Zacks Small-Cap Research

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Parnell Pharmaceuticals Holdings Ltd. (PARN-NASDAQ)

PARN: Revenue Growth of 67% in 1H16; Gearing up for Zydax® Approval in 2Q17…

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 (08/11/16)	$1.64
Valuation	**$11.00**

OUTLOOK

In August 2016, Parnell Pharmaceuticals Holdings Ltd. announced financial results for the first half of 2016. Revenues for the first half of 2016 were $8.2 million, which was a 67% increase compared to the corresponding period in 2015. We estimate total revenues for the year of AUD$24.0 million.

The company is close to completing the responses to the requests from the FDA seeking clarifications in relation to various aspects of the regulatory filing for Zydax®. We anticipate the company filing responses to these inquiries in 3Q16, which should lead to approval of Zydax® in the U.S. in the second quarter of 2017.

SUMMARY DATA

52-Week High	**$4.70**
52-Week Low	**$1.41**
One-Year Return (%)	**-62.91**
Beta	**-0.22**
Average Daily Volume (sh)	**51,271**
Shares Outstanding (mil)	**17**
Market Capitalization ($mil)	**$29**
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	- A	8.2 A	- E	13.8 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	- E	-$0.85 A	- E	-$0.16 E	-$0.96 E
2017					$0.26 E
2018					$1.15 E

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WHAT'S NEW

Financial Update

On August 4, 2015, Parnell Pharmaceuticals Holdings Ltd. (PARN) announced financial results for the six months ending June 30, 2016. Unless indicated, all values are in Australian dollars. Revenues during the first half of 2016 were $8.2 million, which was a 67% increase over the corresponding period in 2015. Total revenues in the U.S. production animal segment were $4.1 million, which was a 40% increase over the same period in 2015, driven by the acquisition of new customers. Production animal revenues in the rest of the world were $0.6 million. Companion animal revenues were $1.5 million, which was a 158% increase compared to the same time period in 2015. The company's contract manufacturing segment generated $2.2 million in revenues through a CMO agreement with Merial.

Net loss for the first half of 2016 was $12.5 million, or $0.85 per share, compared to $3.0 million in 2015. The net loss was driven by $7.8 million in selling and marketing expenses, which was incurred due to the establishment of the company's U.S. companion animal business, and $7.3 million in administration expenses, which was the result of higher staffing and external costs to support a larger commercial and R&D organization in the U.S. As of June 30, 2016, the company had cash and cash equivalents of $4.1 million. Parnell is continuing talks to secure a debt facility of up to $30 million to use for launching Zydax® in the 2017.

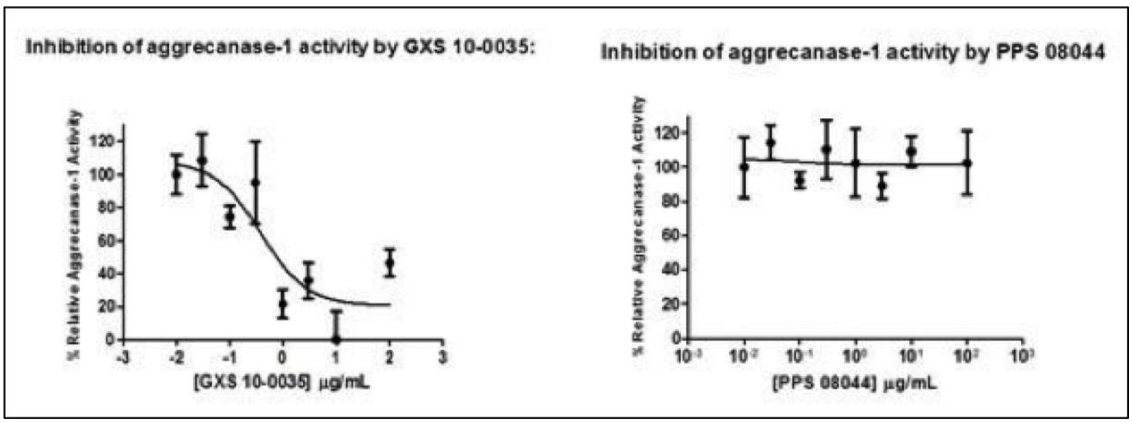
For the full year 2016, we are modeling for total revenues of $24.0 million (USD$18.5 million) and a net loss of $14.9 million.

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.

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 is completing the responses to the FDA and is planning to meet with the agency in September 2016 prior to filing to discuss the proposed responses. Assuming the refilling occurs shortly after meeting with the FDA, we anticipate approval of Zydax® in the second quarter of 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 the second quarter of 2016.

Parnell has completed pilot safety studies of Zydax® in cats for the treatment of OA and has commenced pilot efficacy studies. Assuming the pilot study is successful, pivotal efficacy studies would likely be initiated before the end of 2016, which could lead to a regulatory filing in 2017. 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.

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.

Parnell has commenced manufacturing process development for both PAR121 and PAR122, which will enable drug characterization and *in vitro* and *in vivo* efficacy studies to get underway. If those studies are successful, pivotal efficacy and safety studies could begin in 2017, with the potential for regulatory filings in 2018.

Reviderm™ and Luminous™ to Launch in 2016

Parnell is set to launch two new products in 2016, Reviderm™ and Luminous™. Reviderm™ is a novel liquid bandage product with antimicrobial properties. The current standard of care for pets with lacerations or other wounds is an adhesive bandage. These bandages are usually chewed off by the animal, which can lead to

complications and potential infections of the wound site. Reviderm™ is an impervious elasto-polymer that covers the wound, has antimicrobial properties, and wears off naturally over time as the wound heals. Luminous™ is a nutraceutical product that was developed to treat dermatologic conditions and help dogs have healthy skin and shiny coats. Reviderm™ is likely to be launched in the third quarter of 2016, with Luminous™ being launched later in the year.

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 recorded revenue of $2.2 million 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 in the second half 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 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 as the year goes on.

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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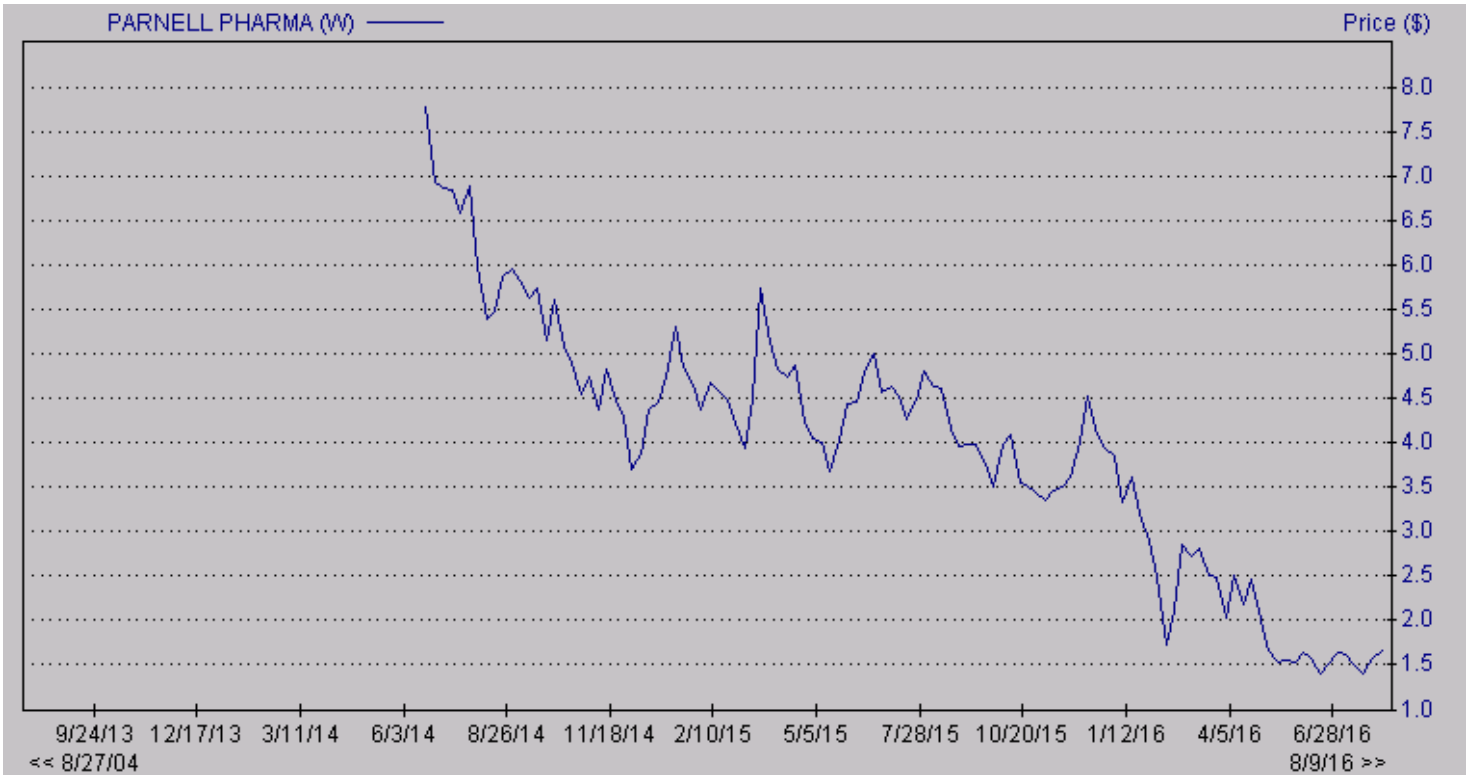
HISTORICAL STOCK PRICE



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