December 8, 2012

OUTPERFORM

Reason for report:

COMPANY UPDATE

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LEERINK SWANN

HEALTHCARE EQUITY RESEARCH

PUMA BIOTECHNOLOGY, INC.

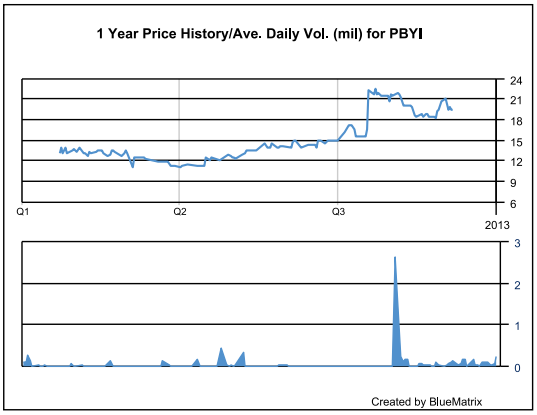
Good Progress in Advancing on Multiple Fronts – Increasing Valuation

• **Bottom Line**:We are in attendance of the San Antonio Breast Cancer Symposium (SABCS) and spoke with PBYI management during the meeting. We are encouraged by a number of updates for the lead candidate neratinib (pan-HER tyrosine kinase inhibitor, TKI) including 1) updated data on Torisel / neratinib combination; 2) agreement with the FDA for potential filing for accelerated approval of Torisel / neratinib combination in 4th line metastatic breast cancer (MBC) based on overall response rate; 3) reports of neratinib's differentiated activity against newly identified HER2 activating mutations; 4) initial experience that prophylaxis leads to significantly reduced diarrhea. Based on the company's recent progress in advancing neratinib, we are increasing our valuation for PBYI from $20 to $27.

• **Torisel / neratinib combination continues to show encouraging data.** Enrolled patients were HER2+ breast cancer patients with progression on Herceptin. They had a median of 3 prior cytotoxic regimens and a median of 2 Herceptin-containing regimens. Patients were on treatment for a median of 4 cycles. Best response at the maximal tolerated dose included 12 partial responses (PR) among 27 treated patients (44%) including 9 (33%) with confirmed PR and remaining 3 had progression disease on the confirmation scan. An additional patient had stable disease (SD) of more than 1 months, 2 had progression of disease and 3 were off trial due to toxicity. The median progression-free survival (PFS) was 4.2 months. Biomarker data show that PIK3CA mutation or PTEN loss, features associated with resistance to HER2 inhibitors, did not preclude response to this combination with PR or SD seen in 2/2 and 6/7 of these patients respectively. Responders include patients who failed Tykerb, T-DM1, Perjeta. The enrollment continues and is expected to reach 34 patients.

• **Potential for accelerated approval for Torisel / neratinib based on response rate.** According to management, as a result of a recent end of Phase II meeting with the FDA, PBYI is planning a 3-arm Phase III study in 4th line HER2+ mBC comparing neratinib + Torisel vs. neratinib alone, vs. physician choice of either gemcitabine + Herceptin or Herceptin + Tykerb. The study will have co-primary endpoints of overall response rate (ORR) and overall survival and the agency has agreed that ORR could be the basis for accelerated approval. The historical ORR for both gemcitabine + Herceptin and Herceptin + Tykerb is approximately 10%; therefore neratinib / Torisel data to date look very encouraging. In addition, there has been increasing scientific data supporting a HER2+ inhibitor / mTOR inhibitor combination.

Key Stats:	**(NASDAQ:PBYI)**
S&P 600 Health Care Index:	**820.89**
Price:	**$19.38**
52 Week High:	$23.25
52 Week Low:	$10.00
Shares Outstanding (mil):	28.8
Market Capitalization (mil):	558.1
Book Value/Share:	(11.24)
Cash Per Share:	$5.25
Dividend (ann):	$0.00
Dividend Yield:	0.0%
Valuation:	$27 fr $20 on DCF
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
2011A	--	--	--	--	0.0	--	--	--	--	($1.32)	NM
2012E - New	**0.0A**	**0.0A**	**0.0A**	**0.0**	**0.0**	**($0.59)A**	**($0.74)A**	**($1.29)A**	**($0.64)**	**($3.25)**	**NM**
2012E - Old	0.0A	0.0A	0.0A	0.0	0.0	($0.59)A	($0.74)A	($0.39)	($0.38)	($2.10)	NM
2013E - New	**--**	**--**	**--**	**--**	**0.0**	**--**	**--**	**--**	**--**	**($2.12)**	**NM**
2013E - Old	--	--	--	--	0.0	--	--	--	--	($1.40)	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 13 - 16 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.

Neratinib showed differentiated activity against newly identified HER2 mutations. Data presented at SABCS and published simultaneously identified 25 breast cancer patients with HER2 somatic mutations in cancers lacking HER2 amplification from eight breast cancer genome-sequencing projects (a total of 1,499 patients). Seven of 13 HER2 mutations that have been functionally characterized as activating mutations. In an in vitro assay, all of the mutations were sensitive to neratinib while some were resistant to lapatinib. While it remains to be shown that these HER2 mutations are the oncogenic drivers of the tumor and drugs like neratinib is active in these patients clinically, some of the HER2 mutations bear resemblance to EGFR activating mutations which are exquisitely sensitive to EGFR TKI. However, initial proof-of-concept preclinical data suggest a potentially promising therapeutic paradigm for neratinib. A Phase II

study in patients with HER2 mutations is underway with planned enrollment of 10 patients (by screening 500+ patients based on estimated incidence of 1.5-2%).

HER2 activating mutations identified in HER2 gene amplification negative and ER/PR positive breast cancer. In the preclinical study published in Cancer Discovery, 16 HER2 somatic mutations were identified in 25 patients out of a pooled screening of 1,499 patients. Analysis on available clinical data in 9 patients suggested these mutations occurred in HER2 negative patients based on standard clinical tests, except one patient (TCGA-C8-A135), whose RNA-seq data however, showed a high HER2 read-out in both mutant and wildtype (WT) alleles. Of the remaining 8 patients, all of them showed positive ER, and 7 of them showed positive PR. Patient with HER2 mutations are in relatively mild stage, and none of them had metastatic breast cancer (Stage IV).

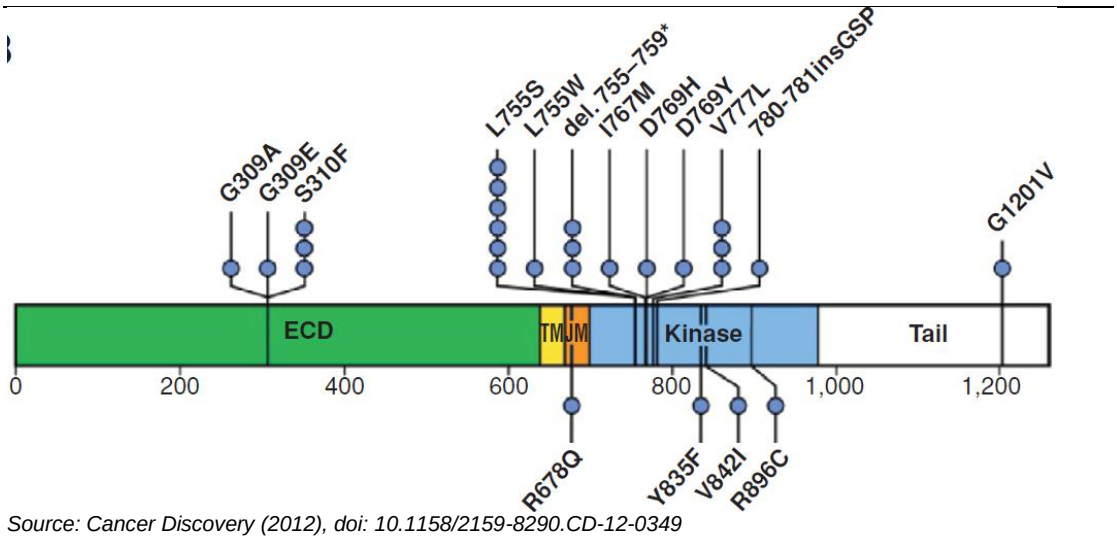
Clinical Information on Patients with HER2 Somatic Mutations

									RNA-seq data		
Patient code	HER2 mutation	Stage	Path. type and grade	ER	PR	HER2 status (per ACOSOG trial or TCGA)	HER2 IHC	HER2 FISH ratio	Mutant allele reads	WT allele reads	Percent of reads from mutant allele
15687 (BRC14)	V777L	IIB	Ductal, Grade 3	+	+	Negative	2+	1.9	see Fig. 1E		
16757	del.755–759	IIB	Ductal, Grade 2	+	+	Negative	1+		see Fig. 1E		
TCGA-A8-A0AB	L755S	IIA	Lobular	+	+	Negative (confirmed by SNP chip)	2+	Not available (sample from commercial source)	864	745	53.7%
TCGA-BH-A18P	L755S	I	Ductal	+	–	Negative (confirmed by SNP chip)	2+	2.05	509	164	75.6%
TCGA-C8-A135	D769H	IIB	Ductal	–	–	Positive	3+		2099	1280	62.1%
TCGA-BH-A0C1	V777L	IIIA	Lobular	+	+	Negative	0		253	143	63.9%
TCGA-A8-A08Z	V842I	IIIB	Ductal	+	+	Negative	1+		N/A	N/A	N/A
TCGA-A8-A06Z	G309A	IIB	Ductal	+	+	Negative	1+		80	416	16.1%
TCGA-A2-A0T6	R678Q + L755W	IIB	Lobular	+	+	Negative	1+		569	538	51.4% for R678Q
									608	585	51.0% for L755W

Source: Cancer Discovery (2012), doi: 10.1158/2159-8290.CD-12-0349

HER2 mutations clustered in two domains. Gene mapping of the mutations showed that these mutations are located in two main areas: 20% (5/25) of patients had mutations in the extracellular domain (ECD) at position of 309-310 amino acid (aa) residues, and 68% (17/25) of patients had mutations in the tyrosine kinase domain between aa residues 755-781.

HER2 Somatic Mutations Observed in 25 Patients



Source: Cancer Discovery (2012), doi: 10.1158/2159-8290.CD-12-0349

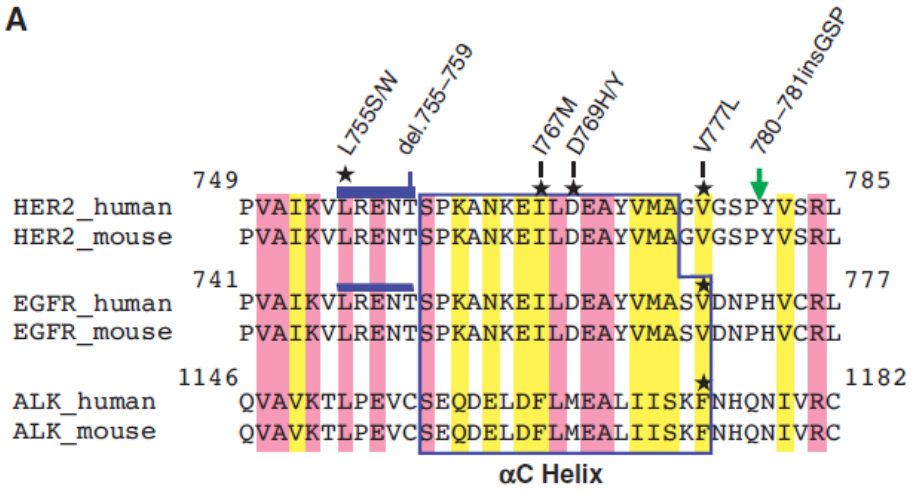
Non-activating mutations seen across all domains. HER2 R678Q, I767M and Y835F mutations are shown to be non-functional mutations; however, the status of the activity does not appear to be associated with a specific location. For example, I767M and Y835F are both located in the kinase domain, a key functional sequence in the HER2 gene. However, these mutations are not the cause of breast cancer in the patient.

HER2 mutations in the ECD domain are likely involved in dimerization. HER2 mutations G309E and S310F in the ECD domain are likely contact the dimerization of the EGFR through a modeling analysis. Mutations in G309 and S310 have also been found in NSCLC, and recent studies in NIH 3T3 fibroblasts also showed that these two are activating mutations.

HER2 mutations in the kinase domain are comparable to other TKIs; however, striking differences are seen in the A-loop. HER2 mutations in the tyrosine kinase domain were either flank or within the alphaC helix. The HER2 780-781 insertion has been previously identified in NSCLC; however, the rest of the mutations were distinct from the HER2 mutations in NSCLC. Multi-sequence alignment showed that the HER2 in-frame aa755-759 deletion matches EGFR exon 19 deletion in NSCLC, an activating mutation that leads to increased sensitivity to gefitinib. The HER2 V777L mutation is homologous to EGFR V769L mutation, a rare mutation associated with NSCLC but no identified function, and ALK F1175L mutation, a known activating mutation found in neuroblastoma. The HER2 L755S mutation is known as a lapatinib-resistant mutation, because the side chain of L755 is in close proximity to the binding site for small-molecule TKI inhibitors. The remaining HER2 mutations Y835F, V842I, R896C in the kinase domain are all

located in the C-lobe, but not from active loop (A-loop) – the location where mutations have been mainly identified from, with prominent examples such as EGFR L858R, BRAF V600E, an ALK R1275Q.

Multi-sequence Alignment of HER2, EGFR and ALK Tyrosine Kinases



Source: Cancer Discovery (2012), doi: 10.1158/2159-8290.CD-12-0349

Differentiated HER2 inhibition by neratinib. Studies in cell culture, Matrigel assay and xenografted mouse model showed that HER2 mutations increase cell growth and tumor formation vs. wild type HER2. In these studies, neratinib showed a broad spectrum of inhibition against all of the HER2 mutations. However, lapatinib was less effective in reducing tumor cell growth in L755S or P780 insertion mutations. Studies using various cell lines suggested that neratinib has potent inhibition against HER2 G309A, V777L, D769H, V842I, 755-759 deletion, and L755S mutations with IC_{50} in a range of ~2 nM vs. >400 nM for lapatinib. Although trastuzumab reduced the formation of invasive colonies in the Matrigel assays, complexity mechanism in activating the immune system makes trastuzumab not a good comparison using a simple cell culture and mouse model system. Although pertuzumab was not tested in this study, since HER2 309-310 are known to be pertuzumab-binding epitope, pertuzumab could be effective in G309A/E and S310F mutations.

Inhibition of Cell Growth by Neratinib and Tykerb (Lapatinib)

	IC_{50} (nmol/L)	
	Neratinib	Lapatinib
MCF10A – HER2 WT	<2	400 ± 60
G309A	<2	470 ± 50
V777L	<2	1,040 ± 570
D769H	<2	980 ± 950
V842I	<2	650 ± 210
del.755–759	2.1 ± 0.2	660 ± 90
L755S	15 ± 6	>10,000
BT474 cells	<2	31 ± 2
MCF7 cells	>3,000	>10,000

NOTE: Cells were incubated with drugs for 6 days, and cell viability and number were measured using Alamar Blue.

Source: Cancer Discovery (2012), doi: 10.1158/2159-8290.CD-12-0349

Prophylaxis appear effective in reducing frequency of grade 3 diarrhea. At SABCS, the designs of the TBCRC 022 trial in brain metastasis patients as well as was the NSABP FB-7 neoadjuvant trial for neratinib were presented during the Ongoing Trials Session. Although no new data were presented, we were able to get an update about these trials from the presenting investigators. For the TBCRC 022 trial, 27 of 40 planned patients have been enrolled. According to the presenter and PBYI, as a result of preemptive prophylaxis, so far only 2 out of 27, or ~7% of patients had grade 3 diarrhea, compared to 28% in a large recent randomized study (Martin et al, SABCS 2011). Although these data are preliminary, it is encouraging that prophylaxis instituted by PBYI appears effective in reducing the frequency of diarrhea. This study has a surgical cohort that will provide information about the CNS penetration of neratinib and results from this study could be available at ASCO, ESMO, and SABCS 2013 based on the current progress. The NSABP FB-7 neoadjuvant study has enrolled 30 patients although all but one was in the neratinib + paclitaxel or Herceptin + paclitaxel groups. The combination group of neratinib + Herceptin + paclitaxel was only recently opened after determining the combination dose. The presenter expressed confidence that the trial will enroll quickly with 120 centers and data could be presented at SABCS 2013.

Combination of neratinib + Torisel continues to look tolerable. The safety profile suggested that major Grade 2 AE were diarrhea (33%), mucositis (33%), leucopenia (30%), hyperglycemia (22%) and fatigue (22%). The main Grade 3 AE was diarrhea (22%) and mucositis (15%). Although incidence of diarrhea AEs is high, we believe these are manageable.

Neratinib+Torisel Combination Therapy Phase II Data in Herceptin-Refractory HER2+ MBC

Table 1. Baseline Patient Characteristics For Phase I and II	
N=22; (Phase I n=6, Phase II n=21)	
Median age, y (range)	48 (31-73)
Median ECOG performance status (range)	0 (0-2)
ER(+) or PR(+)	14
Site of metastases	
Visceral	20
Brain	3
Median # of prior cytotoxic regimens (range)	3 (1-12)
Median # of trastuzumab-containing regimens (range) (n=27)	2 (1-9)
Median # of temsirolimus-neratinib cycles	4 (1-24)

Table 2. Possible Drug-related Toxicity – Maximal grade (N=27)			
Toxicity	**Grade 2 N (%)**	**Grade 3 N (%)**	**Grade 4 N (%)**
Diarrhea	9 (33%)	6 (22%)	-
Mucositis	9 (33%)	4 (15%)	-
Leukopenia	8 (30%)	1 (4%)	-
Hyperglycemia	6 (22%)	1 (4%)	-
Fatigue	6 (22%)	1 (4%)	-
Rash-acneiform	5 (19%)	0	-

Table 3. Best Response by RECIST for patients treated at MTD	
HER2-Amplified (N=27; Phase I n=6, Phase II n=21)	
Complete response	0
Partial response	12*
Stable disease >6 months	1
Progression of disease	2
Off trial due to toxicity	3
** 9 pts have confirmed PRs, 3 pts had progression of disease on confirmation scan*	

Source: Company Reports

Phase III combination therapy with chemo in 3rd line mBC awaits an SPA and is on track for initiation late 2012 / early 2013. The Phase III head-to-head study evaluating neratinib + Xeloda vs. Tykerb + Xeloda in 3rd line MBC is expected to enroll 400-500 patients with an estimated cost of $20-30M (~$50K for each patient).

Model update. PBYI reported financial results on November 14, 2012. Total R&D expenses were $17.8M, higher than our estimated of $6.0M, mainly due to $15.6M accruals for ongoing outside clinical development and CRO licensing service for the neratinib clinical trials. Management expected that the expenses related to these clinical trials will reach the capped limit (pay the CRO up to $22.8M) during the 4Q:12. Total SG&A were $8.0M, higher than our estimate of $1.7M, mainly due to a one-time $6.6M stock-based compensation. The company ended the quarter with $41M cash. PBYI was recently listed at the NYSE and received ~$129M in net proceeds through an underwritten public offering. The current pro forma cash is estimated at ~$150M, and we expect current cash to support operation well through 2014. We are updating our model to reflect these changes. Our new 2012 EPS estimate is ($3.25) vs. previously ($2.10), and our 2013 EPS estimate is ($2.12) vs. previously ($1.40).

PBYI Upcoming Milestones

Timing	Event
Neratinib oral (irreversable HER2/ERBb2 inhibitor)	
4Q:12	Initiate Phase II trial with Torisel in HER2 mutated NSCLC. Trial may qualified for accelerated approval
1Q:13	Initiate Phase III trial w/chemo in 2nd/3rd-line HER2(+) MBC
1Q:13	Data from Phase II trial with Torisel in 4th line HER2(+) MBC; Initiate Phase III trial
1Q:13	Data from Phase II trial in HER2(+) MBC that metastasized to the brain
1Q:13	Submit an IND filing for IV formulation of Neratinib
1Q:13	Initial Phase II data from combination with Torisel in HER2 mutated NSCLC
2013	Data from Phase II neoadjuvant trial in HER2(+) breast cancer

MBC - metastatic breast cancer
Source: Company reports and Leerink Swann LLC

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. Potential to initiate pivotal in 1Q:13
	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 1Q:13
NSCLC	Phase II	Combination with Torisel in HER2 mutated NSCLC to be 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	Submit IND in 4Q:12
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 $20 to $27 based on enhanced conviction on HER2 mutated breast cancer indication, as well as pricing power neratinib may gain if showing superior efficacy vs. Tykerb. In addition to our prior sales projection in HER2 (+) MBC, neoadjuvant therapy in Stage 0-III patients, neoadjuvant maintenance therapy, adjuvant therapy and MBC with brain metastases, we are including an additional indication in HER2 new mutations. Based on recent data on preclinical studies, we believe this new indication could provide neratinib with a competitive position vs. other HER2 inhibitors. We project an initial launch in 2018 with a peak penetration of 15% in 2023 with estimated ~48M sales. We assign 20% probability of success for this indication. Additionally, we increase our price estimate from $4,267 to $5,334 per month, representing a 25% premium vs. Tykerb price. We believe the increase is justifiable if neratinib shows a superior efficacy vs. Tykerb in a head-to-head study. Incorporating these changes and maintaining the other assumptions in our DCF model, we derive a $27 valuation for PBYI.

Our previous $20 valuation was derived from a DCF analysis which included probability-weighted projected neratinib sales in HER2(+) MBC patients (at 65%) and in HER2(+) MBC with brain metastases (at 30%) 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 ~$150M, 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-12E	2012E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Neratinib US sales - pw							0	0	0	9,976	54,353	114,330	194,519	305,539	405,543
Neratinib Ex.-US sales - pw							0	0	0	0	4,988	38,047	102,897	194,519	305,539
Neratinib Ex.-US Royalties - pw									0	0	998	7,609	20,579	38,904	61,108
Collaborative revenues		0	0	0	0	0	0								
Total Revenue	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**9,976**	**55,351**	**121,939**	**215,098**	**344,443**	**466,651**
COGS (including royalty paid to PFE)	0	0	0	0	0	0	0	0	0	2,494	14,835	38,094	74,354	125,014	177,770
R&D		826	10,568	13,006	17,779	10,068	51,422	24,958	31,967	36,977	32,187	28,056	23,006	11,017	11,327
SG&A	7	9,320	1,235	1,702	8,025	8,149	19,111	36,543	41,454	46,317	88,888	94,821	101,169	105,649	110,330
Depreciation and Amortization	0	11	49	69	69	125	312	325	338	351	365	380	395	411	427
Total expenses	**7**	**10,157**	**11,852**	**14,777**	**25,873**	**18,342**	**70,845**	**61,826**	**73,758**	**86,139**	**136,275**	**161,351**	**198,924**	**242,090**	**299,854**
Operating Income	**(7)**	**(10,157)**	**(11,852)**	**(14,777)**	**(25,873)**	**(18,342)**	**(70,845)**	**(61,826)**	**(73,758)**	**(76,164)**	**(80,924)**	**(39,412)**	**16,174**	**102,352**	**166,797**
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	13	76	0	0	0	0	0	0	0	0
Net Income Before Taxes	(7)	(10,233)	(11,826)	(14,755)	(25,859)	(18,329)	(70,769)	(61,826)	(73,758)	(76,164)	(80,924)	(39,412)	16,174	102,352	166,797
Income Taxes		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)	(18,329)	(70,769)	(61,826)	(73,758)	(76,164)	(80,924)	(39,412)	16,174	102,352	166,797
Preferred Dividends	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)**	**(18,329)**	**(70,769)**	**(61,826)**	**(73,758)**	**(76,164)**	**(80,924)**	**(39,412)**	**16,174**	**102,352**	**166,797**
GAAP EPS	**(0.00)**	**(1.32)**	**(0.59)**	**(0.74)**	**(1.29)**	**(0.64)**	**(3.25)**	**(2.12)**	**(2.29)**	**(2.15)**	**(2.24)**	**(1.07)**	**0.38**	**2.36**	**3.75**
Basic Shares Outstanding	4,000	7,747	20,040	20,040	20,040	28,765	22,221	29,127	32,220	35,400	36,114	36,841	37,584	38,341	39,114
Diluted Share Outstanding	4,000	8,178	21,193	21,433	21,463	30,388	23,619	31,138	34,838	38,538	39,738	40,938	42,138	43,338	44,538

Note: pw - probability weighted

Sources: Company reports, Leerink Swann LLC

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

We are increasing our valuation for PBYI from $20 to $27 based on enhanced conviction on HER2 mutated breast cancer indication, as well as pricing power neratinib may gain if showing superior efficacy vs. Tykerb. In addition to our prior sales projection in HER2 (+) MBC, neoadjuvant therapy in Stage 0-III patients, neoadjuvant maintenance therapy, adjuvant therapy and MBC with brain metastases, we are including an additional indication in HER2 new mutations. Based on recent data on preclinical studies, we believe this new indication could provide neratinib with a competitive position vs. other HER2 inhibitors. We project an initial launch in 2018 with a peak penetration of 15% in 2023 with estimated ~48M sales. We assign 20% probability of success for this indication. Additionally, we increase our price estimate from $4,267 to $5,334 per month, representing a 25% premium vs. Tykerb price. We believe the increase is justifiable if neratinib shows a superior efficacy vs. Tykerb in a head-to-head study. Incorporating these changes and maintaining the other assumptions in our DCF model, we derive a $27 valuation for PBYI.

Our previous $20 valuation was derived from a DCF analysis which included probability-weighted projected neratinib sales in HER2(+) MBC patients (at 65%) and in HER2(+) MBC with brain metastases (at 30%) 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

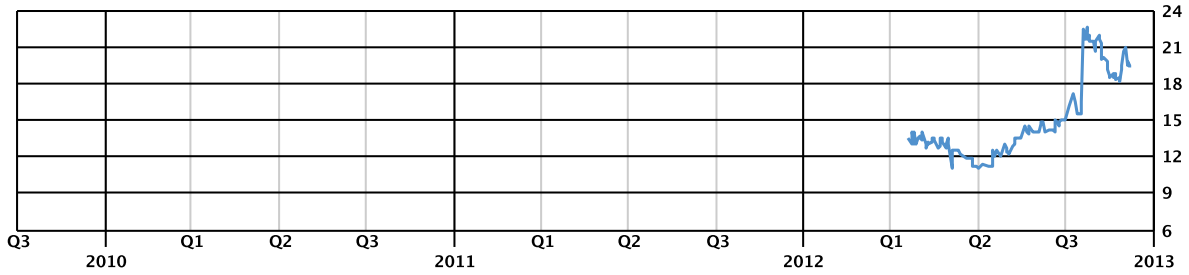
HER2+ breast cancer market has become more crowded with advancement of pertuzumab, T-DM1, Tovok (Boerhinger Ingelheim) in addition to approved agents Herceptin and Tykerb, all of which are ahead of neratinib in development.

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 ~$150M, and we expect current cash to support operation well through 2014. There is likely a need for additional financing before becoming cash-flow positive.

LEERINK SWANN

Rating and Price Target History for: Puma Biotechnology, Inc. (PBYI) as of 12-07-2012

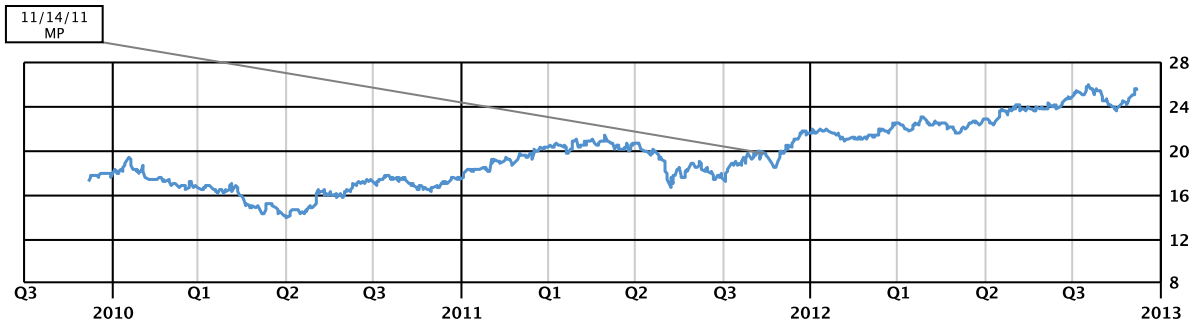


Leerink Swann initiated coverage of PBYI on April 18, 2012 with an Outperform.

OP=Outperform MP=Market Perform UP=Underperform D=Drop Coverage I=Initiate SC=Suspend Coverage

Created by BlueMatrix

Rating and Price Target History for: Pfizer Inc. (PFE) as of 12-07-2012



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 09/30/12				
			IB Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [OP]	102	58.30	29	28.40
HOLD [MP]	73	41.70	3	4.10
SELL [UP]	0	0.00	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

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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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