Parnell Pharmaceuticals Holdings Ltd Announces Third Quarter Business Results

Parnell Continues to Grow Rapidly With Revenue Increasing 55% for the Nine Months Ended September 30, 2015

OVERLAND PARK, Kansas, Oct. 21, 2015 (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 third quarter of 2015 and nine months ended September 30, 2015.

"Quarter three has been another great period of execution for Parnell, delivering significant revenue growth and, as we promised, continued delivery on milestones we have outlined to our investors," said Robert Joseph, President and Chief Executive Officer of Parnell Pharmaceuticals Holdings Ltd. "For the nine-months ended September 30, 2015 revenues increased 55% to $8.5M compared to the same period in 2014. During the third quarter we were proud to deliver on the US launch of Glyde Chews®, our nutraceutical product for dogs with osteoarthritis (OA) and FETCH®, our innovative digital technology that assist veterinarians and dog owners to more effectively identify and manage OA. This successful launch was the culmination of establishing a 55-person sales and marketing team dedicated to commercializing our best-in-class products in the US Companion Animal market. We are also excited to announce that we have submitted to the FDA all remaining sections of our Zydax filings and will soon submit the same in the EU. Finally our contract manufacturing business opportunities are materializing at an even faster rate than we anticipated and we expect to make announcements in the near future."

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

Commercial Highlights

- Significant sales growth of 283% in our U.S. Production Animal segment driven by the continued success of our go-to-market strategy and the initial roll-out in September, 2015 of mySYNCH®; our innovative digital technology that assists dairy farmers to improve the profitability of their operations. The ongoing success of our commercialization model saw our market share reach 9% in September, 2015, its highest level since our launch.
- Sales for Production Animal Rest-Of-World declined 36% in the first nine months of 2015 compared to the same period in 2014, primarily driven by year-over-year differences in the timing of orders from our marketing partners (outside Australia and New Zealand). In Australia and New Zealand, where declining milk prices are causing some headwinds, we expect the upcoming launch of a new version of mySYNCH® to improve sales next breeding season (2016) as the efficiency of breeding programs are even more important during periods of low milk prices. In Canada, although in-market sales year-to-date are up 12% over the same period in 2014, the timing of orders to our Canadian marketing partner will differ in 2015 such that our ex-Parnell sales to Canada will decline year on year.
- Our Companion Animal business segment continued to show increased sales growth in Q3, 2015 as a result of the expansion of our sales team and the launch of Glyde Chews and FETCH. Year-to-date our Companion Animal business segment sales are now up 10% compared to the same period in 2014 and we expect this trend to increase through the end of 2015 and beyond.
- Contract Manufacturing negotiations advanced substantially within the quarter and continue to proceed faster than our initial expectations. We are hopeful of making announcements about these opportunities in the coming months and we expect to generate immediate revenues.

Development Highlights

- The Company has now completed the submission of all remaining sections of the Zydax filings to the Center for Veterinary Medicines (CVM) of the US FDA.
  - This included submission of a Veterinary Master File, relating to the Active Pharmaceutical Ingredient (API) for Zydax by Parnell and our development partner Lonza. We also finalized the terms of a Manufacturing Services Agreement with Lonza which will now see the commencement of the manufacture of API that will be used in the commercial launch of Zydax in the US and EU in 2016.
  - We also submitted the Chemistry and Manufacturing Controls filing with the CVM as well as the Target Animal Efficacy submission.
  - As we have communicated previously, we anticipate that it typically takes two 180-day cycles with the CVM to complete all reviews and we therefore expect the approval of Zydax in the US in October, 2016.
  - We are in the process of translating our US filings to an EU submission which requires obtaining Expert Opinions from an independent European consultant and expect to file with the EMA in December, 2015 and anticipate
approval in Q4, 2016.

- We appointed Karen Greenwood as Vice President of R&D in quarter three. Karen comes to us from a very successful career at Zoetis, recently working on the Apoquel® project. Karen has made immediate advancements on several projects.
- In relation to PAR121 and PAR122; our development compounds for bone healing and wound healing respectively, through CIMTECH (the licensor) we received a grant from the United Nations under the Nagoya Protocol for up to US$1 million to develop infrastructure in the Cook Islands to transform the botanical extracts which make up the precursor for the anticipated drug substances in PAR121 and PAR122. This grant is expected to accelerate our development activities and we look forward to achieving milestones for these highly innovative compounds.

Corporate Highlights

- Further expanded our leased facilities in Overland Park, KS to accommodate the growth in our sales team and other staff.
- Negotiations continued with multiple parties to acquire the rights to market Zydax® and Glyde® in Europe and Asia with a deal expected to be completed in the coming months.
- We continue to assess multiple in-licensing opportunities, including several products that could be swiftly taken to market by our Companion Animal sales team. We expect to make announcements in the near future regarding in-licensing programs.

Operating Results (for the three and nine-month periods ended September 30, 2015)

Total revenues increased by 357% and 55% for the three and nine month periods ended September 30, 2015, compared to the same periods in 2014, with continued strong growth in our major markets.

Our operating segments performed as follows:

- Production Animal - U.S.: Sales for the three months ended September 30, 2015 were $2.5 million, an increase of $2.1 million, or 494%, over the same period in 2014. Sales for the nine months ended September 30, 2015 increased by $4.0 million, or 283%, to $5.4 million, compared to the nine months ended September 30, 2014.
- Production Animal - Rest of World (ROW): Revenues for the three month period ended September 30, 2015 increased by 185% to $0.5 million compared to the same period in 2014. Revenue for the nine month period ended September 30, 2015 declined by $1.1 million, or 36%, compared to the same period in 2014.
- Companion Animal product sales for the three months ended September 30, 2015 increased to $0.5 million, or 223%, compared to the same period in 2014. Sales increased to $0.1 million, or 10%, for the nine months ended September 30, 2015 compared to the same period in 2014.
- We did not undertake contract manufacturing during 2015 or 2014. In 2015, we are focused on identifying revenue-generating opportunities that will, taking advantage of the currently estimated 75% available production capacity in our FDA-inspected sterile manufacturing facility. We anticipate making announcements in regards to these opportunities in the near future.

Net loss for the three months ended September 30, 2015 was $2.4 million compared to a loss of $1.5 million in the same period in 2014. The increased net loss is primarily attributable to the costs associated with the development of our US Companion Animal team during Q3, 2015.

Net Loss for the nine months ended September 30, 2015 was $5.4 million compared to a net loss of $14.4 million for the nine months ended September 30, 2014. The decrease in net loss was primarily driven by re-assessment of previously held provisions, recognition of $3.0 million of income tax expense in 2014 not recognized in 2015 and non-recurring costs associated with our initial public offering and debt transactions of approximately $4.8 million in 2014. Additionally, we experienced substantial revenue growth in 2015 which was partially offset by increased headcount added in the third quarter and increased compliance costs associated with being a public company.

Earnings per share for the three and nine months ended September 30, 2015 was a loss of ($0.18) and ($0.41) respectively, compared to a net loss per share of ($0.11) and ($1.43) in the same respective periods of 2014.

As of September 30, 2015, Parnell had cash and cash equivalents of $13.3 million compared to $17.2 million as of September 30, 2014.

Key Figures

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Conference Call Information

Management will host a conference call on October 21, 2015 at 8:00 a.m. ET to discuss business performance for the third 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# 58797556.

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# 58797556.

About Parnell

Parnell (NASDAQ:PARN) is a fully integrated 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 software platforms - iKAM and mySYNCH. These innovative technology solutions are designed to enhance the quality of life and/or performance of animals, while driving customers' operational efficiency and profitability. Parnell distinguishes itself in the industry by providing value-added solutions that position the Company as a true partner to their customers.

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 Reform Act of 1995. Words such as "may," "anticipate," "estimate," "expects," "projects," "intends," "plans," "develops," "believes," and words and terms of similar substance used in connection with any discussion of future operating or financial performance identify forward-looking statements. Forward-looking statements represent management's present judgment regarding future events and are subject to a number of risk and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks include, but are not limited to, risks and uncertainties regarding Parnell's research and development activities, its ability to conduct clinical trials of product candidates and the results of such trials, as well as risks and uncertainties relating to litigation, government regulation, economic conditions, markets, products, competition, intellectual property, services and prices, key employees, future capital needs, dependence on third parties, and other factors, including those described in Parnell's Annual Report on Form 20-F filed with the Securities and Exchange Commission, or SEC, on September 15, 2014, along with 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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