Zacks Small-Cap Research

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Parnell Pharmaceuticals Holdings Ltd. (PARN-NASDAQ)

PARN: Strong Revenue Growth Through the First Nine Months of 2016…

Based on our financial model that uses a EV/revenue multiple of 3.0x based on projected 2020 revenues, with an 18% discount rate, PARN is valued at $11/share. Additional upside to this valuation is possible from better than expected sales of the company's products and attaining approval for additional products.

Current Price (11/10/16)	$1.28
Valuation	**$11.00**

OUTLOOK

On November 2016, Parnell Pharmaceuticals Holdings Ltd. announced financial results for the first nine months of 2016. Revenues totaled $13.8 million, a 62% increase compared to the corresponding period in 2015. The company announced cost cutting measures that, combined with strong revenue growth, should result in the company being cash flow positive in 2017 before the launch of Zydax®.

Parnell has completed a pilot safety study of Zydax® in cats, setting the stage for pivotal safety and efficacy studies to be conducted in 2017. The company will be refiling the Efficacy and CMC sections for Zydax® for dogs with FDA approval expected in mid-2017.

SUMMARY DATA

52-Week High	**$4.54**
52-Week Low	**$1.02**
One-Year Return (%)	**-63.64**
Beta	**-0.03**
Average Daily Volume (sh)	**44,969**
Shares Outstanding (mil)	**17**
Market Capitalization ($mil)	**$21**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**17**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Value**
Industry	**Med-Generic Drg**

ZACKS ESTIMATES

Revenue
(In millions of AUD$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	3.5 A	6.1 A	3.3 A	7.0 A	19.9 A
2016	2.2 A	8.2 A	5.6 A	10.0 E	24.0 E
2017					51.7 E
2018					73.0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.09 A	-$0.13 A	-$0.18 A	-$0.70 A	-$1.03 A
2016	-$0.55 E	-$0.35 A	-$0.08 E	-$0.08 E	-$0.96 E
2017					$0.26 E
2018					$1.15 E

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WHAT'S NEW

Financial Update

On November 2, 2016, Parnell Pharmaceuticals Holdings Ltd. (PARN) announced financial results for the first nine months of 2016. Unless otherwise indicated, all values are in Australian dollars (AUD). Revenues for the first nine months of 2016 were $13.8 million, which was a 62% increase over the corresponding period in 2015. Revenues were comprised of:

Production Animal (US) – $7.1 million, an increase of $1.0 million (30%) over the same period in 2015. The increase was driven by the continued addition of new customers with the third quarter of 2016 having another record sales month.

Production Animal (ROW) – $1.1 million, which was a 42% decrease compared to the same period in 2015. This portion of the company's business is driven by large orders that can differ from year to year. Parnell plans on launching both estroPLAN® and GONAbreed® in Canada and potentially in Europe in 2017, which should provide additional revenue streams.

Companion Animal – $2.9 million, a 156% increase compared to the same period in 2015, which was driven by the establishment of the company's U.S. operations along with a 32% increase in Australian sales.

Contract Manufacturing - $2.7 million, with no revenue generated in the same period in 2015. This was driven by a CMO contract signed with Merial for the production of sterile injectable products signed in the first half of 2016.

Net loss for the first nine months of 2016 was $18.6 million, or $1.21 per share, compared to $5.4 million, or $0.41 per share, for the same time period in 2015. The net loss was driven in part by $11.3 million in selling and marketing expenses, $1.2 million in regulatory and R&D expenses, and $10.7 million in administration expenses. This compares with $6.8 million in selling and marketing expenses, $0.7 million in regulatory and R&D expenses, and $7.6 million in administration expenses for the same time period in 2015. The company believes it can reduce selling and marketing expenses through to the launch of Zydax® now that the U.S. companion animal business has been established. Additional cost-cutting measures are going to be employed in regards to administration expenses as well. These reductions in expenses should allow the company to be cash flow positive in 2017 even before factoring in sales of Zydax®.

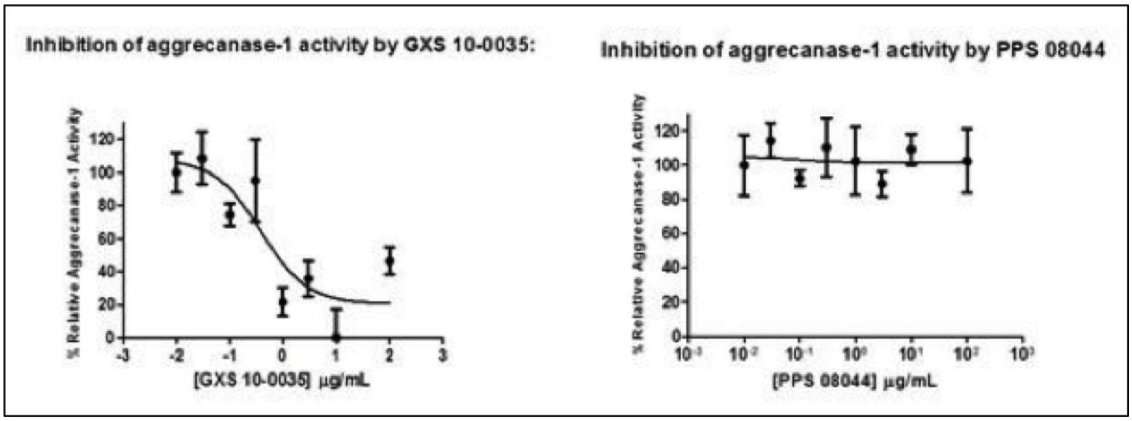
Parnell exited the third quarter of 2016 with $2.1 million in cash and cash equivalents. The company is planning to replace the current $US11 million credit facility with a $US20 million facility, which should be completed during the fourth quarter of 2016. This will support the company's move to profitability in a non-dilutive manner.

Business Update

Parnell is a fully integrated specialty pharmaceutical company focused on the development of novel products for both the production and companion animal markets. The company currently promotes five products across 14 countries, including the U.S. The lead products include two bovine reproductive hormones (GONAbreed® and estroPLAN®) and a prescription medication to treat osteoarthritis in canines (Zydax®), which is currently under review by the FDA with approval expected in the second quarter of 2017. Additional products include Glyde™, a nutraceutical product for osteoarthritis, and Reviderm™, an anti-microbial liquid bandage.

Zydax® Update

Zydax® is a sulfated oligosaccharide with disease-modifying characteristics for the treatment of osteoarthritis (OA) in dogs and horses. *In vitro* testing has shown that Zydax® is able to potently inhibit the aggrecanase-1 enzyme, which is responsible for the degradation of articular cartilage and has been implicated in the pathogenesis of OA. The following figure shows how increasing concentrations of Zydax® (GXS 10-0035) are able to inhibit the activity of aggrecanase-1 while pentosan polysulfate sodium (PPS) is not.



Source: Parnell Pharmaceuticals Holdings Ltd.

Parnell completed a pivotal efficacy study of Zydax® in June 2015. It was a randomized, double blind, placebo controlled study evaluating the field effectiveness and safety of Zydax® in the treatment of clinical signs of OA in dogs. It was conducted at 20 sites in the U.S. and Australia and included 316 client-owned dogs with radiographic evidence of OA who were treated with either Zydax® (n=212) or placebo (n=104). The clinical endpoint was improvement in Client Specific Outcome Measures (CSOM) that included the dog owners' assessment of improvement in activities such as walking, running, and climbing stairs. The dogs were treated with four subcutaneous injections of Zydax® or placebo given one week apart with outcomes measured at baseline, day 14 (one week after the second injection) and day 28 (one week after the fourth injection). The primary outcome of the study was the reduction in the Activity Impairment Score (AIS) compared to baseline at day 28 along with no increase in any individual CSOM between baseline and day 28.

Results from the study showed that Zydax® treated dogs achieved significant improvements in mobility with 56% of Zydax®-treated dogs achieving an AIS reduction of 3 (30% improvement) compared to only 40% of placebo treated dogs (*P*=0.02). In addition, after 28 days of treatment, 81% of Zydax® treated dogs achieved an improvement in AIS of at least 1 (*P*=0.02), while 23% of Zydax® treated dogs achieved an improvement in AIS of at least 5 (*P*=0.03).

Parnell has now submitted all five sections of the New Animal Drug Application (NADA) for Zydax® and, as expected, has received a response from the Food and Drug Administration (FDA) seeking clarifications and responses in relation to various aspects of the filings. The company met with the FDA during the third quarter of 2016 and we anticipate a refiling of the Efficacy and CMC sections of the NADA in the fourth quarter of 2016 that could lead to approval of Zydax® in mid-2017.

The company has also received the first round of questions from the European Medicines Agency (EMA) in regards to the submission for Zydax®, which were very similar to the clarifications sought from the FDA. Thus, Parnell will be in position to submit responses to the EMA shortly after refilling with the FDA, and we believe approval in Europe could also come in mid-2017.

Parnell has completed pilot safety studies of Zydax® in cats for the treatment of OA that included doses up to eight times the expected commercial dose and has now commenced pilot efficacy studies. Assuming the pilot study is successful, pivotal safety and efficacy studies would likely be initiated in 2017, which could lead to regulatory filings in 2018 in the U.S. and Europe. The market for Zydax® in cats with OA is expected to be large. In the U.S. there are approximately 50 million cats. Typically, there are fewer therapeutic options for treating diseases in cats as drug metabolism can be different to that seen in dogs and hence toxicity profiles often preclude the use of many pharmaceuticals in cats. Parnell has sold Zydax® in Australia for 9 years with over 1 million doses being used, thus there is substantial anecdotal feedback to the company from veterinarians who have successfully used Zydax® in cats with OA. Parnell believes that the prevalence of OA in cats is at least as high as that seen in dogs and quite possibly much higher.

PAR121 and PAR122 Update

PAR121 is being developed for bone-related diseases and injuries in dogs, cats, and horses as it has been shown to significantly enhance bone regeneration post-fracture. The active ingredients in PAR121 are derived from botanical extracts of plants native to the Cook Islands, as according to the company these plants have been applied

to bone fractures as a natural remedy for hundreds of years. These plants are the subject of patent applications (and grants) by CIMTECH Pty Ltd, for which Parnell holds exclusive worldwide rights.

Parnell has conducted multiple preclinical studies of PAR121, one of which was in a rabbit ulnar critical defect model. A critical defect is where a bone has a substantial gap (20 mm) resulting in an inability for the bone to heal naturally. Following treatment with PAR121, new cartilage and bone development was seen as early as one week after the injury. The company has also commenced an *in vivo* study in rodents and will initiate a safety study and bone healing study in dogs, as canines will likely be the company's initial target market. Results from the rodent and canine studies will likely be available in the first half of 2017.

PAR122 is being developed for use in Flea Allergy Dermatitis (FAD) and other dermatological conditions. FAD, which is an allergic skin reaction to flea bites, is the most common dermatological disease of dogs in the U.S. While the use of anti-flea medications has limited most dogs' exposure to fleas, once FAD develops the animal is affected for life, with just one flea bite being enough to cause excessive itching. The company will soon be initiating safety and skin healing studies of PAR122 in dogs.

Digital Technologies

One of the key differentiators for Parnell compared to their peers is the use of digital technology assets. mySYNCH is a digital tool that integrates with dairy management computer systems to allow for reporting of breeding metrics. In addition, it allows dairy producers to compare their herd's performance with those of other herds, such that they can enhance their reproductive outcomes. The company reported that there are now several hundred thousand cows enrolled in the mySYNCH app, a number that is expected to continue to rise.

The FETCH app is a digital customer application that is intended for use by dog owners to help educate them about OA and better manage the condition in their pets. Over 10,000 pet parents are now using the FETCH app, a number that is likely to increase with the launch of FETCH 2.0. This large database of pet owners is likely to lead to a successful launch of Zydax® following approval, as those individuals are already educated about OA in dogs, with many of them already using Glyde™.

Manufacturing Contracts

Parnell has a 33,000 square foot FDA and E.U. approved, sterile injectable manufacturing facility that is located in Sydney, Australia. The advantages offered by the facility include a reliable source of low-cost manufacturing for the company's own products and the ability to bring new products to market more quickly since there is no reliance on third-party contract manufacturing organizations (CMOs).

During the first half of 2016, Parnell signed a CMO contract with Merial for the production of sterile injectable products and has recorded revenue of $2.7 million thus far in 2016 in connection with this agreement. Prior to signing the agreement with Merial, Parnell indicated the manufacturing facility had 75% spare capacity, thus we believe there is ample opportunity for the company to pursue additional manufacturing agreements.

Conclusion and Valuation

We value Parnell using an enterprise value/revenue model with a 3.0x multiple based on projected revenues in 2020. This takes into account potential revenues of both currently marketed products as well as products we anticipate the company launching in the coming years. We model for 2020 revenues of approximately 140 million. When accounting for the company's current cash level, the expected debt financing before the end of 2016, the additional shares of common stock that have been sold this year, and an 18% discount rate leads to a current valuation of approximately $11/share.

The company is currently trading at an astoundingly low valuation of approximately 1X expected 2016 revenues. We are unsure why the company's valuation is so low, as it is likely to achieve positive cash flow in 2017 even before the launch of Zydax®, while at the same time continuing development of its pipeline. The approval of Zydax® and recognition of the extremely low valuation currently assigned to the company are both likely to be major drivers for the shares, which we believe will lead to price appreciation more in line with our valuation.

PROJECTED INCOME STATEMENT

Parnell Pharmaceuticals Holdings Ltd.
Income Statement

Parnell Pharmaceutical Holdings, Inc. (in AUD$)	2015 A	1H16 A	2H16 E	2016 E	2017 E	2018 E
Companion Animal	$2.10	$1.50	$3.50	$5.00	$25.00	$45.00
YOY Growth	*50%*			*138.0%*	-	-
Production Animal (U.S.)	$8.08	$4.10	$7.00	$11.1	$15.00	$16.00
YOY Growth	*251%*			*37.3%*	-	-
Production Animal (RoW)	$2.99	$0.60	$2.30	$2.90	$3.20	$3.50
YOY Growth	*-38%*			*-2.8%*	-	-
Contract Manufacturing	$0.00	$2.20	$2.80	$5.00	$8.50	$8.50
YOY Growth	*#DIV/0!*			*#DIV/0!*		
Other Income	$6.73	$0.00	$0.00	$0.00	$0.00	$0.00
YOY Growth	*20%*	-	-	*-100.0%*	-	-
Total Revenues	**$19.89**	**$8.23**	**$15.60**	**$24.0**	**$51.7**	**$73.0**
Total Group Revenues	**$13.17**	**$8.23**	**$15.60**	**$24.0**	**$51.7**	**$73.0**
YOY Growth	*57%*	-	-	*82%*	*115%*	*41%*
Cost of Goods Sold	$7.7	$3.7	$4.3	$8.0	$13.8	$17.0
Gross Margin	*82%*	*79%*	*85%*	*83%*	*81%*	*82%*
Selling and Marketing Expenses	$11.8	$7.8	$7.2	$15.0	$16.0	$17.0
Regulatory Expenses	$0.9	$0.8	$0.2	$1.0	$1.5	$1.8
Administrative Expenses	$11.9	$7.3	$4.7	$12.0	$12.5	$13.0
Net Foreign Exchange Losses on Borrowings	$0.0	$0.0	$0.2	$0.2	$0.0	$0.0
Finance Costs	$1.3	$1.1	$1.1	$2.2	$3.0	$3.0
Other Expenses	$0.0	$0.1	$0.5	$0.6	$0.5	$0.5
Operating Income	($13.7)	($12.5)	($2.6)	($14.9)	$4.4	$20.7
Operating Margin	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($13.7)	($12.5)	($2.6)	($14.9)	$4.4	$20.7
Income Taxes Paid	$0	$0.0	$0.0	$0.0	$0.0	$0.0
Foreign Currency translation	$0	$0.2	$0.1	$0.3	$0.2	$0.2
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($13.7)**	**($12.3)**	**($2.6)**	**($14.9)**	**$4.4**	**$20.7**
Net Margin	-	-	-	-	-	-
Reported EPS	**($1.03)**	**($0.85)**	**($0.16)**	**($0.96)**	**$0.26**	**$1.15**
YOY Growth	-	-	-	-	-	-
Basic Shares Outstanding	13.284	14.434	16.500	15.467	17.000	18.000

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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