April 2, 2013

OUTPERFORM

Reason for report:

ESTIMATE CHANGE

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HEALTHCARE EQUITY RESEARCH

PUMA BIOTECHNOLOGY, INC.

Raise Valuation on Favorable Prospects for Neoadjuvant Expansion

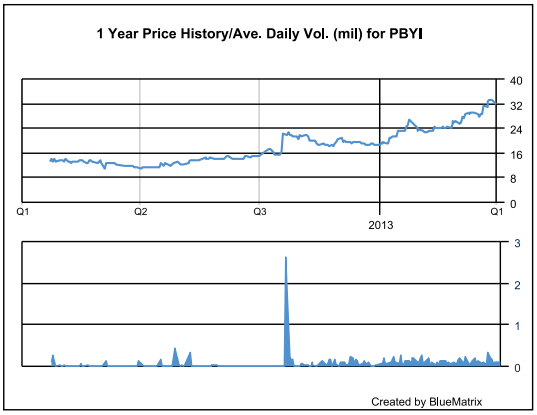
• **Bottom Line:** PBYI reported earnings yesterday and provided an update on pipeline development. Recently the FDA hosted a neoadjuvant breast cancer workshop highlighting approvability on pathologic complete response (pCR) as the primary endpoint. The supportive regulatory environment could allow accelerated development in earlier stage breast cancer. Although the potential for pCR as a regulatory endpoint in neoadjuvant setting has been known for some time, the recent workshop further enhances its prospect in our view and upcoming adjuvant data on both neratinib and Tykerb could generate greater interest in this setting. We are increasing our estimates in the neoadjuvant setting due to more clear regulatory path and as a result, we increase our valuation for PBYI from $27 to $44.

• **FDA neoadjuvant breast cancer workshop was clearly supportive of pCR as an approval endpoint.** Following the initial release of draft guidance for "Pathologic Complete Response in Neoadjuvant Treatment of High-Risk Early-Stage Breast Cancer: Use as an Endpoint to Support Accelerated Approval" in May, 2012, the FDA hosted a neoadjuvant breast cancer workshop on March 22, 2013. The workshop highlighted the advantages of pCR as an approval endpoint with a faster path to approval, smaller sample size and reduced costs. More importantly, pCR has been associated with significant improvement of event free survival (EFS) and overall survival (OS) based on multiple meta analyses. The FDA is clearly supportive of using pCR as an approval endpoint.

• **Neratinib appears likely to generate a sufficient magnitude of pCR improvement.** One issue with pCR as a regulatory endpoint has been the magnitude of improvement that is considered clinically important and likely to lead to improved outcome, and the FDA workshop discussions appear to point to 20% as the hurdle. Dual HER2 inhibitor therapy has consistently performed better than a HER2 inhibitor and in the NeoALLTO study, Tykerb was associated an improvement in pCR of more than 20% when added to Herceptin. Therefore, we believe that neratinib is likely to be associated with sufficient improvement in pCR.

• **Upcoming data increase visibility of the adjuvant setting.** Data from the ongoing I-SPY2 trial for neratinib in neoadjuvant breast cancer are anticipated in mid-2013 followed by data from the second neoadjuvant trial NSABP later in 2013. Based on these data, the neratinib pivotal trial could be quickly started (in the more appropriate patient population, for example), benefiting from new regulatory guidelines. Additionally, adjuvant data on Tykerb (expected this year) and neratinib (1H:14) could further enhance visibility of the early stage potential.

Key Stats:	**(NASDAQ:PBYI)**
S&P 600 Health Care Index:	**932.06**
Price:	**$31.83**
52 Week High:	$34.98
52 Week Low:	$10.00
Shares Outstanding (mil):	28.8
Market Capitalization (mil):	916.7
Book Value/Share:	(11.24)
Cash Per Share:	$4.77
Dividend (ann):	$0.00
Dividend Yield:	0.0%
Valuation:	$44 from $27
Shares Outstanding (mil): Pro Forma	
Cash Per Share: Pro Forma	



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2012A	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**($0.59)**	**($0.74)**	**($1.29)**	**($0.83)**	**($3.42)**	**NM**
2013E - New	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**($0.48)**	**($0.52)**	**($0.51)**	**($0.51)**	**($2.02)**	**NM**
2013E - Old	--	--	--	--	0.0	--	--	--	--	($2.12)	NM
2014E	--	--	--	--	0.0	--	--	--	--	($2.31)	NM

Source: Company Information and Leerink Swann LLC Research
Revenues in $MM; 2011 GAAP EPS, 2012 PF EPS; 2013 GAAP EPS

Please refer to pages 10 - 13 for Important Disclosures, Price Charts and Analyst Certification.

INVESTMENT THESIS

We rate Puma Biotechnology shares Outperform. Puma is a cancer-focused biotechnology company with an in-licensing model founded by the same management team that successfully executed the same strategy with Cougar Biotechnology. Lead agent neratinib, a pan-HER tyrosine kinase inhibitor, is a late-stage compound for breast cancer currently in Phase II, after the rolling back of a Phase III program following the transfer of the asset from Pfizer (MP). HER2+ breast cancer is a large market with over $5B in current sales of Roche's Herceptin (>$5B), and GSK's Tykerb (>$450M), another tyrosine kinase inhibitor (TKI) against HER2. Although Tykerb sales are currently relatively modest, it has been only approved for the metastatic setting and most of the Herceptin sales appear to come from the adjuvant setting. Based on MEDACorp breast cancer key opinion leader feedback, we believe neratinib has the potential to be the best-in-class TKI against HER2. It appears to have superior efficacy compared to Tykerb. Its safety has been demonstrated in a large database of more than 3,000 patients. The adverse event of diarrhea associated with neratinib, while frequent, appears transient and manageable. Neratinib is currently in Phase II studies in combination with Herceptin, including two studies in the neoadjuvant (before surgery) setting. The FDA has stated that it intends to issue a guidance document that allows the use of pathological complete response as a surrogate endpoint for accelerated approval. I-SPY 2, which involved neratinib, was mentioned in the FDA statement. Therefore, we believe there is potential for a rapid registration path in the neoadjuvant setting. In addition, the combination of neratinib with mTOR inhibitor Torisel (PFE) has shown intriguing early data and has a compelling pre-clinical rationale. We see this combination as another interesting path to move forward for neratinib. Additional data on this as well as a Herceptin combination could be available during 2012, potentially providing catalysts for the stock. Although HER2+ market is becoming increasingly crowded, we believe HER2 TKIs will continue to have a role. There have been consistent clinical data as well as a preclinical rationale that HER2 TKIs adds to the activity of Herceptin and we believe there is an opportunity for neratinib to be combined with Herceptin. With the advent of pertuzumab and T-DM1 (both Roche), HER2+ breast cancer has clearly become more crowded but because of non-overlapping mechanism of action, we believe neratinib could potentially be combined with the HER2-antibody based agents or used sequentially. We believe there is significant commercial opportunity that is more than sufficient for the size of Puma.

Neoadjuvant trials to focus on HER2+ HR- patient population. A meta-analysis of 12 neoadjuvant randomized controlled trials with a clearly defined pCR and long-term follow-up EFS and OS data suggested a high pCR rate in selected patient population. Patients with HER2+ but hormone receptor negative appear to achieve the highest pCR (50%) when treated with Herceptin and chemo. Patients with triple negative breast cancer had a pCR of 34% -- promising for this difficult to treat patient population. These data suggest a promising path for the Phase III trial design for neratinib.

Advancing SPA (Special Protocol Assessment) and SA (scientific advice from EU) supported Phase III trial in HER2-positive 3rd line mBC. PBYI recently received a SPA from the FDA as well as a SA from EU for its Phase III trial in metastatic breast cancer (mBC). It is a randomized trial evaluating neratinib + Xeloda vs. Tykerb + Xeloda in patients with third-line HER2-positive metastatic breast cancer. The trial is expected to enroll approximately 600 patients. The co-primary endpoints of the trial are progression-free survival and overall survival. The PFS data will be the base for filing for NDA and MAA for accelerated approval. Initiation of the trial is expected sometime in 2Q:13.

Pipeline continues to progress. In addition to the neoadjuvant breast cancer therapy and 3rd line mBC therapy, neratinib is also being evaluated in a Phase II trial in combination with Torisel in 4th line HER2+ mBC with data anticipated later in 2013 and followed by Phase III initiation. Data from the Phase II trial in Her2+ mBC with brain mets are on track to be reported later in 2013. The Phase II trial in patients with HER2 negative HER2 mutated NSCLC is ongoing with initial data anticipated later in 2013.

Model update. PBYI reported financial results yesterday, 4/1. Total R&D expenses were $8.2M in 4Q:12 and $49.6M in 2012, slightly lower than our estimates of $10.1M and $51.4M, respectively. Total G&A costs were $13.8M in 4Q:12 and $24.8M in 2012, higher than our estimates of $8.1M and $19.1M, respectively. The increase was mainly due to higher stock-based compensation as well as additional charge of $12M associated with warrants recognized in 4Q:12. The adjusted non-GAAP operating expenses were $6.7M in 4Q:12 and $16.9M in 2012. The company ended the quarter with $137M cash, which is sufficient to support operation well through 2014, in our view. We are updating our model to reflect these changes.

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Neratinib Phase II Trials in the Neoadjuvant Setting

- NSABP Trial (FB-7)-Neoadjuvant randomized trial of neratinib, Taxol, Herceptin
- Funded by NSABP (National Surgical Adjuvant Breast and Bowel Project)
  - Taxol plus Herceptin (n=43)
  - Taxol plus Neratinib (n=43)
  - Taxol plus Herceptin plus Neratinib (n=43)
- Endpoint: pathological complete response (path CR) rate (breast and axillary lymph nodes)

I-SPY 2 Trial (Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And moLecular Analysis 2)

- NIH Funded Trial (n=20 (min) - 120 (max) per arm)
- Enrolls patients with higher risk of recurrence (MammaPrint 70 gene signature assay)
- Adaptive trial design using Bayesian predictive probability
  - Taxol plus Herceptin
  - Taxol plus Neratinib
  - *Taxol plus Herceptin plus Neratinib (anticipated)*
- Extensive Biomarker analysis (signatures) being performed
- Endpoint: pathological complete response (path CR) rate (probability of improving path CR for biomarker signature)

Source: Company Reports

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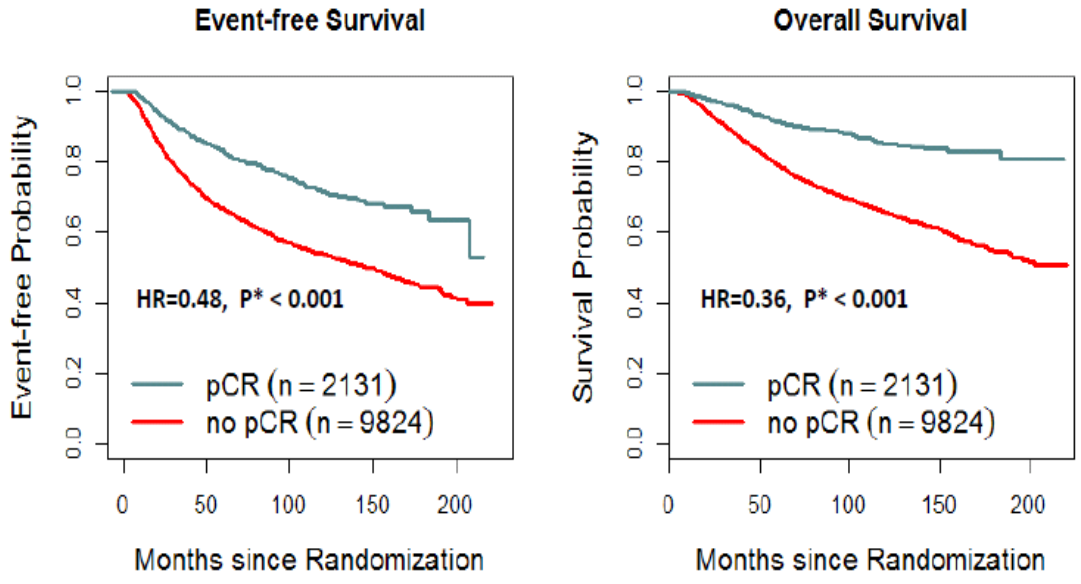
pCR is Associated with EFS and OS



pCR=ypT0/is ypN0 * Nominal p-value

Source: Cortazar et al, "Implications of the CTNeoBC Meta-analysis" FDA Public Workshop – Neoadjuvant Breast Cancer Workshop, March 22, 2013; http://www.fda.gov/Drugs/NewsEvents/ucm339396.htm

Historical Neoadjuvant pCR Data for Herceptin

		pCR		
	Chemo Regimen	**Chemo**	**Chemo + Herceptin**	**N**
NOAH Study	Doxorubin + Paclitaxel, then CMF	19%	38%	228
TECHNO	EC then Paclitaxel	NA	23%	217
MD Anderson	anthracycline-taxane	26%	65%	NA
GeparQuattro	EC & docetaxel +/- Xeloda	16%	32%	445
Average		**20%**	**39%**	

EC = epirubicin-cyclophosphamide

CMF = cyclophosphamide-methotrexate-fluorouracil

Source: Company Reports, reviewed by Minckwitz et al, Oncology (2012) 26

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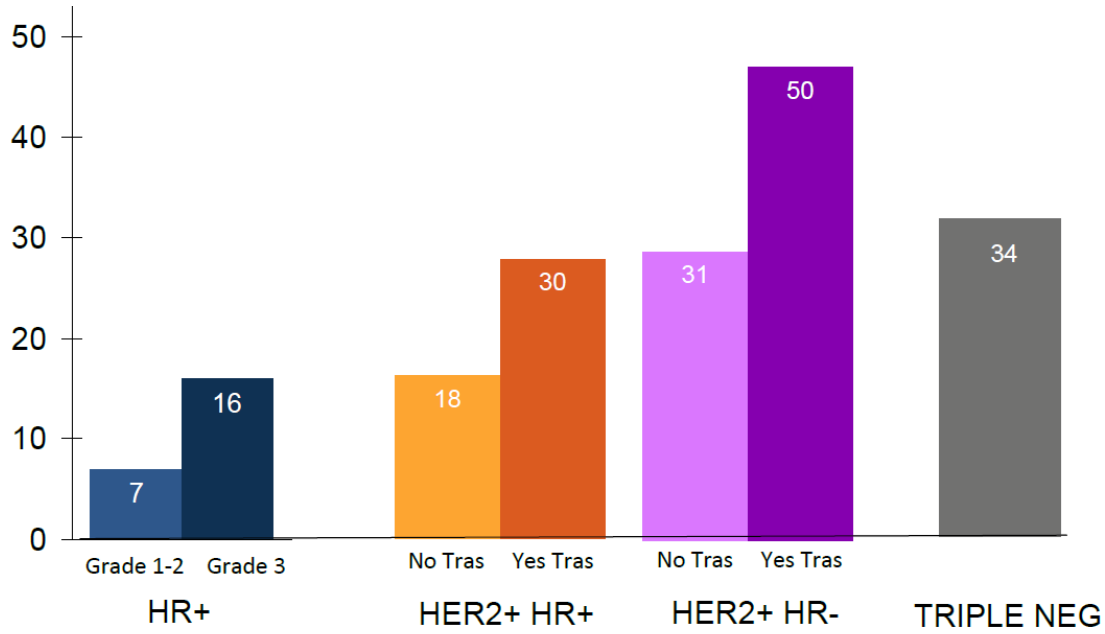
Meta-Analysis of Randomized Neoadjuvant Trials – pCR Rates by Tumor Subtypes



Source: Cortazar et al, "Implications of the CTNeoBC Meta-analysis" FDA Public Workshop – Neoadjuvant Breast Cancer Workshop, March 22, 2013; http://www.fda.gov/Drugs/NewsEvents/ucm339396.htm

PBYI Upcoming Milestones

Timing	Event
Neratinib oral (irreversable HER2/ERBb2 inhibitor)	
2Q:13	Initiate Phase III trial w/chemo in 3rd-line HER2(+) MBC
mid-13 and late 2013	Data from two Phase II neoadjuvant trial in HER2(+) breast cancer
Late 2013	Initial data from Phase II trial with Torisel in HER2 mutated NSCLC. Trial may qualified for accelerated approval
Late 2013	Data from Phase II trial with Torisel in 4th line HER2(+) MBC; Initiate Phase III trial
Late 2013	Data from Phase II trial in HER2(+) MBC that metastasized to the brain
Late 2013	Initial Phase II data from HER2-negative HER2 mutations breast cancer

MBC - metastatic breast cancer

Source: Company reports and Leerink Swann LLC

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PBYI Product Pipeline

Indication	Status	Comments
Neratinib (PB272)-Oral (irreversable HER2/ERBb2 inhibitor)		
Metastatic Breast Cancer (MBC)	Phase II	Phase I/II trial of Torisel + Neratinib in HER2 (+) in triple-negative breast cancer, n=65; enrollment ongoing.
	Phase II	Combination with chemo in 2nd/3rd line HER2(+) MBC. Phase III to be initiated in 1H:13.
	Phase II	Combination with chemo as neoadjuvant. NSABP and I-SPY2 trials with pathological CR as endpoint. 3-arm: taxol + Herceptin, taxol + neratinib, taxol + neratinib + Herceptin
	Phase II	Single agent in MBC with brain metastatics, Phase II initiated in Jan, 2012, results in 2013
NSCLC	Phase II	Combination with Torisel in HER2 mutated NSCLC initiated in 4Q:12. Initial data anticipated in 2013. Trial may qualified for accelerated approval.
Neratinib (PB272)-IV (irreversable HER2/ERBb2 inhibitor)		
Advanced Cancer	Preclinical	
PB357 (irreversable HER2/ERBb2 inhibitor)		
	Preclinical	Back up for PB272, explore additional development

Source: Company reports and Leerink LLC

VALUATION

We are increasing our valuation for PBYI from $27 to $44 based on clearer path to neoadjuvant therapy in breast cancer. We are increasing the percent of patient on neoadjuvant therapy from 25% to 50%. We also increase the probability of success for neratinib in Stage IV breast cancer from 65% to 75% based on enhanced conviction. Incorporating these changes and maintaining the other assumptions in our DCF model, we derive a $44 valuation for PBYI. We believe a 10% discount rate is appropriate given probability weighted sales projection.

Our previous $27 valuation was derived from a DCF analysis which included probability-weighted projected neratinib sales in HER2(+) MBC patients (at 65%), in HER2(+) MBC with brain metastases (at 30%), and in new HER2 mutant BC (at 20%) in the U.S. and 20% royalty on probability-weighted (at 65%) estimated neratinib sales in breast cancer outside the U.S. from 2015 to 2027, assuming a 2-year patent expansion for neratinib after expiry of 2025.

RISKS TO VALUATION

HER2+ breast cancer market has become more crowded with advancement of pertuzumab, T-DM1, Tovok (Boerhinger Ingelheim) in addition to approved agents Herceptin and Tykerb, all of which are ahead of neratinib in development.

Differentiation vs. currently marketed agent remains to be firmly established. The perception of superior efficacy of neratinib relative to Tykerb is based on cross-trial comparisons, and remains to be demonstrated in a randomized study.

Financing risks. The current pro forma cash is estimated at ~$137M, and we expect current cash to support operation well through 2014. There is likely a need for additional financing before becoming cash-flow positive.

PBYI Income Statement ($000)	2010A	2011A	Mar-12A	Jun-12A	Sep-12A	Dec-12A	2012A	Mar-13E	Jun-13E	Sep-13E	Dec-13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Neratinib US sales - pw							0					0	0	13,719	74,751	155,317	253,127	399,409	536,095
Neratinib Ex.-US sales - pw							0					0	0	0	6,860	52,326	139,786	253,127	399,409
Neratinib Ex.-US Royalties - pw													0	0	1,372	10,465	27,957	50,625	79,882
Collaborative revenues		0	0	0	0	0	0	0	0	0	0	0							
Total Revenue	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**13,719**	**76,123**	**165,783**	**281,084**	**450,035**	**615,977**
COGS (including royalty paid to PFE)	0	0	0	0	0	0	0					0	0	3,430	20,403	51,911	98,228	163,134	233,876
R&D		826	10,568	13,006	17,779	8,282	49,636	5,500	6,500	6,500	6,500	25,000	32,010	37,020	32,230	28,101	23,051	11,062	11,372
SG&A	7	9,320	1,235	1,702	8,025	13,852	24,814	7,600	7,600	7,600	7,600	30,400	33,120	35,928	76,264	81,523	85,599	89,333	93,231
Depreciation and Amortization	0	11	49	69	69	(187)	0	0	0	0	0	0	0	0	0	0	0	0	0
Total expenses	**7**	**10,157**	**11,852**	**14,777**	**25,873**	**21,947**	**74,450**	**13,100**	**14,100**	**14,100**	**14,100**	**55,400**	**65,130**	**76,378**	**128,897**	**161,535**	**206,879**	**263,528**	**338,479**
Operating Income	**(7)**	**(10,157)**	**(11,852)**	**(14,777)**	**(25,873)**	**(21,947)**	**(74,450)**	**(13,100)**	**(14,100)**	**(14,100)**	**(14,100)**	**(55,400)**	**(65,130)**	**(62,659)**	**(52,774)**	**4,248**	**74,205**	**186,506**	**277,498**
Other Income (expense)	0	0	0	0	0	0	0					0	0	0	0	0	0	0	0
Interest/Investment Income (expense), Net	0	(76)	26	23	14	35	98	10	10	10	10	40	0	0	0	0	0	0	0
Net Income Before Taxes	(7)	(10,233)	(11,826)	(14,755)	(25,859)	(21,912)	(74,352)	(13,090)	(14,090)	(14,090)	(14,090)	(55,360)	(65,130)	(62,659)	(52,774)	4,248	74,205	186,506	277,498
Income Taxes		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Net Income before preferred stocks	(7)	(10,233)	(11,826)	(14,755)	(25,859)	(21,912)	(74,352)	(13,090)	(14,090)	(14,090)	(14,090)	(55,360)	(65,130)	(62,659)	(52,774)	4,248	74,205	186,506	277,498
Preferred Dividends	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
GAAP Net Income to Common Stocks	**(7)**	**(10,233)**	**(11,826)**	**(14,755)**	**(25,859)**	**(21,912)**	**(74,352)**	**(13,090)**	**(14,090)**	**(14,090)**	**(14,090)**	**(55,360)**	**(65,130)**	**(62,659)**	**(52,774)**	**4,248**	**74,205**	**186,506**	**277,498**
GAAP EPS	**(0.00)**	**(1.32)**	**(0.59)**	**(0.74)**	**(1.29)**	**(0.83)**	**(3.42)**	**(0.48)**	**(0.52)**	**(0.51)**	**(0.51)**	**(2.02)**	**(2.31)**	**(2.03)**	**(1.58)**	**0.11**	**1.79**	**4.36**	**6.31**
Basic Shares Outstanding	4,000	7,747	20,040	20,040	20,040	26,784	21,726	27,052	27,322	27,596	27,871	27,460	28,222	30,795	33,441	34,115	34,802	35,504	36,219
Diluted Share Outstanding	4,000	8,178	21,193	21,433	21,463	30,807	25,749	31,107	31,407	31,707	32,007	31,557	32,757	35,957	39,157	40,357	41,557	42,757	43,957

Note: pw - probability weighted

Sources: Company reports, Leerink Swann LLC

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Disclosures Appendix

Analyst Certification

I, Howard Liang, Ph.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

Valuation

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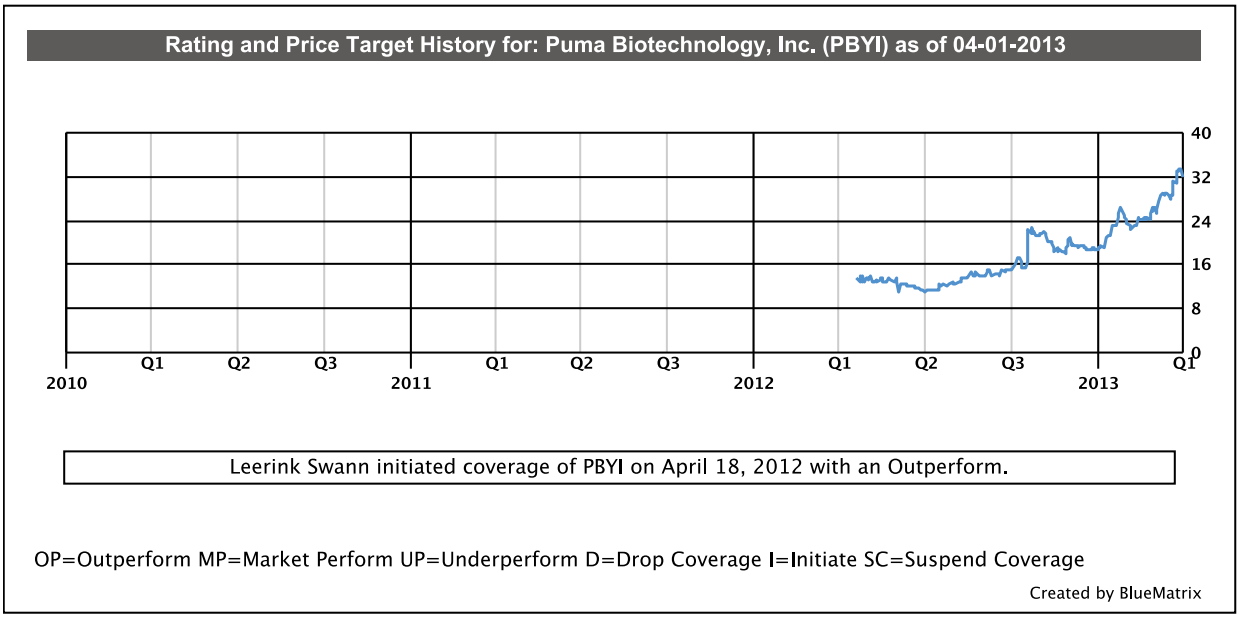

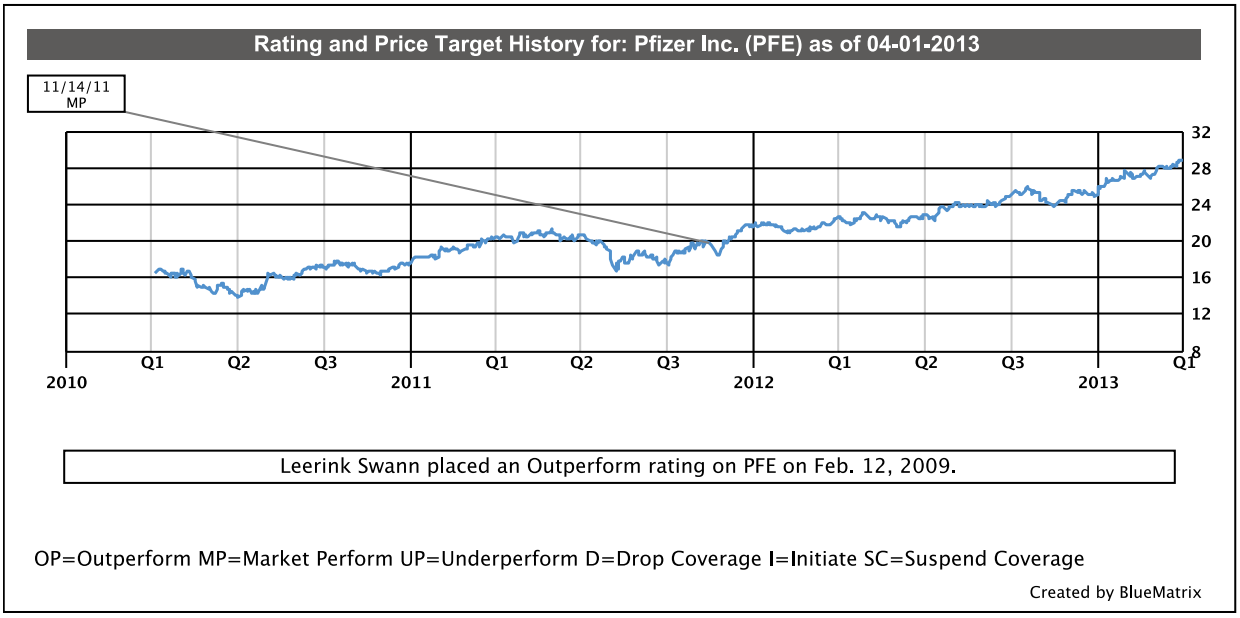
Rating and Price Target History for: Pfizer Inc. (PFE) as of 04-01-2013
11/14/11
MP
32
28
24
20
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8
Q1
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Q1
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Q1
2010
2011
2012
2013
Leerink Swann placed an Outperform rating on PFE on Feb. 12, 2009.
OP=Outperform MP=Market Perform UP=Underperform D=Drop Coverage I=Initiate SC=Suspend Coverage
Created by BlueMatrix

Distribution of Ratings/Investment Banking Services (IB) as of 12/31/12				
			IB Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [OP]	105	61.76	32	30.48
HOLD [MP]	64	37.65	2	3.12
SELL [UP]	1	0.59	0	0.00

Explanation of Ratings

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

Market Perform (Hold/Neutral): We expect this stock to perform in line with its benchmark over the next 12 months.

Underperform (Sell): We expect this stock to underperform its benchmark over the next 12 months.The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than $2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over $2 billion.

From October 1, 2006 through January 8, 2009, the relevant benchmarks for the above definitions were the Russell 2000® Health Care Index for issuers with a market capitalization of less than $2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over $2 billion.

Definitions of Leerink Swann Ratings prior to October 1, 2006 are shown below:

Outperform (Buy): We expect this stock to outperform its benchmark by more than 10 percentage points over the next 12 months.

Market Perform (Hold/Neutral): We expect this stock to perform within a range of plus or minus 10 percentage points of its benchmark over the next 12 months.

Underperform (Sell): We expect this stock to underperform its benchmark by more than 10 percentage points over the next 12 months.

For the purposes of these definitions, the relevant benchmark were the Russell 2000® Health Care Index for issuers with a market capitalization of less than $2 billion and the S&P 500® Index for issuers with a market capitalization over $2 billion.

Important Disclosures

This information (including, but not limited to, prices, quotes and statistics) has been obtained from sources that we believe reliable, but we do not represent that it is accurate or complete and it should not be relied upon as such. All information is subject to change without notice. This is provided for information purposes only and should not be regarded as an offer to sell or as a solicitation of an offer to buy any product to which this information relates. The Firm, its officers, directors, employees, proprietary accounts and affiliates may have a position, long or short, in the securities referred to in this report, and/or other related securities, and from time to time may increase or decrease the position or express a view that is contrary to that contained in this report. The Firm's salespeople, traders and other professionals may provide oral or written market commentary or trading strategies that are contrary to opinions expressed in this report. The Firm's asset management group and proprietary accounts may make investment decisions that are inconsistent with the opinions expressed in this report. The past performance of securities does not guarantee or predict future performance. Transaction strategies described herein may not be suitable for all investors. Additional information is available upon request by contacting the Publishing Department at One Federal Street, 37th Floor, Boston, MA 02110.

Like all Firm employees, analysts receive compensation that is impacted by, among other factors, overall firm profitability, which includes revenues from, among other business units, the Private Client Division, Institutional Equities, and Investment Banking. Analysts, however, are not compensated for a specific investment banking services transaction.

Leerink Swann Consulting LLC, an affiliate of Leerink Swann LLC, is a provider of evidence-based strategy and consulting to the healthcare industry.

In the past 12 months, the Firm has received compensation for providing investment banking services to Puma Biotechnology, Inc.

Leerink Swann LLC makes a market in Puma Biotechnology, Inc.

Leerink Swann LLC is willing to sell to, or buy from, clients the common stock of Pfizer Inc. on a principal basis.

In the past 12 months, an affiliate of the Firm, Leerink Swann Consulting LLC, has received compensation for providing non-securities services to: Pfizer Inc.

Leerink Swann LLC has acted as a co-manager for a public offering of Puma Biotechnology, Inc. in the past 12 months.

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