

# Parnell Pharmaceuticals Holdings Ltd Announces First Quarter Business Update

Parnell continues to grow rapidly with revenue increasing 43% for the three months ended March 31, 2016

OVERLAND PARK, Kan., April 22, 2016 (GLOBE NEWSWIRE) -- Parnell Pharmaceuticals Holdings Ltd (NASDAQ:PARN), a fully integrated, commercial-stage pharmaceutical company focused on developing, manufacturing and marketing innovative animal health solutions, today announced business results for the first quarter of 2016 including strong revenue growth of 43%, the conclusion of negotiations on a contract manufacturing agreement with a major multi-national, the upcoming launch of two new products; Luminous ™ and Reviderm™ for the companion animal market and receipt of the US Food and Drug Administration, (FDA)'s responses for the two remaining Technical Sections for Zydax for dogs in the US.

"Parnell had a fantastic first quarter in 2016 with strong revenue growth across our whole business. We were particularly pleased with our US Production business which performed above our expectations as did our Australian Companion Animal business. Our US Companion team continued to establish a strong footprint in the market with Fetch™ (our digital app) and Glyde™ (our nutraceutical for osteoarthritis, or OA). After several months of negotiations we have now agreed upon terms with a major multi-national pharmaceutical company on a contract manufacturing agreement that we expect to sign as early as next week." said Robert Joseph, President and CEO of Parnell.

Mr. Joseph went on to say, "As we previously communicated to the market, we expected to receive a response this month from the FDA on our final two major Technical Sections for use of Zydax in dogs with OA. When it comes to novel drug applications, the FDA almost invariably has clarifying questions in what is understandably a complex area for drug approvals. The FDA has posed questions in relation to both our technical sections; we have had preliminary discussions with the FDA in relation to these and believe we will be able to provide the required data and adequate responses to the FDA's questions. We remain confident in our ability to file robust data packages and, based on our current expectations, aim to file our responses with the FDA in Q2, 2016. Meeting this response timeframe would keep us on track for a potential Zydax approval in late Q4, 2016. After many years of hard work and innovation, we hope to be approaching the final stage on the path to approval for Zydax in the US. We are equally as excited to be ramping up species and geographical expansion opportunities for Zydax; for example, we are in late negotiations for the appointment of a marketing partner for Zydax in Europe and negotiations have begun for other possible markets including Canada. In 2016, we are embarking on Target Animal Safety and Effectiveness studies for the use of Zydax in Cats which we believe is a very valuable market."

"We are also excited to confirm the pending launch of two new products in the US through our companion animal team. Luminous<sup>TM</sup> is a novel nutraceutical product we have developed for use in dermatological conditions. The dermatology market has seen recent rapid expansion with the introduction of novel pharmaceuticals and, just as we have seen the success of Glyde when used in conjunction with products like Zydax, we expect Luminous to appeal to dog owners who want their dogs to have healthy skin and shiny coats. We are also proud to have recently in-licensed a novel liquid bandage product with strong antimicrobial properties called Reviderm<sup>TM</sup>. The current standard of care for wounds is the adhesive bandage. Poor tolerance causes dogs to chew bandages which can lead to complications at the wound site. We believe Reviderm offers a more elegant solution, combining antimicrobial properties that support wound healing and an impervious elasto-polymer that wears off naturally over time. Both of these product introductions will further bolster our commercial offerings in the US and Australia and position Parnell as a growing player in the valuable Companion Animal market." said Mr. Joseph.

Mr. Joseph went on to say, "Parnell has long been proud of the valuable sterile manufacturing facility we built and had approved by the FDA in 2013 and the European Medicines Agency, or EMA in 2015. With 75% available capacity, we recently commenced negotiations with several major multi-nationals to contract manufacture sterile injectable products. We have now concluded negotiations for one of these deals and expect to sign a contract as early as next week and commence manufacturing shortly thereafter. We believe this deal will bring in millions of dollars of revenue over several years. We also expect more deals to be concluded in the coming months thereby validating the multiple revenue generating opportunities Parnell's business model provides."

Unless otherwise specified, all amounts are presented in Australian Dollars (AUD).

# **Commercial Highlights**

Total Company sales growth of 43% for Q1, 2016 over the same period in 2015 as we continued to grow in our Production Animal segments while expanding our Companion Animal business in the US & Australia;

- Sales growth of 10% over the prior period in our U.S. Production Animal segment was driven by the continued success of our go-to-market strategy of clinical science leadership in the dairy reproduction segment and the continued roll-out mySYNCH®; our innovative digital technology that assists dairy farmers to improve the profitability of their operations. Most pleasing is that our "in-market sales" (sales from the distributor to producers and/or veterinarians) grew 51% as compared to Q1, 2015, demonstrating our continued strong performance in the US Production Animal segment.
- Sales for Production Animal Rest-Of-World increased 83% in Q1, 2016 compared to the same period in 2015, primarily driven by year-over-year differences in the timing of orders from our marketing partners (outside Australia and New Zealand).
- Our Companion Animal business segment continued to show increased sales growth in Q1, 2016 as a result of the expansion of our sales team and the launch of Glyde Chews and FETCH in the U.S. Companion Animal Sales increased 164% compared to the same period in 2015.
- Contract Manufacturing did not generate any revenue in Q1, 2016 but with the conclusion of negotiations on a contract manufacturing agreement we expect single digit millions in revenue to commence in Q2, 2016 and continue on an ongoing basis.
- We reiterate our 2016 revenue guidance as previously stated in our 2015 Earnings Release dated February 24, 2016.

# **Development Highlights**

- We received the FDA's response to our filings of the Target Animal Effectiveness Technical Section and the Chemistry and Manufacturing Controls Technical Section for Zydax. The FDA's Center for Veterinary Medicine has sought clarifications and responses in relation to various aspects of the filings. Parnell has discussed the major areas of these questions with the FDA and believes that adequate responses can be prepared and submitted to the FDA within Q2, 2016. This could lead to a potential approval in late Q4, 2016.
- Parnell submitted a completed dossier for the approval of Zydax in dogs in the European Union in February, 2016. This dossier was subsequently validated by the EMA review team and is now undergoing the assessment process proper. Parnell expects to receive initial responses from the EMA in Q3, 2016.

#### **Corporate Highlights**

- Continued negotiations with multiple parties to acquire the rights to market Zydax<sup>®</sup> in Europe, with a deal expected to be completed in Q2, 2016.
- Completed the in-licensing of Reviderm<sup>™</sup>, a novel antimicrobial liquid bandage for use on wounds in dogs, cats and horses.
- Completed negotiations on a contract manufacturing agreement with a major multi-national and progressed several other contract manufacturing opportunities which may complete in Q2, 2016.
- Completed a private placement with Lincoln Park Capital Fund, LLC, a Chicago-based institutional investor ("Lincoln Park") to purchase 175,000 of our ordinary shares at \$3.50 per share and 150,000 warrants to purchase our ordinary shares at a purchase price of \$5.00 per share. In addition, in January, 2016 we entered into a separate share purchase agreement with Lincoln Park which is structured as an equity commitment and enables us to elect entirely at our discretion to sell up to 35,000 shares (and under certain circumstances up to 55,000 shares) on any one day to Lincoln Park. Parnell commenced using this facility in small volumes in late March which appears to have contributed to an increase in daily share trading volume and thereby meeting our principal objective of entering into this agreement; to improve the liquidity of our stock trading.
- Negotiated key terms for a senior debt facility of approximately \$US30 million that is expected to complete, subject to final terms, in the coming month.
- Appointed Will Hunsinger to our Board of Directors on April 20, 2016. Mr. Hunsinger has been added to the Board based on his substantial experience in the technology industry, having previously been responsible for re-launching the e-commerce business for Gap, Banana Republic and Old Navy clothing retailers and then having worked with TPG Capital as an advisor and executive in various companies invested-in by TPG. Mr. Hunsinger also founded the social -mobile app company, SportStream which he successfully sold to Facebook Inc. Parnell is excited to have a technology executive of Mr. Hunsinger's caliber and capability join the Board and his appointment underpins a strong

focus on developing FETCH and mySYNCH® as pivotal commercialization strategies.

### Operating Revenue Results (for the three month period ended March 31, 2016)

Total revenues increased by 43% for the three month period ended March 31, 2016, to \$2.2 million, compared to the same period in 2015, with continued strong growth in our major markets.

Our operating segments performed as follows:

- Production Animal U.S.: Sales for the three months ended March 31, 2016 were \$1.3 million, an increase of \$0.1 million, or 10%, over the same period in 2015.
- Production Animal Rest of World (ROW): Revenues for the three month period ended March 31, 2016 increased by 83% to \$0.3 million compared to the same period in 2015.
- Companion Animal Companion Animal product sales for the three months ended March 31, 2016 increased to \$0.6 million, or 164%, compared to the same period in 2015.
- We did not undertake contract manufacturing in Q1, 2016 or 2015.
- As of March 31, 2016, cash and cash equivalents of \$3.9 million compared to \$5.7 million at December 31, 2015.

#### **Conference Call Information**

Management will host a conference call on April 22, 2016 at 8:00 a.m. ET to discuss business performance for the first quarter. Investors and analysts may access the conference call by dialing (877) 244-6184 (U.S./Canada) or (920) 663-6271 (International) and using the conference ID# 95345198.

A telephone replay will be available for one week following the call by dialing (855) 859-2056 (U.S./domestic) and (404) 537-3406 using the conference ID# 95345198.

### **About Parnell**

Parnell (PARN) is a fully integrated, veterinary pharmaceutical company focused on developing, manufacturing and commercializing innovative animal health solutions. Parnell currently markets five products for companion animals and production animals in 14 countries and augments its pharmaceutical products with proprietary digital technologies — FETCH<sup>TM</sup> and mySYNCH®. These innovative solutions are designed to enhance the quality of life and/or performance of animals and provide a differentiated value proposition to our customers. Parnell also has a pipeline of 7 drug products covering valuable therapeutic areas in orthopedics, dermatology, anesthesiology, nutraceuticals and metabolic disorders for companion animals as well as reproduction and mastitis for cattle.

For more information on the company and its products, please visit www.parnell.com.

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

This press release contains forward-looking statements and information within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Words such as "may," "anticipate," "estimate," "expects," "projects," "intends," "plans," "develops," "believes," and words and terms of similar substance used in connection with any discussion of future operating or financial performance identify forward-looking statements. Forward-looking statements represent management's present judgment regarding future events and are subject to a number of risk and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks include, but are not limited to, risks and uncertainties regarding Parnell's research and development activities, its ability to conduct clinical trials of product candidates and the results of such trials, as well as risks and uncertainties relating to litigation, government regulation, economic conditions, markets, products, competition, intellectual property, services and prices, key employees, future capital needs, dependence on third parties, and other factors, including those described in Parnell's Annual Report on Form 20-F filed with the Securities and Exchange Commission, or SEC, on March 4, 2016, along with its other reports filed with the SEC. In light of these assumptions, risks, and uncertainties, the results and events discussed in any forward-looking statements contained in this press release might not occur. Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this press release. Parnell is under no obligation, and expressly disclaims any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events, or otherwise.

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