

# Parnell Pharmaceuticals Holdings Ltd Announces Financial Results for the Six-Month Period Ended June 30, 2015

OVERLAND PARK, Kansas, Aug. 11, 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 financial results for the six-month period ended June 30, 2015.

"The first half of 2015 was an exemplary period of strategic success and growth that included an impressive 196% increase in the sales of our Reproductive Hormones in the US compared to the same period in 2014, attributable to the impact of additional territory managers and pre-marketing of our digital technology mySYNCH<sup>®</sup>," said Robert Joseph, President and Chief Executive Officer of Parnell Pharmaceuticals Holdings Ltd.

"In our Companion Animal business, we announced positive top-line results from our pivotal efficacy clinical trial in dogs for our lead osteoarthritis product Zydax<sup>®</sup>, and closed on an USD\$11 million debt offering to fund the development of our new Companion Animal sales team. We expect the second half of 2015 to show stronger sales growth across this portfolio given the imminent launch of Glyde<sup>TM</sup> and FETCH<sup>TM</sup> in the US," Mr. Joseph continued. "Glyde is our nutraceutical product for dogs and FETCH our innovative digital application for use by veterinarians and pet parents. We also expect to file all remaining registration requirements for Zydax with the FDA in August, 2015 and shortly thereafter with the EMA in Europe."

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

## **Commercial Highlights**

- Significant sales growth in US Production Animal driven by the recent expansion of our sales team now covering 7 territories as of May 2015. In 2014 for the same period, we had 4 territories and had not commenced marketing of mySYNCH<sup>®</sup>, our innovative digital technology that assists dairy farmers to improve the profitability of their operations. The ongoing success in commercializing our reproductive hormones in the US saw our market share in June 2015 reach its highest level since our launch and continues to increase month on month in line with our 2015 guidance.
- Sales for Production Animal Rest-Of-World declined in the first half of 2015 compared to 2014 primarily driven by yearto-year differences in the timing of orders to our marketing partners (outside Australia and New Zealand). With several orders due to be shipped to our marketing partners in the second half of 2015, we expect the trajectory of sales in this segment to improve. Nevertheless we continue to focus on improving operational performance in the key markets for this segment. In Australia-New Zealand, where declining milk prices are causing some headwinds, the upcoming launch of a new version of mySYNCH<sup>®</sup> is expected to improve sales as the efficiency of breeding programs are even more important during periods of low milk prices. In Canada the entry of a low price competitor has caused our growth to slow in the last

twelve months but we are working with our marketing partner to increase market share.
Our Companion Animal business segment revenues declined in the first half of 2015 compared to 2014 after a lengthy and unanticipated delay in regulatory approval of a new and soft-chew version of Glyde in Australia. As a result we were out of the market for April and much of May 2015 which negatively impacted our second quarter sales. With the launch of

Glyde Chews in Australia in late May, 2015 and the launch of Glyde Chews in the US planned for September, 2015, we expect sales in our Companion Animal segment to increase significantly in the second half of 2015 and to deliver 2015 full year results in line with guidance.

#### **Development Highlights**

- We announced positive top-line results from our pivotal efficacy clinical trial for our osteoarthritis product, Zydax. A reduction of 3 or more in the Activity Impairment Score was achieved in 56% of Zydax<sup>®</sup> treated dogs against 40% for placebo (p=0.02).
- With the completion of the recent Zydax<sup>®</sup> clinical trial, we expect to complete US and EU regulatory filings for Zydax<sup>®</sup> in the coming months with the potential for product approval in both markets in the third quarter of 2016. This timing assumes a two-cycle review by the FDA as previously communicated.
- We accelerated the development of our proprietary digital technologies, mySYNCH<sup>®</sup> and FETCH<sup>TM</sup>. These innovative

digital tools are designed to support and expand sales of our reproductive hormones and osteoarthritis products, respectively. We believe our digital technologies are a key element of our commercial success, coupling best-in-class medicines with leading technology applications to create fundamental differentiation in our customer offering.

## **Corporate Highlights:**

- We held our inaugural Investor Day in New York presenting results from an array of clinical and laboratory trials for Zydax; regulatory and commercialization plans as well as an update on our product pipeline development.
- We secured a non-dilutive USD \$11 million term loan to fund the establishment of a Companion Animal sales and marketing team in the US in anticipation of the launch of Glyde and Zydax.
- We appointed a new Independent Director, Peter Croden, to the Board of Directors. Mr Croden is the former President of the Worldwide Business for Pharmacia & Upjohn Animal Health, where he oversaw the fastest growing company in the industry. Mr. Croden also previously held the position of President of Upjohn Canada, before which he resided and worked in Germany for 6 years as Regional Marketing Manager for Europe.
- We continued to expand our operations having now added 62 new personnel globally since our IPO in June 2014. Recent key senior appointments include Senior Vice-President of Finance, Vice President of Global Marketing and Vice President of Digital Technologies. To accommodate our expansion, we also exercised an option to increase our leased office space in Overland Park, Kansas.

#### Guidance

Sales of Reproductive Hormones in the US are expected to maintain strong growth in the second half of 2015 compared to 2014 with the ongoing expansion of the US Production Animal sales team and the roll-out of mySYNCH<sup>®</sup> in Q3, 2015. The resulting increase in customer demand is anticipated to translate into a near tripling of sales for 2015 compared to 2014.

Companion Animal sales are expected to show strong double-digit growth in the second half of 2015 driven by the launch of Glyde Chews in the US in September, 2015, the introduction of the latest version of our FETCH digital technology in both the US and Australia and increasing sales of newly launched Glyde Chews in Australia (first marketed in May, 2015).

#### Anticipated Milestones in 2015:

We expect to file the full registration dossiers for Zydax<sup>®</sup> for use in dogs, in the US and EU, to advance our product pipeline candidates, and to actively pursue business development opportunities. Specifically we expect to:

- Launch GlydeChews and FETCH in the US through a newly appointed 40-person national sales team calling on 12,000 Companion Animal veterinary clinics;
- Commence clinical trials to support the extension of our Zydax<sup>®</sup> franchise to Cats and Horses in major markets
- Commence a new, innovative canine clinical trial designed to demonstrate the durability of improvement in Activity
  Impairment Scores after treatment with Zydax<sup>®</sup> in dogs to enhance our regulatory filings and commercialization activities;
- Report full study results for PROCEPT<sup>TM</sup> (our novel cattle breeding program);
- Commence development of clinical trial materials for PAR121 and PAR122;
- Commence formulation development studies for PAR081;
- Advance discussions regarding the appointment of a marketing partner for Zydax and Glyde for Europe, Asia and Latin America;
- Advance discussions relating to our first contract manufacturing agreement;
- Reach agreement on at least one in-licensing deal for a Companion Animal product.

## Financial Results (for the six-month period ended June 30, 2015)

#### Revenue

Total Revenues increased by \$0.2 million, or 5%, to \$4.9 million for the six months ended June 30, 2015 compared to \$4.7 million in the same period in 2014.

Our operating segments performed as follows:

• Production Animal - US: Sales for the six months ended June 30, 2015 increased by approximately \$2.0 million, or 196%, to \$3.0 million, compared to the same period in 2014.

- Production Animal Rest of World (ROW): Sales for the six months ended June 30, 2015 decreased by approximately \$1.5 million, or 51%, compared to the same period in 2014.
- Companion Animal: Sales for the six months ended June 30, 2015 decreased by approximately \$0.3 million, or 32%, to \$0.6 million, compared to the same period in 2014.
- We did not undertake contract manufacturing in 2015 or 2014; however, we are actively pursuing revenue-generating opportunities that could commence in 2016, taking advantage of the large amount of available production capacity in our FDA-, and now EMA-, inspected sterile manufacturing facility.

Cost of Sales decreased to \$3.1 million for the six months ended June 30, 2015, from \$3.4 million in the same period in 2014 primarily due to year-on-year product mix variation as our higher margin US Production Animal business continued to grow rapidly. As a result our gross margin, using Cost of Goods Sold - Product, improved to 84% compared to 81% for the same period in 2014.

Selling and marketing expenses increased \$1.0 million, or 40%, for the six months ended June 30, 2015 compared to the same period in 2014 as a result of the expansion of our US commercial presence in both Production Animal and Companion Animal business segments.

Regulatory and R&D expenses increased by 5.8% for the six months ended June 30, 2015 compared to the same period in 2014, primarily from additional staffing to support our new product filings.

Administration expenses increased \$2.3 million, or 81%, for the six months ended June 30, 2015, compared to the same period in 2014, as a result of increased staffing and external costs to support a substantially larger Commercial and R&D organization in the US; increased compliance, regulatory and statutory costs associated with being a public company since June 2014; and shared-based compensation related to stock options and restricted share units issued for the first time to employees and directors during the first half of 2015.

Finance costs and Net foreign exchange losses on borrowings decreased \$6.3 million, or 95%, for the six months ended June 30, 2015 compared to the same period in 2014. Finance costs decreased in 2015 predominately due to the pay down of our previously held \$25 million senior debt facility. This facility was in place in the first six months of 2014 but was repaid from the proceeds of our initial public offering, or IPO, in June 2014. Further, non-recurring expenses of \$0.3 million in 2014 were associated with our IPO.

Other Income increased \$3.5 million, or 274%, in the six months ended June 30, 2015 compared to the six months ended June 30, 2014. The increase was primarily driven by management's reassessment of contingent provisions associated with supplier obligations. As of June 30, 2015, management made the determination that the obligations no longer met the criteria of a provision, resulting in \$2.6 million (2014: \$Nil) being recorded in Other Income. At June 30, 2015 several further items of Other Income were recorded as follows : \$0.4 million (2014: \$Nil) in government grants from the Kansas Department of Commerce; \$0.3 million (\$2014: \$0.2 million) as part of research and development expenditures in Australia; and foreign exchange gains of approximately \$1.5 million (2014: \$1.0 million).

As a result, Net loss after tax for the six months ended June 30, 2015 improved by \$9.9 million to a loss of \$3.0 million compared to a \$12.9 million loss for the same period in 2014.

Net loss per weighted-average share was \$0.22 for the six-months ended June 30, 2015 compared to a \$1.54 per share loss for the same period in 2014.

At June 30, 2015 Parnell held cash and cash equivalents of \$18.0 million compared to \$15.8 million at December 31, 2014.

#### **Conference Call Information:**

Management will host a conference call on August 11, 2015 at 8:00 a.m. ET to discuss financial results. Investors and analysts may access the conference call by dialing (877) 244-6184 (US/Canada) or (920) 663-6271 (International) and using the conference ID# 98357752.

A telephone replay will be available for one week following the call by dialing (855) 859-2056 (US/domestic) and (404) 537-3406 using the conference ID# 98357752.

#### 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 - FETCH<sup>TM</sup>

and mySYNCH<sup>®</sup>. 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 <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 risks 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.

## **Consolidated Balance Sheets**

(Unaudited)

	June 30,	December 31,
	2015	2014
ASSETS	AUD\$	AUD\$
CURRENT ASSETS		
Cash and cash equivalents	17,987,641	15,819,418
Trade and other receivables	5,080,171	4,825,193
Inventories	3,058,885	2,755,956
Prepayments	386,344	470,568
TOTAL CURRENT ASSETS	26,513,041	23,871,135
NONCURRENT ASSETS		
Trade and other receivables	64,620	50,184
Property, plant and equipment	12,039,225	11,899,006
Intangible assets	14,368,468	12,419,614
TOTAL NONCURRENT ASSETS	26,472,313	24,368,804
TOTAL ASSETS	52,985,354	48,239,939
LIABILITIES		
CURRENT LIABILITIES		
Trade and other payables	4,078,785	8,614,034
Borrowings	2,983,679	4,590,483
Provision for employee benefits	456,476	379,558
TOTAL CURRENT LIABILITIES	7,518,940	13,584,075
NONCURRENT LIABILITIES		
Borrowings	13,596,904	

Provision for employee benefits	118,719	74,364
Other	859,380	668,037
TOTAL NONCURRENT LIABILITIES	14,575,003	742,401
TOTAL LIABILITIES	22,093,943	14,326,476
NET ASSETS	30,891,411	33,913,463
EQUITY		
Ordinary shares	55,343,451	55,343,451
Share-based compensation reserve	772,056	
Reserves	(2,393,699)	(1,585,035)
Accumulated losses	(22,830,397)	(19,844,953)
TOTAL EQUITY	30,891,411	33,913,463

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

	For the Six-Months Ended June 30,		
	2015 AUD\$	2014 AUD\$	
Revenue	4,927,965	4,698,606	
Other income	4,742,229	1,267,735	
Cost of goods sold	(3,140,067)	(3,420,111)	
Selling and marketing expenses	(3,431,718)	(2,455,352)	
Regulatory and R&D expenses	(564,904)	(534,211)	
Administration expenses	(5,165,879)	(2,848,533)	
Net foreign exchange losses on borrowings		(1,021,927)	
Finance costs	(350,964)	(5,622,633)	
Loss before income tax	(2,983,338)	(9,936,426)	
Income tax expense	(2,106)	(2,980,412)	
Loss for the period	(2,985,444)	(12,916,838)	

#### Other comprehensive (loss)/profit, net of income tax

Items that will be reclassified subsequently to profit or loss

Foreign currency translation	(808,664)	161,914
Other comprehensive (loss)/profit for the period, net of tax	(808,664)	161,914
Total comprehensive loss for the period	(3,794,108)	(12,754,924)
Net loss per weighted-average share	AUD\$	AUD\$
Net loss attributable to common stockholders, Basic and diluted	(0.22)	(1.54)

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