

Parnell Pharmaceuticals Holdings Ltd Announces Financial Results for the Six-Month Period Ended December 31, 2014

OVERLAND PARK, Kan., Feb. 25, 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 December 31, 2014.

"The second half of 2014 was a successful period of expansion and growth that included an increase in product sales of 29% across all markets, and a successful pilot efficacy study which paved the way for us to commence the Pivotal Efficacy Clinical Trial of our lead osteoarthritis product Zydax[®]," said Robert Joseph, President and Chief Executive Officer of Parnell Pharmaceuticals Holdings Ltd. "Consistent with our objectives to expand our commercial base in the U.S. and advance our proprietary pipeline, we appointed several talented senior-level animal health industry executives to our leadership team, as well as three new independent directors to our Board."

"We expect 2015 to be a dynamic and eventful year for commercial and pipeline progress. We are currently focused on fulfilling all of the registration requirements for Zydax[®] in the U.S. and Europe with the completion of the pivotal efficacy study and drug master file anticipated in the second quarter. At the same time, we expect to achieve another year of strong sales growth in all major markets across our companion and production animal product lines, in particular by leveraging our proprietary digital technologies. We are also looking forward to progressing all of our development-stage pipeline product candidates."

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

Development Highlights

- Parnell announced positive findings from its large-scale pilot efficacy study of Zydax[®] for the treatment of osteoarthritis (OA) in dogs. This trial demonstrated that treatment with Zydax resulted in a significant improvement of more than 40% in dog-owner assessed pain and mobility scores in 54% of dogs compared to 35% of dogs treated with placebo (p=0.01).
- The company initiated its Pivotal Efficacy Clinical Trial in 2014 at 28 trial sites. This study is expected to be completed in the second quarter of 2015 with results announced shortly thereafter. If the pivotal trial is successful, the company anticipates completing U.S. and EU regulatory filings for Zydax[®] and the potential for product approval in both markets in the first-half of 2016.
- In October 2014, the Active Pharmaceutical Ingredient (API) for Zydax[®] 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), together with the results from the pivotal efficacy study in 2015.
- Parnell continued to advance development of its proprietary digital technologies, mySYNCH[®] and iKAM[®]. These
 innovative digital tools are designed to support and expand current and future sales of the company's reproductive
 hormones and osteoarthritis products. We believe our digital technologies are key to our commercial success, by
 creating a fundamentally differentiated offering to our customers which can directly improve the profitability of their
 operations.

Corporate Highlights:

- Three new U.S.-based independent directors, David L. Greenwood, Phyllis Gardner, M.D. and Thomas E. Duley, were appointed to the company's Board providing key expertise and governance to drive the growth of the company.
- On December 8, 2014, the Board of Directors authorized a change in fiscal year to synchronize fiscal reporting with existing management processes that use calendar year planning and simplify communications with shareholders. As a result of the change, the Company is required to file a transition report for the transition period of July 1, 2014 to December 31, 2014. For a comparison of our operating results for the six-month transition period to the same six-month period ended December 31, 2013, we have presented unaudited numbers for the period of July 1, 2013 to December 31, 2013.
- U.S. operations were further strengthened by an expansion of facilities under a new ten-year operating lease and by the

appointment of Edward J. Robb, DVM, Chief Scientific Officer, and 16 additional roles to drive commercial growth and product development.

Financial Results (for the six-month period ended December 31, 2014)

Revenue

Total revenues increased by \$0.8 million, or 29%, for the six-months ended December 31, 2014, compared to the same period in 2013. This indicates strong revenue growth in the second half of 2014 which we believe places us on a solid trajectory for strong double-digit revenue growth in 2015 across all operating segments.

For the calendar year 2014, total revenues were \$8.4 million, an increase of \$0.8 million or 11% as compared to financial year 2014 (twelve months ended June 30, 2014).

Sales for the calendar year 2014 were lower than the calendar year 2013 (\$8.4 million compared to \$9.0 million, or 7% lower) due to a large distribution channel fill for U.S. reproductive hormones in May and June 2013, as described in the company's previous earnings release.

All of the company's operating segments performed well in 2014:

- Production Animal U.S.: sales (ex-Parnell) for the six months ended December 31, 2014 increased by \$0.5 million, or 85%, to \$1.2 million, compared to the six-months ended December 31, 2013. Furthermore, U.S. sales (ex-Parnell) increased in the second half of 2014 compared to the first half by \$0.2 million, or 18%, showing continued growth throughout the year. Sales in-market (sales from distributors to veterinarians and dairy producers) grew 209% from USD\$1.0 million in 2013 to more than USD\$3.1 million in 2014. Sales ex-Parnell for the full calendar year 2014 were \$2.2 million, which was 49% lower than calendar year 2013 due to the distribution channel fill that occurred in 2013.
- Production Animal Rest of World (ROW): sales increased in the six-months ended December 31, 2014, compared to the same period in 2013 by \$0.4 million, or 25%, to \$1.9 million. Furthermore, ROW sales for the full calendar year 2013 increased by \$1.5 million to \$4.8 million, which was a 44% increase over calendar year 2013.
- Companion Animal product sales continued to grow in Australia seven years after launch with total companion sales growing 5% in calendar year 2014 to \$1.4 million.
- We did not undertake contract manufacturing in calendar year 2014 or calendar year 2013. In 2015, we are focused on identifying revenue-generating opportunities that would commence in 2016, taking advantage of the currently estimated 75% available production capacity in our FDA-inspected sterile manufacturing facility.

Cost of Sales increased to \$3.3 million for the six-months ended December 31, 2014, as compared to \$3.0 million in the same period 2013 primarily as a result of a 29% increase in revenue and product mix variation.

Selling and marketing expenses increased \$0.5 million, or 27%, in the six-months ended December 31, 2014, compared to the same period in 2013, as a result of increased personnel associated with the expansion of our commercial infrastructure in the U.S. Specifically, we added two additional territory managers in our US Production Animal business unit which led to immediate market share gains. Late in 2014 we added two positions to commence the establishment of our Companion Animal commercial team in the U.S.

Regulatory expenses increased \$0.3 million during the second half of 2014 compared to the same period in 2013 primarily due to an increase in R&D activities associated with our product pipeline following the completion of our IPO.

Administration expenses increased \$1.8 million, or 140%, in the six-months ended December 31, 2014 compared to the same period in 2013, primarily as a result of increased headcount and external costs to support a substantially larger Commercial and R&D organization in the U.S. and increased compliance, regulatory and statutory costs associated with being a public organization following our successful IPO in June 2014.

Finance costs and Net foreign exchange losses on borrowings decreased \$1.7 million, or 86%, in the second half of 2014 compared the same period in 2013. Finance costs decreased by \$1.3 million due to full repayment of our senior debt facility with SWK Holdings LLC from the proceeds of the IPO which resulted in reduced interest expense. In the six-months ended December 31, 2013, we incurred Finance costs of \$1.6 million related to interest and borrowing costs on our previous debt facility (\$10 million) financed through Partners for Growth LLC.

Other Income was \$4.3 million for the six-months ended December 31, 2014, compared to \$1.0 million for the same period ended December 31, 2013. The \$3.3 million increase was primarily driven by net favorable foreign currency movements over

the period.

Net loss after tax for the six-month period ended December 31, 2014, was \$1.4 million compared to \$4.4 million for the same period in 2013. The \$3.0 million reduction in net loss was primarily attributable to:

- Increases in revenues of \$0.8 million due to higher revenues and product mix;
- Increase of \$3.4 million in other income primarily attributable to favorable foreign currency trends; and
- \$1.7 million reduction in borrowing and finance costs due to less outstanding debt in 2014.

This was offset by increases of:

- \$0.3 million in cost of goods sold due to product mix;
- \$0.5 million in selling and marketing costs due to increased headcount and marketing costs;
- \$0.3 million in regulatory expenses as a result of increased research and development expenditures; and
- \$1.8 million in administrative costs related to increased headcount and costs associated with being a public company.

"In fiscal period 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 \$0.11 and \$0.59 cents for the six-months ended December 31, 2014 and 2013, respectively.

As of December 31, 2014, Parnell had cash and cash equivalents to \$15.8 million compared to \$20.8 million as of June 30, 2014.

Guidance

Sales of Reproductive Hormones in the U.S. are expected to grow strongly in 2015 compared to 2014 with the recent expansion of the U.S. sales team, the addition of a seventh sales territory, and the roll-out of the mySYNCH digital technology. The resulting increase in customer demand is anticipated to translate into triple digit "ex-Parnell" sales growth in 2015.

Revenues for production animal products in non-U.S. markets are expected to maintain low double-digit growth in 2015.

Companion animal sales are expected to grow at a double-digit rate with the introduction of the latest version of the iKAM[®] digital technology and Glyde[®] Chews in 2015 and added sales personnel in Australia.

Anticipated Milestones in 2015:

We expect to continue the progress of registrations for Zydax[®] and to advance all of our product pipeline candidates as well as consider licensing opportunities. Specifically we expect to:

- Report results from the Pivotal Efficacy Clinical trial in the first half of 2015
- File complete FDA and EMA registration dossiers for the approval of Zydax[®] in the first half of 2015;
- Report full study results for PROCEPT® (novel cattle breeding program);
- Launch Glyde[®] Chews in Australia in the first half of 2015;
- Evaluate the U.S. launch of Glyde[®] and the roll-out of the iKAM[®] platform, which may include the addition of a dedicated national sales team calling on companion animal veterinary clinics, in advance of the launch of Zydax[®] in 2016.
- Commence API characterization and mode-of-action studies for PAR 121 and PAR 122 in the first half of 2015;
- Commence pharmacokinetic studies for PAR101 for laminitis in horses in the second half of 2015;
- Commence in-vivo hormone profile studies for GONADAPRO[®] in the second half of 2015:
- Commence prodrug isolation and antimicrobial studies for PAR 061 for mastitis in dairy cows in the second half of 2015;
 and
- Commence formulation development for PAR 081 for anesthesia 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 2016.

Conference Call Information:

Management will host a conference call on February 25, 2015 at 8:00 a.m. ET to discuss financial 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# 86814336.

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# 86814336.

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.

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 our other reports filed with the SEC. 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)

For the Six-Months Ended December 31,	
2014	2013
AUD\$	AUD\$
3,662,452	2,843,993
4,346,784	980,461
(3,343,802)	(2,997,481)
(2,447,578)	(1,923,181)
(311,931)	(51,938)
(3,042,221)	(1,266,543)
	(362,408)
(289,784)	(1,639,386)
(1,426,080)	(4,416.483)
(2,442)	
	Decemi 2014 AUD\$ 3,662,452 4,346,784 (3,343,802) (2,447,578) (311,931) (3,042,221) (289,784) (1,426,080)

Loss for the period	(1,428,522)	(4,416,483)
Other comprehensive loss, net of income tax		
Items that will be reclassified subsequently to profit or loss		
Foreign currency translation	(1,434,235)	(679,439)
Other comprehensive loss for the period, net of tax	(1,434,235)	(679,439)
Total comprehensive loss for the period	(2,862,757)	(5,095,922)
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Net loss per weighted-average share	AUD\$	AUD\$
Net loss attributable to common stockholders, Basic and diluted	(0.11)	(0.59)

Parnell Pharmaceuticals Holdings Ltd Consolidated Balance Sheets (Unaudited)

	December 31,	June 30,
	2014	2014
ASSETS	AUD\$	AUD\$
CURRENT ASSETS		
Cash and cash equivalents	15,819,418	20,804,339
Trade and other receivables	4,825,193	3,411,316
Inventories	2,755,956	2,009,843
Prepayments	470,568	112,995
TOTAL CURRENT ASSETS	23,871,135	26,338,493
NON-CURRENT ASSETS		
Trade and other receivables	50,184	30,583
Property, plant and equipment	11,899,006	11,210,442
Deferred tax assets		
Intangible assets	12,419,614	10,164,545
TOTAL NON-CURRENT ASSETS	24,368,804	21,405,570
TOTAL ASSETS	48,239,939	47,744,063
LIABILITIES		
CURRENT LIABILITIES		
Trade and other payables	8,614,034	5,726,684
Borrowings	4,590,483	4,135,218
Provision for employee benefits	379,558	305,330
TOTAL CURRENT LIABILITIES	13,584,075	10,167,232
NON-CURRENT LIABILITIES		
Trade and other payables	668,037	530,786
Borrowings		151,963
Provision for employee benefits	74,364	117,862
TOTAL NON-CURRENT LIABILITIES	742,401	800,611
TOTAL LIABILITIES	14,326,476	10,967,843
NET ASSETS	33,913,463	36,776,220
EQUITY		
Ordinary shares	55,343,451	55,343,451
Reserves	(1,585,035)	(150,800)
Accumulated losses	(19,844,953)	(18,416,431)
TOTAL EQUITY	33,913,463	36,776,220

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