Zacks Small-Cap Research

October 7, 2015
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Biopharmx Corp (BPMX-NYSE MKT)

BPMX: A specialty pharma company with a focus on women's health and dermatology – initiating with Buy rating

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	09/30/2015
Current Price (10/06/15)	$1.23
Twelve- Month Target Price	**$3.00**

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, will move forward into Phase II in 1Q16. 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 rating.

SUMMARY DATA

52-Week High	**$4.50**
52-Week Low	**$1.03**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**31,078**
Shares Outstanding (mil)	**21**
Market Capitalization ($mil)	**$23**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**39**
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	$0.00 A	$0.01 E	$0.10 E	$0.11 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	-$0.19 E	-$0.19 E	-$0.88 E
2017					-$0.69 E
2018					-$0.58 E

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

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KEY POINTS

- We are initiating coverage of BioPharmX (BPMX) with a **Buy rating**. Our 12-month price target is $3.00 per share. Our call is based on the company's relatively strong fundamentals.

- BPMX is a specialty pharma with a focus on **women's health** and **dermatology**, two addressable large markets in the US and around the world. Specifically, BPMX's molecular iodine targets the market of fibrocystic breast conditions **(FBC)** and its topical antibiotic minocycline targets the topical **acne** market.

- Currently, BPMX has one product on the market: **VI_2OLET** (an OTC supplement of molecular iodine) for the treatment of FBC. The company launched this product at the end of 2014. So far, sales of VI_2OLET are minimal, but we believe sales could pick up steam in calendar 2016 due to the company's focused and integrated marketing strategy.

- BioPharmX is also developing a prescription molecular Iodine (BPX03), which will complement the current OTC iodine. **BPX03** has completed Phase II studies, and BPMX plans to initiate an **IRB pilot study** in late 2015. Then a pivotal Phase III study will be initiated in **4Q16**. We estimate BPX03 will be approved in the US in 2018. Once approved, BPMX will become the market leader in the FBC market with two products.

- On the front of **dermatology**, BPMX is developing **BPX01**, a topical minocycline, for the treatment of acne, a multi-billion dollar market. BPMX utilizes its patented, innovative drug delivery platform, to topically deliver minocycline, which reduces side effects associated with systemic absorption of oral minocycline. BPX01 will enter Phase II study in 1Q16. If everything goes well, we expect BPX01 will 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.

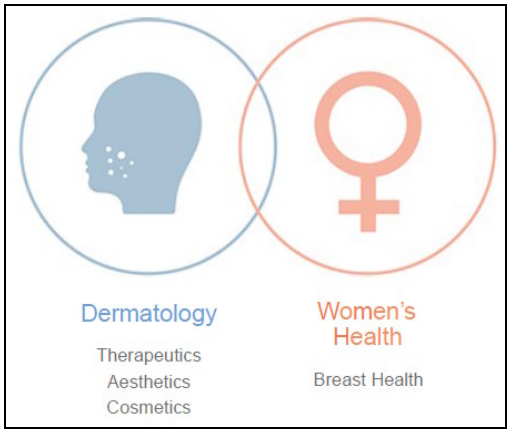
- With three products on the market in 2019, BioPharmX will become a key player in the two targeted markets of women's health and dermatology.

- BPMX's strategy is to identify optimal delivery and/or alternative applications for approved active pharmaceutical ingredients (APIs) using **505(b)(2)** regulatory approval pathway. This strategy has the advantages of reducing the time, cost, and risk associated with new drug development.

- Based on our analysis, we believe BioPharmX shares are undervalued at current market price. We are optimistic about the prospect of the company and therefore assign a **Buy rating** for the company shares. Overall, we think BPMX is a name with relatively favorable risk/reward profile for investors with a long term investment horizon.

OVERVIEW

BioPharmX Corporation (BPMX-NYSE MKT) is a **specialty pharmaceutical company** focused on utilizing its proprietary **drug delivery technologies** to develop and commercialize novel prescription and over-the-counter (OTC) products that address large markets in **women's health** and **dermatology**.



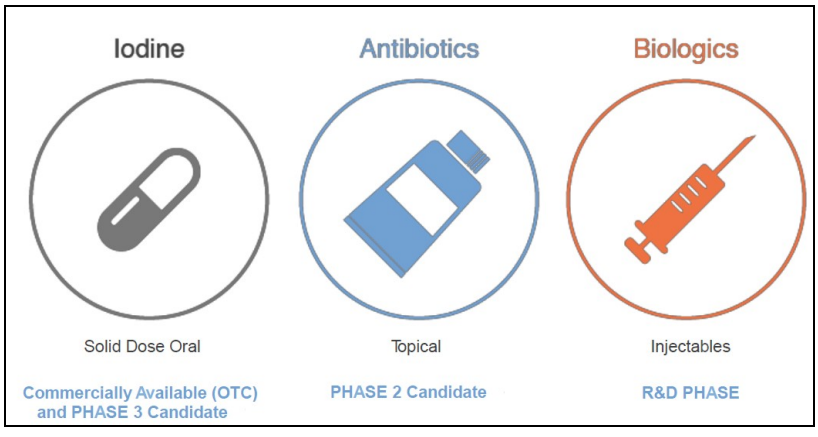
BPMX aims to develop products that target two health or age-related conditions:

- Which are not presently being addressed or treated at all or
- Which are currently treated with drug therapies or drug delivery approaches that are suboptimal.

In order to achieve the above objectives, The Company 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.

BPMX's management team has experience in formulation development, intellectual property generation, clinical trial execution, regulatory strategy definition and commercialization of products through licensing as well as direct to consumer. The company's business model is to outsource its manufacturing and at times commercialization activities in order to maintain its focus on technology sourcing, acquisitions, and strategic partner development to create new products to address unmet needs in well-defined global markets.

Currently, BPMX's product portfolio targets significant market opportunities and includes one commercial OTC product VI_2OLET (dietary supplement molecular iodine tablet) and two clinical stage product candidates: (1) BPX01, a topical antibiotic for the treatment of acne and (2) BPX03, a molecular iodine (I_2) tablet for the treatment of breast discomfort associated with fibrocystic breast condition **(FBC)** and cyclic mastalgia.

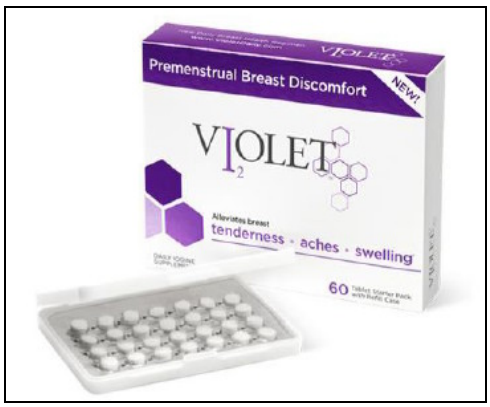


BPMX was incorporated in Delaware and is headquartered in Menlo Park, CA.

INVESTMENT THESIS

VI$_2$OLET, A Commercial Product, May Generate Meaningful Revenue in 2016

As the company's first commercial product, VI$_2$OLET 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$_2$OLET at the end of 2014 and is rolling out the product in drug store and retail chains throughout the US. VI $_2$ OLET is currently available for sale in approximately 2,960 CVS retail pharmacy chains and 650 Vitamin Shoppe stores throughout the United States, as well as online through drugstore.com and walgreens.com.



The commercial launch of VI $_2$ OLET 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.

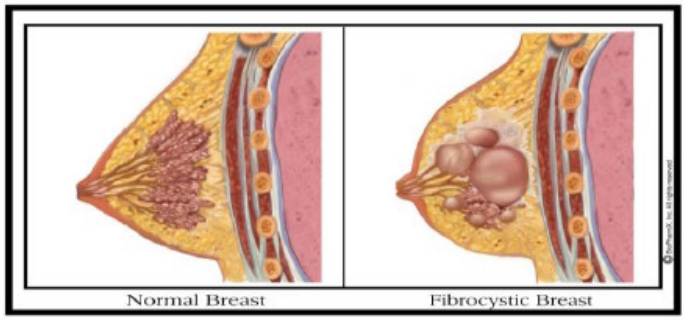
So far, revenue from the product sales is minimal, but we believe the product will generate meaningful revenue for the company in calendar 2016 resulting from the company's focused and integrated marketing strategy.

VI $_2$ OLET 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 $_2$ OLET iodine has been shown to help maintain healthy breast tissue.

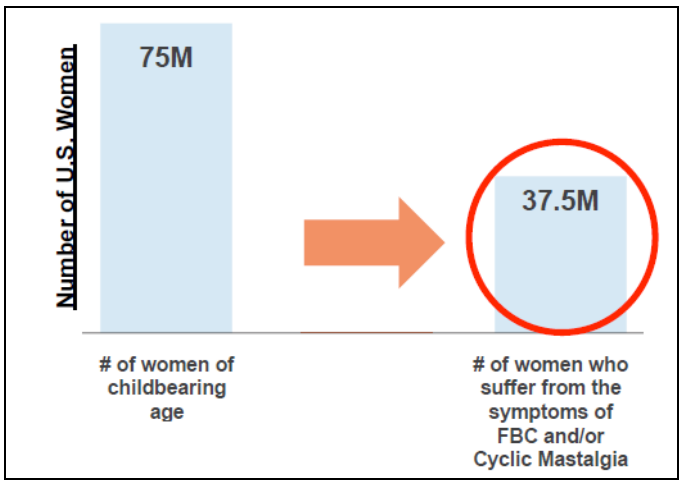
FBC, an Unmet Medical Need

Fibrocystic breast condition **(FBC)** is the generally accepted term to describe breast discomfort caused by the influx of hormones during the menstrual cycle. Previously referred to as “fibrocystic breast disease,” the terminology was changed due to the fact that the breast changes are benign (harmless). Healthcare professionals now prefer to refer to the condition as “fibrocystic breasts,” “fibrocystic breast changes” or “fibrocystic breast condition.”

Fibrocystic breasts are composed of tissue that feels lumpy or rope-like in texture. Doctors call this nodular or glandular breast tissue. It's not uncommon to have fibrocystic breasts. **More than half** of women experience fibrocystic breast condition at some point in their lives. Although FBC is normal, it can cause breast pain, tenderness and lumpiness. Breast symptoms tend to be most bothersome just before menstruation.



FBC occurs most often in women in their 20s to 50s. Rarely do postmenopausal women experience FBC, unless they're on hormone therapy. FBC affects millions of women. In the US alone, about 37.5 million women suffer from the symptoms of FBC each month – a cycle of breast tenderness, aches, swelling, heaviness and, for many, even acute pain caused by high levels of **estrogen** and **prolactin**. While it’s best known for its role in the production of milk, prolactin also causes breast cells to build up month after month with each menstrual cycle. This buildup results in swollen breast tissue, which can develop into lumps and masses that put pressure on surrounding nerves, leading to breast discomfort that can last anywhere from several days to a few weeks each month.



If the symptoms are mild, no treatment is needed for FBC. However, severe pain or large, painful cysts associated with fibrocystic breasts may warrant treatment. Fine-needle aspiration and surgical excision are used to relieve the symptoms, but both methods are invasive, therefore are rarely used. OTC pain killer is used to relieve FBC related breast pain, but does not solve the root problem.

Previously, healthcare professionals have not been able to prescribe their patients an effective remedy to address breast discomfort without side effects. For example, **oral contraceptives** are sometimes prescribed for lowering the levels of cycle-related hormones linked to FBC, but long term use of oral contraceptives have serious side effects such as severe headache, chest pain and shortness of breath. However, now scientists have confirmed that molecular iodine is clinically demonstrated to be effective in alleviating the most common symptoms of fibrocystic breast condition, including tenderness, aches, heaviness and swelling.

Iodine's primary role in the body is in the creation of the thyroid hormones, T3 and T4. The thyroid absorbs iodine to make and release these hormones into the blood. In addition to supporting proper thyroid function, iodine has other important effects, including maintenance of healthy breasts. Iodine-deficient breast tissue is an underlying cause of fibrocystic breast condition. Multiple studies show that iodine supplementation reduces indications of this condition.

There are **two primary forms** of iodine for human consumption: iodide (I-) and molecular iodine (I_2). The thyroid more readily absorbs I- over I_2, which can lead to a change in delicate hormone levels in the thyroid. Iodine from I_2 is absorbed into the thyroid at a lower rate than iodine from iodide and at a higher rate into breast tissue making molecular iodine the preferred form for breast health. Therefore, molecular iodine is superior over iodides when treating fibrocystic breast condition.

Clinical studies have shown that a daily regimen of molecular iodine can provide relief from cyclic breast discomfort. Molecular iodine has been used in clinical trials of 1476 women. A recent study showed that up to 74% of women experienced improvement in their breast discomfort. Following table summarizes the results from a recent study involved 2,242 women who were given one of three treatment protocols. This study clinically examined different forms of iodine for treatment of FBC and demonstrated safety differences between molecular iodine and iodide.

Protocol	Clinical	Result
1.	Tested two forms of iodide in 821 women over two to five years	"70% of subjects treated with sodium **iodide** had clinical improvement in their breast disease, but the rate of side effects was high."
2.	Treated 1,365 women with molecular iodine	Objective improvement was noted in up to 74% of those who received **molecular iodine.**
3.	Treated 56 women in a placebo-controlled, double-blind study of molecular iodine. Clinical measurements included fibrosis resolution and pain assessment by the subject.	**For fibrosis resolution:** Numerical scores for subjects in the **molecular iodine** treatment improved by an average of 65% in comparison to a degradation of 3% for those in the placebo group. **For symptom resolution:** 65% of subjects in the **molecular iodine** treatment group showed subjective improvement in symptoms compared to 33% in the placebo group.

BPX03, a Phase III Ready Candidate, further Strengths the Company's FBC Franchise

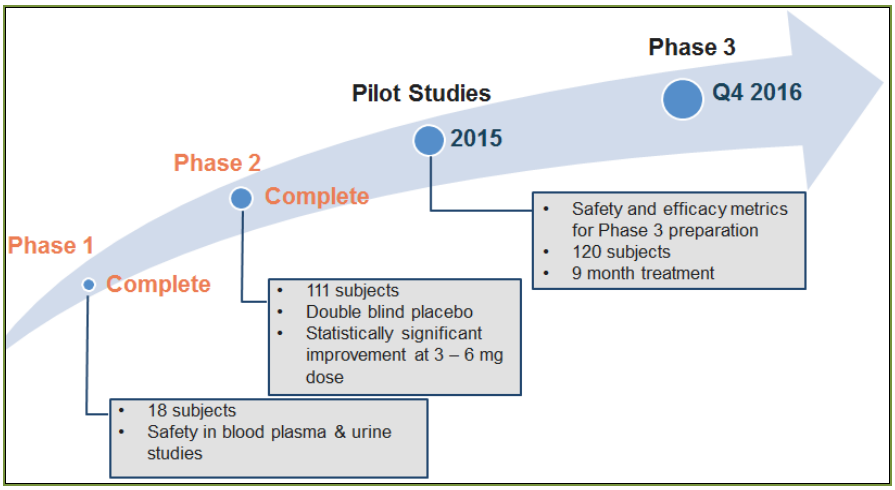
In addition to OTC molecular iodine VI_2OLET, BPMX is also developing a prescription molecular iodine tablet, **BPX03**, for the treatment of benign breast pain associated with FBC and cyclic mastalgia. BPX03 is intended for global distribution, where prescription products may be required due to regulatory 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 late 2015 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.

BPX01, a Topical Minocycline, for Acne

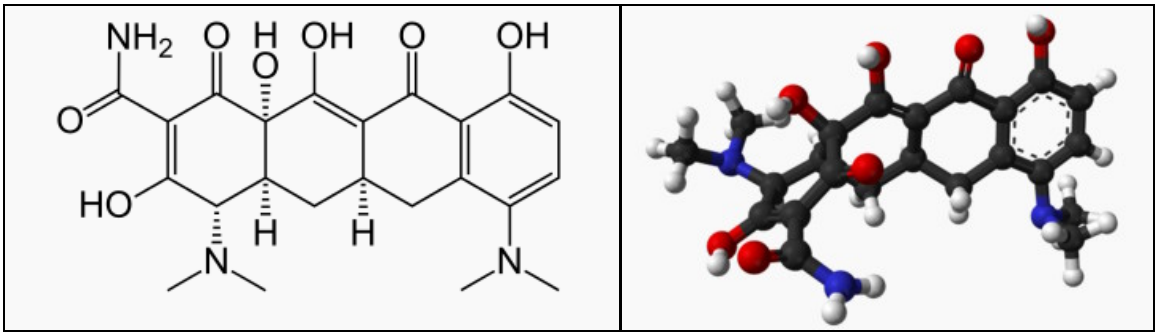
BioPharmX is also developing **BPX01**, a non-lipophilic, topical antibiotic for the treatment of **acne**. BPX01 utilizes a **transepidermal delivery mechanism** for minocycline and other APIs that has the potential to kill p. acnes bacteria without the systemic side effects of orally-administered antibiotics.

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:

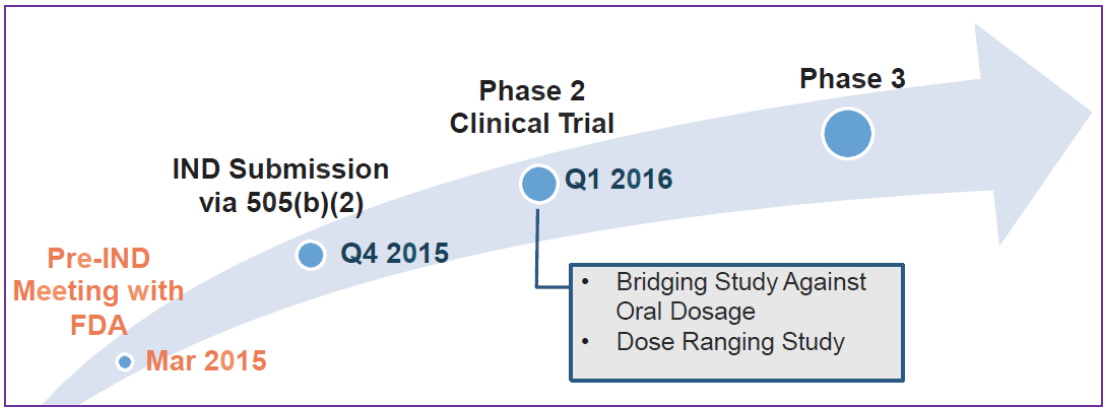
- topical delivery of minocycline,
- controlled dosages targeted directly to affected area,
- increased delivery of API at low dosages,
- non-lipophilic design allowing for faster absorption by the skin,
- potential lower risk of systemic side effects common to orally administered antibiotics,
- Gel-like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

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.

BPMX is currently conducting an **animal toxicity** study, after which the company will submit an IND to the FDA to initiate its first Phase IIa clinical trial of BPX01. The company is also preparing to conduct a

bridging safety study using oral minocycline as the comparator and a Phase II dose-finding clinical study for BPX01.



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.

BPX01 Target the Big Acne Market

Background of Acne

Acne vulgaris (or simply **acne**) is a long-term skin condition characterized by areas of blackheads, whiteheads, pimples, greasy skin, and possibly scarring. The resulting appearance may lead to anxiety, reduced self-esteem, and in extreme cases, depression.

Acne is the most common skin condition in the United States and around the world. According to American Academy of Dermatology, about **40 to 50 million** Americans have acne at any one time. Worldwide, about **650 million** people are affected by acne. Further, not just teens have acne. A growing number of women have acne in their 30s, 40s, 50s, and beyond. Adult acne can be particularly frustrating.

What exactly causes acne is still unknown, but research has shown that **genetics** is estimated to be the cause of 80% of cases. Acne mostly affects skin with a greater number of oil glands including the face, upper part of the chest, and back. During puberty in both sexes, acne is often brought on by an increase in **androgens** such as testosterone. Excessive growth of the bacteria ***Propionibacterium acnes***, which is normally present on the skin, is often involved.

Propionibacterium acnes (*P. acnes*) is the anaerobic bacterium species that is widely suspected to contribute to the development of acne, but its exact role in this process is not entirely clear. There are specific sub-strains of *P. acnes* associated with normal skin and others with moderate or severe inflammatory acne. It is unclear whether these undesirable strains evolve on-site or are acquired, or possibly both depending on the person. These strains either have the capability of changing, perpetuating, or adapting to, the abnormal cycle of inflammation, oil production, and inadequate sloughing of acne pores.

Treatment Options for Acne

Many different treatments exist for acne including benzoyl peroxide, antibiotics, retinoids, antiseborrheic medications, anti-androgen medications, hormonal treatments, salicylic acid, alpha hydroxy acid, azelaic acid, nicotinamide, and keratolytic soaps. They are believed to work in at least **four different ways**, including the following:

- normalizing skin cell shedding and sebum production into the pore to prevent blockage,
- killing *P. acnes*,
- anti-inflammatory effects, and
- hormonal manipulation.

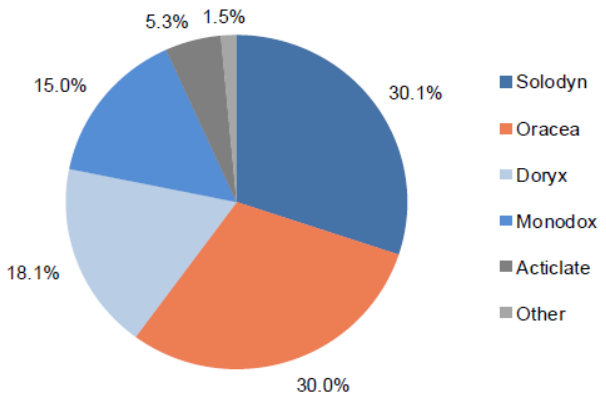
Antibiotics, including topical and oral antibiotics, are frequently used to treat acne by killing P. Acnes. While **topical** antibiotics are frequently used for mild to moderate severe acne, **oral** antibiotics are indicated for moderate to severe cases of inflammatory acne due to their antimicrobial activity against *P. acnes* in conjunction with anti-inflammatory properties. They are believed to work both by decreasing the number of bacterial and as an anti-inflammatory.

The Acne Market

The US market for acne prescription medication was about $3.3 billion in 2014 with 53% for topical treatment and 47% for oral treatment.

Commonly used oral medications are oral antibiotics which include doxycycline and minocycline with total sales of $1.5 billion in 2014. Valeant and Galderma are the two companies with the most market share.

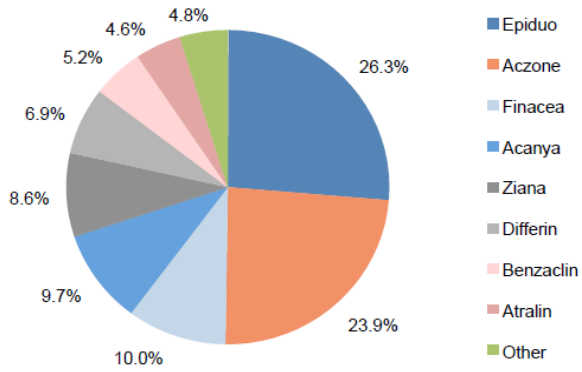
Branded prescription oral acne products
2014 wholesale market share:



Brand Name	Active Pharmaceutical Ingredient(s)	Manufacturer	Sales ($mm)
Solodyn	Minocycline	Valeant	$461
Oracea	Doxycycline	Galderma	459
Doryx	Doxycycline	Actavis	277
Monodox	Doxycycline	Aqua Pharmaceuticals	230
Acticlate	Doxycycline Hyclate	Aqua Pharmaceuticals	81
Other			23
Source: Compiled from Symphony Health Solutions data, accessed via Bloomberg Terminal, January 2014-December 2014		**Total:**	**$1,530**

Commonly used topical medications for acne include adapalene, benzoyl peroxide, clindamycin, dapsone, azelaic acid, and tretinoin. Sales from topical medications were $1.7 million in 2014. Key players in the topical market include Galderma, Bayer and Valeant.

Branded prescription topical acne products
2014 wholesale market share:



Brand Name	Active Pharmaceutical Ingredient(s)	Manufacturer	Sales ($mm)
Epiduo	Adapalene / Benzoyl Peroxide	Galderma	$456
Aczone	Dapsone	Allergan	414
Finacea	Azelaic Acid	Bayer Healthcare Pharmaceuticals	173
Acanya	Clindamycin / Benzoyl Peroxide	Valeant Pharmaceuticals	168
Ziana	Clindamycin / Tretinoin	Valeant Pharmaceuticals	149
Differin	Adapalene	Galderma	120
Benzaclin	Clindamycin / Benzoyl Peroxide	Valeant Pharmaceuticals	89
Atralin	Tretinoin	Valeant Pharmaceuticals	80
Other			83
Source: Compiled from Symphony Health Solutions data, accessed via Bloomberg Terminal, January 2014-December 2014		**Total:**	**$1,732**

BPX01 targets the topical antibiotic market for acne. We believe, once approved, BPX01 should be able to capture a fair share of the total topical market with peak sales around $450 million.

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

Up-listing to NYSE MKT Raises Company Visibility Significantly

BioPharmX shares were up-listed in NYSE MKT in July 2015, which, we believe, greatly raises the company's visibility.

Previously, the company's shares were traded OTC. We all know that there is a limited market for a company's common stocks, if they are quoted on the over-the-counter market (OTC). Trading in stocks quoted on the OTC market is often thin and characterized by wide fluctuations in trading prices, due to many factors that may have little to do with the Company's operations or business prospects.

Moreover, the OTC market is not a stock exchange, and trading of securities there is often more sporadic than the trading of securities listed on a quotation system like NASDAQ or a stock exchange like NYSE.

There is no assurance that a sufficient market will develop or remain stable in the stock, in which case it could be difficult for stockholders to resell their stocks. Liquidity is also an issue for institutional investors.

We believe the uplisting significantly increases the Company's visibility and will attract institutional investors, therefore increase the liquidity of the Company's shares.

Balance Sheet Boosted by Recent Financing

As of July 31, 2015, BioPharmX had cash and cash equivalents of $7.4 million, compared to $1.3 million on January 31, 2015. The working capital was $3.9 million as of July 31, 2015.

In June, 2015, the company completed a public offering of 3,636,364 shares of its common stock at a price to the public of $2.75 per share, which generated net proceeds of $7.8 million. The company also issued an unsecured convertible note with a principal amount of $0.5 million, which was automatically converted into common stock upon the uplisting to the NYSE MKT.

In addition, Korea Investment Partners (KIP) Overseas Expansion Platform Fund, an existing stockholder of the company, has agreed to purchase 1,081,081 shares of common stock from BioPharmX in a private placement in connection with the successful uplisting of the company's common stock to the NYSE MKT. This private placement was anticipated to close within 15 business days of the uplisting of the company's common stock to the NYSE MKT on June 25, 2015. But as of September 14, 2015, the KIP private placement had not closed and the Company has notified KIP that KIP's obligation to pay the $2.0 million purchase price to the Company has become due and payable under the subscription agreement.

Experienced Management Team

Jim Pekarsky, CEO
Mr. Pekarsky has devoted over 30 years to growing diverse medical research and high-tech companies, including Bio Rad Laboratories, Mentor Graphics, MoSys and Virage Logic. He has spent over 10 years as the Chief Financial Officer of several public and private companies and five years as a European General Manager for U.S. multinational corporations. For more than a decade he has been counseling start-ups in Silicon Valley and leading their financings, acquisitions and initial public offerings. Pekarsky holds an M.B.A. in finance from Golden Gate University in San Francisco and a bachelor's degree in accounting from Indiana University of Pennsylvania.

Anja Krammer, Presidnet
A Silicon Valley veteran, Ms. Krammer has deep experience guiding healthcare and other enterprises to identify and fulfill unmet consumer needs. She has overseen marketing at diverse companies, such as aesthetic market leader Reliant Technologies, biomedical engineer Medtronic, print imaging manufacturer Tektronix and telecommunications giant AT&T. She has also counseled companies, such as American Express, GSK, Medicis Pharmaceuticals and Weight Watchers NA. Krammer graduated from the University of South Carolina and completed post-graduate studies at Webster University and the University of Paris – Sorbonne.

Kin F. Chan, Ph.D., EVP Technology
Dr. Chan is a serial biomedical entrepreneur who has developed novel, effective therapies for diverse medical conditions. His research and product development experience spans semiconductors, lasers/photonics, medical devices and biomedical sciences. He has therapeutic experience in dermatology, cardiology, urology and ophthalmology. Prior to BioPharmX, Chan was Vice President of Engineering at Demira, where he helped develop photodynamic therapies, and directed advanced research at Solta Medical, where he helped create fractional photothermolysis technology. He is a named inventor on more than 25 patents and pending patent applications. Chan holds a Ph.D. in electrical and computer engineering from the University of Texas at Austin, where he also achieved his bachelors and masters degrees.

Greg Kitchener, CFO
Mr. Kitchener has over 20 years of broad financial leadership experience in financial planning and analysis, treasury, accounting and investor relations. He has a diverse industry background in financial services, high-technology companies such as Cisco Systems and Synopsys, and with the high-growth medical-technology company, Cepheid, where he served as vice president of finance. Kitchener holds a Master of Business Administration from Cornell University and a Bachelor of Science in mathematics from University of California, Santa Cruz.

Elizabeth Shoemaker, SVP Marketing
As the marketing and brand steward for BioPharmX, Ms. Shoemaker is responsible for setting the direction of its enterprise-wide marketing strategy that encompasses consumer insights, target segmentation, brand strategies, and omni-channel communication across all online and offline paid, earned and owned media. Prior to joining the BioPharmX team, her marketing expertise contributed to business growth for global Fortune 100 companies such as Safeway, Microsoft, Coca-Cola, McDonald's, P&G, Chevron/Texaco, and United/American/Alaska airlines. Shoemaker earned an Honors BFA from Art Center College of Design and completed the Executive Management Program at the University of Washington, Michael G. Foster School of Business.

Ross Portaro, SVP Sales
Mr. Portaro has 30 years of global sales executive experience in dermatology, women's health, and aesthetics. In dermatology, most recently as a sales director at Ulthera, he doubled sales and positioned the company for its 2014 acquisition by Merz. At Medicis, Portaro led the LipoSonix team in Europe and facilitated the sale to Solta in 2011. In Women's Health, he built the original sales team at SenoRx, which was the leader in breast biopsy devices and had a successful 2007 IPO. In aesthetics, Mr. Portaro started at TRIA Beauty as the Vice President of Sales and was the first medical laser executive to globally launch a medical-grade laser for hair removal into the consumer OTC Market. Mr. Portaro received his BS in Commerce from the McIntyre School of Commerce at the University of Virginia.

Nathan Harris, SVP Operations
With over 20 years of experience in life sciences and biotechnology, Mr. Harris most recently served as chief operating officer at Amunix where he focused on the execution of company strategy and managed all business and operational aspects. Mr. Harris established a leading biomarker discovery center in Silicon Valley which was able to support technical sales development activities for the business. The establishment of the discovery center allowed for the company to strengthen its business relationships within the biopharma industry. Prior to his position at Amunix, Mr. Harris held various science and management positions at Molecular Sensing, Inc., was Manager of Functional Genomics at the Moredun Research Institute near Edinburgh, and a European Application Scientist at Vermillion, Inc. (formerly Ciphergen BioSystems). Harris received his MSc at University of Abertay Dundee, Scotland.

VALUATION AND RECOMMENTATION

We are initiating coverage of BioPharmX (BPMX) with a **Buy rating**. Our 12-month price target is $3.00 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 multi-billion dollar **acne market** is the next target for BioPharmX. The company's **BPX01,** a topical formulation of minocycline, will enter Phase II study in 1Q16. 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 are undervalued at current market price. Currently the company's shares are trading at about $1.2 per share, which values the company at $25 million in market capitalization based on 21 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 25 should be used to value the company. Therefore, we come up with our price target of $3.00 per share based on the 25x P/E ratio, discounted at 20% for four years. Our price target of $3.00 per share values the company at $63 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 $7.8 million in June 2015, which boosted its balance sheet, we believe the company may need to raise new funds soon to advance its pipeline, specifically its Phase II candidate BPX01 and Phase III candidate BPX03. We estimate the company may need to tap the capital market as soon as in the mid-2016. 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	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.5	$5.0	$25.0	$50.0
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.1**	**$0.1**	**$0.5**	**$5.0**	**$25.0**	**$50.0**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	*327.4%*	*900.0%*	*400.0%*	*100.0%*
Cost of Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.2	$0.2	$0.20	$2.00	$5.00	$10.00
Gross Income	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.1**	**$0.1**	**$0.3**	**$3.0**	**$20.0**	**$40.0**
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	$1.5	$1.6	$5.3	$6.5	$8.0	$9.5	$11.0
% R&D	-	-	-	-	-	-	-	-	*18750.0%*	*1600.0%*	*4544.4%*	*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	$2.5	$2.5	$9.5	$11.0	$12.5	$15.0	$18.5
% SG&A	-	-	-	-	-	-	*52675.0%*	*48500.0%*	*31250.0%*	*2500.0%*	*8147.0%*	*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)**	**($4.0)**	**($4.2)**	**($15.0)**	**($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)**	**($4.0)**	**($4.2)**	**($15.4)**	**($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%*	*0.0%*	*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)**	**($4.0)**	**($4.2)**	**($15.4)**	**($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*	*22.0*	*17.5*	*25.0*	*30.0*	*35.0*	*40.0*
Reported EPS	**($0.22)**	**($0.14)**	**($0.17)**	**($0.19)**	**($0.25)**	**($0.76)**	**($0.31)**	**($0.23)**	**($0.19)**	**($0.19)**	**($0.88)**	**($0.69)**	**($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)**	**($4.0)**	**($4.2)**	**($15.4)**	**($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)**	**($0.19)**	**($0.19)**	**($0.88)**	**($0.69)**	**($0.58)**	**($0.13)**	**$0.26**

Source: company filings and Zacks estimates

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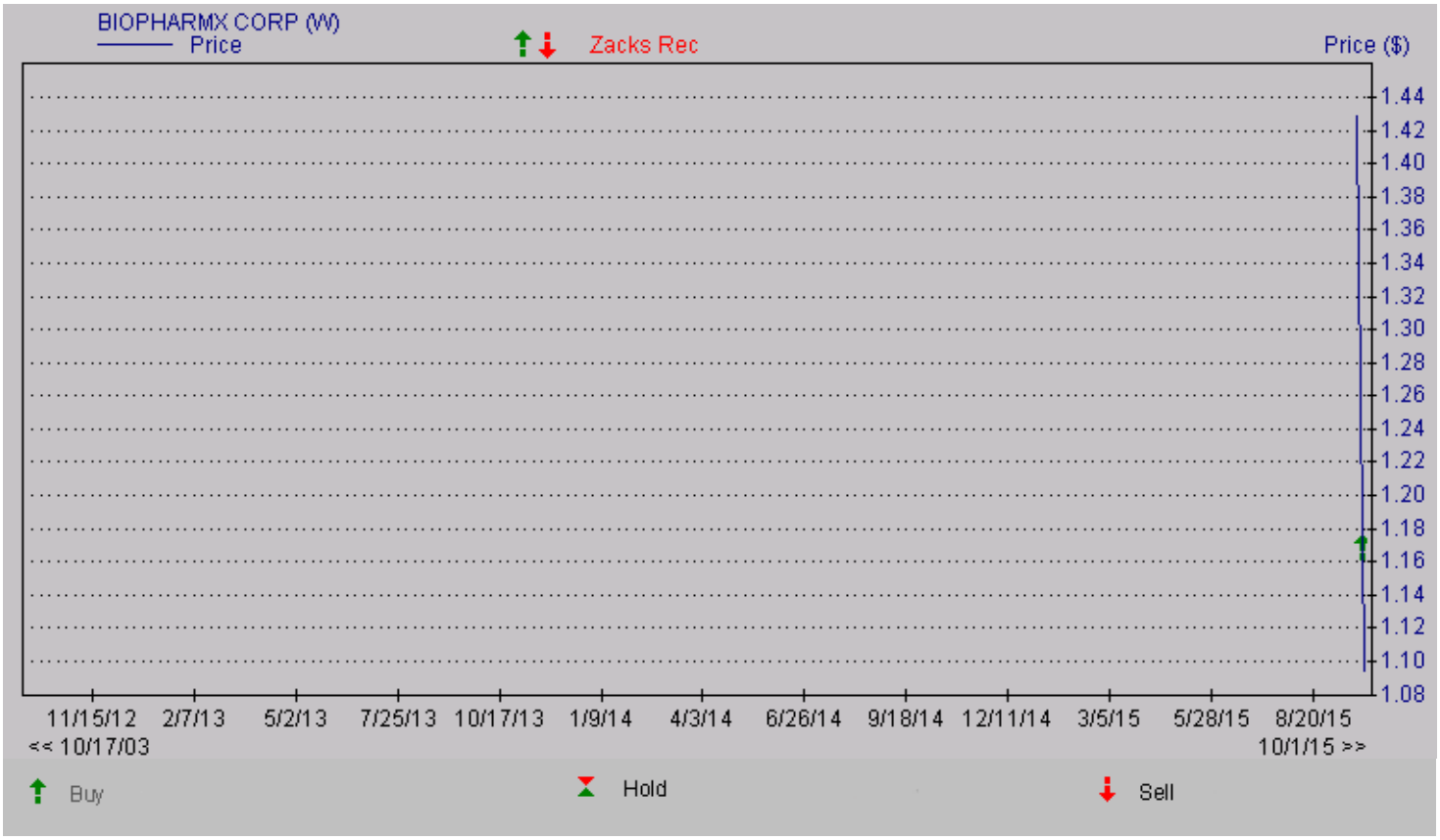

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