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Parnell Pharmaceuticals Holdings Ltd.
(Nasdaq GM/PARN)

BUY

Parnell is an international veterinary pharmaceuticals and services company

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Summary, Six-month Period Report Highlights

Parnell Pharmaceuticals Holdings (Parnell) delivered strong revenue growth for a very busy six months period ended June 30, 2016. Top line revenue rose 67% over that of the 2015 period. The strong revenue growth was driven by above-expectation results from both the US Production Animal business and the Companion Animal business that was coupled with the initiation of contract manufacturing revenue from Parnell's first contract sterile pharmaceuticals manufacturing customer, Merial. Contract manufacturing contributed AUD\$2.2 million in revenue in the second quarter.

As a result of the above-expectation segment performance and near-term prospects for additional contract manufacturing clients, PARN management has guided revenue estimates upward by about 15-20%, for both 2016 and 2017. Additionally, based upon the upwardly revised revenue guidance, which *excludes* any benefit of US, EU or Canadian sales from **Zydax™**, Parnell management anticipates the Company will achieve profitability in the second half of 2017. This would put Parnell in a position to become a leader of our vet biotech group in terms of financial performance, as we believe PARN would be the first company in the group to achieve profitability based upon internally-generated revenue, exclusive of licensing and milestone payments. In contrast, Aratana's (PETX/NASDAQ/\$9.18/Not rated) profitability is dependent at present upon milestone payments from Elanco, its marketing partner for **Galliprant®**.

Parnell has leveraged its long history in drug development to become an international veterinary biotech with strong formulation, clinical development and clinical trial expertise that has contributed to success in operating commercially across 14 countries. Parnell's business strategy focuses on areas of significant need in companion pets (dogs, cats and horses) and performance horses, and in (primarily) dairy cattle, where there is opportunity to be a first mover. We believe Parnell represents an excellent example of the emerging leadership of biotech companies in the evolution and revolution underway in veterinary medicine.

Second Quarter Highlights

1) Parnell reported exceptional growth in its US Production Animal business, which achieved a 40% year-over-year increase in sales and now holds a 12% market share, up from about 10%. Management attributed much of the growth to the further market penetration of **mySYNCH™** which integrates herd animal reproductive management and relevant clinical science with the Company's proprietary hand-held (cow-side) mobile-apps technology. **mySYNCH** has been instrumental in differentiating Parnell from larger competitors and in facilitating the Company's penetration of the US market for sales of its reproductive hormone products. In commenting on the segment's performance, management indicated that the 40% level of YOY growth in sales is expected to continue through the remainder of 2016.

Current Price \$1.60
(PARNELL LISTED ON NASDAQ JUNE 2014)

FY Ended Dec 31 unless otherwise specified

Estimates (MMs)*	CY2014A	FY2015A	FY2016E
Revenues(AUD\$)	\$8.52	\$13.10 A	\$22.91 E
1H	\$4.26	\$4.93 A	\$8.23 A
2H	\$3.65	\$8.42 A	\$14.69 E

2017 Preliminary Revenue Estimate	\$33.47 E
Prev. Rev. Estimate (\$ mil.)	\$31.20

EPS(loss)	(2014)	(2015) A	(2016) E
1H	(\$1.54)	(\$0.22) A	(\$0.85) A
2H	(\$0.68)	(\$0.81) A	(\$0.67) E

2017 Preliminary EPS(loss) Estimate	(\$1.44) E
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Price/Sales	2.01X	0.88X E
P/E (x)	NA	NA

REV/Share	\$0.92	\$0.78	\$1.34 E
EV/EBITDA (x)	NA	NA	NA

Stock Data

52-Week Range	\$1.34-\$4.89
Shares Outstanding (mil.)	14.90
Market Capitalization	\$22.27MM
Enterprise Value	\$35.59MM
Current Ratio (06/16)	1.03X
Book Value/Share (06/16)	\$0.88
Price/Book (06/16)	1.82X
Average Trading Volume (3-Month)	55,440
Insider Ownership	9.3%
Institutional Ownership	48.7%
Short interest (Million shares)	66,310
Dividend / Yield	\$0.00/0.0%

*Some numbers may not add due to rounding. Source: Yahoo Finance/Cap IQ



Please find Important Disclosures beginning on Page 5.

2) Parnell's US sales and marketing team continues to successfully deploy the canine digital platform, **FETCH™**, into small animal veterinary clinics. The Company reports over 7,000 pet parents have now registered and used the **FETCH** app (up from about 2,000 in February 2016) with many going on to use **Glyde™**, Parnell's unique nutraceutical product for osteoarthritis (OA) in dogs. **FETCH** was launched in the US in the fall of 2015. As a result, the Companion Animal business generated a 158% increase in revenue in the first half of 2016, albeit off a relatively small base. Strategically, Parnell has been expanding sales and marketing resources on the deployment of **FETCH** so as to further seed the market for migration over to **Zydax** when it is approved. Based upon current adoption rates of **FETCH** amid an upcoming release of the next generation **FETCH**, Parnell management is anticipating that as many as 20,000 pet parents may be registered by YE 2016 and 50,000 pets could be part of the **FETCH/Glyde** marketing plan by the time **Zydax** is launched in 2017. The **FETCH** roll-out in the US is proceeding as planned based upon the experience gained from the same marketing plan used in Australia, which continues to drive Australian Companion Animal business growth at high double digit rates. On a year-over-year basis, the Australian Companion Animal segment revenue was up 37% over the 2015 period. Management expects second half revenue growth for the Companion Animal segment to be comparable to that seen in the first half, spurred by the release of "**FETCH 2.0**" in the US. Parnell will be adopting **FETCH** to the European market in anticipation of the EU approval of **Zydax** and to support sales from a future European marketing partner(s).

3) New product launches due in the third quarter include **Luminous™**, an innovative nutraceutical product targeting atopic dermatitis in dogs that has been developed internally by Parnell. The product is being positioned to dovetail with **Glyde** and **FETCH**. **Luminous** contains the same anti-inflammatory active ingredient as **Glyde**. Atopic dermatitis is an inflammatory response typically resulting from specific and non-specific allergies to food, dust mites, flea bites and many other causes, and can be very difficult to treat. Parnell is also completing in-licensing of **Reviderm™**, the novel antimicrobial spray-on liquid bandage to more rapidly heal wounds in animals. The addition of these products to the Parnell's sales team's "bag" will facilitate the building of market awareness of the Company ahead of the **Zydax** approval and launch.

4) Raising guidance for both 2016 and 2017. Management expressed confidence that revenue growth trends seen in the first half of 2016 are likely to continue at similar levels overall in the second half of the year. To that end, revenue guidance for 2016 has been raised from USD\$14-16 million, or AUD\$20-22 million, for the full year to USD\$17-18 million, or AUD\$23-24 million. The revenue forecast for 2017 has likewise been raised and guidance is now for AUD\$34 million (USD\$25 million), which would allow Parnell to achieve profitability in the latter part of 2017, before the benefit of any **Zydax** sales.

Zydax Update

Management gave an extensive update on the status of the **Zydax** FDA filing for canine osteoarthritis. As noted in prior calls, the Company is completing its response to questions from the FDA concerning the CMC (Chemistry and Manufacturing Control) and Target Animal Efficacy sections filing. Although **Zydax** is naturally-derived, it is considered a New Chemical Entity in the eyes of the FDA and therefore, receiving questions concerning the CMC section of the filing was not unexpected. PARN is planning to meet with the FDA in September to "seek alignment" on the Company's proposed responses and should be in a position to refile shortly thereafter. This timeline puts the Company about a quarter or so behind previous expectations for FDA approval, which is now expected during the second quarter of 2017. However, management does not view this delay as a material disadvantage as the additional time is allowing PARN to continue to develop awareness and build a larger base among target vets and pet owners, as well as to assess competitive differentiators (or lack thereof) of other recently approved or soon to be approved canine OA treatments. Parnell believes that it holds a significant competitive advantage in terms of **Zydax's** administration/benign side effect profile and the drug's unique mechanism of action.

While responding to FDA questions, PARN has also now received the first set of questions from the EMA which are similar to that received from the FDA. PARN expects that responses to the FDA's questions will largely be acceptable to the EMA. If so, it may allow for the EMA refile to also occur this fall. If both events occur on this schedule, PARN would expect to receive approval from both the FDA and EMA during the first half of 2017. Canadian approval is now expected in the 2nd half of 2017. **Zydax** is already approved in Australia and New Zealand for the treatment of OA in dogs.

Zydax Market Expansion – Cats

PARN has continued to advance other indications for **Zydax** as part of the company's strategy to expand the overall market for **Zydax**. The company has successfully completed a pilot safety study for **Zydax** for feline OA and is now commencing pilot efficacy studies in client-owned cats. Based upon experience with the canine trials, Parnell may be able to commence both the pivotal safety and pivotal efficacy feline trials concurrently, which would allow for an FDA filing in the first half of 2017. Since the CMC section would essentially be identical to that already submitted to the FDA for canine OA, Parnell could anticipate a slightly faster regulatory cycle for the feline indication and may be able to launch **Zydax** for OA in cats in early 2018. The feline market osteoarthritis opportunity may be one in which Parnell can gain a significant market share as there are virtually no treatment options for cats because of their intolerance of NSAIDs. In addition, as mentioned previously, a member of the pentosan polysulfate class of drugs is

already approved in humans for the treatment of interstitial cystitis (IC). A similar urinary condition frequently occurs in house cats. Parnell is exploring investigational studies for feline **Zydax** for the treatment of IC.

PAR121 and PAR122 Advance

During the first half, Parnell advanced both PAR121, Parnell's internally developed osteogenic product for canine and equine orthopedics, and PAR122 for feline and canine dermatological conditions through manufacturing process development. The products are going through drug characterization, in vitro and in vivo efficacy studies. The Company expects to report on the outcomes of these studies later in 2016, which would set the stage for pivotal safety and efficacy trials to begin in 2017.

Financial Overview; 1st Half 2016 Results and Outlook

(Note: Parnell reports all financial results in Australian dollars, (AUD/USD conversions are at AUD\$1=USD\$0.72. As a Foreign issuer, Parnell currently files only semi-annual financial reports under 6-F filings)

Top line revenue for the 1st half of 2016 was reported at AUD\$8.23 million, compared to AUD\$4.93 million for the 1st half of 2015 with the second quarter showing substantial sequential growth over the first quarter 2016. Second quarter revenue slightly exceeded AUD\$6 million up from AUD\$2.2 million in Q1 2016. Product gross margin was reported at 84%, similar to that of the 2015 period and a level which Parnell expects to maintain through the remainder of 2016. Segment results as were reported as follows: US Production Animal, sales for the June quarter rose to AUD\$2.7 million up from AUD\$1.4 million, in Q1 2016 while the Companion (US & Aus) Animal business rose 158% for the first half compared to the first half of 2015, to AUD\$1.5 million, largely driven by market penetration in the US. Directly comparable data for the first half of 2015 is not available as Parnell did not launch any US Companion Animal products until Q3 2015. On a sequential quarterly basis, Companion Animal revenue for Q2 2016 was up over a 100% compared to Q1 2016.

Operating expenses were well managed considering the sales and marketing and clinical activities that took place during the first half and generally tracked below our estimates. This fact largely contributed to the positive performance compared to our model. Forex movements between the Australian and US dollars resulted in an unrealized foreign exchange expense of AUD\$700K in the first six months of 2016 compared to an unrealized foreign exchange gain of AUD\$1.5 million in the 2015 period. The Company reported a net loss of AUD\$12.5 million or \$(0.85) per share compared to AUD\$3.3million or \$(0.22) per share. These results compare to our estimate of a loss of AUD\$15.9 million or \$(0.97) per share. As stated, the positive differential is largely due to favorable operating expense management despite the revenue shortfall versus our estimate which included higher grant and tax credits than reported. As of June 30, 2016, Parnell had cash and cash equivalents of AUD\$4.1 million, compared to AUD\$5.7 million at December 31, 2015.

Outlook

We believe Parnell's revenue "drivers" continue to set the Company apart from its near peer group in terms of an already functioning sales and marketing organization, new products about to be launched and a novel and highly differentiated vet/animal owner integrated mobile app that builds awareness and loyalty among customers in both the companion and production animal segment. The Company's market cap, currently at about 1X this year's revenue estimate, is barely 1/3rd of its next nearest peer-group member, NexVet Biopharma Ltd (NVET/NASDAQ/\$5.27/Not rated) and is less than 1/10th of that of Aratana, Parnell's most comparable peer. Therefore, we see the Company as highly undervalued and continue to rate its shares a **BUY**. SG

Near-term Parnell Revenue Growth Drivers and Catalysts

- Accelerating penetration of **mySYNCH**
- Expansion of **Glyde/FETCH** franchise towards 2016 goal of 1,500 clinics among US vet clinics (20,000 pet parents), in anticipation of **Zydax** launch. Parnell hopes to eventually have 3,600 vet clinics enrolled in the **FETCH** program.
- Launch of **Luminous** and **Reviderm** products in Q3
- Initiation of second pharmaceutical contract manufacturing agreement

Upcoming Event

Timing

Impact

<u>Upcoming Event</u>	<u>Timing</u>	<u>Impact</u>
1. FDA resubmission mtg	Sept. 2016	Sets stage for Zydax refiling
2. Refiling of Zydax Tech. and CMC sections (US& EMA)	Q3 2016	US and EMA filings would coincide for 1H 2017 approval
3. Launch of Luminous and Reviderm	Q3 2016	Expand market presence/base building for Zydax
4. Zydax European Partner	Q3-4 2016	Distribution of Zydax in Europe
5. Announce 2 nd contract manufacturing client	Q4 2016	Revenue generation
6. Zydax Canadian filing	Q4 '16/Q1 '17	Approval in Canada 2H of 2017
7. Initiation of pivotal safety and efficacy studies for Zydax feline OA	YE '16/Q1 '17	Indication expansion strategy for Zydax

Table 1
Parnell Financial Results and Estimates

As reported in Australian Dollars

	As Reported		As Reported			Estimates			
	Year Ended June 30		Year Ended December 31*			Year Ended December 31			
	2013	2014	6 Mo End 6/30	6 Mo End 12/31	2015 Year	As Reported 6 Mo End 6/30A	Year Ended December 31		
						6 Mo End 12/31E	2016 YearE	2017E	
Revenues:									
Sales of goods	\$9,538,161	\$ 7,542,600	\$ 4,927,965	\$ 8,241,788	\$ 13,169,753	\$ 6,025,614	\$ 11,192,297	\$ 17,217,911	\$ 24,868,306
Contract Manufacturing						\$ 2,200,000	\$ 3,500,000	\$ 5,700,000	\$ 8,600,000
Total Revenue	\$9,538,161	\$ 7,542,600	\$ 4,927,965	\$ 8,241,788	\$ 13,169,753	\$ 8,225,614	\$ 14,692,297	\$ 22,917,911	\$ 33,468,306
Other income (expense)	2,203,355	2,248,195	4,742,229	1,982,913	6,725,142	(147,815)	1,200	(146,615)	1,000
Revenue	11,741,516	9,790,795	9,670,194	10,224,701	19,894,895	\$ 8,077,799	\$ 14,693,497	\$ 22,771,296	\$ 33,469,306
Cost of Goods Sold	5,641,732	6,417,593	3,140,067	4,605,798	7,745,865	3,650,959	6,171,269	9,822,228	\$ 5,020,396
Gross Profit	6,099,784	3,373,202	6,530,127	5,618,903	12,149,030	4,574,655	8,522,229	13,096,884	28,448,910
Expenses:									
Research and development, regulatory expense	138,915	586,149	564,904	317,005	881,909	761,282	860,249	1,621,531	\$ 810,765
Less research tax credits and grants	0.00	0.00	0.00	0.00	0.00				0.00
General and administrative	1,903,573	3,018,782	5,165,879	6,774,367	11,940,246	\$ 7,298,121	\$ 7,663,027	\$ 14,961,148	\$ 13,465,033
Sales & Marketing	3,341,341	5,474,826	3,431,718	8,345,774	11,777,492	\$ 7,760,463	\$ 8,458,905	\$ 16,219,368	\$ 14,597,431
Total Operating Expenses	(5,383,829)	(9,079,757)	(9,162,501)	(15,437,146)	(24,599,647)	\$ (15,819,866)	\$ (16,982,180)	\$ (32,802,046)	\$ 28,873,229
Results from operating activities	\$ 715,955	(5,706,555)	(2,632,374)	(9,818,243)	(12,450,617)	\$ (11,245,211)	\$ (8,459,952)	(19,705,163)	\$ (23,852,834)
Net finance income (costs):									
Net foreign exchange losses on borrowings	(2,027,404)	(1,384,335)	0.00	0.00	0.00	0.00	0.00	0.00	(1,000,000)
Finance costs	(2,839,595)	(7,262,020)	(350,964)	(933,838)	(1,284,802)	(1,073,931)	(1,350,000)	(2,423,931)	(1,000,000)
Loss Before Income Taxes	\$ (4,151,044)	(14,352,910)	(2,983,338)	(10,752,081)	(13,735,419)	\$ (12,467,007)	\$ (9,809,952)	(22,276,959)	\$ (24,852,834)
Income (expense) benefit	672,989	(2,980,412)	(2,106,000)	(7)	(2,113)	(10,924)	(15,000)	(25,924)	(28,516)
Income (Loss)	(3,478,055)	(17,333,322)	(2,985,444)	(10,752,088)	(13,737,532)	(12,477,931)	(9,824,952)	(22,302,883)	(24,881,350)
Foreign Currency translation	(32,084)	(517,525)	(808,664)	(820,859)	(1,629,523)	\$ 209,401	(200,000)	9,401	\$ 500,000
Total Comprehensive Loss for the Year	\$ (3,510,139.00)	(17,850,847.00)	(3,794,108)	(11,572,947.00)	(15,367,055)	\$ (12,268,530)	(10,024,952)	(22,293,482)	\$ (24,381,350)
Net Loss per share (AUD\$)	(0.46)	(2.18)	(0.22)	(0.81)	(1.03)	(0.85)	(0.67)	(1.52)	(1.44)
Weighted average number of common shares outstanding	7,630,737	8,188,461	13,245,945	13,283,722	14,919,471	14,432,834	15,035,667	14,936,361	\$ 16,900,000

Some numbers may not add due to rounding

*Parnell changed from fiscal to calendar year in 2015

As a Foreign issuer, Parnell currently reports semiannually

Source: Company SEC filings, press releases, quarterly call transcripts, DJ estimates

Company Summary

Parnell is a fully integrated international veterinary pharmaceuticals business with drug development, formulation, multi-national clinical development and operations/manufacturing expertise. The Company currently operates in three primary veterinary segments: companion veterinary, reproductive veterinary and equine performance in both US and ex-US markets. Parnell has direct marketing and sales presence in the US, Australia and New Zealand and utilizes a range of multi-national and local marketing partners in other markets, such as in Canada. The company sells products in 14 countries. The primary ex-US markets are Australia, New Zealand, Asia, the Middle East and Canada. Parnell is expected to launch its market-disruptive OA product, Zydax for dogs in 2017

Risk Factors

In addition to normal economic and market risk factors that impact most equities and the common risks shared by Parnell Pharmaceuticals Holdings with other companies in the industry, we believe an investment in PARN involves the following risks:

- **FDA, CVM and regulatory risks** – Parnell is subject to regulatory review for its ongoing research and development activities, commercial marketing approval as well as laboratory facilities, principally with the US Food and Drug Administration Center for Veterinary Medicine but also with the EMA and other international regulatory agencies as well.
- **Need to defend patents, trade secrets and other intellectual property** – At present, Parnell holds a limited number of patents relating to its products, methods and manufacturing and depends in part on trade secrets. The Company may need to defend its intellectual property in the US and overseas in the future. Further, Parnell currently has limited patent protection for some of its pipeline product candidates. The Company, or our licensing partners, have made various applications which may never result in effective patents, as there is already an existing array of prior art that may preclude granting of patents.
- **Need to raise additional capital** – Although Parnell has historically successfully raised funds in the public markets, there can be no guarantee of such success in the future. Currently, the Company has limited cash on hand to fund ongoing research and development programs, ongoing clinical trials and product commercialization and launch activities. Until such time as cash flows from product sales surmount R&D, clinical and operational activities, Parnell will need to seek additional funding as the Company does not have a history of profitable operations. Unforeseen events including potential delays in product

sales, clinical programs and regulatory approvals could require Parnell to raise additional capital through the sale of equity, therefore potentially diluting current shareholders.

- **Limited stock liquidity** – Trading volume in Parnell has been comparatively light compared to other stocks in its industry, and as such, news regarding Parnell, its target markets, partners and/or competitors could lead to significant volatility in the stock price.
- **Competitive Markets** – The Company competes in its companion and production animal health markets with a number of other manufacturers, marketers and service companies, many of whom represent much larger companies with substantial resources. There can be no assurance that the Company will be able to successfully launch new products into these competitive markets in the future.
- **Currency Risk**- Parnell reports financial information and revenue in Australian dollars, yet the majority of revenues are derived in US dollars and to a lesser extent in New Zealand dollars. A significant appreciation of the Australian dollar would negatively impact revenues and profits. As such the Company is heavily exposed to foreign currency fluctuations. Parnell does not maintain structured hedging positions to protect from currency movements.
- **Pricing risk**- Changes in distribution channels for pet therapeutics could negatively impact market share, margins and distribution of Parnell’s products. Historically, animal owners (companion animals and production animals) have purchased animal health pharmaceuticals through their veterinarians. There have been changes in regulations in many countries that have allowed non-veterinary practices to supply pharmaceuticals directly to the public on the prescription of a veterinarian. Both these trends have seen downward price pressure exerted on pharmaceutical companies as the distribution channel seeks to offer increasingly attractive pricing to consumers.

Important Disclosures:

Price Chart:



Price target and ratings changes over the past 3 years:

Initiated – May 24, 2016– at \$1.56
 Price Target- No price target published.
 Rating change: None

Company Updates provide current information we believe might be noteworthy to investors regarding the subject companies. Company Updates are not intended to be complete research reports. More detailed information concerning the rated companies referenced in this Update, including the full reports, basis for price targets and other disclosures, may be found at:

http://dawsonjames.com/research_coverage.

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- 1) **Buy:** the analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
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The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	5	56%	3	60%
Market Perform (Neutral)	1	11%	1	100%
Market Underperform (Sell)	0	0%	0	0%
Rating Suspensions*	3	33%	2	33%
Total	9	100%	6	44%

*Suspensions are ratings under review for possible change due to unusual market-moving news, and/or analyst departure/change

Analyst Certification:

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