Zacks Small-Cap Research

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Depomed, Inc. (DEPO-NASDAQ) UPDATE

DEPO: *NUCYNTA sales continued to grow since in 4Q15; Acquisition of Phase III ready cebranopadol enhances its Pain Management Franchise---Buy*

Current Recommendation	**Buy**
Prior Recommendation	Hold
Date of Last Change	08/09/2011
Current Price (02/24/16)	$17.11
Target Price	**$36.00**

DepoMed just reported another strong quarter of its financials.

We are impressed with the NUCYNTA sales of $68.3 million in 4Q15, compared to $44 million in 4Q14, an increase of 55%. We continue to remain optimistic regarding the Depomed story, especially as it pertains to the NUCYNTA® franchise, as we strongly believe the transaction will be transformational for the company.

The company recently acquired Phase III ready cebranopadol, which further enhances its pain management franchise.

Current market price undervalues the company. We continue to rate its shares a Buy.

SUMMARY DATA

52-Week High	**$33.28**
52-Week Low	**$13.82**
One-Year Return (%)	**-24.02**
Beta	**1.30**
Average Daily Volume (sh)	**1,842,127**
Shares Outstanding (mil)	**60**
Market Capitalization ($mil)	**$1,035**
Short Interest Ratio (days)	**9.20**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**7.9**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/M**
P/E using 2016 Estimate	**14.3**
P/E using 2017 Estimate	**8.8**

Risk Level	**Average,**
Type of Stock	**Small-Blend**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	32.2 A	94.5 A	104.9 A	111.2 A	342.7 A
2016	115.4 E	120.4 E	126.6 E	135.2 E	497.6 E
2017					600.5 E
2018					726.0 E

Earnings per Share
(Adjusted EPS)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.13 A	$0.27 A	$0.33 A	$0.16 A	$0.70 A
2016	$0.22 E	$0.28 E	$0.32 E	$0.38 E	$1.20 E
2017					$1.94 E
2018					$2.49 E

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WHAT'S NEW

NUCYNTA Continued Momentum in 4Q15

On Feb 22, DepoMed reported its fourth quarter financials ended December 31, 2015.

Total product sales for 4Q15 reached $111.1 million, compared to $33.9 million for 4Q14, an increase of 227.8%, and an increase of 6.1% compared to $104.7 million for third quarter of 2015. Total product sales for 4Q15 were slightly below our estimate of $114.5 million.

Sales from the company's flagship **NUCYNTA** franchise (including NUCYNTA immediate release and NUCYNTA ER) continued its momentum. Sales of NUCYNTA contributed $68.3 million to the total product revenue for 4Q15, an increase of 55.1% from $44 million for 4Q14 under JNJ control. Net sales of NUCYNTA reached $190 million since acquisition from JNJ on April 2, 2015.

According to SHA PHAST, NUCYNTA ER December year-over-year prescription volume grew 20.7% and NUCYNTA ER recorded all-time high prescription volume of over 30,000 reached in December.

Other products also contributed to the strong 4Q15 product sales growth.

Gralise sales for 4Q15 increased to $21.7 million from $18.1 million for 4Q14, an increase of 20.0%. Full-year net sales of Gralise were $81 million, an increase of 34% compared to $60 million in 2014 2015 total prescriptions of Gralise were over 327,000, an increase of 13% over 2014. In December 2015, the company recorded an all-time monthly high prescription volume of over 29,000.

Cambia® sales for 4Q15 were a record $8.2 million, an increase of 30% compared to $6.3 million in the fourth quarter of 2014. For the fiscal year 2015, total net sales of Cambia were $27.4 million, an increase of 26% compared to $21.7 million in 2014. Total prescriptions of Cambia in 2015 surpassed 136,000, an increase of 28% over that in 2014. The drug booked a record all-time monthly high prescription volume of over 13,000 reached in December 2015.

Lazanda® sales for 4Q15 were $5.2 million, an increase of 96% compared to $2.7 million in the same period last year. For fiscal 2015, full-year net sales were $17.7 million, an increase of 154% compared to $7.0 million in 2014. Total bottles sold for the full year were over 71,000, an increase of 138% over 2014. Lazanda also booked a record all-time monthly high volume of over 7,000 bottles reached in December 2015.

After an 11.8% decline in 2Q15 and a flat sales growth (0.5%) in 3Q15, **Zipsor** sales resumed strong growth in 4Q15. Zipsor sales in 4Q15 were $7.7 million, compared to $6.8 million for 4Q14, an increase of 12.1%.

Three Months Ended December 31 (in $millions)			
	4Q2015	**4Q2014**	**Increase (%)**
NUCYNTA	$68.3	$44.0	55.0%
Gralise	$21.7	$18.1	20.0%
Cambia	$8.2	$6.3	30.2%
Lazanda	$5.2	$2.7	96.5%
Zipsor	$7.7	$6.8	12.1%
Total	**$111.1**	**$33.9**	**227.8%**

GAAP net loss for 4Q15 was $30.7 million ($0.51 per share), compared to GAAP net income of $98 million ($1.23 per share) for 4Q14.

Non-GAAP adjusted earnings for the 4Q15 were $11 million ($0.16 per share), compared to non-GAAP adjusted earnings of $14.4 million ($0.21 per share) for 4Q14.

Non-GAAP adjusted EBITDA for 4Q15 was $38.8 million, compared to non-GAAP adjusted EBITDA of $3.6 million for 4Q14.

As of December 31, 2015, DepoMed had $210 million in cash. Cash generated during the quarter was $60 million and $167 million for the first nine months since the close of the NUCYNTA acquisition, in both cases before payment of the $25 million cebranopadol licensing fee in December, 2015. The strong balance sheet allows the company to focus on long term growth strategy without any worry for short term cash burn.

Guidance for 2016

During the fourth quarter conference call, management provided its financial outlook for total revenue, non-GAAP SG&A expense, non-GAAP R&D expense, non-GAAP adjusted earnings and non-GAAP adjusted EBITDA for the full year 2016.

	2016 Guidance
Total Revenue	$485 to $525 million
Total Non-GAAP SG&A Expense	$180 to $195 million
Total Non-GAAP R&D Expense	$30 to $40 million
Non-GAAP Adjusted Earnings	$95 to $115 million
Non-GAAP Adjusted EBITDA	$175 to $205 million

We estimate total revenue will be $497.6 million, representing an increase of 45.2% year over year.

Initial Sales Ramp Convinces US that NUCYNTA Has Blockbuster Potential

Since DepoMed took control of NUCYNTA in early April 2015, sales growth from this franchise is accelerating. The franchise has become the company's flagship product.

DepoMed recorded full second quarter NUCYNTA net sales of $56.7 million in 2Q2015, an increase of 29% compared to sales of $44 million in 4Q14 generated by JNJ.

Product franchise was officially re-launched in mid-June 2015 with expanded sales force of 275 plus full marketing and medical support. The sales force of 275 reps more than tripled compared to sales force of 80-90 reps for JNJ.

Per management, product positioning has been focused on NUCYNTA's dual mechanism of action designed to target both nociceptive and neuropathic pain. The company plans to capture market share in large and growing markets including chronic pain and chronic lower back pain (CLBP). Over 100 million US patients suffer from chronic pain, while 31 million US patients suffer from chronic lower back pain. DepoMed will specifically targeting the CLBP patient population. The company also launched NUCYNTA for moderate to severe painful diabetic peripheral neuropathy (DPN), which affects another 1-2 million patients.

As a result of the relaunch strategy, third quarter net sales of NUCYNTA increased to $64.9 million, an increase of 15% compared to $56.7 million from second quarter of 2015. And sales of NUCYNTA continued to grow in 4Q15 with a record net sales of $68.4 million, which compared to $44 million in 4Q14 generated by JNJ, an increase of 55%.

Three Months (in $millions)				
	4Q14 (JNJ)	**2Q15**	**3Q15**	**4Q15**
NUCYNTA	$44.0	$56.7	$64.9	$68.3

We believe the effect of the re-launch strategy and the tripled sales force is expected to impact NUCYNTA prescription growth further in 2016 and beyond. The strong initial sales, combined with the relaunch strategy, make us believe that NUCYNTA has blockbuster potential and will become the company's flagship brand.

Depomed Enhances its Pain Management Franchise by Acquiring Cebranopadol

The Deal

In Nov, 2015, Depomed entered into a definitive agreement to acquire the U.S. and Canadian rights to **cebranopadol** and its related follow-on compound from Grünenthal GmbH.

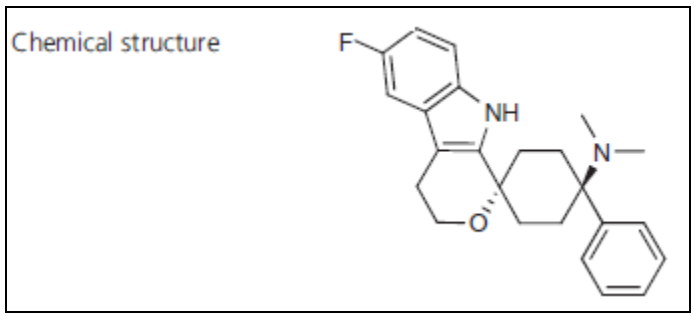
Pursuant to the agreement, Depomed has entered into a settlement agreement with Endo Pharmaceuticals to resolve Depomed's ongoing patent litigation against Endo for alleged infringement of three of Depomed's patents by Endo's OPANA® ER product. As the formulator of OPANA® ER, Grünenthal indemnified Endo for certain intellectual property matters, including Depomed's ongoing patent infringement lawsuit against Endo. The settlement agreement grants Endo a non-exclusive patent license in the United States, and a covenant not to sue outside the United States, for the currently marketed form of OPANA® ER. In addition, Depomed is providing Grünenthal with a limited covenant not to sue under certain Depomed Acuform® drug delivery patents with specific drug substances.

In connection with the acquisition, Depomed will pay Grünenthal $25 million in cash. Depomed will also pay Grünenthal royalties on net sales and one-time net sales milestones. There are no clinical, regulatory or approval milestone payments.

The deal was closed on December 30, 2015. The settlement agreement with Endo became effective upon the closing under the license agreement.

Cebranopadol

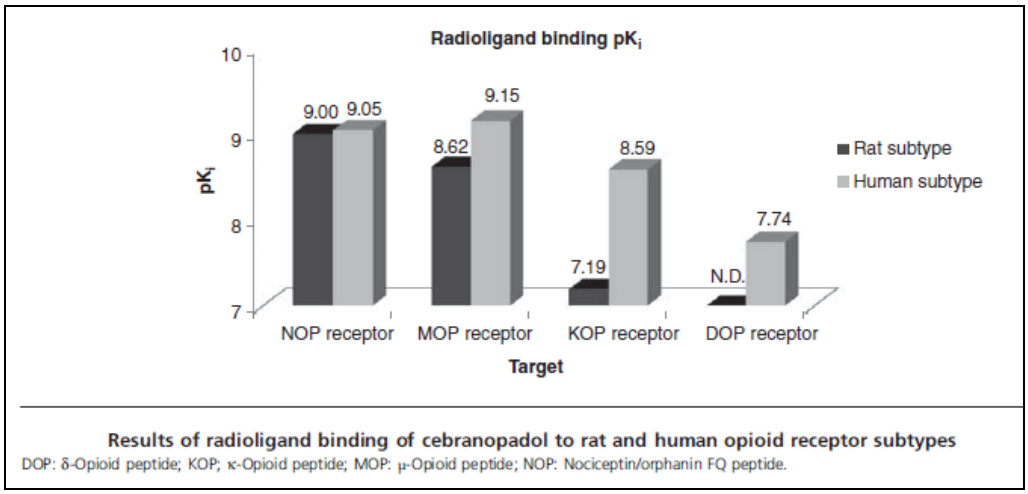
Cebranopadol is a novel, first-in-class analgesic in development for the treatment of moderate to severe chronic nociceptive and neuropathic pain.



Cebranopadol is a differentiated molecule with a novel **dual mechanism-of-action**, functioning as a high-potency agonist of both the mu-opioid **(MOP)** and the nociceptin receptors **(NOP).** Cebranopadol's pharmacology is likely to confer analgesic efficacy equivalent to that of traditional opioids in peripherally-mediated, nociceptive pain conditions, while potentially conferring great efficacy in neuropathic pain and other pain states characterized by more centralized pain. Moreover, the product does not appear to impact respiratory function to the degree that traditional mu-opioid receptor agonists do, and the nociceptin receptor pharmacology also appears to substantially mitigate the abuse potential of cebranopadol.

The in vitro Binding Assay

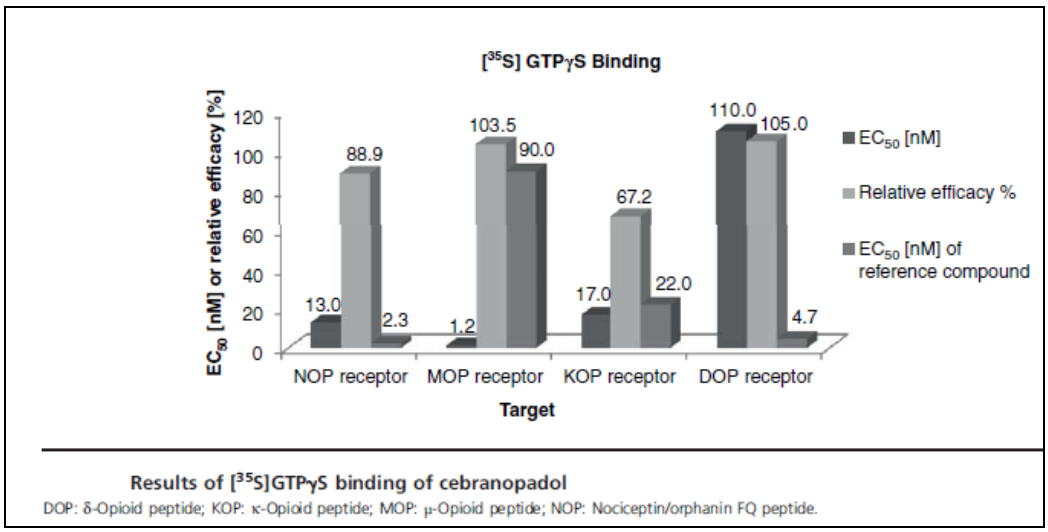
In ***in vitro*** radioligand binding testing, Cebranopadol showed the highest receptor affinities at NOP and MOP, both rat and human receptors, while the affinity at KOP receptors was ~ 3-fold weaker, and ~ 20-fold weaker for DOP receptors for human receptors. The affinity at the rat KOP and DOP receptor was even lower (Linz K,et al: J Pharmacol Exp Ther 2014;349(3):535-48).



Results of radioligand binding of cebranopadol to rat and human opioid receptor subtypes

DOP: δ-Opioid peptide; KOP; κ-Opioid peptide; MOP: μ-Opioid peptide; NOP: Nociceptin/orphanin FQ peptide.

The agonistic activity of cebranopadol at human opioid receptors was determined in [^{35}S] guanosine-5′-[□-thio] triphosphate binding assays. These data showed that cebranopadol was a full agonist of human MOP and DOP receptors, almost a full agonist of human NOP receptors, and a partial agonist of human KOP receptors (Linz K,et al: J Pharmacol Exp Ther 2014;349(3):535-48).



Results of [^{35}S]GTPγS binding of cebranopadol

DOP: δ-Opioid peptide; KOP: κ-Opioid peptide; MOP: μ-Opioid peptide; NOP: Nociceptin/orphanin FQ peptide.

Preclinical Animal Studies

In preclinical **animal studies**, Cebranopadol demonstrated excellent anti pain efficacy in both acute and chronic animal models. In one acute rat model, Cebranopadol was antinociceptive after intravenous and oral administration, and its activity lasted longer (7 h) than that of equianalgesic doses of morphine (3 h) and fentanyl (30 min). Intravenous cebranopadol was also effective in chronic pain models: complete Freund's adjuvant (CFA)-induced arthritis (a model of nociceptive/inflammatory pain), bone cancer pain (nociceptive and neuropathic pain), painful diabetic neuropathy and the spinal nerve ligation model (neuropathic pain models). In these experimental models, intravenous cebranopadol was 2 -- 3 orders of magnitude more potent than the reference drug -- morphine, and the obtained ED50 values for cebranopadol ranged from 0.5 µg/kg in streptozotocin-induced painful diabetic neuropathy, to 5.5 and 5.6 µg/kg in CFA-induced arthritic pain and the tail-flick model, respectively (Br J Anaesth 2015;114(3):364-6).

Clinical Studies and Development Plan

To date, cebranopadol has been studied in sixteen **Phase I**, four **Phase IIa** and three **Phase IIb** trials in painful diabetic peripheral neuropathy (PDPN), osteoarthritis (OA) and chronic lower back pain as well as a human abuse potential study. In total, cebranopadol has been studied in approximately 2,000 patients worldwide. These studies have confirmed a profile of high potency and efficacy with good tolerability and the potential for a lower abuse profile.

Based on all the data available from both preclinical and clinical studies, Depomed anticipates conducting an End-of-Phase-II meeting with the FDA in 2016 and commencing **Phase III** development for chronic lower back pain (cLBP) and other pain indications **by 2017**. Cebranopadol has patent protection through at least 2032 with the potential for patent term extension to 2037.

Our Takeaway

We welcome this deal which adds a highly complementary late stage development candidate with a strong efficacy profile, favorable tolerability and low abuse potential with patent protection into the 2030's to Depomed's broad commercial platform of pain and neurology marketed products.

Based on both the animal data and clinical results, we have a strong feeling that cebranopadol has a high probability of success for approval. Developmentally, Depomed has a well-defined pathway to follow, which further convince us that cebranopadol will be a great addition to the company's existing portfolio.

We also think the acquisition of cebranopadol fits well with the company's strategy to expand its leading pain management portfolio. With the addition of cebranopadol, Depomed pain management franchise is greatly enhanced. This will make the company a key player in the chronic pain management market place.

We will further update investors on the clinical data when they are available and on the development plan as the company integrates this acquisition and meets with the FDA.

We Continue to Be Bullish on DepoMed Shares

We maintain our Buy rating on Depomed shares and reiterate our 12-month price target of $36 per share.

We continue to remain positive on the DepoMed story, especially as it pertains to the NUCYNTA® franchise, as we believe the transaction to acquire NUCYNTA® / ER is transformational for the company. The strategic fit is excellent and past execution has been outstanding. There is clearly a lot of future execution that still must take place for this to benefit shareholders but the plan is in place, and in our opinion, looks solid. We view the name as a good core-holding in the specialty pharmaceutical industry with significant upside should the NUCYNTA® / ER product take off.

In 4Q15, DepoMed generated $68.3 million in NUCYNTA sales, an increase of 55% from $44 million in 4Q14 under JNJ control.

Based on the initial sales and the prescription data so far, we have solid reasons to believe that NUCYNTA sales are poised to take off in 2016 and beyond.

We model NUCYNTA sales will be $317 million for 2016, and will reach $400 million in 2017.

In terms of valuation, we think Depomed shares are undervalued at current market price. Currently share price of Depomed is trading at about $17 per share, valuing the company at $1.0 billion in terms of market cap. We think this deeply undervalues Depomed.

Based on our financial model, revenue will reach $498 million in 2016 with non-GAAP earnings per share (EPS) of $1.20. We continue to expect that the NUCYNTA® / ER deal will be strongly accretive, and that DepoMed will generate $400 million in sales from NUCYNTA franchise in 2017. Non-GAAP EPS will grow from $0.70 in 2015 to $1.94 in 2017 based on total revenue of $600 million. EPS will further grow to $2.91 in 2019 based on total revenue of $807 million.

We think DepoMed shares should be valued using a 25x P/E multiples, which is close to the biotech industry's average P/E ratio of 22.6. Using this P/E ratio, multiplied by our estimated EPS of $2.91 for 2019, discounted at 25% for three years, we come up with our fair value of DepoMed **at $36 per share**. Our price target values the company at $2.2 billion, which is still conservative in our view.

We consider Hillary Clinton's comments on drug price control more as politics rather than policy. Any proposal with respect to drug price control is unlikely to become a law in a short period of time in our view. Therefore, the recent decline in share price of Depomed due to the industry correction should be considered great buying opportunity.

We also noticed that Horizon recently withdrew its offer to acquire Depomed. We believe Depomed's Board and management team are committed to enhancing long-term value of the company and will continue to execute on its strategy and deliver significant and sustainable returns for all shareholders.

PROJECTED INCOME STATEMENT

DEPOMED, INC.	2014 A	Q1A	Q2A	Q3A	Q4A	2015 A	Q1	Q2	Q3	Q4	2016 E	2017 E	2018 E	2019 E
Total Product Sales	$114.2	$31.7	$94.3	$104.7	$111.1	$341.7	$115.3	$120.3	$126.5	$135.1	$497.2	$600.0	$725.0	$805.0
YOY Growth	*35.9%*	*47.3%*	*233.6%*	*242.4%*	*227.8%*	*199.2%*	*264.1%*	*27.6%*	*20.8%*	*21.6%*	*45.5%*	*20.7%*	*20.8%*	*11.0%*
Total Royalties	$110.9	$0.5	$0.2	$0.1	$0.1	$1.0	$0.1	$0.1	$0.1	$0.1	$0.4	$0.5	$1.0	$1.5
YOY Growth	*146.4%*	*-98.8%*	*-99.4%*	*-99.4%*	*-99.2%*	-	-	-	-	-	-	-	-	-
Total Licenses Revenues	$165.2	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0.0	$0.0	$0.0
YOY Growth	*828.5%*	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$390.4**	**$32.2**	**$94.5**	**$104.9**	**$111.2**	**$342.7**	**$115.4**	**$120.4**	**$126.6**	**$135.2**	**$497.6**	**$600.5**	**$726.0**	**$806.5**
YOY Growth	*190.3%*	*-57.3%*	*39.5%*	*103.7%*	*-42.9%*	*-12.2%*	*258.4%*	*27.4%*	*20.7%*	*21.6%*	*45.2%*	*20.7%*	*20.9%*	*11.1%*
Cost of Goods Sold	$15.1	$3.1	$22.9	$20.9	$21.0	$67.9	$23.06	$24.06	$25.30	$27.02	$99.44	$120.0	$145.0	$161.0
Product Gross Margin	*96.7%*	*90.2%*	*75.8%*	*80.0%*	*81.1%*	*80.1%*	*80.0%*	*80.0%*	*80.0%*	*80.0%*	*80.0%*	*80.0%*	*80.0%*	*80.0%*
SG&A	$121.1	$34.5	$57.4	$49.1	$58.3	$199.4	$50.0	$53.0	$58.0	$64.0	$225.0	$250.0	$275.0	$290.0
% SG&A	*31.0%*	*107.3%*	*60.7%*	*46.8%*	*52.5%*	*58.2%*					*45.2%*	*41.6%*	*37.9%*	*36.0%*
R&D	$7.1	$1.9	$4.7	$4.6	$61.2	$72.4	$7.0	$8.5	$9.5	$10.0	$35.0	$45.0	$55.0	$65.0
% R&D	*1.8%*	*5.8%*	*5.0%*	*4.4%*	*55.1%*	*21.1%*	*6.1%*	*7.1%*	*7.5%*	*7.4%*	*7.0%*	*7.5%*	*7.6%*	*8.1%*
Amortization	$10.2	$2.5	$26.7	$27.0	$27.1	$83.3	$27.0	$27.0	$27.0	$27.0	$108.0	$110.0	$110.0	$110.0
Operating Income	$236.8	($9.8)	($17.2)	$3.2	($56.5)	($80.3)	$8.3	$7.8	$6.8	$7.2	$30.2	$75.5	$141.0	$180.5
Operating Margin	*60.7%*	-	-	-	-	*-23.4%*	*7.2%*	*6.5%*	*5.4%*	*5.3%*	*6.1%*	*12.6%*	*19.4%*	*22.4%*
Non-Cash PDL Int. Exp.	($71.9)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Other Income (Net)	($9.6)	($6.0)	($4.4)	($22.6)	$25.8	($7.2)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	$155.3	($15.8)	($21.7)	($19.3)	($30.7)	($87.5)	$8.3	$7.8	$6.8	$7.2	$30.2	$75.5	$141.0	$180.5
Taxes	$20.1	($4.2)	$0.0	($7.6)	$0.0	($11.7)	$0.0	$0.0	$0.0	$0.0	$0.0	$19.6	$36.7	$46.9
Tax Rate	*13%*	*26%*	*0%*	*39%*	*0%*	*13%*	*0%*	*0%*	*0%*	*0%*	*0%*	*26%*	*26%*	*26%*
GAAP Net Income	$136.0	($11.6)	($21.7)	($11.8)	($30.7)	($75.7)	$8.3	$7.8	$6.8	$7.2	$30.2	$55.9	$104.3	$133.6
Net Margin	*34.8%*	-	-	-	-	*-22.1%*	*7.2%*	*6.5%*	*5.4%*	*5.3%*	*6.1%*	*9.3%*	*14.4%*	*16.6%*
GAAP EPS	**$2.05**	**($0.20)**	**($0.36)**	**($0.20)**	**($0.51)**	**($1.26)**	**$0.14**	**$0.13**	**$0.11**	**$0.12**	**$0.49**	**$0.86**	**$1.49**	**$1.78**
YOY Growth	*172.4%*	-	-	-	-	*-161.4%*	*-170.6%*	*-135.6%*	*-156.6%*	*-122.9%*	*-139.1%*	*74.6%*	*73.4%*	*19.5%*
Adjustments to GAAP	($119.2)	$3.6	$41.7	$36.7	$43.5	$132.2	$10.0	$15.0	$20.0	$25.0	$70.0	$70.0	$70.0	$85.0
Non-GAAP Net Income	$16.0	($8.0)	$20.0	$24.9	$12.9	$56.4	$18.3	$22.8	$26.8	$32.2	$100.2	$125.9	$174.3	$218.6
Adjusted (Non-GAAP) EPS	**$0.26**	**($0.13)**	**$0.27**	**$0.33**	**$0.16**	**$0.70**	**$0.22**	**$0.28**	**$0.32**	**$0.38**	**$1.20**	**$1.94**	**$2.49**	**$2.91**
Diluted Wt. Ave Shares Out	66.3	59.6	60.0	60.3	60.6	60.1	60.5	61.0	61.5	62.0	61.3	65.0	70.0	75.0

Source: Company filing and Zacks Estimates

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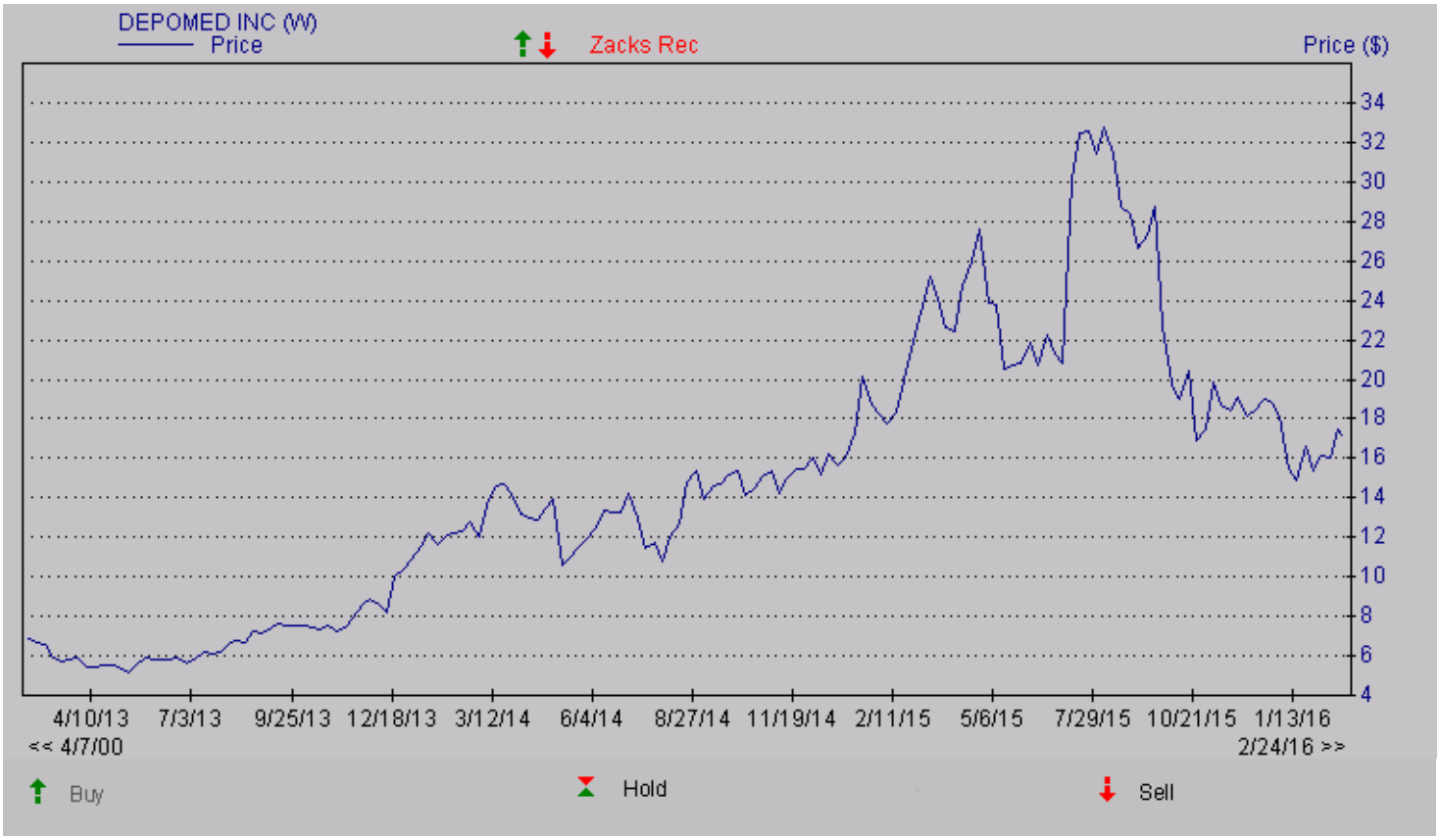
HISTORICAL ZACKS RECOMMENDATIONS



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