

Parnell Pharmaceuticals Holdings Ltd Announces Financial Results for the Year Ended December 31, 2016

OVERLAND PARK, Kan., March 21, 2017 (GLOBE NEWSWIRE) -- Parnell Pharmaceuticals Holdings Ltd (OTC:PARNF), 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, 2016 including; strong revenue growth of 45% to \$19.0 million.

President and CEO, Robert Joseph commented, "Since becoming a public company, Parnell has consistently grown revenues and 2016 demonstrated another strong performance with revenue growing 45% over 2015 to \$19.0 million. In conjunction with our recent move from the NASDAQ market to the OTC Pink Open Market, we have realized significant cost savings which we believe will enable us to become EBITDA profitable during 2017 whilst continuing to achieve strong revenue growth."

"We continue to refine and implement our differentiated commercialization strategy of combining great veterinary products with innovative digital technology solutions. We now have over 400,000 cows enrolled in the mySYNCH app and over 11,000 pet parents using FETCH. We believe this strategy will enable us to partner with veterinarians to help them drive substantial and sustainable revenue growth in our chosen therapeutic categories and it is a less expensive strategy than fielding large sales teams."

"Since the commencement of our Contract Manufacturing operations in Q2, 2016, we have continued to source multiple potential contracts and expect that we may announce the commencement of additional contracts throughout 2017."

"We have made excellent progress in compiling our FDA responses for the Efficacy as well as the Chemistry and Manufacturing Controls technical sections for Zydax for dogs and we are also close to refiling our European submission. We continue to seek expansion opportunities for the Zydax franchise with the completion of pilot safety and efficacy trials in cats and we have commenced working on a significant opportunity for Zydax in human use. If successful, we believe this project could substantially increase the value of the Zydax franchise. The R&D team also completed successful pilot studies for PAR121 and PAR122."

Mr. Joseph went on to say that "We have been very pleased with the successful transition from the NASDAQ market to the OTC Pink Open Market earlier this year, with share trading volumes appearing to remain consistent with previous periods and we have been able to realize significant cost savings. As we have previously communicated we remain focused on growing our business organically and becoming EBITDA profitable in 2017 whilst also identifying and pursuing opportunities that may unlock the potential value in our assets."

Unless otherwise specified, all amounts are presented in Australian Dollars (AUD) and are for the twelve-months ended December 31, 2016.

Commercial Highlights

• 45% increase in total Company revenues to \$19.0 million for the year ended December 31, 2016 compared to \$13.2 million for the corresponding period in 2015, driven by organic growth in all three business segments (Production Animal, Companion Animal and Contract Manufacturing);

- U.S. Production Animal revenues were \$9.2 million, growing \$1.1 million (14%) compared to the same period in 2015 driven by the addition 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.
- Total Companion Animal revenues were \$3.9 million, growing \$1.8 million (86%) compared to the same period in 2015. This rapid year-over-year increase is the combined effect of growth in the US (\$1.3 million), AU (\$0.4 million) and the US launch of Reviderm (\$0.1 million) in Q4, 2016. The successful roll-out of FETCH, our digital application for dogs, is now been used by over 11,000 pet parents in the US and Australian markets. We expect the continued growth in our digital marketing strategy will position us for a successful launch of new products such as Luminous and Zydax.
- Contract Manufacturing generated \$3.9 million in revenues for 2016. The Company did not generate any Contract Manufacturing revenue in 2015.

• During 2017, we expect to see continued strong revenue growth from all three Business Segments, and coupled with cost reductions instituted in the 4th quarter of 2016, we anticipate Parnell returning to EBITDA profitability during 2017.

- We expect double digit growth in our Production Animal business segment driven by growth in the US, Australian and New Zealand markets as well as the resumption of sales in some Middle Eastern markets and Canada where we did not make sales in 2016 due to the transition to new marketing partners. We anticipate mySYNCH will continue to be the main driver of sales in the US market. In total, we expect our Production Animal business segment to deliver over 50% EBITDA margin in 2017.
- Our Companion Business is expected to achieve strong double digit revenue growth in 2017, driven by increasing sales of Zydax in Australia and Glyde for Dogs in the US and Australia; achieved through expanding use of the FETCH platform. We also expect strong growth of Reviderm, recently launched in the US and a potential launch in Australia, along with the launch of Glyde for Cats and Luminous in the US. With recent cost reductions in our Companion Animal business segment, coupled with strong revenue growth, we expect to be approximately EBITDA breakeven in 2017 for this business segment.
- The Contract Manufacturing business segment is expected to grow in 2017 with the potential commencement of at least one new contract manufacturing agreement. We continue to field a number of inbound enquiries for contract manufacturing services and in 2017 we will increase our outbound promotion of our services. We expect that, with recent regulatory challenges being faced by other contract manufacturers, our facility will become more attractive as a modern and compliant sterile manufacturing facility. We also anticipate that we will commission new manufacturing equipment to enable us to manufacture medicated "chews" for dogs and cats. Once complete, this would not only ensure a high quality, low cost supply of our own products (Glyde and Luminous) but may enable us to expand our contract manufacturing capabilities to manufacture pharmaceutical "chews" for other companies. We believe that the "chew" dosage form is an area of high demand due to ease of administration for the pet owner yet there is limited supply capability and capacity from other contract manufacturers who are FDA approved.

Development Highlights

• Zydax for Dogs: in 2016 we received a response to our filings of the two remaining major technical sections; Efficacy and Chemistry and Manufacturing Controls, or CMC, from the FDA and we also received an initial response to our European submission. Throughout 2016 we compiled the necessary data and we had pre-submission conferences with the FDA to plan our responses. We now expect to submit our FDA filing of the CMC section in March, 2017 and the efficacy section in late Q2, 2017. If both sections are deemed acceptable, we could achieve a potential approval in late 2017 and launch shortly thereafter. We also expect to refile our European submission in April, 2017 which could potentially lead to an approval in late 2017. This is later than anticipated but we continue to be optimistic about the commercial prospects for Zydax, especially considering recent events associated with other investigative or recently launched products.

• Zydax Cats: as we have previously communicated, we believe the market for osteoarthritis, or OA, treatments for cats is a large and underserved market. In the US there are no approved products for the long term treatment of the clinical signs of OA in cats yet there are over 50 million cats and the incidence of degenerative joint disease in cats is estimated to be as high as 90%. One of the major obstacles to successfully treating OA is the higher rates of toxicity of many drugs in cats. We completed a successful pilot safety study of Zydax in cats and we believe that we have a high chance of success of replicating these results in a Target Animal Safety study for submission to regulatory authorities. We also believe that we can utilize a substantial portion of the CMC section from Zydax for dogs. During 2016, we also investigated the use of potential measurement tools for assessing changes in the clinical signs of osteoarthritis in cats. This pilot efficacy study has informed us as to potential designs for a pivotal efficacy study.

• Disease Modification Claim for Zydax: we have long believed that Zydax may have the potential to be the first drug approved with a true disease modification claim. We have investigated a number of potential trial designs that could be used to justify this claim and we expect to complete one of these trials in 2017.

• Zydax Geographic Expansion: we continue to receive interest from potential marketing partners for Zydax, including Europe. As we have previously communicated, we believe the terms of any such deal are likely to be more favorable as we progress closer to approval. Once we complete our EU and US re-filings, we anticipate commencing the registration process for Zydax for dogs in other markets such as Canada.

• Zydax Human Use: Zydax contains an active substance that is closely related to products currently being used for human use. In 2015, Parnell acquired the rights which are believed to be the only available supply of the starting material for these drugs and thus the companies investigating the development of human drugs need Parnell to supply this material. In addition to owning the supply of the starting material, Parnell's patented manufacturing process is also an attractive asset to these companies, as is our Drug Master File that has been compiled for veterinary products but which may also be applicable to the human drugs. A number of companies have expressed interest in partnering with Parnell in this area which

may lead to a potential deal signing in 2017.

• PAR121: we successfully completed in-vitro and in-vivo studies in 2016 that demonstrated the bone-regeneration properties of PAR121. We now expect to progress in-vivo studies in larger species and if successful move into pivotal safety and efficacy studies in dogs. We continue to believe that the market for a bone regenerating agent is substantial and that PAR121 would be a very unique therapeutic proposition.

• PAR122: we successfully completed in-vivo and in-vitro efficacy and safety studies which demonstrated that PAR122 can thicken the epidermal layer of skin and is not an irritant when applied topically. We believe there are various paths to market for this compound that may result in a marketable product quickly and inexpensively.

Corporate Highlights

• In November, 2016 we entered into a four-year USD\$20.0 million senior secured credit facility with US based lenders, SWK Holdings LLC, HI PPH LLC, and R-S Healthcare Management. A portion of these proceeds, (USD\$11.8 million), was used to retire the term loan we established with Midcap Financial in June, 2015. We expect the new senior secured credit facility to provide sufficient capital to complete the transition from our investment phase to planned profitability in 2017. Given the strong cash generation of our commercial stage businesses, this debt finance provides attractive non-dilutive capital, especially as there were no equity instruments associated with this loan. The interest rate is low double digits and there is an interest only period of 24 months.

• After assessing the costs associated with remaining a NASDAQ listed company, and the substantial costs of becoming a US issuer as at January 1, 2017 (estimated in totality to exceed \$USD3.0 million in 2017), the Board elected to file a Form 25 to voluntarily delist our shares from the NASDAQ Global market as at December 31, 2016. In January 2017, Parnell securities began trading on the OTC Pink Open Market under a new ticker: PARNF. Since making this transition, the company's shares are trading in volumes similar to or exceeding that which was occurring whilst on the NASDAQ. It is also notable that since becoming a publicly listed company in June 2014, none of the founders or key management personnel have sold any Parnell shares and in some cases, continued to buy shares. The Board continues to strongly believe in the prospects for Parnell and in the inherent value of the assets that have been developed over the last ten or more years.

Financial Results (for the year ended December 31, 2016)

Revenue

Total revenue of \$19.0 million for the year ending December 31, 2016, a 45% increase compared to the same period in 2015.

Our operating segments performed as follows:

• Production Animal - US: Revenue for year ended December 31, 2016 was \$9.2 million, an increase of \$1.1 million, or 14%, over the same period in 2015. Our market share continues to grow lending support to our differentiated value proposition combining clinical science leadership (through the PROCEPT[™] breeding program) with digital technology (mySYNCH) for this high margin business segment.

• Production Animal - Rest of World (ROW): Revenue for year ended December 31, 2016 decreased by \$0.9 million (31%) to \$2.1 million compared to the same period in 2015. This decrease is the combined effect of increases in Australia (\$0.1 million) and Africa (\$0.2 million), offset by declines in New Zealand (\$0.3 million) due to a year with very low milk prices driving dairy farmers to seek cost savings. Revenues in the Middle East also declined (\$0.2 million) due to the transition to a new marketing partner which meant no sales were booked in 2016 but are expected to return in Q1, 2017. We also saw a decline in revenues for Canada (\$0.7 million) for the same reason. In Canada, we expect revenues to return in 2017 with the appointment of a new marketing partner and in future years we expect substantial growth with the introduction of our reproductive hormone Gonabreed. Previously we have only sold Estroplan in Canada. We also expect to pursue geographic expansion in 2017 for our reproductive hormone products, in particular in Europe which we expect could provide an attractive additional revenue stream.

• Companion Animal: Companion Animal revenues were \$3.8 million, growing \$1.8 million (86%) for the year ending December 31, 2016 compared to the same period in 2015. This increase is due to growth in Glyde sales in the US (\$1.3 million), growth in both Zydax and Glyde sales in Australia (\$0.4 million) and the US launch of Reviderm (\$0.1 million). We expect our Companion Business to grow again in 2017 from sales of Glyde, Reviderm and Luminous in the US as well as Glyde and Zydax in Australia. With this revenue growth and a right-sizing of our sales and marketing expenditure, we expect to bring this business segment to profitability in 2017. We also expect to see significant growth in the utilization of our FETCH digital application. This entirely new business paradigm has been implemented in approximately 700 veterinary clinics in the US. In 2017, we expect to refine the focus of FETCH to become an effective customer acquisition and retention tool which we believe will grow our customer base (of veterinary clinics and pet owners) but also drive a significant increase

in profit margins. As we have consistently stated, we believe this business model is superior to traditional animal pharmaceutical models that mostly rely on large and expensive sales forces and product bundling and price discounting to acquire market share. We believe that the progress we have made to date in the US Companion Animal business demonstrates the success of this model and replicates the success we have achieved in Australia over many years.

• Contract Manufacturing - Revenue of \$3.9 million was generated for the year ending December 31, 2016. No revenue was generated during the comparable period in 2015. We continue to prospect additional CMO opportunities, and given the rarity of our FDA and EMA approved sterile manufacturing facility, we expect to attract several new opportunities in 2017.

Expenses

<u>Cost of Sales</u> for the year ending December 31, 2016 was \$9.0 million, compared to \$7.7 million for the comparable period in 2015. This 16% increase year on year, was driven by a 45% increase in sales. 2016 Gross margin as a percentage of revenue, using a Cost of Goods Sold - Product basis, was 81.4% compared to 82.1% in 2015, due to a higher mix of Companion and Contract Manufacturing sales in 2016 compared to 2015.

<u>Selling and Marketing</u> expenses increased \$2.3 million, or 20%, for the year ended December 31, 2016 compared to the same period in 2015 resulting from the full year effect of the Companion Animal sales and marketing team and associated support functions to launch Glyde Chews and FETCH in the U.S. in September 2015. Our Production Animal business segment has long been profitable, as has our Australian Companion Animal Business however during Q4, 2016 we reviewed the level of investment in Selling and Marketing costs for the US Companion Animal business and decided to reduce the level of expenditure through to the launch of Zydax thereby improving our profitability of this operating segment. We anticipate the combination of reduced personnel expenditure with an increased focus on our digital technologies will drive faster and more profitable revenue growth of Glyde, Reviderm and Luminous. In total, we expect this will reduce annual expenditure on sales and marketing costs by approximately \$6 million in 2017 as compared to 2016.

<u>Regulatory and R&D</u> spending in 2016 of \$1.5 million was an increase of \$0.6 million over the prior year. The increase is the full year effect of additional staffing added in 2015 to support our new product filings, in addition to incremental expenditure on product development projects (PAR121 and PAR122). All development costs directly associated with the Zydax development work during the years ended December 31, 2016 and 2015 have been capitalized. We believe our R&D processes are cost and time efficient, and are sufficiently precise to determine the feasibility of prospective products. This approach affords us the ability to both progress our current portfolio of pipeline candidates while simultaneously pursuing in-licensing opportunities in 2017.

<u>Administration expenses</u> increased \$1.3 million, or 11%, in the year ended December 31, 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. As with Sales and Marketing Expenses, the Board of Directors determined that significant cost savings could be made in Administration expenses and these were put into effect during Q4, 2016. We therefore expect to see a reduction in these expenditures in 2017 of nearly \$4 million.

<u>Finance costs and Net foreign exchange losses on borrowings</u> costs increased \$2.5 million, or 197%, for the year ended December 31, 2016 compared to the same period in 2015. This increase in 2016 is predominantly due to the fees associated with the pay down of our previously held \$USD11.0 million term loan. This facility was in place in the first 10 months of 2016 and was paid off with the proceeds from of our new \$USD20.0 million term loan in November 2016. In addition, the previously held term loan of \$USD11.0 million commenced in June 2015, so was only in place for 6 months of 2015.

<u>Other Income</u> for the year ended December 31, 2016 was \$0.9 million compared to \$6.7 million in 2015. This decline is due to foreign exchange movements of \$3.1 million, primarily between the Australian dollar and the US dollar. In 2015 we also reported non-recurring other income of \$2.6 million. In addition, in 2015, \$0.4 million in government grants were received from the Kansas Department of Commerce compared to \$0.1 million in 2016. For 2016, \$0.9 million was recorded in Other Income as part of research and development incentives received in Australia, compared to \$0.8 million in 2015.

<u>Net loss after tax</u> for the year ended December 31, 2016 increased to \$21.7 million compared to \$13.7 million in 2015. As stated previously, we expect the Net loss after tax to reduce markedly in 2017 due to ongoing reduction in expenses and increasing revenues.

<u>Net loss per weighted-average share</u> was (\$1.37) for the year ended December 31, 2016 compared to a (\$1.03) per share loss for the same period in 2015.

Cash and cash equivalents as of December 31, 2016, were \$7.1 million compared to \$5.7 million at December 31, 2015.

Conference Call Information

Management will host a conference call on March 21, 2017 at 5:00 pm ET to discuss financial results and answer questions. Investors and analysts can access the conference call by dialing (877) 244-6184 FREE (U.S./Canada) or (920) 663-6271 (International) and using conference ID# 78918738.

A telephone replay will be available for one week following the call by dialing (855) 859-2056 FREE (U.S./domestic) and (404) 537-3406 using the conference ID# 78918738.

About Parnell

Parnell (PARN) is a fully integrated, veterinary pharmaceutical company focused on developing, manufacturing and commercializing innovative animal health solutions. Parnell currently markets six products for companion animals and production animals in 14 countries and augments its pharmaceutical products with proprietary digital technologies - FETCH[™] 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 <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 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 or OTC Markets. 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 31 December 2016 2015	
	AUD\$	AUD\$
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	7,115,498	5,666,679
Trade and other receivables	4,922,086	7,266,662
Inventories	3,622,891	3,426,926
Prepayments	441,189	531,843
TOTAL CURRENT ASSETS	16,101,664	16,892,110
NON-CURRENT ASSETS		
Trade and other receivables	723,739	67,457
Property, plant and equipment	12,128,392	12,666,214
Intangible assets	18,624,832	16,583,360
TOTAL NON-CURRENT ASSETS	31,476,963	29,317,031
TOTAL ASSETS	47,578,627	46,209,141
LIABILITIES		
CURRENT LIABILITIES		

Trade and other payables	7,875,987	6,780,440
Borrowings	10,178	3,122,553
Provision for employee benefits	623,574	438,008
TOTAL CURRENT LIABILITIES	8,509,739	10,341,001
NON-CURRENT LIABILITIES		
Trade and other payables	1,087,670	1,106,360
Borrowings	29,831,992	14,353,203
Provision for employee benefits	85,528	153,781
TOTAL NON-CURRENT LIABILITIES	31,005,190	15,613,344
TOTAL LIABILITIES	39,514,929	25,954,345
NET ASSETS	8,063,698	20,254,796

EQUITY

Ordinary shares	63,522,251	55,343,451
Share-based compensation reserve	3,757,536	1,708,388
Reserves	(3,942,161)	(3,214,558)
Accumulated losses	(55,273,928)	(33,582,485)
TOTAL EQUITY	8,063,698	20,254,796

Consolidated Statement of Loss and Comprehensive Loss

	12 months to 31 December 2016 AUD\$	12 months to 31 December 2015 AUD\$
Revenue Other income		69,753 25,142
Cost of goods sold Selling and marketing expenses	(8,977,871) (7,74 (14,121,493) (11,77	15,865)
Regulatory and research and development expenses Administration expenses		31,909)
Finance costs Loss before income tax	(3,821,345) (1,28 (21,682,389) (13,73	35,419)
Income tax expense Loss for the period Other comprehensive loss, net of income tax	(9,054) (21,691,443) (13,73	(2,113) 37,532)
Items that will be reclassified subsequently to profit or loss Foreign currency translation	(727,603) (1,62	29,523)
Other comprehensive loss for the year, net of tax Total comprehensive loss for the year	(727,603) (1,62 (22,419,046) (15,36	29,523) 67,055)
Net loss per share Net loss attributable to common stockholders, Basic and dilute	AUD\$ d (1.37)	AUD\$ (1.03)

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