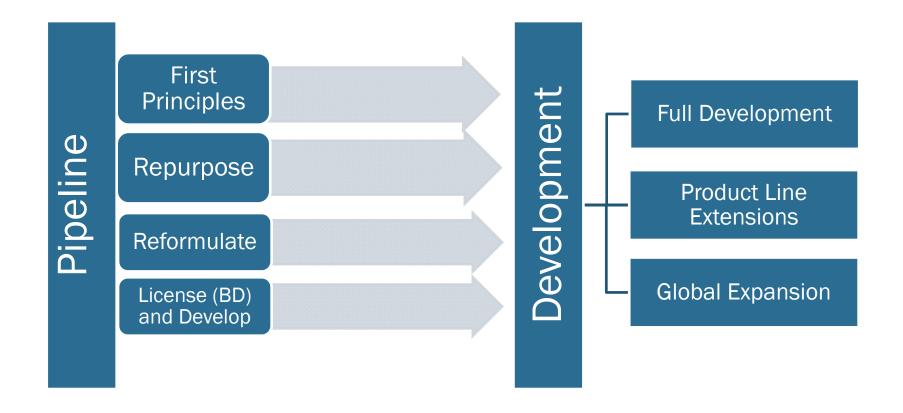








## **Parnell Product Development**



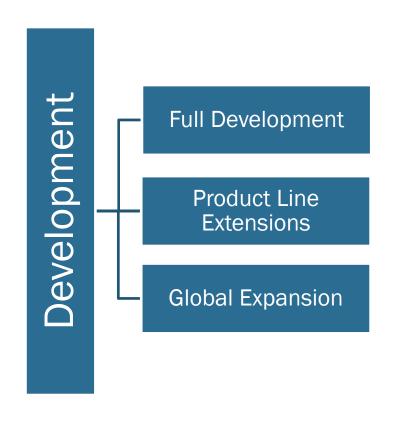








## **Development**



Zydax (US, EU) Glyde (AU) Tergive **EstroPLAN GONAbreed** Zydax Glyde (US)







#### **Product Development Pipeline**

#### First Principles

- PAR 121- Bone Regrowth Orthopedics
- PAR 122- Epithelial Growth Dermatology
- PAR 061- ProDrug for Mastitis

#### Repurpose

 PAR 101 PPAR for Equine Metabolic Syndrome (Laminitis)

#### Reformulate

- PAR 081 Improved Propofol
- Tergive
- Gonadopro (some 1st Principle Aspects)

## License (BD) and Develop

• BD Projects









## **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
PARO81 (Anesthesia): Dogs & Cats			2017	\$120m
PAR101 (Diabetes & Laminitis): Dogs & Horses			2017	~\$100m
GONADOPRO™ (Fertility): Cattle			2017	\$200m
PAR061 (Mastitis): Cattle			2019	\$400m

Production Animal Companion Animal









# **Zydax**<sup>®</sup> **Species and Claim Expansion**

#### **Activities**

- Expansion of MOA
  - Pharmacokinetics Pharmacodynamics
  - In vivo In vitro correlation
  - BioMarkers
- Canine Clinical Label Expansion
  - Duration of Action
    - Market Support with FETCH!
    - Durability and Breakthrough (CSOM)
    - Therapeutic Multi-Modality Treatment
  - DMOAD benefit of early Tx (onset mobility changes)
  - Prevention
    - Study paired litter mates of working dogs









# **Zydax**<sup>®</sup> **Species and Claim Expansion**

## **Activities**

- Target Animal Safety
  - Cats
  - Horses
- Efficacy
  - Cats remain difficult to assess for changes in mobility and pain
  - Equine locomotion/mobility assessments are challenging but can be accomplished













- PAR 121- Bone Regrowth Orthopedics
- PAR 122- Epithelial Growth Dermatology
- PAR 061- ProDrug for Mastitis

# PAR121 - Orthopedics

## **Market Need**

- Dogs, and especially horses, do not tolerate casts or prolonged immobilization
- Multi-billion dollar canine orthopedic 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

## **Milestones**

2015: Harvest Extraction

2016: Pilot efficacy read out





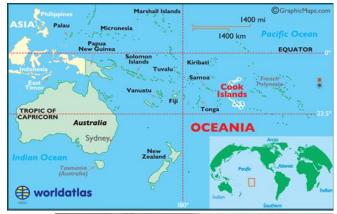




- PAR 121- Bone Regrowth Orthopedics
- PAR 122- Epithelial Growth Dermatology
- PAR 061- ProDrug for Mastitis

# PAR121 - Orthopedics

- Dr Graham Matheson
  - Grew Up in the Cook Islands
  - Observed Islanders Remarkable Healing After Injury
  - Reduced to Practice in PhD work at UNSW
    - Rat
    - Rabbits











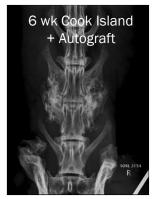




# Positive Findings From 4 POC Models

- Rat Surgical Femur Fracture
  - 18m old Sprague Dawley Rats Ovarectomized at 12 weeks of Age
  - Index Score of Callus, Union, Marrow and Cortex Changes @ 3 weeks post
- Ulnar Defect Model Rabbits
  - Optimized Extraction Process and Resolved Active in Plant A
- Spinal Fusion Model Rabbits
  - 12 NZ White Rabbits Iliac crest autograph
    - Evaluation at 6 weeks(n=4) and 8 Weeks (n=8)
- Distal Femoral Defect (cancellous bone medial distal femur NZ White Rabbits (6m)
  - 3 and 12 weeks following surgery (Right Empty- Left Autograph) TMT and CTL









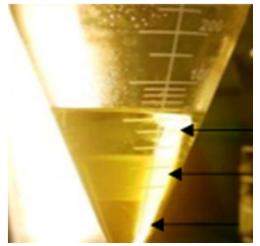




# **PAR121 - Orthopedics**

- Schedule of Events
  - IP
    - Continue Patent Applications
  - Extraction
    - Begin Q3, 2015
  - Biology
    - Reconfirm Signal in Animals Models
      - Test various dose regimens
  - Chemistry
    - Begin Characterization















# PAR121 - Orthopedics

# Nagoya Protocol

The Nagoya Protocol on Access to Genetic Resources provides a framework for the fair and equitable sharing of benefits arising out of the utilization of genetic resources.

The Nagoya Protocol on ABS was adopted on 29 October 2010 in Nagoya, Japan and entered into force on 12 October 2014,



- UN Awarded the Cook Islands \$2.4 M Administered thru the Global Environmental Facility (GEF) to the Cook Islands Ministry of Finance Feb, 2015
- Our Partner CIMTECH has an agreement with the Cook Island Council of Chiefs (Koutu Nui) for this project. Over \$400k earmarked for the extraction efforts
- Parnell has Patent Rights









- PAR 121- Bone Regrowth Orthopedics
- PAR 122- Epithelial Growth Dermatology
- PAR 061- ProDrug for Mastitis

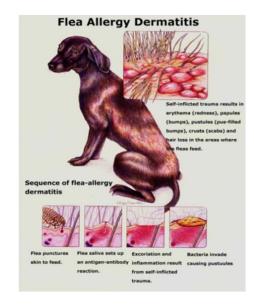
# PAR122 Dermatology

## **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



## **Milestones**

 2015-16 To follow PAR122 Extractions and Testing









PAR 121- Bone Regrowth
PAR 122- Epithelial Growth
PAR 061- ProDrug for Mastitis

# **PAR061 Mastitis -Cattle**

## **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



## **Significant Innovation**

Aligned with FDA A'biotic Policy

## Milestones

2015: Analog Program

2016: In vitro Testing,

**NCE** selection









## Repurpose

 PAR 101 PPAR for Equine Metabolic Syndrome (Laminitis)

# **PAR101** Diabetes and 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



#### **Milestones**

2015: Pilot efficacy partner identification

2016: Pivotal efficacy & TAS









## Reformulate

- PAR 081 Improved Propofol
- Tergive
- Gonadopro (some 1<sup>st</sup> Principle Aspects)

# 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.
  - Multi use
  - Room Temp Storage
  - More predictable anesthetic induction



From this

To this

## Milestones

2015: Formulation development

**CRO** Agreement Signed

2016: Pivotal efficacy & TAS









## Reformulate

- PAR 081 Improved Propofol
- Tergive
- Gonadopro

# Gonadopro<sup>™</sup>

## **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



## **Milestones**

2015: In vivo hormone profiles

2016: Formulation Development

Pharmacokinetics

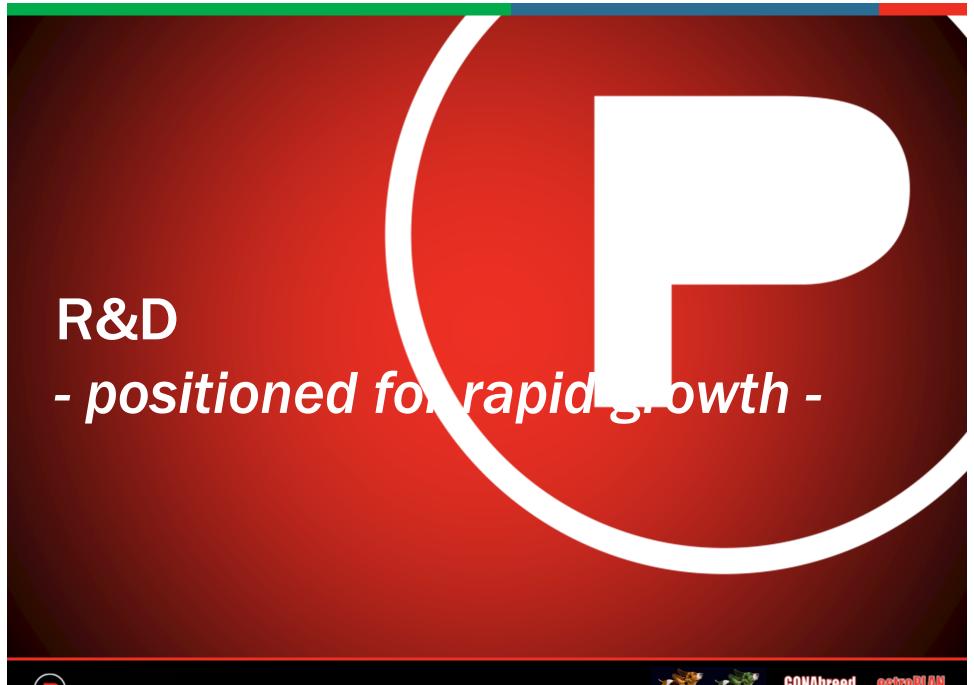
Residues





















# **2015** Major Milestones and Catalysts

- 1H 2015 Earnings Release: August
- FDA filing of Zydax: Jul, 2015
- EMA filing of Zydax: Sep, 2015
- Appointment of Zydax Marketing Partner for EU, ROW: Q3 2015
- US launch of Glyde: Sep, 2015
- Launch of FETCH! and mySYNCH Digital Tools: Sep, 2015
- Multiple milestones on Pipeline and updates on Licensing developments in 2H, 2015.









# **The Parnell Opportunity in Animal Healthcare:**

**Established Commercial Presence & Valuable Product Pipeline** 

5 Marketed Products; US Market Expansion Underway

**Robust Pipeline with 7 Products in Development** 

**Integrated Development, Manufacturing & Commercial Capabilities** 

**Unique Commercialization Model Utilizing Digital Technologies** 

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







