

Parnell Pharmaceuticals Holdings Ltd Announces Financial Results for the Nine-Month Period Ended September 30, 2016

OVERLAND PARK, Kansas, Nov. 02, 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 first nine months of 2016 including; strong revenue growth of 62% to \$13.8 million, promising results from studies for Zydax for cats, PAR121 and PAR122 as well as the launch of Reviderm™ and agreement of terms on a new \$US20 million debt facility.

President and CEO, Robert Joseph commented, "Once again, Parnell has announced strong financial results with revenues of \$13.8 million for the first nine-months of 2016; growth of 62% compared to the same period in 2015. We have also made adjustments to our operating costs, which we anticipate will allow us to deliver the previously announced expectation of turning profitable in 2017, before the launch of Zydax. We believe that, with the planned closing of a new \$US20 million debt facility, Parnell is well positioned to deliver significant accretion to shareholder value.

Our sales organization continues to demonstrate the success of our differentiated commercialization strategy; combining great veterinary products with innovative digital technology solutions. We now have hundreds of thousands of cows enrolled in the mySYNCH app and over 10,000 pet parents using FETCH. We were excited to recently launch RevidermTM; a unique antimicrobial liquid bandage that we believe has an array of applications and has garnered significant interest from veterinarians already.

Since the commencement of our Contract Manufacturing, or CMO, operations in Q2, 2016, we have continued to source new potential contracts and we are hopeful that 2017 will be another strong year for CMO operations.

Our R&D team once again had a strong quarter delivering positive results for our Zydax franchise including successful completion of a safety trial in cats and commencement of a pilot efficacy study for treating osteoarthritis in cats. We are also running additional studies for Zydax for dogs that if successful could lead to an expanded label. The R&D team also completed successful in-vitro and in-vivo studies for PAR121 and PAR122 respectively.

We had a productive meeting with the FDA regarding the efficacy technical section for Zydax for dogs and expect to refile both the Efficacy section and the Chemistry and Manufacturing Controls, or CMC, section with the FDA this quarter. That could lead to a potential approval in late Q2, 2017. We also expect a potential approval for Zydax in Europe and Canada at approximately the same time."

Mr. Joseph went on to say that "Despite consistently strong business performance, and delivery of essentially all our milestones, there seems to be an inexorable incongruence between the value of Parnell and our market cap. Recently, this gap has widened significantly. We believe that Parnell owns an array of attractive underlying assets including 6 marketed products, an FDA and EMA approved manufacturing facility and a valuable pipeline, including Zydax and innovative digital technology apps. Parnell's Board of Directors believe that a rational assessment of these underlying assets combined with recent buoyancy of animal health M&A activity should give an expectation that the realizable value of Parnell's assets could be many times higher than what is reflected by the current share price. The Board of Directors is not aware of any reason why the share price should have declined so significantly. Conversely we are confident in the assets Parnell has worked for many years to create; our marketed products and manufacturing facility are generating strong profit margins and as revenues grow in 2017 and the level of growth related investments naturally winds down, we believe the company is well positioned to deliver profitability and asset value accretion."

Unless otherwise specified, all amounts are presented in Australian Dollars (AUD) and are for the nine-months ended September 30, 2016.

Commercial Highlights

- 62% increase in total Company sales to \$13.8 million for the nine-months ending Q3, 2016 compared to \$8.5 million for the corresponding period in 2015. Growth continues to be driven by organic growth in Production Animal, Companion Animal, and Contract Manufacturing businesses;
 - 30% revenue growth in our U.S. Production Animal segment over the prior 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. Q3, 2016 saw yet another record

sales month underpinning our continued growth expectations.

- 156% revenue growth in our Companion Animal business compared to the same period in 2015. The continued roll-out of Glyde and FETCH in the US market complemented ongoing strength in Australia, where Companion Animal revenues grew 32% over the first nine-months of 2015. FETCH, our digital application for dogs, has now been used by over 10,000 pet parents in the US and Australian markets. This large and growing base of new "Parnell clients" bodes well for the revenue growth of new products such as Reviderm, Luminous and Zydax.
- Contract Manufacturing has generated \$2.7m in revenues through for the first nine months of 2016. The Company did not generate any Contract Manufacturing revenue in 2015.
- For the remainder of 2016 and in to 2017, we expect to see continued strong revenue growth from all three of our Business Segments which we anticipate will lead to Parnell returning to profitability in 2017. This will complete the investment phase undertaken for the last five years and with the potential launch of Zydax for dogs and cats as well as potential launch of PAR121 (bone regeneration) and PAR122 (skin regeneration) in 2017 through 2018 we believe that we have strong revenue growth prospects that will build on our foundation of existing, high-margin revenues.

Development Highlights

- We successfully completed a pilot safety study for the use of Zydax in cats. Doses up to eight times the expected commercial dose were administered to cats over four weeks with no clinically significant changes observed. This paved the way for commencing a pilot efficacy study which is currently underway. Both these studies, once completed could enable the commencement of Pivotal Safety and Efficacy studies for the use of Zydax to treat osteoarthritis in cats. There are currently no approved products in the US or Europe for treating this very common disease long term. We believe Zydax could be the first product approved for long term, safe use to treat OA in cats. This could be a very large opportunity for the Zydax franchise given there are over 50 million cats in the US with the prevalence of OA in cats reported to be over 60%. At this stage, we believe we could achieve potential registration in the US and Europe in 2018.
- We also continued enrollment for a large study to assess new clinical end-points for the use of Zydax in dogs that if successful, may lead to a potential Disease Modification claim. We have a further study in the DMOAD area planned to commence later this year. Combined, we believe these studies could lead to a significant increase in the value of the Zydax franchise.
- We successfully completed an in-vitro study for PAR121, our developmental compound that is expected to speed bone healing. This study demonstrated increased mineralization of bone, an important marker of bone healing, as compared to control samples. We also commenced an in-vivo rodent study to demonstrate enhanced bone healing and expect to commence a safety study and a bone healing study in dogs. We anticipate results of all these studies by the first half of 2017. We believe a combination of positive results from these studies could lead to a significant increase in the value of this asset.
- We also completed successful in-vivo studies for PAR122 our developmental compound that is expected to speed skin healing. This study showed a marked increase in the thickness of the epidermis. As with PAR121, we expect to commence safety and skin healing studies in dogs and if successful, we believe this could lead to a significant increase in the value of this asset.

Corporate Highlights

- We have negotiated terms to replace our current \$US11 million debt facility with a new \$US20 million facility. We are in final stages of documentation and expect to close in the coming weeks. We expect this 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.
- We have recently reviewed aspects of our planned investments and prioritized those investments that we believe will provide the fastest accretion to shareholder value. As a result, we have materially reduced our cost base in line with our goal of planned profitability in 2017.

Financial Results (for the nine month period ended September 30, 2016)

Revenue

Total revenue of \$13.8 million for the nine month period ending September 30, 2016, a 62% increase compared to the same period in 2015.

Our operating segments performed as follows:

- Production Animal US: Sales for the nine months ended September 30, 2016 were \$7.1 million, an increase of \$1.0 million, or 30%, 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 the nine months ended September 30, 2016 decreased by 42% to \$1.1 million compared to the same period in 2015. As we have disclosed in previous announcements, our ROW business is driven primarily by large orders that can span differential quarters from one year to the next. Conversely, we believe our reproductive hormone products represent attractive assets with the opportunity for geographic expansion in 2017. In particular, we plan on launching both our products estroPLAN and GONAbreed in Canada (estroPLAN was previously marketed in Canada on our behalf by Vetoquinol) and also potentially in Europe in 2017 which we expect could provide an attractive revenue stream.
- Companion Animal: Revenue for the nine months ended September 30, 2016 grew 156% to \$2.9 million driven by establishment of our US operations and a 32% increase in Australian sales compared to the same period in 2015. We expect full-year 2016 revenue growth to be of similar magnitude. Our Companion Business is expected to grow strongly 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.
- Contract Manufacturing Revenue of \$2.7 million was generated for the nine months ended September 30, 2016. No revenue was generated during the comparable period in 2015. We continue to prospect additional CMO opportunities. Given the rarity of our FDA and EMA sterile manufacturing facility, we expect to attract several new opportunities in 2017.

Expenses

Cost of Sales for the nine months ended September 30, 2016 was \$6.3 million, compared to \$5.2 million for the comparable period in 2015. This was a 21% increase year on year, driven by a 62% increase in sales, clearly demonstrating the ability of our manufacturing facility to generate significantly greater output with only a marginal increase in variable costs. Gross margin as a percentage of revenue, using a Cost of Goods Sold — Product basis, remained consistent with the first nine months of 2015, at 83%. We expect this gross margin level to continue for the full year 2016.

Selling and marketing expenses increased by \$4.5 million to \$11.3 million for the nine months ended September 30, 2016. This increase was driven by the full year effect of establishing our US Companion Animal business and launch FETCHTM, our digital technology that has now been used by over 10,000 pet parents. We have recently reviewed the level of investment to establish our US presence and we have determined that we can reduce the level of expenditure through to the launch of Zydax thereby improving our profitability of this operating segment. Our Production Animal business segment has long been profitable, as has our Australian Companion Animal Business. Our objective through to 2017 is to make our US Companion Animal Business profitable before the launch of Zydax. We anticipate this will be achieved by increasing revenues of Glyde, Reviderm and Luminous as well as attenuation of expenses on sales and marketing by focusing on utilization of our existing digital technologies.

Regulatory and R&D expenses increased by \$0.5 million to \$1.2 million for the first nine months of 2016 due to costs associated with the initiation of several preclinical and studies aimed at developing our pipeline products PAR121 and PAR122.

Administration expenses increased by \$3.1 million to \$10.7 million for the nine months ended September 30, 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 have determined that significant cost savings can be made in Administration expenses and we therefore expect to see this amount reduce materially in 2017, in line with our broader expectation of returning to profitability in 2017.

<u>Finance costs and Net foreign exchange losses on borrowings</u> increased by \$0.7 million to \$1.6 million for the nine months ended September 30, 2016 from the comparable period in 2015 due to interest costs on the debt facility that was established in June, 2015.

Other Income/(Expense): for the nine-month period ending 30, June 2015 we reported Other Income of \$7.4 million and for the same period in 2016 this declined by \$8.5 million to be an Expense of \$1.1 million. This was due to Foreign Exchange

movements of \$6.2 million, primarily between the Australian dollar and the US dollar, resulting from an unrealized foreign exchange expense of \$1.7 million in the first nine months of 2016 compared to an unrealized foreign exchange gain of \$4.2 million in the same period of 2015. In 2015 we also reported non-recurring other income of \$2.6 million. In addition, in the first nine months of 2015, \$0.4 million in government grants were received from the Kansas Department of Commerce compared to \$0.1 million in 2016. In the first nine months of 2016, \$0.4 million was recorded in Other Income as part of research and development incentives received in Australia, compared to \$0.3 million in 2015.

<u>Net loss after tax</u> for the nine months ended September 30, 2016 increased to \$18.6 million compared to \$5.4 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.

Net loss per weighted-average share was (\$1.21) for the nine-months ended September 30, 2016 compared to a (\$0.41) per share loss for the same period in 2015.

Cash and cash equivalents as of September 30, 2016, were \$2.1 million compared to \$5.7 million at December 31, 2015. Cash utilization has reduced significantly with recent cost reductions and prioritizations of R&D investments. We also expect to increase our debt funding by replacing our current \$US11 million facility with a \$US20 million facility. We expect this new loan could close in the coming weeks. Combined with our organic cash generation we believe Parnell will start to be cash flow positive in 2017, before the launch of Zydax.

Conference Call Information

Management will host a conference call on November 2, 2016 at 5:00 pm EDT to discuss financial results and answer questions. Investors and analysts may access the conference call by dialing (877) 244-6184 FREE (U.S./Canada) or (920) 663-6271 (International) and using the conference ID# 10159582.

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# 10159582.

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 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 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. 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)

	30 September 2016 \$AUD	31 December 2015 \$AUD
CURRENT ASSETS		
Cash and cash equivalents	2,072,951	5,666,679
Trade and other receivables	3,208,774	7,266,662
Inventories	3,676,599	3,426,926
Prepayments	589,184	531,843
TOTAL CURRENT ASSETS	9,547,508	16,892,110
NON CURRENT ASSETS		
Trade and other receivables	64,983	67,457
Property, plant and equipment	12,072,998	12,666,214
Intangible assets	17,367,621	16,583,360
TOTAL NON CURRENT ASSETS	29,505,602	29,317,031
TOTAL ASSETS	39,053,110	46,209,141
LIABILITIES CURRENT LIABILITIES Trade and other payables Borrowings Provision for employee benefits TOTAL CURRENT LIABILITIES NON CURRENT LIABILITIES Trade and other payables Borrowings Provision for employee benefits - non-current TOTAL NON CURRENT LIABILITIES TOTAL LIABILITIES	8,006,121 7,003,797 680,242 15,690,160 1,057,476 9,938,247 193,064 11,188,787 26,878,947	6,780,440 3,122,553 438,008 10,341,001 1,106,360 14,353,203 153,781 15,613,344 25,954,345
NET ASSETS	12,174,163	20,254,796
EQUITY Ordinary Share Capital Share based Compensation Reserves (Accumulated losses)/retained earnings TOTAL EQUITY	63,301,764 3,027,222 (1,988,781) (52,166,042) 12,174,163	55,343,451 1,708,388 (3,214,558) (33,582,485) 20,254,796
TOTAL EQUIT	12,174,103	20,234,190

Consolidated Statements of Comprehensive Loss (Unaudited)

For the Nine-Months Ended September 30.

	Ended September 30,	
	2016	2015
	AUD\$	AUD\$
Revenue	13,774,480	8,490,393
Other income/(expense)	(1,147,162)	7,352,397
Cost of goods sold	(6,339,699)	(5,231,768)
Selling and marketing expenses	(11,340,528)	(6,832,457)
Regulatory, R&D expenses	(1,163,578)	(651,774)
Administration expenses	(10,713,500)	(7,612,336)
Net foreign exchange losses on borrowings	-	-
Finance costs	(1,642,645)	(930,192)
Loss before income tax	(18,572,632)	(5,415,738)

Income tax expense	(10,924)	(2,113)
Loss for the period	(18,583,557)	(5,417,851)
Other comprehensive (loss)/profit, net of income tax		
Items that will be reclassified subsequently to profit or loss		
Foreign currency translation		
_	1,225,777	(2,711,872)
Other comprehensive (loss)/profit for the period, net		
of tax	1,225,777	(2,711,872)
Total comprehensive loss for the period	(17,357,780)	(8,129,723)
Net loss per weighted-average share	AUD\$	AUD\$
Net loss attributable to common stockholders, Basic and diluted	(1.21)	(0.41)