

Parnell Pharmaceuticals Holdings Ltd Announces Business Results Update

Parnell continues strong revenue growth increasing 13% for the three months ended March 31, 2017

OVERLAND PARK, Kan., May 24, 2017 (GLOBE NEWSWIRE) -- Parnell Pharmaceuticals Holdings Ltd (OTC:PARNF), a fully integrated, commercial-stage pharmaceutical company focused on developing, manufacturing and marketing innovative animal health solutions, today announced an update on business results including strong revenue growth of 13% and substantial improvement in profitability for the first quarter, the recent conclusion of negotiations on a contract manufacturing agreement with a major multi-national and refiling of Zydax submissions in the US and Europe.

"Parnell has had another strong start to the year with revenue growth continuing at the same pace across our whole business. Our US Production Animal business continues to grow strongly ex-Parnell and in-market sales off the back of the continued roll out of mySYNCH® and our Companion Animal business is growing strongly in the US and Australia off the back of the continued roll out of FETCH®. We have been negotiating several contract manufacturing deals and expect to commence the technology transfer phase on a major multi-year, multi-million dollar deal in the coming days and we are hopeful of securing one or more additional contracts this year. We believe this will elevate our contract manufacturing business into a very profitable and sought after business.

Mr. Joseph went on to say, "As we previously communicated to the market, we completed the refiling process of our Zydax dossier in Europe for all technical sections (Safety, Efficacy and Manufacturing) and expect initial comments in mid-July. If this application progresses to completion, we could expect an approval of Zydax in Europe in Quarter 4, 2017. We also filed with the FDA our Chemistry and Manufacturing section and the Drug Master File for Zydax in the USA and expect a response on this section in approximately November 2017. We expect to complete a currently running study on Zydax in late June 2017 and anticipate refiling the Efficacy section very shortly thereafter which would lead to a response from the FDA in December, 2017. We remain optimistic about the opportunity for Zydax and as we observe the osteoarthritis market first hand through our sales of Glyde® we believe that Zydax has the potential to be a high revenue product in multiple species in multiple countries".

Mr. Joseph added, "In the fourth quarter of 2016 we initiated a major focus on rapidly improving the profitability of Parnell by refocusing investments on high opportunity projects and reducing the costs associated with being a public company. Just in the first quarter of 2017 we reduced our operational expenditure by \$3.6 million compared to the same period in 2016. We continue to expect that we will return to EBITDA profitability in 2017 and with both continued product and contract manufacturing revenue growth we anticipate to deliver a strong profit result in 2018."

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

Commercial Highlights

• Total Company sales growth of 13% for Q1, 2017 over the same period in 2016, as we continued to grow in our Production Animal segments while expanding our Companion Animal business in the US & Australia;

- ⁱ Sales growth of 12% over the corresponding period in 2016 in our Production Animal segment was driven by the continued roll out of our strategy of clinical science leadership and differentiation through the use of mySYNCH®; our innovative digital technology that assists dairy farmers to improve the profitability of their operations. We also improved the profitability of this segment to a contribution margin of over 50+%.
- Our Companion Animal business segment grew 13% in Q1, 2017 as a result of the continued roll out of FETCH in the U.S. and Australia. Notably, our profitability of this segment has improved markedly from Q1, 2016 with a right-sizing of the sales force, resulting in reduced operating expenses of \$1.8 million in this segment compared to the same period in 2016, and a larger focus on the use of FETCH to drive demand realization.
- Contract Manufacturing did not generate any revenue in Q1, 2017 but with the conclusion of negotiations on a new contract manufacturing agreement we expect single digit millions in revenue to commence in Q2, 2017 and continue on an ongoing basis each quarter.

• We reiterate our 2017 revenue guidance as previously stated in our 2016 Earnings Release dated March 21, 2017 of:

Double digit revenue growth in our Production Animal Business across the US, Australia/New Zealand and Rest of

World.

- Companion Animal business is expected to achieve strong double digit revenue growth in the US and Australia
- Contract Manufacturing will grow strongly in 2017 with the commencement of at least one new agreement and we will continue to increase our outbound activities to seek new contracts each year. We also expect to complete upgrades to our manufacturing facility to manufacture medicated chews for dogs and cats opening up new opportunities of contract manufacturing in the future.

Development Highlights

• We have now completed the refiling of the Chemistry and Manufacturing Controls, or CMC, section as well as the Drug Master File, or DMF, for Zydax for dogs with the FDA. We believe that the time taken to compile these responses, including productive meetings with the Center for Veterinary Medicines, or CVM, section of the US FDA has placed in a strong position to have this section of the dossier approved.

• In compiling the CMC and DMF sections of the Zydax dossier, we also believe we have enhanced the robustness of the manufacturing process to even higher levels and this in turn has opened up the possibility to more rapidly pursue human indications for the active ingredient in Zydax and potentially has also enhanced our opportunities for additional patent filings. Whilst this process has taken longer than we desired it has been a process that has yielded significant uplift in the potential value of the Zydax asset. In particular we are hopeful that we will sign an agreement in the coming months with a partner company to progress the development of drugs for human use using the active ingredient of Zydax. In particular we believe there may be a path to market for some indications that are relatively short which could see revenues from human use within the next two to three years.

• Parnell also submitted a full response to the European Medicines Agency, or EMA, for Zydax for dogs. Unlike the US where a phased submission is permitted, all sections of an application dossier must be submitted in Europe simultaneously. We anticipate receiving a first response to this refiling from the EMA in mid-July and if successful could lead to a potential approval in Q4, 2017. The refiling of the full dossier in Europe now allows us to create a Common Technical Dossier, or CTD, for filing in multiple other countries including Canada, China and other potentially large markets for Zydax.

• We have nearly completed a study into the efficacy of Zydax, looking at different end-points that may in turn lead to an enhanced label for Zydax if approved by the FDA. Data from this study is expected to be available in late June 2017 and we expect to refile the Efficacy section of the Zydax dossier for dogs with the FDA shortly after that. If successful, this could lead to a potential approval of Zydax late in Q4, 2017.

• We expect to introduce new manufacturing capabilities at our FDA and EMA approved facility in Sydney, Australia. Specifically we are in the process of installing "Single Use" manufacturing technology which we believe enhances our sterility assurance (at a time when several other manufacturers are receiving warning letters from the FDA) and it also increases our operational efficiencies. We are also installing manufacturing equipment that will enable us to manufacture 'soft-chew' dosage forms for dogs and cats, which are a significantly preferred method of administration, with very few FDA approved facilities operating in this segment. We are also progressing new opportunities for manufacturing sterile injectable products in plastic vials. These vials have significant appeal in the production animal setting with glass vials posing a user safety and financial risk from vial breakage when dropped.

• We reiterate our 2017 guidance as previously stated in our 2016 Earnings Release dated March 21, 2017 of:

- We expect to refile our dossier for Zydax for dogs in the US and Europe leading to a potential approval in both markets in Q4, 2017 and we expect to file applications in several additional countries in 2017.
- We also expect to progress development of Zydax for cats and the use of the active ingredient in Zydax in humans.
- We expect to progress to pilot studies for PAR121 (bone healing) and PAR122 (skin healing)
- We expect to further enhance the capabilities and operational efficiencies of our manufacturing facility thereby attracting new opportunities for contract manufacturing.

Corporate Highlights

• With the recent refiling of Zydax in Europe and the US, we expect to recommence the process of appointing a marketing partner for the commercialization of Zydax in countries outside the US and Australia. We believe that with a potential near-term approval the value of this asset has increased substantially.

• Completed negotiations on a contract manufacturing agreement with a major multi-national and progressed several other contract manufacturing opportunities which may complete in 2017.

• We reiterate our 2017 guidance as previously stated in our 2016 Earnings Release dated March 21, 2017 of:

We expect to markedly improve our profitability returning to EBITDA profit in 2017 having removed over \$10 million in annualized costs from the business operations, including a large saving in corporate administration expenses as a result of moving from the NASDAQ to the OTC Open market.

Conference Call Information

Management will host a conference call on May 24, 2017 at 5:00 pm ET to discuss the business update and answer questions. Investors and analysts may access the conference call by dialing (877) 244-6184 FREE (U.S./Canada) or (920) 663-6271 (International) and using the conference ID# 27440696.

A telephone replay will be available for one week following the call by dialing (855) 859-2056 FREE (U.S./domestic) and (404) 537-3406 using the conference ID# 27440696.

About Parnell

Parnell (OTC:PARNF) 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[™] 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 <u>www.parnell.com</u>.

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, 2017, 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.

CONTACT:

For more information, contact:

Parnell Pharmaceuticals Holdings

Robert Joseph, 913-274-2100

robert.joseph@parnell.com

Brad McCarthy, 913-274-2100

brad.mccarthy@parnell.com



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