

Parnell Pharmaceuticals Holdings Ltd Announces Financial Results for the Year Ended December 31, 2015

Strong Growth in the U.S. Market Drives Revenue 58% Higher to \$13.2 Million for the Year Ended December 31, 2015

OVERLAND PARK, Kan., Feb. 24, 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 year ended December 31, 2015.

"In 2015 we executed on our commercial and development milestones and demonstrated successful transfer of our proven business model from Asia Pacific origins to the large U.S. market. We nearly tripled the size of our U.S. Production Animal business while establishing a substantial sales and marketing presence in the U.S. Companion Animal sector. Most impressive was the rapid development of our digital technology assets which continue to evolve as a key differentiator in our value proposition to veterinarians and animal owners. In 2016 we expect revenues to again grow rapidly and our goal is to launch at least two new products including; Zydax and Luminous; in the U.S. and generate our first revenues from our Contract Manufacturing operations" said Robert Joseph, President and Chief Executive Officer of Parnell Pharmaceuticals Holdings Ltd.

Unless otherwise specified, all amounts are presented in Australian Dollars (AUD). For convenience 2016 Guidance is presented in U.S. dollars based on a consistent foreign exchange rate of \$0.72 AUD to \$1.00 USD.

2015 COMMERCIAL HIGHLIGHTS: GROUP SALES GROW 58% OVER 2014

- U.S. Production Animal: significant sales growth of 269% to \$8.1 million 260% driven by the expansion of our sales team to 7 territories and 9% driven by favorable exchange gains. In 2014 for the same period, we had 4 territories and had not commenced marketing of mySYNCH[®], our innovative digital technology designed to assist dairy farmers in improving the profitability of their operations. Ongoing success commercializing our reproductive hormones saw our U.S. market share in December 2015 reach 10.5%, the highest level since our launch.
- Rest-of-World Production Animal: sales declined by \$1.8 million to \$3.0 million in 2015 compared to 2014, primarily driven by year-to-year differences in the timing of orders to our international marketing partners and a decline in sales in Australia-New Zealand, where sharply lower milk prices adversely impacted demand. In 2016, we intend to launch a new version of mySYNCH[®], which we expect to improve sales given the efficiency of breeding programs becomes even more important during periods of low milk prices. In Canada sales improved in 2015 with in-market sales (from our marketing partner (Vetoquinol) to distributors) growing 17% over 2014.
- Companion Animal: sales grew 51% to \$2.1M primarily from the establishment of our companion team in the U.S. and the launch of Glyde Chews and FETCH in September 2015.
- Contract Manufacturing: no revenues were recorded in 2015. We have negotiated the key terms of contracts with two multi-national customers with whom we expect to sign agreements in the coming weeks.

2015 DEVELOPMENT HIGHLIGHTS

- Zydax[®]: we completed and submitted all remaining technical sections to the Center for Veterinary Medicines (CVM) of the U.S. FDA, namely:
 - Veterinary Master File, for the Active Pharmaceutical Ingredient (API) of Zydax in conjunction with our development partner Lonza AG
 - Chemistry and Manufacturing Controls
 - Target Animal Efficacy
- As communicated previously, we understand that it typically takes two 180-day cycles at CVM to complete all reviews. We therefore anticipate approval of Zydax in the U.S. in Q4, 2016 and once approved, an immediate commercial launch.
- We converted our U.S. filings to an EU submission and intend to file with the EMA in February, 2016, anticipating approval in early Q1, 2017.

- We completed a full development plan for Zydax for Cats and expect to commence pilot and pivotal studies in 2016, leading to a potential approval in early 2018.
- Our development partner Lonza AG has commenced commercial scale manufacture of the Zydax API for the launch of Zydax, once approved in the U.S. and EU.
- PAR121 and PAR122 (developmental compounds for bone healing and wound healing respectively): through CIMTECH (the licensor) we received a grant from the United Nations under the Nagoya Protocol for up to US\$1 million in matched funding to develop infrastructure and capability in the Cook Islands enabling us to transform the botanical extract precursors for the anticipated drug substances in PAR121 and PAR122. We expect to complete manufacturing process development in early 2016 to be followed by in-vitro and in-vivo pilot efficiency studies during 2016.
- mySYNCH[®] and FETCHTM: we launched the latest versions of our innovative digital tools which we have designed to drive sales growth 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 offering to veterinarians and animal owners.
- Luminous TM: we developed an innovative nutraceutical product that we believe is applicable to the sizeable dermatology market for dogs. This category is undergoing rapid expansion and we believe that Luminous will fill an unmet need by aiding in the reduction of inflammation associated with atopic dermatitis and supporting the growth of healthy new skin and hair. We will launch Luminous in the U.S. in Q2, 2016 beside our current companion animal product offerings Glyde and FETCH.

2015 CORPORATE HIGHLIGHTS:

- <u>Board</u>: we appointed two new Independent Directors, Ellen Richstone and David Rosen, to our Board of Directors. These Directors bring significant finance and animal pharmaceutical experience to the strategic oversight and governance our Company.
- Business Development: we are negotiating with multi-national parties interested in acquiring the rights to market Zydax[®] and Glyde[®] in Europe and Asia. We have taken a measured approach to this deal as we believe that it is imperative that we optimize both the terms and selection of a long-term partner given the significant potential value of Zydax in these markets. We remain confident a deal will be completed in ample time prior to potential approval and launch in these markets.
- <u>Licensing</u>: we continue to assess multiple in-licensing opportunities, including several products that could be swiftly taken to market by our Companion Animal sales team spanning pharmaceutical, nutraceutical and medical device products.
- Capital: On January 11, 2016, we entered into a share purchase agreement with Lincoln Park Capital Fund, LLC, a Chicago-based institutional investor ("Lincoln Park"). The agreement is structured as an equity commitment and enables us to elect entirely at our discretion to sell up to 35,000 shares (and under certain circumstances up to 55,000 shares) on any one day to Lincoln Park at a price that is known to Parnell before we choose to issue shares. Up to the date of this press release we have not utilized this facility and plan only to do so with discretion. We see the Lincoln Park facility as a way for us to sell modest amounts of new shares to Lincoln Park, in turn bringing in growth capital and loosening the tightly held nature of our stock.

Unrelated to the equity commitment and in recognition of Lincoln Park's belief in our company's business and the potential value of our stock, Lincoln Park agreed to purchase 175,000 unregistered shares at \$3.50 per share, which represents a 10% premium to the closing price on February 23, 2016, in addition, Lincoln Park has the option to purchase up to a further 150,000 shares at \$5 per share for cash consideration as provided in the option, which would represent a 57% premium to the February 23 closing price.

Furthermore, we have negotiated key terms for a senior debt facility of approximately \$US30 million that we expect to announce in coming weeks subject to completion of an agreement.

FINANCIAL RESULTS (for the year ended December 31, 2015)

Revenue

Total revenues were \$13.2 million for the twelve months ended December 31, 2015, an increase of \$4.8 million, or 58% (of which 7 percentage points related to a favorable exchange variance), over the same period in 2014. Growth momentum accelerated in the second half of 2015, with total revenues increasing by \$4.7 million, or 130%., as both our U.S. operating segments (Production and Companion Animal) performed strongly.

- Production Animal U.S.: sales ex-Parnell (sales from Parnell to distributors) increased by 269% (of which 9 percentage points related to a favorable exchange variance), or \$5.9 million, compared to 2014, to reach \$8.1 million for the year ended December 31, 2015. Sales increased in the second half of 2015 over the first half by \$3.9 million, or 330%. Full year sales in-market (sales from distributors to veterinarians and dairy producers) grew 55% from US\$3.1 million in 2014 to US\$4.9 million in 2015. This clearly demonstrates that distributors ran down the large inventories they had been holding in 2013 and 2014 and that ex-Parnell sales in 2015 continued to track in-market demand.
- Production Animal Rest of World (ROW): sales declined in 2015 by \$1.8 million, or 37%, compared to 2014, to be \$3.0 million for the year ended December 31, 2015. This was primarily due to timing difference of shipments to our distribution partners in Canada and Turkey. In Canada, our distribution partner Vetoquinol placed only one order in 2015 compared to two in 2014, and our marketing partner in Turkey moved their normal Q4, 2015 order into 2016. We expect that inventory levels and timing of orders have now normalized and we expect in 2016 to show growth over 2015. The decline was partially offset by favorable exchange gains of 4%.
- Companion Animal: sales increased \$0.7 million, or 51%, compared to 2014 to be \$2.1 million for the year ended December 31, 2015. The increase in revenue was related to the launch of Glyde Chews and FETCH in the U.S. in September 2015. Our Companion Animal segment in Australia continued to perform strongly nine years after launch, although regulatory delays for the approval of Glyde Chews impacted Australian sales in the first half of 2015, such that full year sales in 2015 were flat when compared to the same period in 2014. With this fully resolved in May 2015, sales of our Companion Animal products in Australia for the six-months to December 31, 2015, were up 51%, compared to the same period in 2014, building strong momentum as we proceed into 2016.
- Contract Manufacturing: We have not yet derived revenue for this operating segment but we were very pleased to be successfully appointed through a tender process by a major multinational as their contract manufacturer for a range of sterile injectable products. We have reached agreement on the major terms of this contract and expect the contract to be finalized in the coming month. Technology transfer would commence on contract signing likely followed by initial commercial supply in 2016. The terms of the deal and expected revenues will be announced in more detail upon completion of the contract.

We also reached agreement on key terms with a second major multinational to undertake contract manufacturing services for a sterile injectable product. We expect to complete the final contract in the coming weeks from which we will derive a contract establishment fee as well as immediate commercial supply of this product. The terms of the deal and expected revenues will be announced in more detail upon completion of the contract.

Cost of Sales

\$7.7 million for the year ended December 31, 2015, up from \$6.7 million in the same period in 2014 primarily as a result of increased revenues. Our product gross margin continued to improve throughout 2015, increasing 3.6% to 82.1% for the full year of 2015 compared to 78.5% in 2014.

Selling and marketing expenses

Increased \$5.8 million, or 96%, for the year ended December 31, 2015, compared to 2014, 88% of this increase was a result of increased personnel costs associated with the expansion of our commercial infrastructure in the U.S and a further 8% was driven by unfavorable foreign exchange fluctuations. The increased personnel costs was driven by the recruitment of 55 new staff to establish our U.S. Companion Animal sales and marketing team to launch Glyde and FETCH in the U.S. in September 2015 and in anticipation of the launch of Zydax in Q4, 2016. Furthermore, this team is expected to launch both Luminous[™] — a nutraceutical product for dermatological disorders in dogs and Reviderm[™] — a unique liquid bandage for use in companion animals in Q2, 2016.

Regulatory expenses

Increased by 4.3% compared 2014 primarily due to an increase in staff to support our new product filings.

Administration expenses

Increased \$8.9 million, or 149%, for the year ended December 31, 2015 compared to 2014, primarily as a result of increased headcount and external costs to support a substantially larger Commercial and R&D organization in the U.S., as well as increased compliance, regulatory and statutory costs associated with being a public organization for the full year of 2015, unfavorable foreign exchange fluctuations and the recording of share-based compensation expense for the first time.

Finance costs and Net foreign exchange losses on borrowings

Decreased \$5.6 million, or 86%, for the year ended December 31, 2015 compared to 2014. Finance costs decreased by \$4.6 million due to full repayment of our senior debt facility with SWK Holdings LLC from the proceeds of our IPO which resulted in reduced interest expense and \$1.0 million due to current borrowings being denominated in their functional

currencies.

Other Income

Increased to \$6.7 million for the year ended December 31, 2015, compared to \$5.6 million in 2014. The increase in other income was primarily driven by management's re-assessment of contingent provisions associated with supplier obligations. As of June 30, 2015 management determined that a provision was no longer necessary resulting in \$2.6 million (2014: \$Nil) being recorded in other income. This was partially offset by more favorable exchange gains in 2014 as compared to 2015.

Earnings

Our Net loss after tax for the year ended December 31, 2015 was \$13.7 million or \$1.03 per weighted-average share compared to \$14.3 million or \$1.32 per weighted-average share for the same period in 2014.

At December 31, 2015 Parnell held cash and cash equivalents of \$5.7 million compared to \$15.8 million at December 31, 2014.

2016 GUIDANCE

Commercial: Total Group Revenue expected to grow 50% - 70% to \$20 — \$22 million (US\$14 to US\$16 million)

- U.S. Production Animal: We expect double digit sales growth in 2016 driven by acquiring new customers through our mySYNCH digital technology. In Q4, 2016 we expect to launch "cow-side care" a revolutionary function within mySYNCH that will provide vital health management information to farmers at the point of contact with individual cows. We also expect the promotion of PROCEPT™ (a new patent-pending breeding program) will provide us with a point of differentiation and increased revenues. In Australia and New Zealand after a challenging 2015 we expect sales to improve in 2016 as farmers seek to optimize efficiency of milk production with reproductive breeding programs.
- Companion Animal: we expect sales to grow to rapidly primarily driven by our US business with a full year of sales of Glyde and the Q2' 2016 launch of Luminous. We have not yet estimated our 2016 sales of Zydax in the U.S., where we expect a Q4'2016 launch if approved by the FDA, nor have we estimated sales of Zydax for Europe.
- Contract Manufacturing: we expect to sign final contracts with two multinationals in the coming weeks. We expect to derive income of single digit millions from establishment fees, technology transfer fees and manufacturing income in 2016.

Development

Zydax: we expect to receive initial responses from the Center for Veterinary Medicines (CVM) of the U.S. FDA regarding the two major technical sections; Chemistry and Manufacturing Controls (CMC) and the Target Animal Efficacy (TAE) in Q2, 2016 and therefore expect we could achieve marketing authorization in the US in Q4, 2016.

We expect the early establishment of our Companion Animal commercial team in the U.S. and concurrent development of our innovative digital technology platform — FETCH™ will lead to rapid revenue growth immediately following FDA approval of Zydax.

We expect to further leverage our core Zydax asset by:

- signing a marketing partner appointment for Europe and Asia. We have held discussions with several companies and expect that such a deal if signed would bring several million dollars in establishment and milestone fees in 2016/2017.
- commencing pilot and pivotal safety and efficacy trials to seek an approval for the use of Zydax in Cats. We estimate there are over 50 million cats in the U.S. alone (compared to over 70 million dogs) and we believe there are very few viable therapeutic options for the very common disease of osteoarthritis in cats.
- further evaluating the regulatory path for Zydax in horses in the US and Europe. We already have regulatory approval in multiple markets where we have historically sold Zydax. We have more recently concentrated our product development and commercial efforts on the much larger market for dogs and cats but expect that Zydax has worthwhile potential in the Equine market in many countries.
- We expect to continue to receive patent grants relating to Zydax in 2016.
- PAR121 and PAR122 we expect to complete pilot-scale manufacturing process development in the Cook Islands in Q2, 2016 the extracts from which will lead to the commencement of pilot efficacy studies in Q2, 2016. We expect to announce results from these studies in Q3, 2016. We also expect to undertake chemical characterization studies for PAR121 and PAR122 in 2016. We continue to receive patent grants in a number of countries for both compounds.

mySYNCH[®] and FETCHTM: we continue to invest in our digital technology assets and expect to launch over 10 new enhancements for mySYNCH and FETCH in 2016. We expect this new functionality to continue to bolster our commercial point of differentiation with our customers by combining best-in-class new medicines with digital tools that help animal owners maximize the use of our products through better animal health management.

Corporate

- Board: we expect to make an additional appointment of an Independent Directors to our Board of Directors in Q2, 2016. The candidates being considered are focused on consumer and digital technology commercial experience.
- <u>Business Development</u>: we anticipate continuing to investigate various in-licensing opportunities and will seek additional contract manufacturing opportunities as well as seeking a marketing partner for Zydax in various markets where we do not currently operate.
- <u>Capital</u>: as we have previously communicated, we expect to use debt financing to augment our growth capital. We are in the final stages of negotiating terms for an approximate \$30 million debt facility which we anticipate we will conclude in the coming months. If we complete this transaction, this new larger facility will replace our current US\$11 million dollar debt facility.

We continue to focus on value creating opportunities in our business and believe that we have balanced our growth needs with capital utilization. As our core business continues to grow, and the business development opportunities from these core assets (such as Zydax US launch, Zydax EU partner appointment and contract manufacturing) continue to evolve, we expect to generate increasing amounts of revenue from our current business segments.

We also believe that we need to address the lack of liquidity in our stock which we believe is due to the small amount of available shares that are not held by our founders and their families and the major institutional investors who bought our Initial Public Offering. We believe the Lincoln Park agreement that we recently entered into allows us to prudently release small amounts of new shares to the market in a discretionary manner that remains entirely within our control. Of course, our major focus in 2016 is commercial success of our products in the U.S. and the launch of Zydax if approved in the U.S. and E.U. which could generate increasing cash flow and could result in us becoming profitable by late 2017.

Conference Call Information:

Management will host a conference call on February 24, 2016 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# 54549550.

A telephone replay will be available for one week following the call by dialing (855) 859-2056 (U.S./domestic) and (404) 537-3406 (International) using the conference ID# 54549550.

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 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 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

	31 December 2015 3 AUD\$	1 December 2014 AUD\$
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	5,666,679	15,819,418
Trade and other receivables	7,266,662	4,825,193
Inventories	3,426,926	2,755,956
Prepayments	531,843	470,568
TOTAL CURRENT ASSETS	16,892,110	23,871,135
NON-CURRENT ASSETS		
Trade and other receivables	67,457	50,184
Property, plant and equipment	12,666,214	11,899,006
Intangible assets	16,583,360	12,419,614
TOTAL NON-CURRENT ASSETS	29,317,031	24,368,804
TOTAL ASSETS	46,209,142	48,239,939
LIABILITIES		
CURRENT LIABILITIES		
Trade and other payables	6,780,440	8,614,034
Borrowings	3,122,553	4,590,483
Provision for employee benefits	438,008	379,558
TOTAL CURRENT LIABILITIES	10,341,001	13,584,075
NON-CURRENT LIABILITIES		
Trade and other payables	1,106,360	668,037
Borrowings	14,353,203	-
Provision for employee benefits	153,781	74,364
TOTAL NON-CURRENT LIABILITIES	15,613,344	742,401
TOTAL LIABILITIES	25,954,345	14,326,476
NET ASSETS	20,254,796	33,913,463
EQUITY		
Ordinary shares	55,343,451	55,343,451
Share-based compensation reserve	1,708,388	-
Reserves	(3,214,558)	(1,585,035)
Accumulated losses	(33,582,485)	(19,844,953)
TOTAL EQUITY	20,254,796	33,913,463

Consolidated Statements of Comprehensive Loss

For the Year Ended December 31,
2015 2014
AUD\$ AUD\$

13,169,753 8,361,058
6,725,142 5,614,519

Revenue Other income

Cost of goods sold Selling and marketing expenses	(7,745,865) (11,777,492)	(6,763,913) (5,999,223)
Regulatory and research and development expenses Administration expenses	(881,909) (11,940,246)	(846,142) (4,794,461)
Net foreign exchange losses on borrowings	(11,940,240)	(1,021,927)
Finance costs	(1,284,802)	(5,912,417)
Loss before income tax	(13,735,419)	(11,362,506)
Income tax (expense)/benefit	(2,113)	(2,982,854)
Loss for the period	(13,737,532)	(14,345,360)
Other comprehensive loss, net of income tax		
Items that will be reclassified subsequently to loss		
Foreign currency translation	(1,629,523)	(1,272,235)
Other comprehensive loss for the year, net of tax	(1,629,523)	(1,272,235)
Total comprehensive loss for the year	(15,367,055)	(15,617,757)

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