Zacks Small-Cap Research

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Biopharmx Corp (BPMX-NYSE MKT)

BPMX: Phase IIa of BPX01 for acne initiated– Buy

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	09/30/2015
Current Price (03/18/16)	$1.35
Twelve- Month Target Price	**$4.50**

OUTLOOK

BPMX is a specialty pharma with a focus on women's health and dermatology. The company's VI_2OLET is a commercially available OTC for breast discomfort associated with FBC. BPX03, a prescription iodine for FBC, will enter Phase III trial in 4Q16 and BPX01, a topical minocycline, for acne, just moved into Phase II trial. By 2019, BPMX will become a key player in the targeted markets of women's health and dermatology with 3 products commercially available targeting FBC and acne respectively.

We are optimistic about BPMX prospect and rate its shares a Buy.

SUMMARY DATA

52-Week High	**$2.23**
52-Week Low	**$1.03**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**23,377**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$34**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
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 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**N/A**
Type of Stock	**N/A**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Apr)	Q2 (Jul)	Q3 (Oct)	Q4 (Jan)	Year (Jan)
2015	$0.00 A	$0.00 A	$0.00 A	$0.00 A	$0.00 A
2016	$0.00 A	$0.01 A	$0.02 A	$0.05 E	$0.08 E
2017					$0.50 E
2018					$5.00 E

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

	Q1 (Apr)	Q2 (Jul)	Q3 (Oct)	Q4 (Jan)	Year (Jan)
2015	-$0.14 A	-$0.17 A	-$0.19 A	-$0.25 A	-$0.76 A
2016	-$0.31 A	-$0.23 A	-$0.18 A	-$0.16 E	-$0.83 E
2017					-$0.61 E
2018					-$0.58 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW

BioPharmX commences Phase II clinical study under U.S. FDA IND for BPX-01

BioPharmX is developing **BPX01**, a non-lipophilic, topical antibiotic for the treatment of **acne**. BPX01 utilizes a **transepidermal delivery mechanism** for minocycline and other APIs that has the potential to kill p. acnes bacteria without the systemic side effects of orally-administered antibiotics.

In March 2015, BioPharmX completed its planned pre-IND (Investigational New Drug) meeting with the US FDA which was focused on the company's proposed strategy for advancing BPX01and plans for conducting safety and toxicology studies, along with human clinical trials. Following the conclusion of the meeting, the company believes that it has sufficient guidance from the FDA for advancing toward an IND application for **phase II** clinical trials.

On March 3, 2016, BioPharmX announced that it will **immediately** commence a **Phase IIa** clinical study under its U.S. FDA IND application for BPX-01. This clinical study will assess effectiveness in reducing the number of acne-causing bacteria in study patients at four weeks and evaluate the drug's safety and tolerability. This is the first clinical study in the clinical development program for BPX-01.

The Phase IIa clinical study will be conducted by KGL Skin Center, a Philadelphia-based independent clinical research facility recognized as a leader in clinical testing of cosmetics, personal care products, over-the-counter and prescription drugs, and devices for the skin. The principal investigator is Dr. Stuart Lessin, a board-certified dermatologist who serves as KGL's medical director.

The company's preclinical studies have found the unique **gel formulation** of minocycline in BPX-01 can deliver the antibiotic to the layer of skin where the condition develops, suggesting that the skin penetration needed to reach an efficacious dose in humans while minimizing systemic exposure is possible.

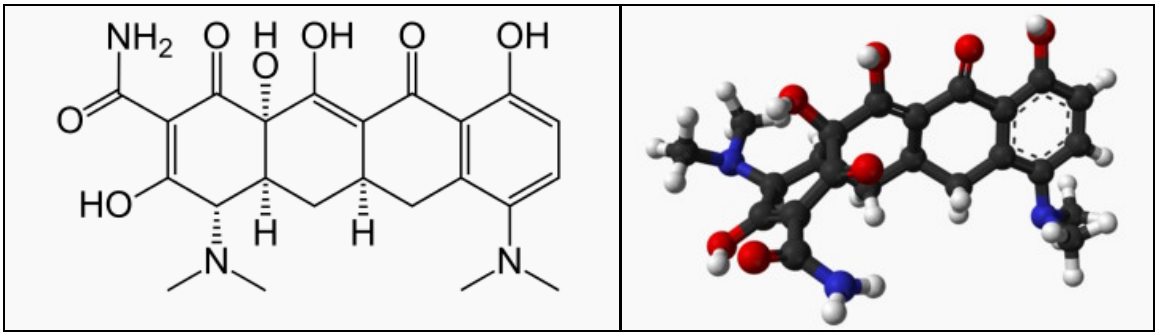
BPMX intends to pursue regulatory approval of BPX01 under Section 505(b)(2) of the FDC Act. The 505(b)(2) regulatory pathway may reduce the drug development risks and costs by using prior findings of safety and/or efficacy for an approved product. In BPX01 case, part of the safety and efficacy data from the oral formulation of minocycline may be used for the filing of a NDA for BPX01.

If everything goes well, we estimate BPX01 will be approved by the FDA in calendar 2019. Peak sales of BPX01 should be around $450 million.

Background on Minocycline

Minocycline is a broad-spectrum tetracycline antibiotic, and has a broader spectrum than the other members of the group. It is a bacteriostatic antibiotic, classified as a long-acting type. As a result of its long half-life it generally has serum levels 2–4 times that of the simple water-soluble tetracyclines.

Minocycline is the most lipid-soluble of the tetracycline-class antibiotics, giving it the greatest penetration into the prostate and brain, but also the greatest amount of central nervous system (CNS)-related side effects, such as vertigo. A common side effect is diarrhea. Uncommon side effects (with prolonged therapy) include skin discoloration and autoimmune disorders that are not seen with other drugs in the class.



Structure of Minocycline

Minocycline and doxycycline are the two most frequently used oral antibiotics for the treatment of acne vulgaris. Both of these closely related antibiotics have similar levels of efficacy, although doxycycline has a slightly lower risk of adverse side effects.

The most common **side effects** of minocycline include upset stomach, diarrhea, dizziness, unsteadiness, drowsiness, mouth sores, headache and vomiting. Occasionally minocycline therapy may result in autoimmune disorders such as drug related lupus and auto-immune hepatitis. Minocycline can cause *vestibular disturbances* with dizziness, ataxia, vertigo and tinnitus. These effects are again thought to be related to minocycline's greater penetration into the central nervous system. Vestibular side effects are much more common in women than in men, occurring in 50% to 70% of women receiving minocycline. As a result of the frequency of this bothersome side effect, minocycline is rarely used in female patients.

BPX01's Advantages over Oral Minocycline

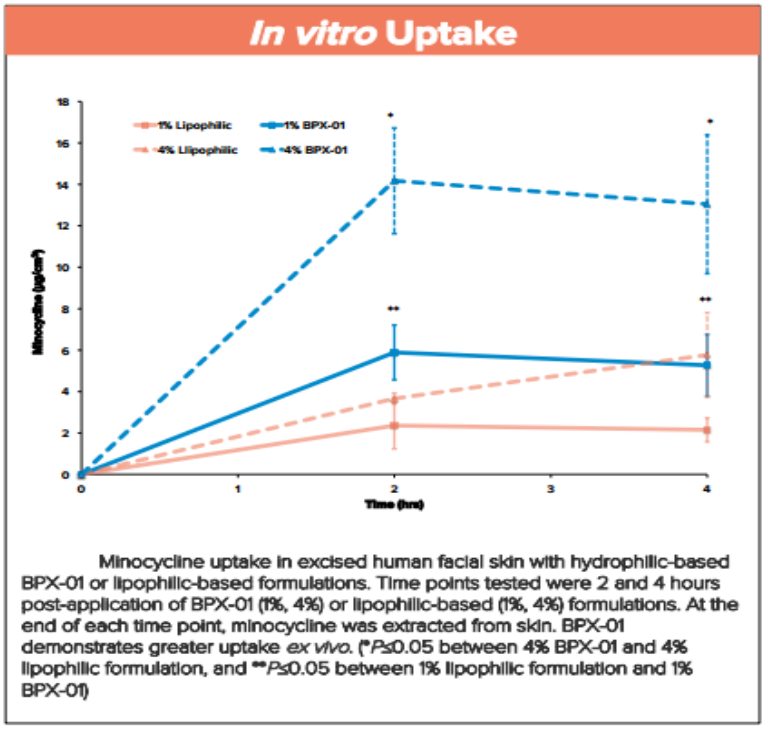
All the side effects discussed above limit the use of **oral minocycline** for the treatment of acne. As a result, BioPharmX formulated BPX01 as a topical cream using a proprietary drug delivery technology. BPX01 is a new anhydrous, non-oil based topical antibiotic targeting acne bacteria.

BPX01 is designed to have several advantages compared to both orally-administered and other topically-administered retinoid- and antibiotic-based solutions. Advantages of BPX01 include:

- topical delivery of minocycline,
- controlled dosages targeted directly to affected area,
- increased delivery of API at low dosages,
- non-lipophilic design allowing for faster absorption by the skin,
- potential lower risk of systemic side effects common to orally administered antibiotics,
- Gel-like form rubs on like a sanitizer.

In addition, BPX01 has been shown in pre-clinical studies to possess **anti-inflammatory** properties, which reduce swelling and slow hyper-cornification.

During the third quarter, the company presented pre-clinical data at three key dermatology seminars suggesting that a 1% dose of minocycline in BPX-01 can work as well as the 4% topical products that are under development by competitors, lowering the likelihood of side effects.



Minocycline uptake in excised human facial skin with hydrophilic-based BPX-01 or lipophilic-based formulations. Time points tested were 2 and 4 hours post-application of BPX-01 (1%, 4%) or lipophilic-based (1%, 4%) formulations. At the end of each time point, minocycline was extracted from skin. BPX-01 demonstrates greater uptake *ex vivo*. (*$P \leq 0.05$ between 4% BPX-01 and 4% lipophilic formulation, and **$P \leq 0.05$ between 1% lipophilic formulation and 1% BPX-01)

Balance Sheet Boosted by Recent Financing

On December 10, 2015, BioPharmX closed a direct investment of approximately $5.9 million through the sale of 4.1 million shares of the Company's common stock at a purchase price of $1.43 per share to investment vehicles of Franklin Advisers.

This investment not only boosts the company's balance sheet, but more importantly, it is an important validation of the company's technology and clinical programs.

This new financing will help the company accelerate the development of its clinical pipeline, and support its marketing plan for VI_2OLET.

The company also expects proceeds of $2 million in cash from the closing of a previously announced private placement with Korea Investment Partners Overseas Expansion Platform Fund, an existing shareholder.

As of October 31, 2015, BioPharmx held cash and cash equivalents of $2.2 million. With the addition of the proceeds from the new financing, and the expected $2 million proceeds, the cash balance sheet supports the company's operations into 3Q16.

Update on VI_2OLET

As the company's first commercial product, VI_2OLET is a once-a-day OTC dietary supplement **molecular iodine** tablet (3.0 mg daily iodine supplement) that promotes overall breast health and is for the alleviation of benign breast pain associated with fibrocystic breast condition **(FBC).**

The Company commercially launched VI_2OLET at the end of 2014 and is rolling out the product in drug store and retail chains throughout the US. VI_2OLET is currently available for sale in approximately 2,960 CVS retail pharmacy chains, 650 Vitamin Shoppe stores, and Harris Teeter grocery stores throughout the United States, as well as online through drugstore.com and walgreens.com.



In November, 2015, BioPharmX added 3,025 **GNC store** locations supplying Violet® iodine, raising its U.S. retail footprint to more than 7,500 stores. Availability of Violet iodine at GNC is expected to begin in **mid-December**.

GNC is a leading global specialty retailer of health and wellness products and is devoted to helping its customers improve the quality of their lives. We believe the addition of GNC stores will accelerate VI_2OLET revenue growth in the coming quarters.

The commercial launch of VI_2OLET iodine is supported by an extensive consumer marketing program targeting women between the ages of 30 and 44. With a combination of brand and shopper marketing, both nationally and locally, the company is generating awareness, engagement, education, consideration and purchase interest.

So far, revenue from the product sales is minimal, but the growth (from $5000 in fiscal 2Q15 to $20,000 in fiscal 3Q15) has been impressive. We believe the product will generate meaningful revenue for the company in calendar 2016 resulting from the company's focused and integrated marketing strategy.

VI_2OLET iodine is the only OTC molecular iodine dietary supplement that addresses cyclic breast discomfort and is clinically demonstrated to alleviate the symptoms associated with fibrocystic breast changes including tenderness, swelling and aches. The company's patented molecular iodine (I_2) formula is delivered to breast tissue and reduces the breast cell build-up that results in breast discomfort. Women who suffer from menstrual-related breast discomfort are recommended to take one tablet per day on an empty stomach for at least 60 days to realize initial symptom relief. They may take a second tablet every evening if they have more severe symptoms. Additionally, with consistent daily use, VI_2OLET iodine has been shown to help maintain healthy breast tissue.

Update on BPX-03

In addition to OTC molecular iodine VI_2OLET, BPMX is also developing a prescription molecular iodine tablet, **BPX03**, for the treatment of benign breast pain associated with FBC and cyclic mastalgia. BPX03 is intended for global distribution, where prescription products may be required due to regulatory requirements.

BPMX licensed both VI_2OLET and BXP03 from **Iogen** in March 2013. Under the terms of the agreement, BPMX received an exclusive worldwide perpetual irrevocable license to Iogen's patented technology relating to an oral iodine tablet. In exchange, BioPharmX agreed to pay to Iogen a non-refundable license issue fee of $150,000, and 30% of net profit associated with direct commercialization of an OTC iodine tablet product or 30% of net royalties received from any sub-licensee. For other products developed and commercialized using licensed technology and associated intellectual property covered by this agreement, including a prescription iodine tablet, BPMX agreed to pay to Iogen a royalty of 3% of net sales for the first 12 months of commercialization and 2% of net sales thereafter.

BPX03, like OTC VI_2OLET, is a new non-hormone treatment for FBC and mastalgia. BPX03 promotes antiproliferative and apoptotic activity in breast tissue. Prior sponsor has completed a **Phase I** and a

Phase II study which demonstrated that BPX03 was safe and well tolerated. BPX03 also demonstrated statistically significant improvement of FBC symptoms at 3-6 mg does in the completed Phase II trial.

BPMX is preparing to conduct a pivotal **Phase III** safety and efficacy clinical study, which is intended to support the FDA and foreign regulatory requirements. The company also plans to initiate an institutional review board (**IRB) pilot study** in **early 2016** for the preparation of the planned pivotal Phase III study. The pilot study will enroll 120 subjects for a 9-month treatment. Based on data from the pilot study, BPMX intends to commence the Phase III study in **4Q16.**

We estimate data from the Phase III trial should be available in mid-2017. A NDA will be submitted in late 2017, and a final nod from the FDA will be obtained in 2H18. BioPharmX will seek approval only in those countries where the company will seek to market the prescription product.

We believe the company's FBC franchise will be greatly strengthened by the addition of prescription molecular iodine. With both OTC and prescription iodine, BioPharmX is poised to be the market leader in the unmet FBC market.

Peak sales from the company's VI_2OLET and BXP03 could reach $250 million globally.

Update on BPX02, A Biologic for Dermatology

BioPharmX has a collaboration and supply agreement with **NuTech**, a private biologics company specializing in the spinal and orthopedics market. This agreement describes the collaboration between Nutech and BioPharmX to develop products in the field of dermatology. Products and intellectual property developed under this agreement are exclusively owned by BioPharmX and licensed to NuTech for use in indications outside of dermatology. In exchange for an exclusive license to NuTech's intellectual property in the field of dermatology, BioPharmX will pay to NuTech a royalty of 3% of net sales on product sold in the field of dermatology. In exchange for granting NuTech an exclusive license to BioPharmX IP and IP developed in collaboration with NuTech in indications outside of dermatology, BioPharmX shall receive from NuTech a royalty of 3% of net sales on products sold by them.

BPX02, which is developed in collaboration with NuTech, is a biologic for the dermatology indications. This candidate is still in R&D stage as the company continues to make progress in the development of a prescription drug formulating biologics materials for a dermatology application.

We believe BPX02 will further strengthen the company's dermatology franchise. We will keep investors posted when we have any update on this product development.

Valuation still Attractive

Since our initiation of BioPharmx in early October 2015, the company's share price nearly doubled.

We maintain our **Buy rating** on BioPharmX (BPMX) shares and reiterate our 12-month price target of $4.5 per share.

BPMX is a specialty pharmaceutical company with a focus on **women's health** and **dermatology**. We believe that the industry dynamics in the areas of women's health and dermatology represent significant opportunities for innovative new products to emerge as attractive solutions for unmet needs in multi-billion dollar therapeutic categories. In particular, we believe that both the women's health and dermatology markets are large specialty markets with significant global patient demand.

On the front of **women's health**, BPMX is marketing an OTC molecular **VI_2OLET** for the treatment of fibrocystic breast condition (FBC). Although sales of VI_2OLET have been minimal so far since it was launched at the end of 2014, we believe sales could pick up steam in the calendar 2016 due to the company's focused and integrated marketing strategy.

In addition to the marketed OTC product VI_2OLET, BioPharmX is also developing BPX03, the company's prescription molecular iodine, for FBC. **BPX03** will enter pivotal Phase III trial in 4Q16, which we expect will be approved in 2018. If approved, BPX03 will complement the company's currently marketed OTC molecular Iodine VI_2OLET. With both OTC and prescription Iodine, BPMX is poised to become the market leader in FBC market.

The multibillion-dollar **acne market** is the next target for BioPharmX. The company's **BPX01,** a topical formulation of minocycline, has entered to Phase II study. If everything goes well, we expect BPX01 to be approved in 2019. The company's dermatology franchise will be further boosted by the successful development of **BXP02**, a biologic under R&D stage for the dermatology indications.

With three products on the market in 2019, BioPharmX will become a key player in the two targeted markets of women's health and dermatology.

We are also happy with the company's development strategy. BPMX utilizes a unique strategy designed to bring new products to market by identifying optimal delivery mechanisms and/or alternative applications for FDA-approved active pharmaceutical ingredients (APIs). A big advantage of the company's strategy is that it can reduce the time, costs and risks typically associated with new product development by repurposing drugs with demonstrated safety profiles, taking advantage of the regulatory approval pathway under Section **505(b)(2)** of the Federal Food, Drug and Cosmetic Act available for repurposed/reformulated drugs.

With all that said, when it comes to the company's valuation, we believe the company's shares still have enough room for further appreciation. Currently the company's shares are trading at about $1.5 per share, which values the company at $37 million in market capitalization based on 25 million outstanding shares. This is certainly a deep discount.

As we discussed above, by 2019, BioPharmX will have three commercially available products targeting the two big markets: women's health and acne. Based on our financial model, BPMX will become profitable in fiscal 2020 with an earnings per share (EPS) of $0.26 based on total revenue of $50 million. Considering the company's growth potential, we think a P/E multiple of 36, which is the biotech industry's average P/E ratio, should be used to value the company. Therefore, we come up with our price target of $4.50 per share based on the 36x P/E ratio, discounted at 20% for four years. Our price target of $4.50 per share values the company at $113 million in market cap, which is still conservative in our view.

But keep in mind the **risks**.

Our model assumes product approval of BPX03 and BPX01 in 2018 and 2019 respectively. Investors should know that any drug development is a high risk business that will navigate through both clinical and regulatory hurdles, which has proven to be high. Although the company's development strategy reduces risks associated with drug development, **a failure of clinical trial or/and regulatory approval** can't be completely ruled out. This will make the company's shares to decline dramatically.

Another concern we have is the company's **cash balance**. Although the company raised about $5.9 million in Dec 2015, which boosted its balance sheet, we believe the company may need to raise new funds to advance its pipeline, specifically its Phase II candidate BPX01 and Phase III candidate BPX03. We remind investors that any equity financing will dilute existing shareholder base, and cause share price to decline.

But overall, we think BPMX is a name with relatively favorable risk/reward profile for investors with a long term investment horizon.

INCOME STATEMENT

	Jan2014	Jan2015					Jan2016					2017	2018	2019	2020
$ in millions except per share data	FY	Q1	Q2	Q3	Q4	FY	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE	FYE
License Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Grant/contract Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
Product Sales	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.01	$0.02	$0.05	$0.08	$0.50	$5.00	$25.00	$50.00
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.01**	**$0.02**	**$0.05**	**$0.08**	**$0.50**	**$5.00**	**$25.00**	**$50.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	*532.3%*	*900.0%*	*400.0%*	*100.0%*
Cost of Revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.01	$0.01	$0.02	$0.05	$0.09	$0.20	$2.00	$5.00	$10.00
Gross Income	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**($0.01)**	**($0.01)**	**$0.00**	**$0.00**	**($0.01)**	**$0.30**	**$3.00**	**$20.00**	**$40.00**
Gross Margin	-	-	-	-	-	-	-	-	-	-	-	*60.0%*	*60.0%*	*80.0%*	*80.0%*
R&D	$0.7	$0.5	$0.6	$0.8	$0.5	$2.5	$1.1	$1.1	$1.6	$1.6	$5.5	$6.5	$8.0	$9.5	$11.0
% R&D	-	-	-	-	-	-	*26900.0%*	*22820.0%*	*8245.0%*	*3200.0%*	*6919.0%*	*1300.0%*	*160.0%*	*38.0%*	*22.0%*
SG&A	$0.8	$0.7	$1.2	$1.3	$2.1	$5.3	$2.1	$2.4	$2.2	$2.5	$9.2	$11.0	$12.5	$15.0	$18.5
% SG&A	-	-	-	-	-	-	*52675.0%*	*48500.0%*	*11000.0%*	*5000.0%*	*11686.1%*	*2200.0%*	*250.0%*	*60.0%*	*37.0%*
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
% Other	-	-	-	-	-	-	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Operating Income	**($1.5)**	**($1.3)**	**($1.8)**	**($2.1)**	**($2.6)**	**($7.8)**	**($3.2)**	**($3.6)**	**($3.8)**	**($4.1)**	**($14.7)**	**($17.2)**	**($17.5)**	**($4.5)**	**$10.5**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Income (Net)	($0.1)	($0.1)	$0.0	$0.0	($0.0)	($0.0)	($0.4)	$0.0	$0.0	$0.0	$0.4	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	**($1.6)**	**($1.3)**	**($1.8)**	**($2.1)**	**($2.6)**	**($7.8)**	**($3.6)**	**($3.6)**	**($3.8)**	**($4.1)**	**($15.1)**	**($17.2)**	**($17.5)**	**($4.5)**	**$10.5**
Net Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*-0.1%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($1.6)**	**($1.3)**	**($1.8)**	**($2.1)**	**($2.6)**	**($7.8)**	**($3.6)**	**($3.6)**	**($3.9)**	**($4.1)**	**($15.1)**	**($17.2)**	**($17.5)**	**($4.5)**	**$10.5**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Weighted avg. Shares Out	*7.1*	*9.4*	*10.6*	*10.6*	*10.3*	*10.2*	*11.7*	*15.4*	*21.0*	*25.0*	*18.3*	*28.0*	*30.0*	*35.0*	*40.0*
Reported EPS	**($0.22)**	**($0.14)**	**($0.17)**	**($0.19)**	**($0.25)**	**($0.76)**	**($0.31)**	**($0.23)**	**($0.18)**	**($0.16)**	**($0.83)**	**($0.61)**	**($0.58)**	**($0.13)**	**$0.26**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
One-time charge	$0.00	$0.00	$0.00	$0.00	$0.01	$0.01	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Non GAAP Net Income	**($1.6)**	**($1.3)**	**($1.8)**	**($2.1)**	**($2.6)**	**($7.8)**	**($3.6)**	**($3.6)**	**($3.9)**	**($4.1)**	**($15.1)**	**($17.2)**	**($17.5)**	**($4.5)**	**$10.5**
Non GAAP EPS	**($0.22)**	**($0.14)**	**($0.17)**	**($0.19)**	**($0.25)**	**($0.76)**	**($0.31)**	**($0.23)**	**($0.18)**	**($0.16)**	**($0.83)**	**($0.61)**	**($0.58)**	**($0.13)**	**$0.26**

Source: company filings and Zacks estimates

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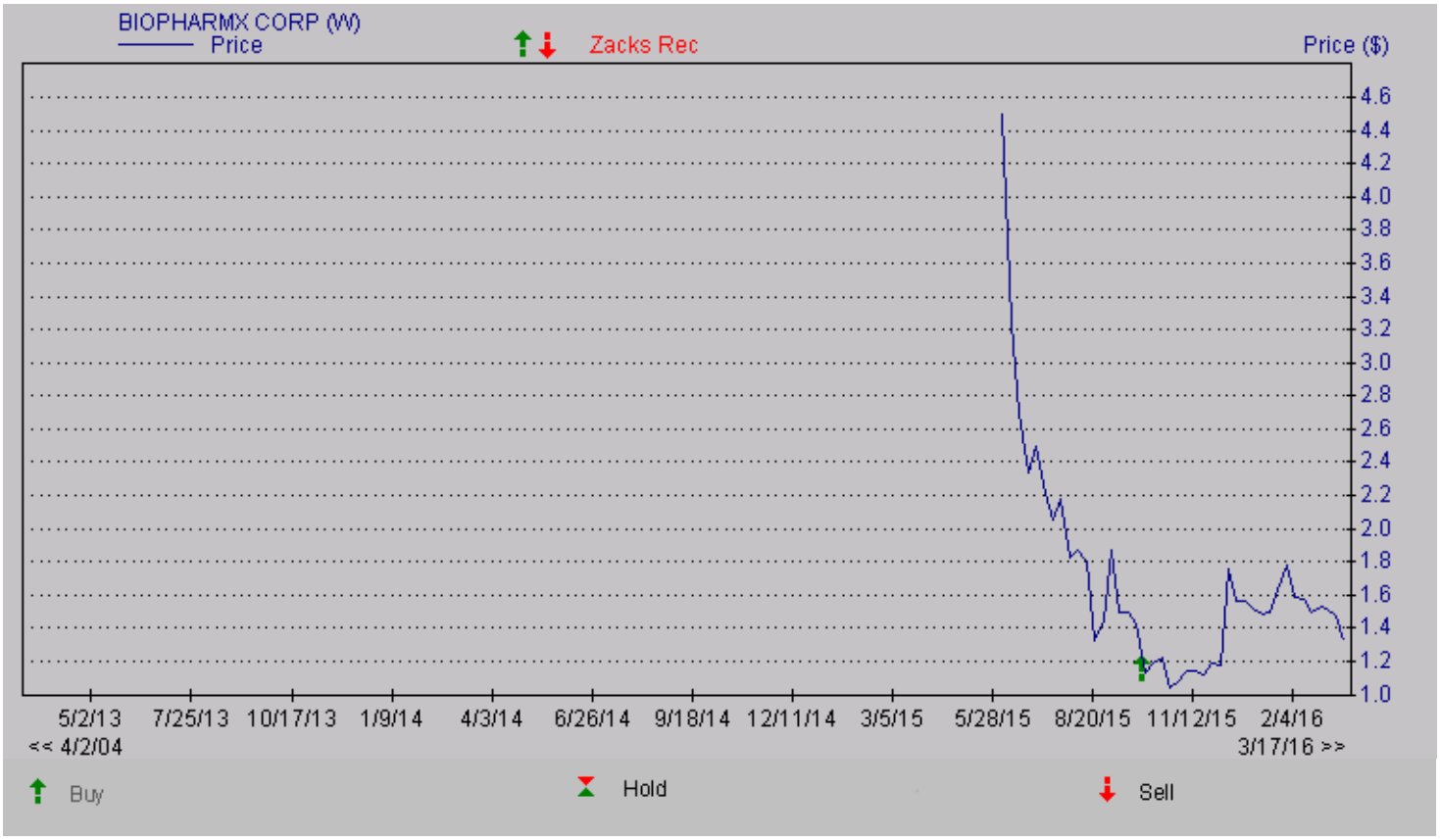
HISTORICAL ZACKS RECOMMENDATIONS



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