Zacks Small-Cap Research

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Parnell Pharmaceuticals Holdings Ltd. (PARN-NASDAQ)

PARN: Manufacturing Contract Set to Be Signed; Zydax® Approval Likely by the First Quarter of 2017…

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 (05/20/16)	$1.57
Valuation	**$11.00**

OUTLOOK

In April 2016, Parnell Pharmaceuticals Holdings Ltd. announced financial results for the first quarter of 2016. Revenues for the first quarter were $2.2 million, which was slightly ahead of our estimate for $1.7 million. We forecast total revenues for the year of $22.6 million.

The company has received a response from the FDA seeking clarifications and responses in relation to various aspects of the regulatory filing for Zydax®. We anticipate the company filing responses to these inquiries by mid-2016, which should lead to approval of Zydax® in the U.S. by the first quarter of 2017.

SUMMARY DATA

52-Week High	**$5.98**
52-Week Low	**$1.34**
One-Year Return (%)	**-55.71**
Beta	**-0.18**
Average Daily Volume (sh)	**143,648**
Shares Outstanding (mil)	**13**
Market Capitalization ($mil)	**$22**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**22**
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	5.6 E	8.0 E	6.8 E	22.6 E
2017					54.7 E
2018					71.5 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	-$0.54 E	-$0.35 E	-$0.50 E	-$1.94 E
2017					$0.12 E
2018					$0.71 E

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WHAT'S NEW

Financial Update

On April 22, 2016, Parnell Pharmaceuticals Holdings Ltd. (PARN) announced financial results for the first quarter of 2016. Revenues in the first quarter were $2.2 million, which was slightly ahead of our estimate of $1.7 million. Revenues grew 43% compared with the same time period in 2015 through growth of the production animal segment as well as expansion of the companion animal segment in both the U.S. and Australia. Total revenues in the production animal segment in the U.S. were $1.3 million for the first quarter of 2016, an increase of 10% compared to the first quarter of 2015. Production animal revenues in the rest of the world were $0.3 million, an 83% increase over the same time period in 2015. Revenues for companion animal products were $0.6 million, a 164% increase over the same period in 2015. The company exited the first quarter with $3.9 million in cash and cash equivalents.

Subsequent to the end of the first quarter, Parnell announced the pricing of an underwritten public offering of 2.55 million shares of common stock for gross proceeds of $4,207,500. Parnell also granted the underwriters a 30-day option to purchase up to an additional 382,500 shares of common stock. This offering is in line with the company's previously stated desire to increase the daily trading volume in the company's shares. This includes an ordinary share purchase agreement that was entered into with Lincoln Park Capital Fund, LLC. As part of the purchase agreement, Parnell issued 47,746 shares to Lincoln Park. In addition, since closing the purchase agreement, Parnell has issued 281,524 shares to Lincoln Park. Another 175,000 shares of common stock have been issued to Lincoln Park under a separate purchase agreement.

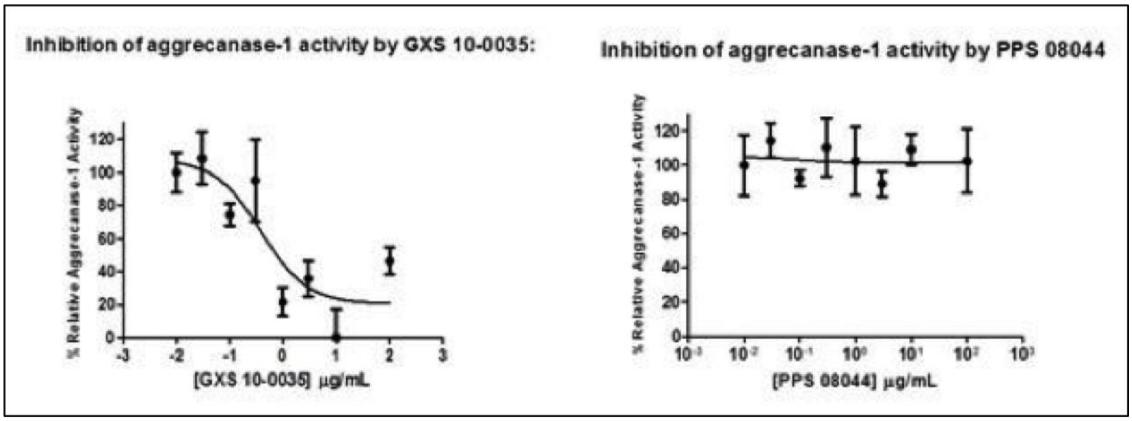
According to Yahoo Finance, the company's average trading volume in 2015 was approximately 18,000 shares per day. Thus far in 2016, the company's average trading volume has been almost 103,000 shares per day, with the 30-day daily average trading volume as of May 20, 2016 being approximately 237,000. Thus, the company has clearly executed on its strategy to increase liquidity in the company's shares. This could allow additional institutional investors to be able to enter into positions in the stock, which may not have been possible with the average trading volume as low as it was in 2015.

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 first quarter of 2017.

Zydax®

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 recently 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 looking to meet with the FDA to get assurances that the information they are providing is adequate to enable approval. We anticipate the company preparing and submitting responses to the FDA inquiries in mid-2016, which could lead to an approval most likely in the first quarter of 2017.

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 second quarter of 2016, with Luminous™ being launched later in the year.

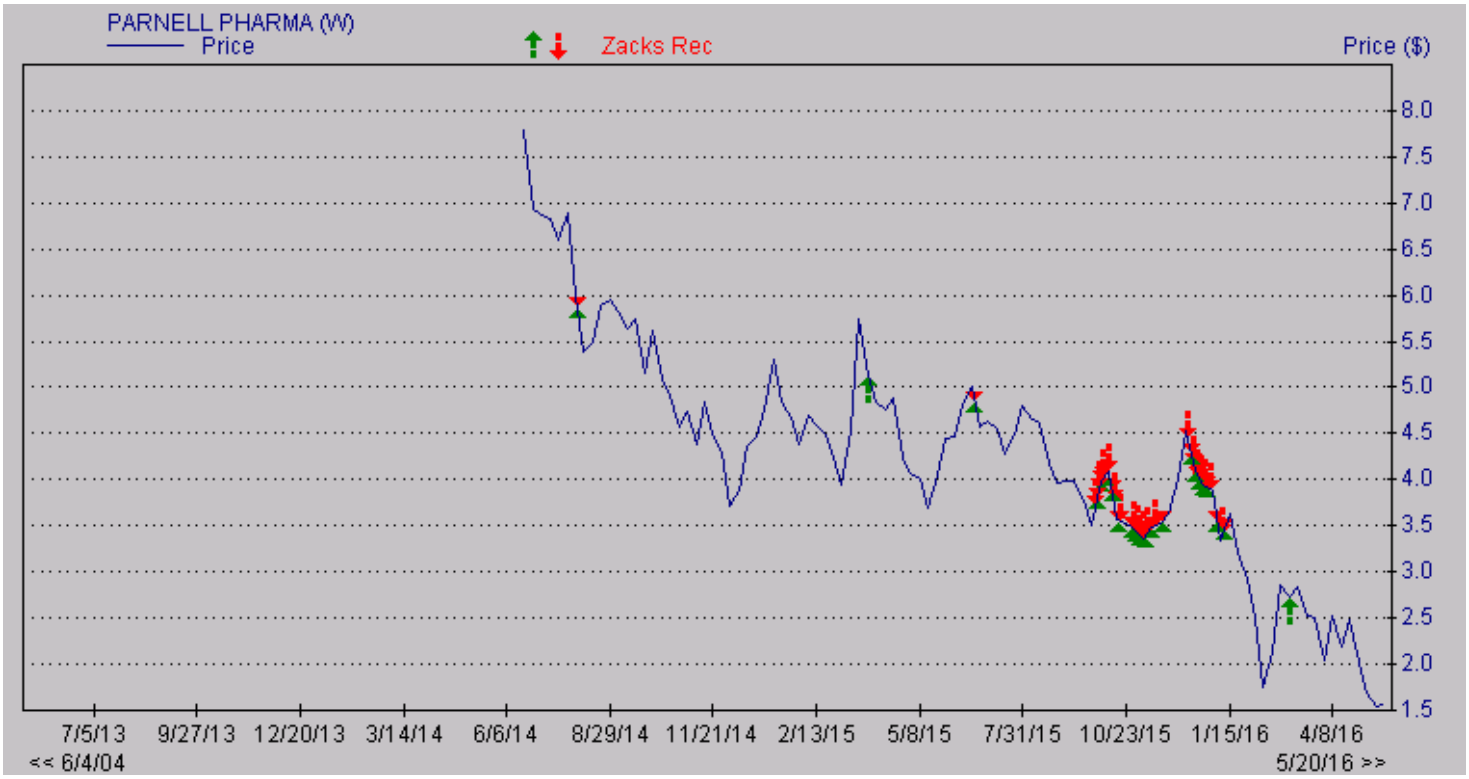
Manufacturing Contracts

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). The company estimates that there is approximately 75% spare capacity at the facility, which can be utilized through lucrative contract manufacturing opportunities. The company has guided that it is very close to signing a manufacturing contract with a large, multinational corporation that would likely result in an upfront payment to the company of low single digit millions and the ten year value of the contract being high single digit to double digit millions. With 75% spare capacity, Parnell is actively pursuing additional manufacturing contracts and expects to announce at least one additional contract in 2016.

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 mid-2016, the additional shares of common stock that have been sold this year, and an 18% discount rate leads to a currently valuation of approximately $11/share. The current share price is well below this valuation, and the stock is currently trading at approximately 1x 2016 revenues, which we believe vastly undervalues the company. 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.

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