

Parnell Pharmaceuticals Holdings Ltd Announces Financial Results for the Six-Month Period Ended June 30, 2016

OVERLAND PARK, Kan., Aug. 04, 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 financial results for the first six months of 2016 including; strong revenue growth of 67%; the commencement of contract manufacturing revenues; the upcoming US launch of two new companion animal products, Luminous ™ and Reviderm™; and the commencement of several new studies for PAR121, PAR122 and Zydax for cats.

"We have consistently communicated our strength in being a fully integrated animal health company, and our results for the first half of 2016 are certainly illustrative of that strength," said Robert Joseph, President and CEO of Parnell. "Year-to-date we have achieved excellent revenue growth across our business with notable above-budget performances in US Production Animal, Australian Companion Animal and Contract Manufacturing. Our US Companion Animal team continued to establish a meaningful market footprint with FETCH™, our digital app., and Glyde™, our nutraceutical for osteoarthritis, or OA, and will soon launch Luminous™, our nutraceutical for dermatology, and Reviderm™, an antimicrobial spray on liquid bandage."

Mr. Joseph went on to say, "Our R&D team is making excellent progress on our lead projects; in the first half we commenced several investigational studies into PAR121, our osteogenic drug candidate, and PAR122, our dermatotrophic drug candidate. We expect to report results from these studies in the second half of 2016. We have commenced studies into the potential use of Zydax for osteoarthritis in cats, and expect to commence investigational studies into applicability of Zydax for interstitial cystitis in cats."

"We progressed preparations for the re-filing of the two remaining technical sections for the use of Zydax in treating osteoarthritis in dogs and expect to submit those filings to the FDA this quarter," continued Mr. Joseph. "We will meet with the Center for Veterinary Medicine of the FDA prior to re-filing the Chemistry and Manufacturing Controls (CMC's) section and the Target Animal Efficacy (TAE) section seeking to align with the Agency on our responses to their questions. We anticipate attending that meeting, subject to scheduling, in early September and re-filing shortly thereafter. Under statute, the Agency then has 180 days to consider our responses after which, provided there are no further Agency questions, at this time we expect a potential approval and immediate launch of Zydax for dogs in Q2, 2017. Whilst later than our original expectations, we do not anticipate this updated timeline being likely to have a material impact on our revenue expectations for Zydax in 2017 given our strategy of establishing a US companion animal presence in osteoarthritis with FETCH and Glyde in advance of the launch of Zydax. Because the additional time to US launch provides us a greater opportunity to engage with more pet parents through FETCH and Glyde, we believe we could have access to a larger population of dogs ready to commence Zydax treatment programs immediately once approved. Importantly, as time has progressed, we have been able to observe the competitive landscape for Zydax directly through our sales team and we continue to believe that Zydax has a unique position in the market. As we have shown to be the case in the analogous Australian market, Zydax can effectively be used as a first-line treatment for OA in earlier stage, younger dogs and can also be used adjunctively with non-steroidal anti-inflammatory drugs (NSAIDs). We also remain excited about geographical expansion for Zydax and we continue to progress discussions with various potential marketing partners. We are seeking a deal structure that will ensure long term value for this important franchise by leveraging our experience in marketing and manufacturing Zydax, balanced with a marketing partner who can bring focus and expertise to the launch of Zydax in Europe. Strong interest has been expressed by a number of parties and we remain confident of signing an appropriate deal in advance of a potential launch in Europe, Canada and other markets in 2017 and beyond", Mr. Joseph said.

Unless otherwise specified, all amounts are presented in Australian Dollars (AUD) and are for the six-months ended June 30, 2016.

Commercial Highlights

- 67% increase in total Company sales to \$8.2 million for the six months ending Q2, 2016 compared to \$4.9 million for the corresponding period in 2015 as we continued to experience accelerated growth in both our Production Animal and Companion Animal businesses and now in Contract Manufacturing;
 - 40% revenue growth in our U.S. Production Animal segment over the prior period in 2015 driven by strong acquisition of new customers including many from the continued roll-out of mySYNCH®; our innovative digital technology that assists dairy producers to improve the profitability of their operations.
 - 158% revenue growth in our Companion Animal business across the US and Australia over the prior period in 2015. The continued roll-out of Glyde and FETCH in the US market complemented a strong first half year in

Australia, where Companion Animal revenues grew 37% over the first half of 2015. FETCH, our digital application for dogs, has now been used by over 7,000 pet parents in the US market. Based on such strong uptake in the first half of the year, we expect pet parent users to increase to over 20,000 by year end.

- Our Contract Manufacturing segment generated its first revenues through the previously announced CMO agreement with Merial, taking advantage of excess capacity in our FDA-approved injectables manufacturing facility. This is a significant milestone and we anticipate potentially adding further contract manufacturing deals in 2016. The Company did not generate any Contract Manufacturing revenue in 2015.
- We previously provided full year 2016 revenue guidance of US\$14 US\$16 million. Given our significant outperformance in the first half, we now increase full year 2016 guidance to US\$17 US\$18 million. For our current business operations, we expect 2017 revenues to grow to approximately \$25 million which we estimate will make the Company profitable in the second half of 2017. This guidance excludes the impact of launching Zydax in the US, Canada and Europe which we estimate, if approved, would add substantially to revenues and earnings in 2017.

Development Highlights

- We are close to completing our responses to the FDA's questions from our filings of the Target Animal Effectiveness Technical Section and the Chemistry and Manufacturing Controls Technical Section for Zydax. As is customary, we will meet with the Agency prior to filing to discuss and seek alignment on our proposed responses. Subject to scheduling, we anticipate this meeting taking place in early September and our re-filing to proceed shortly thereafter.
- We have received the first round of questions from the European Medicines Agency, or EMA, for our submission of the use of Zydax to treat osteoarthritis in dogs. These questions are in line with our expectations and in large part similar to the questions received from the FDA. We therefore anticipate compiling our responses in line with the work we are undertaking for the FDA re-filing.
- We anticipate that we could potentially obtain approval of Zydax in both the US and EU in the first half of 2017. We also believe we may be able to file for approval in Canada adopting the dossier compiled for the FDA and that approval may be achieved in the second half of 2017.
- We have successfully completed pilot safety studies for the use of Zydax in cats and have now commenced pilot efficacy studies in client-owned cats. If this study is successful, we anticipate commencing pivotal studies for Target Animal Safety and Target Animal Effectiveness in late 2016 and potentially filing for approval with the FDA in the first-half of 2017.
- We are also preparing to commence studies investigating the use of Zydax for treating feline interstitial cystitis, a disease that we believe is both common and difficult to treat.
- We commenced manufacturing process development for PAR121 and PAR122 in the first half of 2016. This in turn has enabled the commencement of drug characterization studies and in-vitro and in-vivo efficacy studies. We expect to report results from these studies in the second half of 2016 which, if positive, could lead to the commencement of pivotal efficacy and safety studies in 2017. We continue to believe both these compounds have the potential to be highly valuable assets if approved.

Corporate Highlights

- Continued negotiations with multiple parties to acquire the rights to market Zydax in Europe.
- Completed the in-licensing of Reviderm™, 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 if successful, could commence in the second-half of 2016.
- Completed a strategic equity issuance to broaden our institutional and retail shareholding.
- Continued negotiations to increase our debt facility up to \$30 million to underpin the launch of Zydax in 2017.
- Continued to optimize operational and development expenditure to ensure a robust business model, potentially returning to profit in 2017 prior to the launch of Zydax.

Financial Results (for the six month period ended June 30, 2016)

Revenue

Total revenue of \$8.2 million for the six month period ending June 30, 2016, a 67% increase compared to the same period in 2015.

Our operating segments performed as follows:

- Production Animal US: Sales for the six months ended June 30, 2016 were \$4.1 million, an increase of \$1.2 million, or 40%, over the same period in 2015 and we expect full-year 2016 revenue growth to be similar.
- Production Animal Rest of World (ROW): Revenue for the six months ended June 30, 2016 decreased by 68% to \$0.4 million compared to the same period in 2015, primarily driven by year-over-year differences in the timing of

- orders from our distribution partners in these markets. We expect full year 2016 revenues for this segment to show single-digit revenue growth over 2015.
- Companion Animal: Revenue for the six months ended June 30, 2016 grew 158% to \$1.5 million driven by establishment of our US operations in this segment and a 37% increase in Australian sales compared to the same period in 2015. We expect full-year 2016 revenue growth to be of similar magnitude.
- Contract Manufacturing Revenue of \$2.2 million was generated for the six months ended June 30, 2016. No revenue was generated during the comparable period in 2015. We expect continued growth for the full year of 2016 from the existing contract and anticipate potentially adding further contracts in the second-half of 2016.

Expenses

Cost of Sales for the six months ended June 30, 2016 was \$3.6 million, compared to \$3.1 million in the same period of 2015. This increase was driven by sales growth of 67% on a year-over-year basis. Gross margin as a percentage of revenue, using a Cost of Goods Sold — Product basis, remained consistent with the first half 2015, at 84%. We expect this gross margin level to continue for the full year 2016.

<u>Selling and marketing</u> expenses increased by \$4.3 million to \$7.8 million for the six months ended June 30, 2016. This increase was driven by the establishment of our US Companion Animal business to launch our nutraceutical product Glyde and FETCHTM, our digital technology, that has now been used by over 7,000 pet parents and we expect pet parent users of FETCHTM to increase to over 20,000 by year end. Having established this new team and our digital presence, we expect growth in sales and marketing expenditure to flatten in the remainder of 2016.

Regulatory and R&D expenses increased by \$0.2 million to \$0.8 million for the first six months of 2016 due to costs associated with the initiation of several preclinical and target animal studies aimed at developing our product pipeline.

Administration expenses increased by \$2.1 million to \$7.3 million for the six months ended June 30, 2016, compared to the same period in 2015. This increase was driven by higher staffing and external costs to support a substantially larger Commercial and R&D organization in the US; increased compliance, regulatory and legal costs associated with being a public company; and shared-based compensation related to stock options and restricted share units to a larger base of US and Australian employees. Having established our fully-integrated pharmaceutical operations we expect Administration costs to now remain flat for the remainder of 2016.

<u>Finance costs and Net foreign exchange losses on borrowings</u> increased by \$0.7 million to \$1.1 million for the six months ended June 30, 2016 from the comparable period in 2015 due to interest costs on the debt facility that was established in June, 2015.

Other Income/(Expense): for the six-month period ending 30, June 2015 we reported Other Income of \$4.7 million and for the same period in 2016 this declined by \$4.9 million to be an Expense of \$0.1 million. This was primarily driven by non-recurring income that occurred in 2015 including management's reassessment of a contingent provision associated with supplier obligations which resulted in a one-time, non-cash release of \$2.6 million being recorded in Other Income in 2015. Also, Foreign Exchange movements, primarily between the Australian dollar and the US dollar, resulted in an unrealized foreign exchange expense of \$0.7 million in the first six months of 2016 compared to an unrealized foreign exchange gain of \$1.5 million in the same period of 2015. In addition, in the first six months of 2015, \$0.4 million in government grants were received from the Kansas Department of Commerce compared to \$0.1 million in 2016. In the first six months of 2016, \$0.4 million was recorded in Other Income as part of research and development incentives received in Australia, compared to \$0.3 million in 2015.

As a result, Net loss after tax for the six months ended June 30, 2016 increased to \$12.5 million compared to \$3.0 million in 2015.

Net loss per weighted-average share was (\$0.85) for the six-months ended June 30, 2016 compared to a (\$0.22) per share loss for the same period in 2015.

As of June 30, 2016, cash and cash equivalents were \$4.1 million compared to \$5.7 million at December 31, 2015.

Conference Call Information

Management will host a conference call on August 4, 2016 at 8 am EST to discuss financial results 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# 56384980.

A telephone replay will be available for one week following the call by dialing (855) 859-2056 FREE (U.S./domestic) and

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 — FETCHTM 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.

Consolidated Balance Sheets (Unaudited)

	30 June 2016 AUD\$	31 December 2015 AUD\$
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	4,103,548	5,666,679
Trade and other receivables	8,936,093	7,266,662
Inventories	3,790,815	3,426,926
Prepayments	423,867	531,843
TOTAL CURRENT ASSETS	17,254,323	16,892,110
NON-CURRENT ASSETS		
Trade and other receivables	66,515	67,457
Property, plant and equipment	12,254,506	12,666,214
Intangible assets	17,086,104	16,583,360
TOTAL NON-CURRENT ASSETS	29,407,125	29,317,031
TOTAL ASSETS	46,661,448	46,209,142
LIABILITIES		
CURRENT LIABILITIES		
Trade and other payables	7,701,003	6,780,440
Borrowings	8,390,378	3,122,553
Provision for employee benefits	676,356	438,008
TOTAL CURRENT LIABILITIES	16,767,737	10,341,001
NON-CURRENT LIABILITIES		
Trade and other payables	1,097,312	1,106,360

Borrowings	11,812,407	14,353,203
Provision for employee benefits	171,156	153,781
TOTAL NON-CURRENT LIABILITIES	13,080,875	15,613,344
TOTAL LIABILITIES	29,848,612	25,954,345
NET ASSETS	16,812,836	20,254,796
EQUITY		
Ordinary shares	63,301,764	55,343,451
Share-based compensation reserve	2,576,642	1,708,388
Reserves	(3,005,157)	(3,214,558)
Accumulated losses	(46,060,413)	(33,582,485)
TOTAL EQUITY	16,812,836	20,254,796

Consolidated Statements of Comprehensive Loss (Unaudited)

	For the Six-Months Ended June 30,	
	2016	2015
	AUD\$	AUD\$
Revenue	8,225,614	4,927,965
Other income/(expense)	(147,815)	4,742,229
Cost of goods sold	(3,650,959)	(3,140,067)
Selling and marketing expenses	(7,760,463)	(3,431,718)
Regulatory, R&D expenses	(761,282)	(564,904)
Administration expenses	(7,298,121)	(5,165,879)
Net foreign exchange losses on borrowings	-	-
Finance costs	(1,073,981)	(350,964)
Loss before income tax	(12,467,007)	(2,983,338)
Income tax expense	(10,924)	(2,106)
Loss for the period	(12,477,931)	(2,985,444)
Other comprehensive (loss)/profit, net of income tax		
Items that will be reclassified subsequently to profit or loss		
Foreign currency translation	209,401	(808,664)
Other comprehensive (loss)/profit for the period, net of tax	209,401	(808,664)
Total comprehensive loss for the period	(12,268,530)	(3,794,108)
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Net loss per weighted-average share	AUD\$	AUD\$
Net loss attributable to common stockholders, Basic and diluted	(0.85)	(0.22)

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