

September 15, 2014

## Parnell Pharmaceuticals Holdings Ltd Announces Fiscal Year 2014 Financial Results

OVERLAND PARK, Kan., Sept. 15, 2014 (GLOBE NEWSWIRE) -- Parnell Pharmaceuticals Holdings Ltd (Nasdaq:PARN), a fully integrated pharmaceutical company focused on developing, manufacturing and commercializing innovative animal health solutions, today announced year-end financial results. The company's fiscal year (FY) ended June 30, 2014 at which time Parnell had approximately \$20.8 million in cash and cash equivalents.

"FY2014 was a transformational year for Parnell with the completion of our initial public offering, strong sales growth in our established markets and the impressive expansion of our new U.S. commercial business. We were also pleased to achieve a number of important milestones in the development of our high potential pipeline products and our innovative digital technologies," said Robert Joseph, President and Chief Executive Officer of Parnell Pharmaceuticals Holdings Ltd. "In the year to come, we will be focused on driving Zydax<sup>®</sup> toward regulatory approval in the U.S. and Europe following the positive results of our large-scale pilot study, continuing double-digit sales growth in our major markets and advancing our product pipeline and digital technologies."

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

### Recent Development Highlights

- Parnell announced positive findings from a large-scale pilot efficacy study of Zydax<sup>®</sup> for the treatment of osteoarthritis (OA) in dogs. Zydax<sup>®</sup> demonstrated statistically significant efficacy compared to placebo in reducing pain and interference. The company plans to initiate a pivotal efficacy study designed to support product registration in major markets, which is anticipated to commence in the fourth quarter of 2014 and complete in the first half of 2015.
- In September 2014, the Active Pharmaceutical Ingredient (API) for Zydax<sup>®</sup> was successfully scaled up for commercial manufacture. This will enable the completion of a drug master file to be submitted to the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) with the results from the pivotal efficacy study in the first half of 2015.
- A 3,500 cow efficacy study investigating the patent-pending cattle breeding program PROCEPT<sup>®</sup>, which uses a novel combination of Parnell's reproductive hormones estroPLAN<sup>®</sup> and GONAbreed<sup>®</sup>, was successfully completed. PROCEPT was shown to increase pregnancy rates by 10 percent compared to conventional breeding programs. The development of PROCEPT underscores Parnell's clinical science leadership which is a competitive advantage in gaining new dairy customers.
- Parnell's innovative digital technologies have been advanced with the roll out of mySYNCH<sup>®</sup> to dairy customers in the third quarter of 2015. This unique program drives operational efficiencies and profits for dairy farmers and is a major point of differentiation for Parnell.
- Parnell launched an enhanced version of iKAM<sup>®</sup>, a proprietary digital technology for use by veterinarians in diagnosing and initiating treatment of osteoarthritis in the third quarter of 2015. The enhanced version is designed for home use by dog owners to monitor the improvement of their dog's osteoarthritis.
- Parnell licensed two compounds from Australian-based CIMTECH Pty Ltd in the third quarter of 2015. In preclinical studies, PAR 121 and PAR 122 demonstrated impressive abilities to dramatically speed bone regeneration and dermal regeneration, respectively. Parnell received a license to develop the compounds for the veterinary market with the potential to also seek human drug approvals.

### Corporate Highlights:

- On June 18, Parnell completed an initial public offering raising net proceeds of approximately AUD\$47.4 million and commenced trading on the NASDAQ Global Market under the ticker symbol "PARN". Proceeds from the IPO were used to retire USD\$25 million of historic debt and will fund the expansion of commercial infrastructure and R&D activities.
- Following the IPO, Parnell expanded its corporate headquarters in Overland Park, Kansas and was granted USD\$400,000 (plus USD\$300,000 in other program benefits) from the Department of Commerce in the State of Kansas. The larger office facilities will support increased staffing for future companion animal product launches, the

continued growth of the reproductive hormone portfolio, as well as R&D personnel to support the pipeline development.

- Two new US-based independent directors, David L. Greenwood and Phyllis Gardner, M.D., were appointed to the company's Board. In conjunction with these appointments, Andrew Want and Peter Molloy resigned their Board positions.

## **Financial Results (stated in fiscal year ended June 30, 2014)**

### Revenue

Total revenues for FY2014 were \$7.5 million compared to \$9.5 million for FY2013. Revenues in FY2014 were driven by sales growth in established (non-U.S.) markets and offset by lower "ex-Parnell" sales of US reproductive hormones due to product launch-related channel stocking in FY2013. However, "in-market" sales of U.S. reproductive hormones demonstrated strong quarter-over-quarter growth in FY2014.

- U.S. Reproductive Hormones: Distributors purchased \$3.7 million of initial inventory in May 2013 and June 2013 in conjunction with the launch of **estroPLAN<sup>®</sup>** and **GONAbreed<sup>®</sup>**. Distributor inventory carried over into FY2014, limiting ex-Parnell sales to \$1.6 million. In FY2014, sales from distributors to veterinarians (in-market sales) grew quarter-over-quarter. Therefore, the effect of the initial inventory build is resolving and ex-Parnell sales will begin to align with in-market sales growth.
- Rest-of-World Reproductive Hormones: Sales increased 10 percent to \$4.4 million in FY2014 with sales growth of 14 percent and 22 percent in Australia and New Zealand, respectively.
- Osteoarthritis: Sales of our nutraceutical product **Glyde<sup>®</sup>** increased 9 percent while sales of **Zydax<sup>®</sup>** declined in FY2014 due to a lack of API supply for the first seven months of FY2014. Once back in stock, however, **Zydax<sup>®</sup>** sales grew 25 percent in the second half of FY2014, as compared to the second half of FY2013.

Cost of Sales increased to \$6.4 million in FY2014 compared to \$5.6 million in FY2013 primarily as a result of operating the newly commissioned manufacturing facility for the full year. Underlying "Cost of Sales - Product" averaged 22 percent in FY2014 and our unutilized manufacturing factory capacity was more than 75 percent.

Selling and marketing expenses increased to \$5.5 million in FY2014 compared to \$3.3 million in FY2013 due to the launch of the reproductive hormone products in the U.S. and associated promotional costs and increased employee headcount.

Regulatory and Research & Development (R&D) expenses were \$0.6 million in FY2014 compared to \$0.1 million in FY2013. The increase was primarily due to the first occurrence of FDA GMP license fees and product renewal fees of \$0.2 million, following the approval of the company's sterile manufacturing facility and reproductive hormones, and \$0.2 million in R&D costs related to PAR 121 and PAR 122 development activities.

Administration and transaction related expenses for FY2014 were \$3.0 million compared to \$1.9 million in FY2013. The \$1.1 million increase related to \$0.4 million of transaction costs associated with the IPO, a \$0.3 million increase in headcount costs and a \$0.2 million increase in professional, insurance and audit fees related to the establishment of our US head-office and a \$0.2 million increase in depreciation and amortization cost.

Net realized foreign exchange losses on borrowings decreased to \$1.4 million compared to \$2.0 million in FY2013. This decrease in foreign exchange losses was a result of U.S. dollar denominated credit facilities being impacted by year-over-year foreign exchange movements against the Australian dollar. As of June 30, 2014, all of the company's U.S. dollar denominated credit facilities had been repaid.

Financing costs increased to \$7.3 million in FY2014 compared to \$2.8 million in FY2013. The increase was driven by \$0.8 million higher interest costs and \$3.6 million in one-time costs associated with establishment and termination of credit facilities. With the repayment of the USD\$25 million SWK credit facility after the IPO, interest costs will decline dramatically in the future.

Income tax expense was approximately \$3.0 million in FY2014 compared to an income tax benefit of \$0.7 million in FY2013. The variance is the result of management determining that certain carry forward tax losses held on the balance sheet would not be recognized as of June 30, 2014 and hence were removed from the balance sheet and expensed. These tax losses can be carried forward as an off-balance sheet item. At June 30, 2014, total accumulated tax losses were \$20.0 million.

Other Income was approximately \$2.2 million for FY2014, which was the same amount in FY2013. Other Income comprises government incentives (including R&D incentives received from the Australian Tax Office and an expansion grant from the Kansas State Government) of \$0.2 million in FY2014 and \$1.2 million in FY2013. Other Income also comprised unrealized

foreign exchange gains of \$1.9 million in FY2014 and \$1.0 million in FY2013.

Net loss after tax for FY2014 increased to \$17.3 million compared to \$3.5 million for FY2013. The \$13.8 million increase in net loss was attributable to:

- \$4.8 million increase in financing costs and transaction expenses; reconfiguring then paying down debt facilities and the IPO;
- \$3.7 million increase in income tax expense; removing carried forward tax losses from the balance sheet;
- \$2.1 million increase in selling and marketing costs, establishing the US business to market the newly approved reproductive hormones;
- \$1.6 million decrease in gross margin due to lower revenues;
- \$1.0 million increase in operating costs for the newly approved manufacturing facility; and
- \$0.5 million increase in Regulatory and R&D expenses.
- \$0.7 million increase in administration costs mostly offset by a \$0.6 million reduction in net realized foreign exchange losses on borrowings

"In fiscal year 2014, we invested heavily in establishing our U.S. business and our new manufacturing facility, and we incurred one-time costs associated with recapitalizing our company for future growth. Those investments aside, our underlying, individual business units are growing, remain profitable and are cash generating," said Brad McCarthy, Parnell's Chief Financial Officer.

Net loss per weighted-average share was \$2.18 and \$0.46 cents for the years ended June 30, 2014 and June 30, 2013.

As of June 30, 2014, Parnell had increased cash and cash equivalents to \$20.8 million compared to \$0.9 million as of June 30, 2013 and had decreased total debt from \$20.2 million to \$4.3 million.

## **Guidance**

Sales of Reproductive Hormones in the U.S. are expected to grow strongly "in-market" over 2014 sales with the recent expansion of the sales team and launch of the mySYNCH digital technology. Increasing customer demand is anticipated to translate into "ex-Parnell" sales growth in 2015 and beyond. mySYNCH<sup>®</sup> is also expected to generate further growth in our established markets in 2015.

Revenues for established production animal products and geographies are expected to maintain double-digit growth in 2015.

Companion animal sales are also expected to grow at a double-digit rate with the roll-out of the latest version of the iKAM<sup>®</sup> digital technology and Glyde<sup>®</sup> Chews in 2015.

## **Anticipated Milestones in 2015**

- Initiate pivotal efficacy study of Zydax<sup>®</sup> for the treatment of osteoarthritis in dogs third quarter, 2014.
- Report data from Zydax<sup>®</sup> pivotal study and complete Drug Master File in the second quarter of 2015.
- File complete FDA and EMA registration dossiers for the approval of Zydax<sup>®</sup> in the first half of 2015.
- Report full study results for PROCEPT<sup>®</sup> (novel cattle breeding program) in fourth quarter of 2014.
- Launch Glyde<sup>®</sup> Chews in the first quarter of 2015.
- Commence API characterization and mode-of-action studies for PAR 121 and PAR 122 in the first half of 2015.
- Commence in vivo hormone profile studies for GONADAPRO<sup>®</sup> in the first half of 2015.
- Commence prodrug isolation and antimicrobial studies for PAR 061 for mastitis in dairy cows in the first half of 2015.
- Commence formulation development for PAR 081 for anesthesia in the first half of 2015.
- Commence pharmacokinetic studies for PAR101 to treat laminitis in horses in the second half of 2015.

With Parnell's established markets generating operating cash flows and current cash reserves, the company anticipates it is well positioned to execute on its current development pipeline objectives and in building its U.S. commercial capabilities through at least FY2015.

## **Conference Call Information:**

Management will host a conference call on September 15, 2014 at 5 p.m. ET to discuss fiscal year-end results. 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#3019647.

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# 3019647.

## 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 or performance of animals, while driving customers' operational efficiency and profitability. Parnell believes its value-added solutions help establish them as a business partner with customers rather than only as a commodity provider, differentiating them from competitors.

For more information on Parnell and its products, please visit [www.parnell.com](http://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 Form F-1 Registration Statement effective June 18, 2014. In light of these assumptions, risks, and uncertainties, the results and events discussed in the 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.

**Parnell Pharmaceuticals Holdings Ltd**  
**Consolidated Statements of Comprehensive Loss**  
**(Unaudited)**

	2014	2013
	AUD\$	AUD\$
Revenue	7,542,600	9,538,161
Other income	2,248,195	2,203,355
Cost of goods sold	(6,417,593)	(5,641,732)
Selling and marketing expenses	(5,474,826)	(3,341,341)
Regulatory expenses	(586,149)	(138,915)
Administration expenses	(3,018,782)	(1,903,573)
Net foreign exchange losses on borrowings	(1,384,335)	(2,027,404)
Finance costs	(7,262,020)	(2,839,595)
<b>Loss before income tax</b>	<b>(14,352,910)</b>	<b>(4,151,044)</b>
Income tax benefit/(expense)	(2,980,412)	672,989
<b>Loss for the year</b>	<b>(17,333,322)</b>	<b>(3,478,055)</b>
<b>Other comprehensive loss, net of income tax</b>		
<b>Items that will be reclassified subsequently to profit or loss</b>		
Foreign currency translation	(517,525)	(32,084)
<b>Other comprehensive loss for the year, net of tax</b>	<b>(517,525)</b>	<b>(32,084)</b>
<b>Total comprehensive loss for the year</b>	<b>(17,850,847)</b>	<b>(3,510,139)</b>

<b>Net loss per weighted-average share</b>	<b>AUD\$</b>	AUD\$
Net loss attributable to common stockholders, Basic and diluted	<b>(2.18)</b>	(0.46)

**Parnell Pharmaceuticals Holdings Ltd**  
**Consolidated Balance Sheets**  
(Unaudited)

	<b>2014</b>	<b>2013</b>
	<u>AUD\$</u>	<u>AUD\$</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	<b>20,804,339</b>	859,708
Trade and other receivables	<b>3,411,316</b>	4,705,693
Inventories	<b>2,009,843</b>	1,907,145
Prepayments	<b>112,995</b>	104,328
<b>TOTAL CURRENT ASSETS</b>	<b><u>26,338,493</u></b>	<u>7,576,874</u>
<b>NON-CURRENT ASSETS</b>		
Trade and other receivables	<b>30,583</b>	14,466
Property, plant and equipment	<b>11,210,442</b>	11,999,356
Deferred tax assets	--	2,595,918
Intangible assets	<b>10,164,545</b>	9,376,256
<b>TOTAL NON-CURRENT ASSETS</b>	<b><u>21,405,570</u></b>	<u>23,985,996</u>
<b>TOTAL ASSETS</b>	<b><u>47,744,063</u></b>	<u>31,562,870</u>
<b>LIABILITIES</b>		
<b>CURRENT LIABILITIES</b>		
Trade and other payables	<b>5,726,684</b>	2,303,004
Borrowings	<b>4,135,218</b>	16,532,717
Provision for employee benefits	<b>305,330</b>	245,957
Derivatives	--	2,317,123
<b>TOTAL CURRENT LIABILITIES</b>	<b><u>10,167,232</u></b>	<u>21,398,801</u>
<b>NON-CURRENT LIABILITIES</b>		
Trade and other payables	<b>530,786</b>	1,797,000
Borrowings	<b>151,963</b>	3,667,511
Deferred tax liabilities	--	1,358,930
Provision for employee benefits	<b>117,862</b>	92,597
Derivatives	--	860,000
<b>TOTAL NON-CURRENT LIABILITIES</b>	<b><u>800,611</u></b>	<u>7,776,038</u>
<b>TOTAL LIABILITIES</b>	<b><u>10,967,843</u></b>	<u>29,174,839</u>
<b>NET ASSETS</b>	<b><u>36,776,220</u></b>	<u>2,388,031</u>
<b>EQUITY</b>		
Ordinary shares	<b>55,343,451</b>	3,104,415
Reserves	<b>(150,800)</b>	366,725
Accumulated losses	<b>(18,416,431)</b>	(1,083,109)
<b>TOTAL EQUITY</b>	<b><u>36,776,220</u></b>	<u>2,388,031</u>

CONTACT: For more information, contact:

Robert Joseph, 913-312-0786

robert.joseph@parnell.com