Zacks Small-Cap Research

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Parnell Pharmaceuticals Holdings Ltd. (PARN - NASDAQ)

PARN: Initiating Coverage of Parnell Pharmaceuticals Holdings Ltd.; A Fully Integrated Animal Specialty Pharmaceutical Company…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	03/07/2016
Current Price (03/07/16)	$2.74
Target Price	**$11.00**

INITIATION

We are initiating coverage of Parnell Pharmaceuticals Holdings Ltd. with a Buy rating and a $11.00 price target.

Parnell is a fully integrated, commercial stage, specialty pharmaceutical company focused on developing innovative animal health solutions. The company has approved and marketed products in 14 countries, including the U.S., and a full pipeline of new product opportunities with potential approvals over the next few years.

The animal health market is valued at over $80 billion, and Parnell is well positioned to take full advantage of this large market opportunity. We believe that Parnell will successfully bring multiple new products to market and that the expected launch of Zydax® at the end of 2016 is a near-term catalyst to propel the shares higher.

SUMMARY DATA

52-Week High	**$5.75**
52-Week Low	**$1.75**
One-Year Return (%)	**-30.81**
Beta	**0.45**
Average Daily Volume (sh)	**69,894**
Shares Outstanding (mil)	**13**
Market Capitalization ($mil)	**$37**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**22**
Insider Ownership (%)	**63**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2013 Estimate	**N/A**
P/E using 2014 Estimate	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of AUD$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	3.5 A	6.1 A	3.3 A	7.0 A	19.9 A
2016	6.0 E	7.7 E	8.0 E	6.7 E	28.4 E
2017					38.1 E
2018					61.2 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.09 A	-$0.13 A	-$0.18 A	-$0.70 A	-$1.03 A
2016	-$0.26 E	-$0.14 E	-$0.16 E	-$0.27 E	-$0.83 E
2017					-$0.25 E
2018					$0.93 E

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WHAT'S NEW

Initiating Coverage

We are initiating coverage of Parnell Pharmaceuticals Holdings Ltd. (PARN) with a Buy rating and a $11.00 price target.

Parnell is a fully integrated specialty pharmaceutical company focused on the development of novel medications for both the production and companion animal markets. The company currently promotes five products across 14 countries, including the U.S. The lead products include two bovine reproductive hormones (GONAbreed® and estroPLAN®) and a prescription medication to treat osteoarthritis in canines (Zydax®), which is currently under review by the FDA with approval expected in the fourth quarter of 2016.

The companion animal market is characterized by products for dogs, cats, and horses. This market has grown tremendously due to a number of factors, including increased pet ownership, growing disposable incomes, and a growing emphasis on the development of medical therapeutics specifically for pets. In support of this, the American Pet Products Association (APPA) reported that in 2012, U.S. consumers spent an estimate $53 billion on their pets, which was an increase of 36% from 2006. While the market for pet therapeutics is growing, there are still only a limited number of products approved by the FDA for use in pets. In 2012, 39 new human drugs were approved by the FDA, in comparison to only 11 new animal drugs. As a result, veterinarians typically prescribe human drugs off-label to treat pets, which is not always successful as differences between humans and other species can lead to an effective drug in humans being ineffective or even toxic in animals. Parnell believes that pharmaceuticals designed specifically for pets can improve their quality of length of life and lead to improved medical outcomes.

The production animal market is growing due to increased demands for food for a growing global population, with increased standards of living leading to increased consumption of animal proteins. As a result, livestock owners are continually in need of improved products that will drive increased production efficiency. Parnell is particularly focused on the dairy market, where U.S. milk production exceeded more than 200 billion pounds for the first time in 2013. We expect the demand for milk and milk products will continue to grow and that this will in turn drive the necessity for animal health products to help dairy producers meet their productivity enhancement needs.

Parnell is well-suited to take advantage of the growing animal health market based on a number of factors:

- **Established Commercial Model Ready to Enter the U.S.**: The company currently sells five products in 14 countries. For the year ended December 31, 2015, Parnell reported total revenues of AUD$13.2 million, which was a 58% increase over the same time period in 2014. In addition, the U.S. production animal business nearly tripled. The company has established a sales team for the U.S. companion animal sector ahead of the expected launch of Zydax® later in 2016.

- **Differentiation Through Add-on Technology Resources**: Parnell has sought to differentiate itself from other animal health companies through the use of two technology platforms, *mySYNCH* and *Fetch*. *mySYNCH* is a digital tool that integrates with existing dairy management computer systems to allow for breeding optimization that can lead to improved economic outcomes. *Fetch* is a digital customer application that can be used by dog owners at home to monitor the progress of their pet while on Zydax®. No other animal health company has similar applications and we view these tools as a clear differentiator for Parnell.

- **Large Pipeline of Products Set to Enter the Market Over the Next Few Years**: The company is currently focused on getting Zydax® approved in the U.S., which should be a meaningful growth driver. After Zydax®, Parnell has six other products in development that could be launched over the next two to three years.

We believe that the market is currently under-valuing the company's assets and does not fully appreciate the opportunity available in the company's pipeline. Our price target of $11.00 is fully supported by our discounted cash flow model, and we believe Parnell is a suitable investment opportunity for those looking for exposure in the burgeoning animal healthcare sector.

INVESTMENT THESIS

Parnell Pharmaceuticals Holdings Ltd. (PARN) is a commercial stage specialty pharmaceutical company focused on developing innovative animal health solutions. The company focuses on both the production and companion animal markets and has a fully integrated approach that combines in-house research and development, a manufacturing facility, and direct sales capabilities in the U.S., Australia, and New Zealand. The key differentiating factor for the company is the combination of the company's products with unique digital platforms that both help to build customer loyalty and enhance the user experience.

COMPANY OVERVIEW

The company was originally formed in 1986 as Parnell Laboratories Pty Ltd to develop animal health products for the equine and cattle markets. In 2009, the company merged with Parnell Pharmaceuticals Holdings Ltd as part of a corporate restructuring. The company completed an initial public offering on the NASDAQ global market on June 18, 2014 through the sale of 5 million shares at $10 per share.

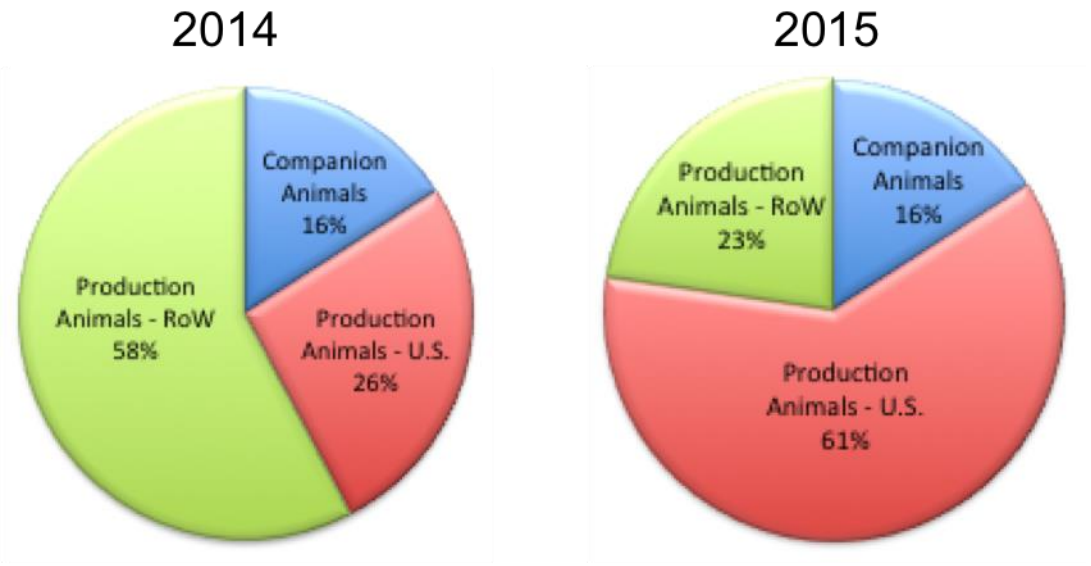
Parnell currently manufactures and markets five products for companion and production animals in 14 countries and differentiates itself from other companies through the use of proprietary digital applications: *FETCH*™ for companion animals and *mySYNCH*® for production animals. The company also has a pipeline of six drug products covering a number of different therapeutics areas including orthopedics, dermatology, anesthesiology, nutraceuticals, and metabolic disorders for companion animals and reproduction and mastitis for production animals.

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

☐ Production Animal ☐ Companion Animal

Source: Parnell Pharmaceuticals Holdings Ltd.

For the fiscal year ending December 31, 2015, the company reported AUD$13.2 million in revenues, which was a 58% increase over the same time period in 2014. The company derives revenue from three major categories – companion animal, production animal, and contract manufacturing services. Approximately 61% of the $13.2 million in revenue was from the production animal segment in the U.S., while 16% was from the companion animal segment. While the company has production animal products in development, as the chart above shows the majority of the company's pipeline is concentrated on the companion animal market, and we believe that the approval of Zydax®, which is likely to occur in the fourth quarter of 2016, will initiate a shift in the company's revenue composition to be more companion animal concentrated over the next few years. In addition, the company has an FDA and EU-approved sterile manufacturing facility that currently has 75% spare capacity, thus enabling revenue-generating opportunities from contract manufacturing in the near term.



Source: Parnell Pharmaceuticals Holdings Ltd / Zacks SCR

The company is currently focused on developing treatments for chronic conditions that affect a large number of animals for which animal owners are willing to seek treatment. In particular, the company is currently focused on four core areas to increase value for the immediate future:

- ✓ **Obtain Regulatory Approval for Zydax® and Commercially Launch in the U.S. and E.U.**: Zydax® has disease-modifying characteristics for the treatment of osteoarthritis (OA) in dogs and horses. It is currently approved for sale in Australia and New Zealand for the treatment of OA in dogs and in Asia and the Middle East for the treatment of OA in horses. The company is seeking approval of Zydax® for the treatment of OA in dogs in the U.S. It completed all regulatory filings in the fourth quarter of 2015 and expects to receive an initial response from the Food and Drug Administration (FDA) in the second quarter of 2016. While the FDA is not mandated to seek additional information, it almost always occurs, thus the company is planning to respond to those inquiries in a refiling of the complete New Animal Drug Approval (NADA) shortly thereafter, which would lead to a likely approval in the fourth quarter of 2016. The company also completed similar filings for approval of Zydax for dogs in Europe in the first quarter of 2016 and expects approval in that market in the first quarter of 2017. Additional regulatory filings are expected in other markets for Zydax including Canada in the second quarter of 2016 and Asia and other desirable markets throughout 2016, which could lead to approvals in over 30 countries in the next two years.

- ✓ **Continue the Development of Next Generation Digital Technologies**: Parnell currently offers two digital technologies for customers of both production and companion animal products.

    - ❖ *Fetch* is the digital application for dog owners, which was originally developed for use by dog owners in the waiting room of veterinary clinics as a self-education and self-diagnostic platform and contributed to the tripling of sales of Zydax® in Australia since its launch five years ago. The success of *Fetch* is based upon the expectation that 20% - 40% of dogs have osteoarthritis at any point in time yet less than 5% are being treated. *Fetch* has been an effective way for Parnell to capture this latent demand of dog owners who would otherwise be willing to treat osteoarthritis but have previously been unaware of the development of the disease in their dogs. The company is planning to utilize the program to capture new potential patients for Zydax prior to the launch in the U.S. and thus potentially accelerate sales upon approval by the FDA. The company has also developed a consumer version of *Fetch* to be used by dog owners at home to monitor the progress of their pet while on Zydax® and which also enables Parnell to communicate directly with dog owners and create an immersive brand experience for its products.

    - ❖ *mySYNCH* is a digital tool that integrates with existing dairy management computer systems to allow for optimization of breeding programs that can lead to improved economic outcomes. The program allows dairy producers to monitor the performance of their breeding programs and to compare their breeding programs to other comparable farming operations, allowing them to

implement best practices and optimize breeding outcomes. *mySYNCH* was originally launched in mid-2014 in a successful pilot program and is now available to all users to help drive sales growth. The company expects to bring multiple new features to the *mySYNCH* application in 2016 that could further differentiate Parnell from its competitors.

- ✓ **Capturing Larger Market Share of Reproductive Hormones in the U.S.**: The company currently offers two reproductive hormone products that are utilized in breeding programs. Parnell first began selling the products in the U.S. in 2013 and now has seven sales territories covering the top 20 states in the dairy sector, which represents 80% of the estimated 9.3 million dairy cows in the U.S. In addition to offering hormone products and *mySYNCH*, Parnell is hoping to differentiate itself from competitors through the introduction of a new patent pending breeding program called PROCEPT®, which the company has submitted for publication in late 2015. Sales of reproductive hormones in the U.S. grew 269% in 2015 to $8.1 million with market share reaching 10% in December 2015. The company is expecting sales to continue to grow strongly and has stated previously that they believe they can capture 20% - 25% of the $80 million U.S. hormone market.

- ✓ **Establish a Presence in the U.S. Companion Animal Market**: The company recently established a material commercial presence in the U.S. companion animal market with a team of 40 sales executives that cover the 40 largest metropolitan areas in the U.S, which represents approximately 12,000 of the total 24,000 veterinary clinics in the country and over 80% of companion animal market revenues. The sales team is currently focused on selling Glyde™, a nutraceutical product that supports healthy joints and reduces the signs of OA in dogs. Glyde™ is sold in to veterinary practices paired with the *Fetch* digital application and together the offering is expected to enable Parnell to establish a relationship with veterinarians and pet owners ahead of the company's expected launch of Zydax® in the fourth quarter of 2016. Given the appeal to pet owners of using nutraceuticals alongside pharmaceutical products (such as using Glyde™ with Zydax®), Parnell is launching Luminous™ in the second quarter of 2016. Luminous is a nutraceutical product aimed at the dermatology market and follows on the recent significant success of a new product for treating atopic dermatitis that was launched by Zoetis (ZTS) in 2014. The company believes that new innovations have demonstrated that significant category expansion can occur and they are seeking to take advantage of the attention dermatological conditions have recently attracted.

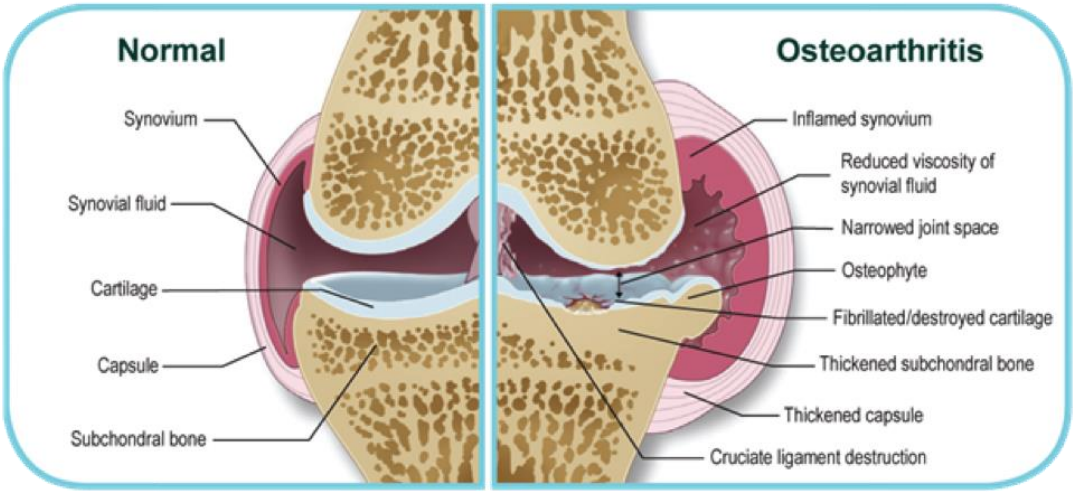
COMPANION ANIMAL COMMERCIAL PRODUCTS

Parnell's companion animal commercial products include a prescription treatment for osteoarthritis (Zydax®), a nutraceutical treatment for osteoarthritis (Glyde™), an improved formulation of the non-steroidal anti-inflammatory drug (NSAID) carprofen (Tergive™), and the upcoming launch of Luminous™ a nutraceutical treatment for dermatological conditions.

Osteoarthritis

Osteoarthritis (OA) is a chronic, debilitating, inflammatory joint disease that is highly prevalent in both dogs and horses. OA affects articular cartilage, which is the smooth, white tissue that covers the ends of bones where they come together to form a joint. Articular cartilage is characterized by a very low friction and a high resistance to wear; however it also has poor regenerative properties.

The exact cause of OA is unknown, however chondrocytes (cells that produce the cartilage matrix) are known to play a role that leads to increased catabolism (breaking down) of cartilage as opposed to anabolism (building up). Once the degradation of cartilage begins, small pieces of it can be released into the joint and initiate an inflammatory response. Continued breakdown of the cartilage can lead to areas where the bones are exposed and rub against each other, leading to bone spurs and cysts.



Source: westtownevet.com

Symptoms of OA in dogs vary based on the severity of the condition, but typically include an inability to move as quickly as they once did, difficulty in climbing stairs, and trouble when standing up. Parnell estimates that up to 90% of dogs will experience OA in their lifetime and that at least 20% of dogs have it at any one time (and some orthopedic specialist estimate the prevalence to closer to 40%). However, only a very small fraction of those animals are currently receiving treatment. Given that there are approximately 70 million dogs in the U.S. and over 50 million in the E.U., this represents a sizeable patient population that is currently being underserved.

Treatment of OA in Canines

There is no cure for OA, however there are a number of treatment options currently available. Most animals do not receive treatment until the disease is at an advanced stage, and the treatments they receive only work to alleviate the pain and discomfort associated with OA, and do not alter the course of the disease.

NSAIDs: Non-steroidal anti-inflammatory drugs (NSAIDs) are the most popular treatment option for OA, but also include some serious side effects, which include liver and kidney toxicity as well as gastrointestinal bleeding and gastric ulcers. High doses and/or extended treatment periods increases the likelihood of those side effects, thus limiting the use of NSAIDs in animals that would otherwise require prolonged treatment. While unrelated to side effects, the use of NSAIDs is restricted in performance animals, including race horses. Despite the limitations, the U.S. NSAID market is estimated to be $220 million, which increases to over $400 million when including the E.U. Zoetis' Rimadyl® (carprofen) is the market leader and was the first drug approved for the treatment of OA. Additional treatment options include Metacam® (meloxicam), Deramax® (deracoxib), and Previcox® (firocoxib). NSAIDs approved for use in horses include phenylbutazone, flunixin, and firocoxib.

Nutraceuticals: These are supplements that can be used in conjunction with other treatment options to control the clinical signs of OA. They typically contain glucosamine and chondroitin sulphate, which are two of the building blocks of cartilage, however since they are not regulated like prescription medications the amount of active ingredient can vary considerably from one product to another. Parnell estimates that the global nutraceutical market is approximately $500 million in annual sales.

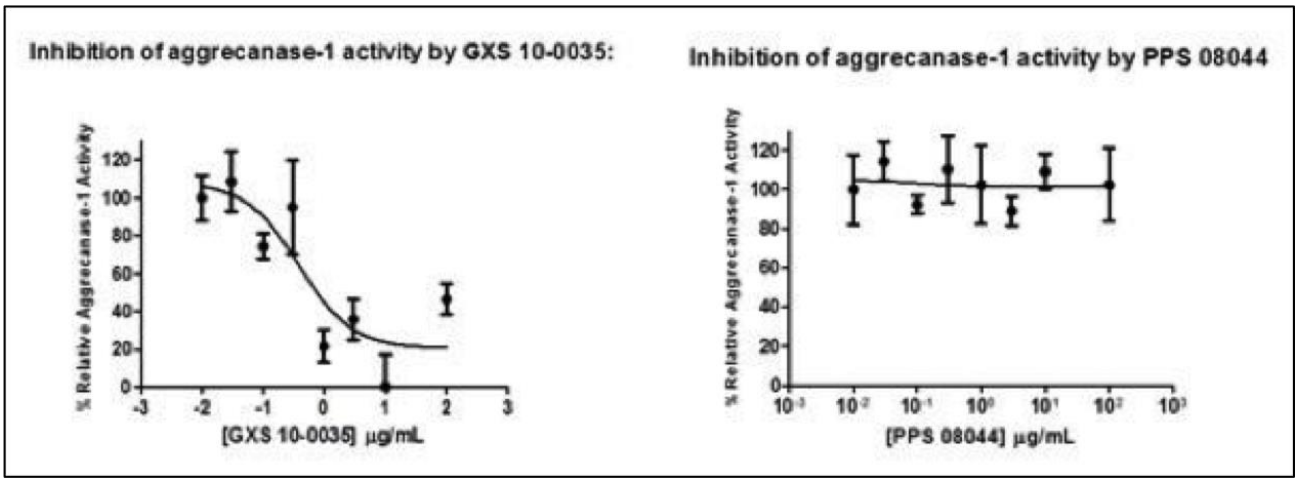
Pentosan Polysulfate Sodium (PPS): These are a class of drugs that are utilized in some countries to treat the clinical signs of OA in dogs and horses and also have disease-modifying properties. The mechanism of PPS in OA is multifactorial and includes both the stimulation of cartilage matrix synthesis and the prevention of cartilage breakdown. A clinical study of 40 dogs showed that those treated with PPS had better clinical outcomes in regards to pain and willingness to exercise (Read *et al*., 1996). The problem with PPS is that it has an unpredictable and inconsistent efficacy profile.

Polysulfated Glycoaminoglycan (PSGAG): This is a highly sulfated chondroitin sulfate product and just as with PPS the exact mechanism of action is unknown, however it also stimulates the production of cartilage while inhibiting its degradation. In the U.S., PSGAG is marketed under the brand name Adequan®, however it has not necessarily demonstrated sufficient efficacy and safety under the standards now required by the FDA. Thanks in part to the lack of adequate efficacy data, the PPS and PSGAG global market is only estimated at $50 million in annual sales.

Zydax®

Zydax® is a sulfated oligosaccharide with disease-modifying characteristics for the treatment of OA in dogs and horses. It attempts to overcome the shortcomings of the PPS class of drugs, namely that there is a lack of consistency in molecular weight and the degree of sulfation for PPS due to the fact that it is a polymer made up of various sub-fractions that have different characteristics.

In vitro testing has shown that Zydax® is able to potently inhibit the aggrecanase-1 enzyme, which is responsible for the degradation of articular cartilage and has been implicated in the pathogenesis of OA. The following figure shows how increasing concentrations of Zydax® (GXS 10-0035) are able to inhibit the activity of aggrecanase-1 while PPS is not.



Source: Parnell Pharmaceuticals Holdings Ltd.

Parnell recently completed a pivotal efficacy study in June 2015. It was a randomized, double blind, placebo controlled study evaluating the field effectiveness and safety of Zydax® in the treatment of clinical signs of OA in dogs. It was conducted at 20 sites in the U.S. and Australia and included 316 client-owned dogs with radiographic evidence of OA who were treated with either Zydax (n=212) or placebo (n=104). The clinical endpoint was improvement in Client Specific Outcome Measures (CSOM) that included the dog owners' assessment of improvement in activities such as walking, running, and climbing stairs. The dogs were treated with four subcutaneous injections of Zydax® or placebo given one week apart with outcomes measured at baseline, day 14 (one week after the second injection) and day 28 (one week after the fourth injection). The primary outcome of the study was the reduction in the Activity Impairment Score (AIS) compared to baseline at day 28 along with no increase in any individual CSOM between baseline and day 28.

Results from the study showed that Zydax® treated dogs achieved significant improvements in mobility with 56% of Zydax®-treated dogs achieving an AIS reduction of 3 (30% improvement) compared to only 40% of placebo treated dogs (*P*=0.02). In addition, after 28 days of treatment, 81% of Zydax® treated dogs achieved an improvement in AIS of at least 1 (*P*=0.02), while 23% of Zydax® treated dogs achieved an improvement in AIS of at least 5 (*P*=0.03).

U.S. Regulatory Process for Veterinarian Pharmaceuticals

The Center for Veterinary Medicine (CVM) is the division of the FDA responsible for regulation of veterinary pharmaceuticals. A New Animal Drug Application (NADA) contains five major technical sections (safety, efficacy, CMCs, human food safety, environmental safety) and additional sections on labeling, freedom of information summary, and all other information. The FDA is required to approve or not approve a complete NADA within 180 days, however the FDA encourages phased submissions of each technical section of the NADA. As each section is submitted, the FDA applies the same 180-day review period, and following submission of the final section the FDA may take 180 days, but it is usually completed within 60 days. At the end of the 180-day review period, the FDA may either deem the section complete or incomplete, however instead of deeming a section incomplete the FDA will typically request an end-review amendment (ERA). This requires the company to submit additional information or clarifications for issues that the FDA brought up within 30 days, and then the FDA takes another 135 days to complete the review.

For Zydax®, Parnell has now submitted all five sections of the NADA and expects to hear back from the FDA during the second quarter of 2016. This will likely involve a series of questions being posed by the FDA, either as an ERA or a further P-submission (180 day review) request, as almost no NADA's, especially for a new class of drugs, are approved without having to submit additional information. If the company can get the response filed during the second quarter, then approval would be likely in the fourth quarter of 2016.

Glyde™ and Tergive™

Glyde™ is a nutraceutical treatment that contains a therapeutic dose of the building blocks of cartilage (glucosamine and chondroitin), and eicosatetranoic acid derived from New Zealand green-lipped mussel powder, which is a natural anti-inflammatory. In Australia, Glyde™ is marketed with Zydax® as a combination treatment. The company launched Glyde™ Chews, which are flavored dog treats containing the active ingredients of Glyde™ (replacing the previous formulation which was a powder sprinkled onto the dogs food), in the second quarter of 2015 and then launched them in the U.S. in the fourth quarter of 2015 by establishing a U.S. companion animal sales and marketing team. Parnell estimates that the global market for alternative OA therapeutics is approximately $500 million.

Tergive™ is an injectable NSAID currently available in Australia that contains carprofen, the same active ingredient in Rimadyl®. Tergive™ is an improved formulation of Rimadyl® that is less viscous and easier to inject, stable at room temperature, and has a six-month stability. Just as with any NSAID, Tergive™ is designed for short-term anti-inflammatory use. The company will seek a generic registration for Tergive™ in the U.S. such that it can be marketed alongside Zydax® and Glyde™.

Fetch

Fetch is a digital customer application that is intended for use by dog owners. The application was originally designed to be used by pet owners as they waited in a veterinarian's clinic and included educational materials on the OA disease state, a customized risk-factor analysis for the pet parent to complete on their dog and more recently Parnell has incorporated the same mobility assessment program that it has used in its FDA clinical trials. The *Fetch* application has been successful at significantly increasing the proportion of dog owners who are willing to more proactively treat OA rather than waiting until the dog is old and has severe signs of OA. In the first year that *Fetch* was introduced in Australia (nearly five years ago), sales of Zydax® nearly tripled. The company has also recently developed a *Fetch* application for use by pet parents at home. The app allows them to monitor the progress of their dog using the mobility assessment tool used in Parnell's clinical trials and also to create video diaries, share their experiences through social media (and thus advocate Parnell's products to friends and family), and in 2016, the company expects to launch e-commerce capabilities to allow pet parents to purchase Parnell products through the App. Parnell also captures data about the use of the app and its products and can customize communications with pet parents to create an immersive brand experience and thus a clear differentiator from other animal healthcare providers.

COMPANION ANIMAL PIPELINE PRODUCTS

Zydax®

In addition to filings in the U.S. and E.U for the treatment of OA in dogs, Parnell expects to make similar filings in Canada that could lead to approval in the first quarter of 2017. The market for Zydax® in dogs is also expected to be attractive in established markets such as Japan and in emerging markets where pet ownership is increasing with the growth in the middle class such as China and Latin America.

The market for Zydax® in cats with OA is also expected to be large. In the U.S. there are over 70 million dogs, yet there are approximately 50 million cats. Typically there are fewer therapeutic options for treating diseases in cats as drug metabolism can be different to that seen in dogs and hence toxicity profiles often preclude the use of many pharmaceuticals in cats. Having sold Zydax® in Australia for nine years with over 1 million doses being used, there is substantial anecdotal feedback to the company from veterinarians who have successfully used Zydax® in cats with OA. Parnell believes that the prevalence of OA in cats is at least as high as that seen in dogs and quite possibly much higher. Furthermore, there are limited options available to treating OA in cats with most NSAIDs not approved for use in cats. Parnell is therefore pursuing an approval for using Zydax® in cats in the U.S. and will complete pilot and pivotal safety and efficacy clinical studies in 2016 which could lead to an approval in in the U.S. and E.U. in 2017 and other markets thereafter.

Similarly, Zydax has been used in horses for many years in Australia, New Zealand, Hong Kong, Singapore, Malaysia and Dubai. Parnell is expecting to seek an approval for treating OA in horses in the U.S. and E.U.

PAR121

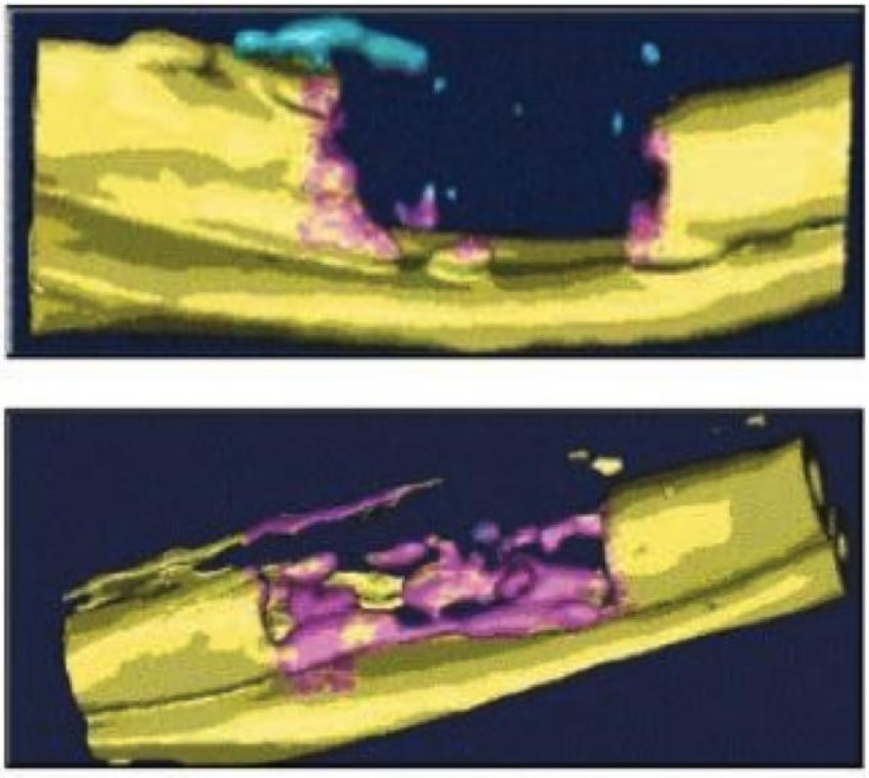
PAR121 is being developed for bone-related diseases and injuries in dogs, cats, and horses as it has been shown to significantly enhance bone regeneration post-fracture. The active ingredients in PAR121 are derived from botanical extracts of plants native to the Cook Islands, as according to the company these plants have been applied to bone fractures as a natural remedy for hundreds of years. These plants are the subject of patent applications (and grants) by CIMTECH Pty Ltd, for which Parnell holds exclusive worldwide rights.

There are currently no drug treatments available to aid in bone healing. If recovery could be accelerated, performance animals could return to competition sooner and pets with fractures could become mobile sooner. In recent years, Bone Morphogenic Proteins (BMPs) have entered the human market. BMPs are applied directly to the bone during surgery to promote bone healing, however PAR121 could potentially be a superior product as it would not require direct placement on the bone during surgery but may offer similar efficacy in bone healing.

Approximately $1.5 billion is spent each year on surgical intervention in dogs that ultimately require a cast. The recovery time for these animals typically lasts several weeks, during which time the dog must be immobilized and forced to wear lampshade devices to keep them from chewing on the cast. Any opportunity to minimize the recovery time following a fracture or other orthopedic surgery would be of considerable interest to the owner as it would increase the animal's quality of life and minimize the disruptions associated with post-surgical care.

An additional area of focus for PAR121 will be on the horse racing community, which is comprised of approximately 800,000 horses in the U.S. It is estimated that 70% of young racehorses will experience microfractures, with the recovery period accounting for 12,000 lost training days. A treatment that could shorten recovery times following an orthopedic injury would be well received.

Parnell has conducted multiple preclinical studies of PAR121, one of which was in a rabbit ulnar critical defect model. A critical defect is where a bone has a substantial gap (20 mm) resulting in an inability for the bone to heal naturally. Following treatment with PAR121, new cartilage and bone development was seen as early as one week after the injury, as shown in the following figure where bone healing is indicated by the purple color.



Source: Parnell Pharmaceuticals Holding Ltd.

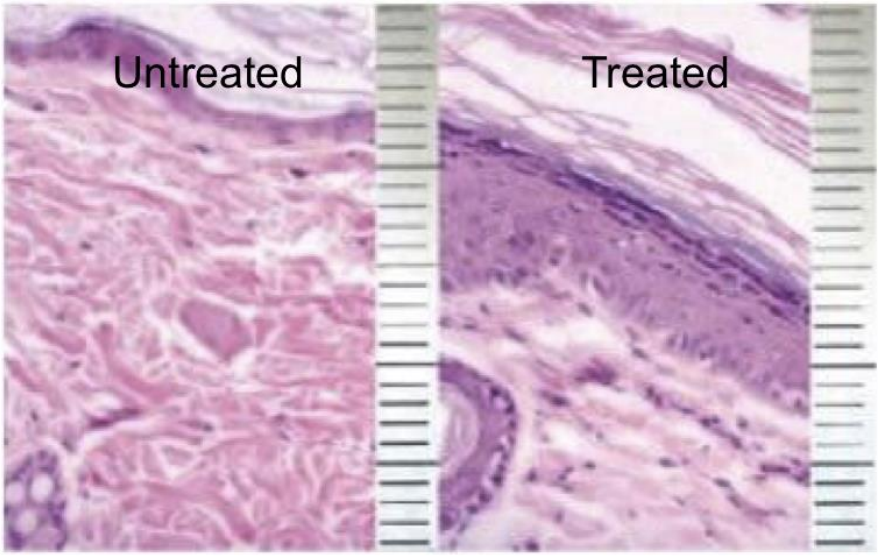
The company is planning to isolate and identify the active ingredient(s) from the plants and then develop a synthetic manufacturing process to optimize formulation development. In addition, multiple *in vitro* studies will be conducted to determine the exact mechanism of action for how PAR121 stimulates bone formation. The plan is to conduct clinical proof-of-concept studies during 2016, which could lead to completing pivotal efficacy and safety studies in 2017 and a potential FDA approval in 2018.

PAR122

PAR122 is being developed for use in Flea Allergy Dermatitis (FAD) and other dermatological conditions. FAD, which is an allergic skin reaction to flea bites, is the most common dermatological disease of dogs in the U.S. While the use of anti-flea medications has limited most dogs' exposure to fleas, once FAD develops the animal is affected for life, with just one flea bite being enough to cause excessive itching.

Treatment for FAD and other atopic dermatitis conditions is focused on reducing itching, or pruritus, which if uncontrolled can lead to excessive licking, chewing, scratching, and rubbing. The end result is typically an exposed skin wound that can ultimately lead to an infection. Glucocorticoids are usually prescribed to reduce itching, but they can result in thinning of the skin over time.

To counteract the thinning of the skin, Parnell is developing PAR122, which in preclinical models has shown the ability to increase skin thickness considerably. The following figure shows how after treatment with PAR122 there is thickening of the epithelium, which was typically an increase over 100% compared to the adjacent regions of the same animal.



Source: Parnell Pharmaceuticals Holding Ltd.

Just like PAR121, PAR122 is sourced from botanical extracts and the company has exclusive worldwide rights to the intellectual property from CIMTECH. The company is planning to isolate and identify the active ingredient(s) from the plants and then develop a synthetic manufacturing process to optimize formulation development. Clinical proof-of-concept studies are likely to initiate within the next year.

PAR081

PAR081 is a novel propofol-based product for general anesthesia and sedation in dogs and cats. Propofol is used for the induction and maintenance of anesthesia during surgery, as well as for sedation in those receiving mechanical ventilation. It has largely replaced the use of sodium thiopental for starting anesthesia due to the recovery from propofol being faster. All current formulations of propofol are based on a lipid-emulsion, which is necessary because propofol is highly insoluble in water. These lipid-emulsions are very susceptible to microbial growth due to the presence of egg and soybean lipids, thus the products typically contain antimicrobial excipients, such as benzyl alcohol. There have been reports of toxicity due to benzyl alcohol in cats, thus limiting their use. A propofol formulation that lacks antimicrobial agents can only be used once after it is opened, no matter how much is left in the vial, presenting a very economically adverse situation for the veterinarian. Lastly, the current propofol formulations are white in color, which makes it difficult to see if there are any contaminants in the vial from either

bacterial growth or other particulates. A few well publicized cases of contaminated propofol products have occurred in the U.S., which has increased preferences for a clear, transparent propofol product.

Parnell is developing a novel, water-soluble propofol-based formulation designed to overcome the aforementioned drawbacks to the current formulations. The company believes this novel formulation will allow for fewer excipients to be used and will be safe for use in both cats and dogs, while still allowing for rapid induction of anesthesia in patients. The anesthesia market is estimated to be approximately $60 million in the U.S., with a similar size market in the E.U. The company currently expects to complete formulation development studies in 2016 such that an investigational new animal drug (INAD) application can be filed with the CVM to commence target animal safety and efficacy studies. If those studies are successful, the company could be in a position for approval in late 2017.

PAR101

PAR101 is being developed for the treatment of laminitis, which is a common, debilitating, and progressive disease in horses that can result in symptoms from the slightest hint of lameness to a situation known as “sinking”, which can be fatal. Inside the hoof of a horse, the pedal, or coffin, bone is attached to the hoof wall by tissues known as laminae. Laminitis refers to the weakening of the supporting lamina within the hoof, leading to painful tearing of the support structures suspending the pedal bone within the hoof. If not treated promptly, the pedal bone can drop, or “sinks”, or the pedal bone can rotate downwards, both of which are extremely painful for the animal.

Currently, there are no products or treatments that have been approved to prevent or reverse laminitis. Treatments typically include weight loss, targeted exercise, special horseshoes, and anti-inflammatory medications. Prascend®, which is marketed by Boehringer Ingelheim GmbH, is FDA-approved for the treatment of Cushings syndrome (an endocrine disease) and pituitary pars intermedia dysfunction (PPID), both of which have been implicated in the onset of laminitis. Once a horse is initiated on Prascend® they must take it for the rest of their life, and the medication is known to have a number of adverse side effects such as low blood pressure (that can lead to fainting), irregular heart beat, and various gastrointestinal issues.

Recent results have shown a direct correlation between insulin resistance, hyperinsulinaemia, and laminitis. Screening for horses at risk for laminitis includes evaluation of body condition score, with horses and ponies having a score >6 (on a scale of 1 [emaciated] to 9 [obese], otherwise known as the equine metabolic syndrome) considered at risk, with the other risk factor being an animal with persistent, unilateral, non-weight bearing lameness.

Parnell is currently investigating various compounds that may be able to combat key predisposing factors to laminitis, such as insulin resistance and hyperinsulinaemia. One such compound, pioglitazone, increases the sensitivity of cell binding sites to insulin and has been the subject of several studies in both horses and dogs. The company believes that an effective laminitis treatment may also have applicability in treating obesity and other metabolic diseases in canines. Parnell is planning to commence proof-of-concept studies in horses for laminitis and dogs for metabolic syndrome in 2016, which could lead to pivotal safety and efficacy studies in 2017 and potential approval in late 2017.

PRODUCTION ANIMAL COMMERCIAL PRODUCTS

The company’s production animal commercial products consist of reproductive hormones (GONAbreed® and estroPLAN®) designed to improve cattle breeding performance. These products are currently available in 12 countries. Parnell was the first company to receive approval from the Food and Drug Administration (FDA) for estrous synchronization in lactating dairy and beef cows.

Systematic Breeding Programs in Bovines

Optimum reproductive performance on dairy farms is crucial to maximizing economic output. Every day that a dairy cow is not pregnant beyond 120 days past calving costs approximately $3.00 per cow per day (Penn State University College of Agriculture Sciences). For a 250 cow herd with an average of 140 days open (the time between calving and becoming pregnant), the cost would be approximately $60 per cow or $15,000 per year compared to 120 days open.

The rate-limiting step in increasing reproductive performance is failure to detect cows in heat in a timely and accurate manner. Estrous synchronization is a very valuable tool for dairy farmers as it typically leads to a decrease in the days in milk (DIM) of the herd (the longer the DIM for a cow past 120 days, the less milk that is produced), decreases the DIM at first service, and decreases the calving interval. In addition, estrous synchronization can

facilitate artificial insemination (AI), which helps eliminate the spread of sexually transmitted diseases, allows for a known date of conception (and thus, accurate dry-off dates), and reduces the risk of injury for farm workers.

The estrous cycle is a series of coordinated events regulated by hormones that allow a female to become pregnant. The cycle starts with estrus and ends with the subsequent estrus. The time between the two estrus events is typically 21 days, however it can vary between 17 and 24 days. Estrus in cattle typically lasts for 15 hours, however it may be as few as six hours or as many as 24 hours. Ovulation occurs approximately 24-32 hours following estrus. If allowed to proceed naturally, it would be necessary for dairy farmers to track each cows estrous cycle and determine when they were in estrus such that insemination could occur. The use of an estrous synchronization program circumvents the need for constant monitoring, and allows the cow's reproductive cycle to be manipulated to fit the farmer's schedule.

In order to synchronize a group of cows or heifers into heat and induce ovulation requires the administration of reproductive hormones at specific times following a standardized system. The major hormones used in these systems are:

- **Prostaglandin (PG)**: Toward the end of the estrous cycle the cow naturally produces PG to regress the corpus luteum (CL), which has been producing progesterone during the middle of the estrous cycle. When this occurs the dominant follicle is allowed to complete development and produce estrogen, which allows the cows to come into heat and ovulate. If PG is injected at the correct stage of the cycle the same sequence of events will occur.

- **Gonadotropin Releasing Hormone (GnRH)**: This is produced naturally in the brain and leads to the release of other hormones that are required for follicular development and ovulation. When injected into cattle, GnRH causes either ovulation of the dominant follicle or formation of luteal tissue within the follicle that will regress when PG is injected later.

- **Progesterone (P4)**: This hormone is produced in high levels by the CL between day 5 and 16 of the estrus cycle and works by preventing heat and ovulation. When used in estrus synchronization programs, progesterone is released slowly from an intra-vaginal device for five or seven days. This progesterone treatment before an injection of PG ensures regression of the CL in response to a PG injection because most cattle will have a CL that has developed over the seven-day period. Progesterone will also delay heat in cattle that undergo natural regression of the CL during the five or seven day period before a PG injection.

There are a number of protocols utilized to synchronize the estrous cycle and ovulation, including:

- ***Presynchronization***: Most cows will respond better to estrus synchronization if they are first presynchronized, which gets cows to the point in their cycle when they respond best to estrus synchronization. There are two common presynchronization (Presynch) protocols: 1) 2xPG, which involves two injections of PG, 14 days apart, followed by Ovsynch protocol (discussed below) 12 days later; and 2) GnRH-PG-GnRH, which requires GnRH on day 0, PG on day 7, and GnRH on day 10 followed by an Ovsynch protocol seven days later.

- ***Ovsynch***: The Ovsynch protocol was the first synchronization protocol developed for the use of timed artificial insemination (TAI). TAI is advantageous because it does not require the detection of estrus and it ensures all females are inseminated. There are two variations of Ovsynch that differ only in the timing of the final injection. Ovsynch48 requires a GnRH injection on day 0, an injection of PG 7 days later, a GnRH injection 48 hours later, and the cow is inseminated 8 to 24 hours after the final injection of GnRH. Ovsynch56 also has a GnRH injection on day 0 and an injection of PG 7 days later, however the final GnRH injection is then given 56 hours after the PG injection and the cow is inseminated 16 hours later.

- ***CIDR Synch***: A CIDR is a vaginal insert that releases P4 and can be used with either Ovsynch protocol. The CIDR is inserted at the time of the first GnRH injection and is removed when PG is injected. While the use of CIDR can increase conception rates, it also increases the cost of the protocol.

The expected pregnancy rate for the Ovsynch program is around 35%, while for the Presynch-Ovsynch program it is around 45%. The Ovsynch program takes approximately 10 days to implement, while the Presynch-Ovsynch program takes up to 38 days. The addition of the CIDR increases the conception rates of each program by approximately 5%.

Reproductive Hormone Market

According to the USDA, as of January 1, 2016 there were 92.0 million head of cattle and calves on U.S. farms, with 9.32 million of those being milk cows and 30.3 million of them beef cows. There are an estimated 100 million dairy cows globally, including 20 million in Europe and six million in Australia and New Zealand. Approximately 40 million doses of GnRH and PG are sold annually in the U.S. for approximately $80 million. The total worldwide market is estimated to be $200 million.

In the U.S., the reproductive hormone market is filled with larger competitors, while overseas these same companies compete with smaller, local firms. All manufacturers of reproductive hormones market generic products and include the following:

Zoetis: Markets Factral (GnRH) and Lutalyse (PG); have been granted FDA approval for use in estrous synchronization programs
Bayer: Markets Ovacyst (GnRH) and Prostamate (PG)
Merck: Markets Fertagyl (GnRH) and Estrumate (PG); have been granted FDA approval for use in estrous synchronization programs
Merial: Markets Cystrolenin (GnRH) but do not have a PG product

GONAbreed® and estroPLAN®

The active ingredients in Parnell's GONAbreed® and estroPLAN® are generic versions of GnRH and PG, respectively, however the company was the first to ever receive FDA approval for the use of a PG with a GnRH for use in estrous synchronization in the Ovsynch breeding program. Other companies had previously been selling the hormones "off-label" for use in estrous synchronization programs.

Included for customers who purchase GONAbreed® and estroPLAN® is a software program called *mySYNCH*, a digital tool that integrates with dairy management computer systems to allow for reporting of breeding metrics. In addition, it allows dairy producers to compare their herd's performance with those of other herds, such that they can enhance their reproductive outcomes. The combination of the company's drug products with a proprietary software platform helps to improve profitability for producers, leading to an increase in market share through a clear differentiation from larger competitors. Anecdotally, the effectiveness of the company's products coupled with *mySYNCH* was shown when a large North American dairy farm switched from a competitor's products to Parnell's and saw a 25% increase in pregnancy rates.

A field study was conducted to test the effectiveness of GONAbreed® in combination with PG to allow for fixed time artificial insemination (FTAI) in lactating dairy cows. A total of 1607 healthy, non-pregnant, lactating dairy cows within 40-150 days postpartum were enrolled in the study. 805 cows were administered GONAbreed® and 802 cows were administered an equivalent volume of water according to the Ovsynch protocol. FTAI was performed approximately 11-31 hours after the second GONAbreed® or water injection. The pregnancy rate for cows treated with GONAbreed® (33.4%) was significantly higher than the pregnancy rate in cows treated with water (13.6%) ($P < 0.0001$).

PRODUCTION ANIMAL PIPELINE PRODUCTS

GONADOPRO

GONADOPRO is a novel combination formulation of GnRH and P4 (prostaglandin) given as an intramuscular injection. Currently, P4 is only utilized in CIDRs, however GONADOPRO is expected to be given as the first injection of an Ovsynch program instead of GnRH, thereby eliminating the need for the intravaginal devices. Parnell believes that the addition of GONADOPRO could improve conception rates by 15% to 30% compared to the use of CIDRs.

While P4 delivery devices are used for seven days, Parnell believes that the administration of P4 through an injection results in an elevation of P4 for approximately 24 hours, which is sufficient to provide the hypothalamic-pituitary resetting effect and improve pregnancy rates. An injection of P4 is preferable to the intra-vaginal devices as they are impractical, uneconomic, and result in unsatisfactory animal welfare outcomes. The Presynch-Ovsynch program can deliver similar results as the use of a P4 device with an Ovsynch program, however it takes 38 days to implement. GONADOPRO, when used as the first shot in an Ovsynch program, could potentially deliver the same results but in a much shorter time frame (10 days).

Parnell has conducted a series of proof-of-concept studies that showed an injectable P4 could raise plasma levels for a sustained time that are theorized to be sufficient to deliver the progesterone priming effect. A field study was then conducted in Australia involving 363 lactating dairy cows, which were given either GONADOPRO as the first injection of the Ovsynch program or the standard Ovsynch program alone. Pregnancy rates were 10% higher in the GONADOPRO group compared to the control group.

Both ingredients in GONADOPRO have been utilized safely for a number of years in clinical cattle studies, thus Parnell is going to request a waiver for the animal safety study portion of approval. In addition, the company believes that there is little threat to the food or dairy supply from GONADOPRO due to the low dose of P4 that is administered along with its rapid metabolism. While progesterone is currently banned in the EU due to its potential use as a growth promoting substance, the fact that P4 is a naturally occurring hormone means there should little pushback in gaining approval.

PROCEPT

PROCEPT is the company's next generation breeding program that is being developed in conjunction with Dr. Milo Wiltbank, and is expected to increase absolute conception rates by 3% to 5% above the traditional Ovsynch program while still maintaining the 10-day duration of the program. The company believes this uptick in conception rates would improve profitability by as much as $4,200 per year for every 300 dairy cows. PROCEPT is closely related to Ovsynch, uses the company existing products estroPLAN® and GONAbreed®, but uses an enhanced delivery framework to maximize reproductive outcomes. Parnell has filed for a method of use patent that would cover the process in which the drugs are utilized, and because the drugs are already approved, the company does not expect to have to obtain regulatory approval.

PAR061

PAR061 is being developed for the treatment of mastitis, which is a bacterial infection of the udder that usually occurs in lactating animals and is generally considered to be the most costly cow disease. Intramammary infections are often described as subclinical or clinical mastitis. Subclinical mastitis involves the presence of an infection without apparent signs of local inflammation or systemic involvement. All dairy herds have cows with subclinical mastitis, however the prevalence of infected cows varies significantly from herd to herd. Clinical mastitis can result in injury to the milk secreting tissues and various ducts throughout the mammary gland by toxins produced by invading bacteria. In addition, the elevated leukocytes produced in response to the infection can lead to a reduction in milk quality and alter milk composition.

The treatment for clinical mastitis involves an intramammary infusion of antibiotics. This is a very labor-intensive procedure that requires workers to clean the infected teat with an alcohol swab prior to insertion of a cannula that contains the antibiotic. Due to the high rate of mastitis, it has been standard protocol for most dairy farms to use prophylactic antibiotic treatment on all cows during the "drying off" period, which is a period of time prior to calving where lactation is stopped. This allows the cow time to recover before entering another lactation cycle.

In the U.S., sales of dry cow therapy products are estimate to be approximately $50 million per year, and according to Parnell the global market is approximately $400 million per year. The market is currently dominated by individual, one-per-teat infusion tubes that contain various β-lactam or cephalosporin antibiotics. The following chart summarizes the different products that are currently available:

Drug	Company	Active Ingredient(s)
ALBADRY PLUS®	Zoetis	Novobiocin sodium Penicillin G procaine
DRY-CLOX®	Zoetis	Cloxacillin benzathine
ORBENIN-DC®	Merck Animal Health	Cloxacillin benzathine
SPECTRAMAST® DC	Zoetis	Ceftiofur Equivalents (as the hydrochloride salt)
ToMORROW®	Boehringer Ingelheim GmbH	Cephapirin benzathine

Source: Parnell Pharmaceuticals

Mastitis causes a significant financial impact based on the loss of milk production, drug and treatment costs, replacement of cows with chronic mastitis infections, and the extra labor required to manage infected cows. It is estimated that the total annual cost of mastitis is approximately $300 per cow per year in the U.S. Based on a national herd size of approximately 9.3 million dairy cows that represents a total economic burden from mastitis of approximately $2.8 billion per year.

Parnell is developing PAR061 for the treatment of mastitis in dairy cows. PAR061 is a novel injectable antimicrobial prodrug, which means that the drug is inactive until it is injected into the cow and metabolized to the active ingredient. There are currently no antimicrobial agents approved for systemic administration to treat mastitis in dairy cows due to the fact that those drugs are inefficient at crossing from the bloodstream into the udder. Parnell currently has a series of compounds that they believe possess the proper pharmacokinetic profile and required anti-microbial characteristics. Each of the compounds could have patentable claims as new analogues of β-lactam antibiotics. The company will be performing additional *in vitro* studies by testing the compounds against the major pathogens that cause mastitis to determine which compound to move forward into animal testing.

MANUFACTURING FACILITY

Parnell has a 33,000 square foot FDA and E.U. approved, sterile injectable manufacturing facility that is located in Sydney, Australia. The advantages offered by the facility include a reliable source of low-cost manufacturing for the company's own products and the ability to bring new products to market more quickly since there is no reliance on third-party contract manufacturing organizations (CMOs). The company estimates that there is approximately 75% spare capacity at the facility, which can be utilized through lucrative contract manufacturing opportunities. We anticipate the company entering into at least two such contracts during 2016.

FINANCIALS AND CAPITAL STRUCTURE

As of December 31, 2015, the company had AUD$5.7 million in cash and cash equivalents and AUD$14.4 million in long-term debt. The company recently announced a share purchase agreement with Lincoln Park Capital Fund, LLC, whereby Parnell can sell up to 35,000 (or 55,000 under certain circumstances) shares of common stock on any one day to Lincoln Park. Parnell has complete control over the timing and amount of any sale to Lincoln Park and could elect to sell up to a maximum of USD$15 million of ordinary shares over a 36-month period. In support of Lincoln's Park support for Parnell's growth prospects, the company recently announced that Lincoln Park purchased 175,000 unregistered shares of common stock at $3.50 per share, which was a 10% premium to the closing price on February 23, 2016. In addition, Lincoln Park received the option to purchase for cash consideration up to a further 150,000 shares at $5 per share within a five-year period.

Parnell went public on the NASDAQ in June 2014 and currently has 13.3 million shares of common stock outstanding. Chairman Alan Bell, CEO Robert Joseph, and CFO Brad McCarthy and their families and friends collectively own approximately 62.5% of the outstanding shares. Of the 5 million shares that were issued under the IPO, over 30% of these are held by major institutional investors including Fidelity, Blackrock, Invus, and several family offices of high net worth individuals. The company has indicated that the lack of liquidity in the stock is due to the small amount of available shares that are not held by insiders and institutional investors involved in the IPO. The purchase share agreement with Lincoln Park was therefore intended to allow the company to release small amounts of new shares into the market at the company's discretion, which should help to increase liquidity.

RISKS

Zydax® May Not Gain Approval in the U.S.: The company has completed all regulatory filings required by the FDA to seek approval for Zydax® in the U.S. Typically, it takes two 180-day cycles to complete the review of all sections of the filing, thus the first response from the FDA will most likely be a request for additional information. However, there is no guarantee that the FDA will approve Zydax® after the second 180-day review cycle, and with the infrastructure already put in place by the company any delay in getting Zydax® approved could have a detrimental effect on the company's operations.

Competition: Parnell's reproductive hormones face competition from a number of larger pharmaceutical companies that may be difficult for Parnell to compete with in terms of pricing or additional offerings.

Pipeline Development: The company has six products in its pipeline that will necessitate safety and efficacy trials being conducted in order to seek regulatory approval. There is no guarantee that the company will be able to successfully develop any of those products, which could have a meaningfully adverse effect on the company's future revenues.

Liability: As with any drug developer, Parnell is at risk for potential product liability lawsuits associated with adverse events caused by the company's products. These adverse events may not have been detected in the company's clinical trials and may only present themselves through future commercial experience, and could prompt the removal of the causative product from the market.

Intellectual Property: The company does not have patent protection covering all of its commercial products and pipeline assets. The reproductive hormones are available as generics and there is no intellectual property covering its nutraceutical products. The company has made multiple patent filings for Zydax, PAR121, and PAR122. Patents have been granted in many markets but are still under review in the U.S. and E.U.

MANAGEMENT PROFILES

Mr. Robert Joseph – President and Chief Executive Officer
Mr. Joseph assumed the role of President and Chief Executive Officer in 2006. Along with Chief Financial Officer Brad McCarthy, Robert has raised over $90 million to develop two of Parnell's drug products and digital technology platforms and to construct a new sterile manufacturing facility. Robert started his finance career in the manufacturing operations of Australian-based Herron Pharmaceuticals before joining Allergan in their Sydney office as the Financial Planning and Analysis Manager. Robert then made the switch to commercial operations at Eli Lilly as the Strategic Marketing Manager then moved to the Indianapolis global headquarters where he was part of the Global Diabetes Marketing team responsible for the highly successful launch of Lilly's insulin products and drug delivery devices. Mr. Joseph has undergraduate degrees in Medicine, Finance, and Marketing and is a qualified CPA.

Mr. Brad McCarthy – Chief Financial Officer and Chief Operating Officer
Mr. McCarthy joined Parnell as Chief Financial Officer in January 2010, and in 2012 assumed the additional role of Chief Operating Officer of Parnell Manufacturing. He commenced his career as one of the first employees to join Volkswagen Group Australia in the finance team before moving to London and commencing a six-year stint at SIRVA Inc., the largest removals and relocation organization in the world. As VP of Forecasting Planning and Analysis; Europe, Mr. McCarthy was responsible for 13 European countries with a turnover of $US350M. Mr. McCarthy has an undergraduate degree in Science, majoring in Physiology and Pharmacology before completing degrees in Business Administration and Commerce as well as his CPA.

Mr. Wes Dittmer – Senior Vice President & CFO, North America
Mr. Dittmer brings over two decades of finance and accounting leadership experience, having held executive positions at both public and private companies including AgJunction, NRTC, Embarq, and NovaCare. He most recently was the CFO for AgJunction where he oversaw Finance, IT, Human Resource, and Investor Relations. Previously, he served as the CFO for NRTC, Vice President of Corporate Development with Embarq, and Controller for NovaCare. Additionally, Mr. Dittmer has an extensive background in capital formation, mergers and acquisitions, and operations in senior roles at Sprint. He is a Certified Public Accountant and holds a BA in Accounting from the University of Missouri and an MBA in Finance from Rockhurst University.

Mrs. Jennifer Lindsey – Vice President, Global Marketing
Mrs. Lindsey brings 23 years of international strategy development and marketing experience in the areas of food ingredients and products for humans and companion animals, as well as human supplements. Prior to joining Parnell, Mrs. Lindsey was the Global Lead – Strategic Planning & Product Marketing for the Health division of DuPont Nutrition and Health. She held the positions of Director of Marketing for the NAFTA region, as well as various commercial lead positions in Product Management, Global Industry Management, and technical lead positions in Product Development and Sensory science. Mrs. Lindsey has a BS in Food Science & Human Nutrition with emphasis in Sensory Science and Biochemistry from the University of Missouri-Columbia.

Mr. Andy Ferrigno – Vice President, Global Sales
With an MBA from the University of Tampa, Mr. Ferrigno had a successful 20-year career with Novartis Animal Health, holding a number of increasingly senior commercial roles within the US and International markets. In the US, he has held the positions of Director of Marketing in companion animal therapeutics; Director of Business Development and Licensing for North America, and, most recently; Vice President of the companion animal sales team. Internationally, Mr. Ferrigno spent nearly three years in Australia/New Zealand, leading the farm and companion animal sales teams.

Mr. Doug Pettes – Vice President, Digital Technology
Mr. Pettes has over 20 years' experience in leading Information Technology initiatives for large and small corporations managing million-dollar projects for Fortune 500 and mid-sized companies. He began his career developing e-commerce applications for the financial services industry and then was a Senior Manager with Ernst & Young. Prior to joining the Parnell team, Mr. Pettes was Global Delivery Director for Ciber Inc. where he managed software development teams from across the world for US customers. Mr. Pettes has a BA and Masters degree in Information Systems from the University of Kansas.

Mrs. Karen Greenwood – Vice President, Research and Development

Mrs. Greenwood is an experienced Research and Development scientist with 26 years in the pharmaceutical industry including senior roles at Zoetis (formerly Pfizer Animal Health). She has a track record of directing the development of highly valuable pharmaceutical products from idea to commercialization including recent success on the Apoquel® project. She also has experience in developing leading livestock, parasitology and companion animal projects. Mrs. Greenwood has a degree in Biochemistry from the University of Southampton, has served on various scientific grant review boards, and is an author on multiple publications.

Mr. Lee Whaley – Vice President, Regulatory

Mr. Whaley has more than 21 years of animal drug industry experience, with his first six years spent in Clinical Research/Project Management and the past 15 years in various roles of increasing responsibility within Regulatory Affairs. He began his career with Intervet in 1994 and subsequently held regulatory managerial roles at Novartis and Merck Animal Health, managing regulatory teams devoted to product registration and stewardship. Prior to joining Parnell, Mr. Whaley was most recently the Director of US/Canadian Regulatory Affairs at Norbrook. He received an A.A. degree in Livestock Management and Technology, a B.S. in Animal Science, and an M.S. in Physiology (specializing in Swine Reproduction) from North Carolina State University.

Mr. Leonardo Avendano – Vice President, Manufacturing

Mr. Avendano is the Vice President of Manufacturing based in Sydney, Australia responsible for managing global manufacturing operations including contract manufacturing. He began his career in the medical device sector in 1996 with Becton Dickinson, Mexico before moving to France for two years and then to the U.S. completing certification in Lean Manufacturing and Six Sigma. In 2004, Mr. Avenado was promoted to Plant Director for one of Becton Dickenson's plants in Mexico, responsible for over 300 staff. In 2010, he immigrated to Sydney where he initially worked for Cochlear Ltd. in the Quality Leadership Team and in 2012 he joined Parnell. Mr. Avenado holds a Bachelor's degree in Science, majoring in Mechanical and Electrical Engineering from ITESM Mexico.

VALUATION AND RECOMMENDATION

We are initiating coverage of Parnell Pharmaceuticals Holdings Ltd. (PARN) with a Buy rating and an $11 price target. Parnell is a fully integrated specialty pharmaceutical company focused on the development of novel medications for both the production and companion animal markets. The company currently promotes five products across 14 countries, including the U.S. The lead products include two bovine reproductive hormones (GONAbreed® and estroPLAN®) and a prescription medication to treat osteoarthritis in canines (Zydax®), which is currently under review by the FDA with approval expected in the fourth quarter of 2016.

In 2012, U.S. consumers spent an estimate $53 billion on their pets, which was an increase of 36% from 2006. Parnell is well-suited to take advantage of the growing animal health market based on a number of factors:

- **Established Commercial Model Ready to Enter the U.S.**: For the year ended December 31, 2015, Parnell reported total revenues of AUD$13.2 million, which was a 58% increase over the same time period in 2014. In addition, the U.S. production animal business nearly tripled. The company has established a sales team for the U.S. companion animal sector ahead of the expected launch of Zydax® later in 2016.

- **Differentiation Through Add-on Technology Resources**: Parnell has sought to differentiate itself from other animal health companies through the use of two technology platforms, *mySYNCH* and *Fetch*. *mySYNCH* is a digital tool that integrates with existing dairy management computer systems to allow for breeding optimization that can lead to improved economic outcomes. *Fetch* is a digital customer application that can be used by dog owners at home to monitor the progress of their pet while on Zydax®. No other animal health company has similar applications and we view these tools as a clear differentiator for Parnell.

- **Large Pipeline of Products Set to Enter the Market Over the Next Few Years**: The company is currently focused on getting Zydax® approved in the U.S., which should be a meaningful growth driver. After Zydax®, Parnell has six other products in development that could be launched over the next two to three years.

Valuation Methodology

We value Parnell using a discounted cash flow model that takes into account our revenue and expense forecasts both for the compounds currently on the market as well as those in development. We utilize a DCF model as it accounts for the company's rapid growth prospects following the approval of Zydax® as well as the expected introduction of a number of other compounds to the market over the next two to three years.

Growth in the companion animal product group will be driven by Zydax®, which we model for approval toward the end of 2016. We model for revenues in the companion animal group of $4.3, $6.7, and $23.0 million in 2016, 2017, and 2018, respectively. We believe Parnell will introduce an additional four products by 2018 in the form of PAR121, PAR122, PAR081, and PAR101.

The production animal market is likely to experience slower growth than the companion animal group, however our model calls for double-digit growth in sales of estroPLAN® and GONAbreed®, with the introduction of GONADOPRO and PAR061 in 2018 and 2019, respectively. We model for sales in the production animal market of $14, $16.4, and $22.4 million in 2016, 2017, and 2018, respectively.

Our model calls for the company to become cash flow positive in 2018, which we believe will be driven both by the introduction of new products and increased sales growth for currently marketed products. We apply an 18% discount rate to future cash flows, which yields a net present enterprise value of $170 million. After accounting for the company's cash and debt we arrive at a net present market cap of $145.5 million, and when divided by the fully diluted share count of approximately 13.3 million shares results in a fair value of approximately $11 per share and we are assigning a 'Buy' rating to the shares.

PROJECTED FINANCIALS

Parnell Pharmacueticals Holdings Ltd.
Income Statement (all values in AUD$)

Parnell Pharmaceutical Holdings, Inc. (in AUD$)	2015 A	Q1 E	Q2 E	Q3 E	Q4 E	2016 E	2017 E	2018 E
Companion Animal	$2.10	$1.00	$1.00	$1.10	$1.20	$4.30	$6.70	$23.00
YOY Growth	*50%*					*104.7%*	-	-
Production Animal (U.S.)	$8.08	$2.50	$2.50	$2.50	$2.50	$10.0	$11.00	$15.20
YOY Growth	*251%*					*23.7%*	-	-
Production Animal (RoW)	$2.99	$1.00	$1.00	$1.00	$1.00	$4.00	$5.40	$7.20
YOY Growth	*-38%*					*34.0%*	-	-
Contract Manufacturing	$0.00	$0.00	$1.50	$1.50	$0.00	$3.00	$7.50	$7.80
YOY Growth	*#DIV/0!*					*#DIV/0!*		
Other Income	$6.73	$1.50	$1.70	$1.90	$2.00	$7.10	$7.50	$8.00
YOY Growth	*20%*	-	-	-	-	*5.6%*	-	-
Total Revenues	**$19.89**	**$6.00**	**$7.70**	**$8.00**	**$6.70**	**$28.4**	**$38.1**	**$61.2**
Total Group Revenues	**$13.17**	**$4.50**	**$6.00**	**$6.10**	**$4.70**	**$21.3**	**$30.6**	**$53.2**
YOY Growth	*57%*	-	-	-	-	*62%*	*44%*	*74%*
Cost of Sales	$7.7	$2.3	$2.3	$2.3	$2.3	$9.0	$10.8	$15.0
Product Gross Margin	*82%*	*79%*	*84%*	*84%*	*80%*	*82%*	*82%*	*82%*
Selling and Marketing Expenses	$11.8	$3.1	$3.1	$3.3	$3.5	$13.0	$14.3	$15.7
Regulatory Expenses	$0.9	$0.2	$0.3	$0.3	$0.3	$1.0	$1.0	$1.0
Administrative Expenses	$11.9	$3.0	$3.0	$3.2	$3.3	$12.5	$12.8	$13.0
Net Foreign Exchange Losses on Borrowings	$0.0	$0.2	$0.3	$0.3	$0.2	$1.0	$0.0	$0.0
Finance Costs	$1.3	$0.7	$0.7	$0.8	$0.8	$3.0	$3.0	$3.0
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($13.736)	($3.470)	($1.910)	($2.130)	($3.630)	($11.100)	($3.800)	$13.470
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($13.7)	($3.5)	($1.9)	($2.1)	($3.6)	($11.1)	($3.8)	$13.5
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($13.7)**	**($3.5)**	**($1.9)**	**($2.1)**	**($3.6)**	**($11.1)**	**($3.8)**	**$13.5**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.03)**	**($0.26)**	**($0.14)**	**($0.16)**	**($0.27)**	**($0.83)**	**($0.27)**	**$0.90**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	13.284	13.300	13.400	13.400	13.500	13.400	14.000	15.000

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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