SUNTRUST ROBINSON HUMPHREY

Puma Biotechnology, Inc.

June 14, 2012

PBYI

Price (Jun. 12, 2012)	$12.25
Mkt. Cap. (mil.)	$245.5

Biotechnology

Rating:	**Buy**
Previous:	*NA*
Price Target:	**$19.00**
Previous:	*NA*
Risk Rank:	**Speculative**
Previous:	*NA*
Sector Rating:	**Market Weight**

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Initiating Coverage: Neratinib Could Become Oral HER2+ of Choice

We are initiating coverage of Puma Biotechnology with a Buy rating and $19 price target. We believe the company's lead program, neratinib, for HER2+ breast and gastric cancers, has the potential to become an important new therapy for ≥2nd-line metastatic disease. We expect the shares to outperform as data from ongoing trials mature and the regulatory strategy evolves.

Results from ongoing phase II trials in HER2+ metastatic breast cancer (MBC) are expected 2H12. We believe two important readouts will be data from a phase II combination trial of neratinib and temsirolimus in heavily pretreated patients, and a phase II trial in patients with CNS metastases. Positive data from either study could potentially lead to a pivotal program in 2013.

Prior data have demonstrated neratinib's efficacy in pretreated populations, including patients who have received prior HER2-targeting therapies such as Herceptin and Tykerb. In addition, phase II trials have shown neratinib may be safely combined with chemotherapies such as paclitaxel, vinorelbine, and capecitabine, and provide benefit comparable to other HER2-based chemo combinations. We believe this profile suggests broad utility in HER2+ MBC.

The competitive landscape for new oral therapies in metastatic breast cancer creates an opening for a differentiated therapy such as neratinib. Key advantages include an irreversible mechanism of action, activity against mutant ErbB kinases, and binding at the intracellular domain of HER2. These may improve neratinib's chances for success in future randomized studies.

We currently model a 2H15 U.S. market entry and 2020 sales of $534M. We expect Puma to retain U.S. rights, and partner neratinib ex-U.S. Per the company's license with Pfizer, Puma will pay Pfizer a royalty of 10%-20%.

FYE – Dec.	2011A	2012E		2013E	
EPS	**Current**	**Previous**	**Current**	**Previous**	**Current**
1Q	NA	NA	-$0.59A	NA	-$0.40E
2Q	NA	NA	-$0.38E	NA	-$0.35E
3Q	-$0.09A	NA	-$0.39E	NA	-$0.28E
4Q	-$1.24A	NA	-$0.41E	NA	-$0.28E
Year	-$1.32A	NA	-$1.77E	NA	-$1.27E
P/E	-9.3x		-6.9x		-9.6x
Mean EPS Estimate	-$1.32		-$1.65		-$1.90
Revenue (mil.)	**Current**	**Previous**	**Current**	**Previous**	**Current**
1Q	NA	NA	$0.0A	NA	$0.0E
2Q	NA	NA	$0.0E	NA	$0.0E
3Q	$0.0A	NA	$0.0E	NA	$0.0E
4Q	$0.0A	NA	$0.0E	NA	$0.0E
Year	-$10.2A	NA	$0.0E	NA	$0.0E
EV/EBITDA	NA		0.0x		NA
Operating Margin	NA	NA	NA	NA	NA

Market Data:

52-Week Range	$14.03-$10.00
Shares Out. (mil.)	20.0
Float (mil.)	16.0
Avg. Daily Vol. (000)	38
Dividend/Yield	$0.00/0.0%

Financial Highlights:

Long-Term Debt (mil.)	$0.0
Debt/Cap.	0.0%
Debt/EBITDA	NA
ROE	NA
Book Value/Share	$12.75
Free Cash Flow/Share	NA
Net Cash/Share	$2.50
Shareholders' Equity (mil.)	$42.6
Est. 5-Year EPS Growth	NA
Convertible	No
Key Indices	

EPS Est. Changes	2012	2013
NA	NA	NA
NA	NA	NA
NA	NA	NA

Comments

Investment Thesis

We are initiating coverage of Puma Biotechnology with a Buy rating and $19 price target. Puma is developing novel small molecule therapeutics for cancer. The company's lead program and primary value driver is neratinib, for HER2 positive metastatic breast and gastric cancers. Preliminary data have demonstrated neratinib's promise in previously-treated patients, both as a single agent and in combination with other therapies. Neratinib is currently in multiple phase II trials, with data possible by year-end. Pending the results from one or more studies, we believe Puma could initiate phase III trials in 2013. If successful, the company could potentially apply for marketing approval in 2H14/1H15, with a possible U.S. product launch in 2H15. Positive data in 2H12/2013 would be a catalyst for shares and could lead to partnering interest ahead of a phase III program. Puma is also developing an I.V. formulation of neratinib as well as a second ErbB inhibitor, PB357, in phase I for solid tumors. The company's entire portfolio was licensed from Pfizer in 2011, in exchange for milestones and future royalties. We view Puma as an under-followed story built around novel drug candidates with promising clinical data, upcoming share catalysts, and the potential for long-term upside from multiple indications. The following table summarizes Puma's pipeline.

Puma Biotechnology – Product Pipeline

Product	Mechanism of Action	Indication	Status	Partner
Neratinib	HER1/2/4 inhibitor	Breast cancer	Phase II	None
		Gastric cancer	To enter phase II	None
Neratinib I.V.	HER1/2/4 inhibitor	Breast/gastric	Preclinical	None
PB357	HER1/2/4 inhibitor	Cancer	Phase I	None

Source: SunTrust Robinson Humphrey and Puma Biotechnology

Our Buy rating and $19 price target are based neratinib's potential to become an important new therapy in the breast and gastric cancer markets. Neratinib is a potent, irreversible inhibitor of the HER2/ErbB2 kinase, which is amplified or overexpressed in approximately 25% of breast and gastric cancers. Activated HER2 initiates cell signaling cascades that result in a multitude of responses, including cell growth, migration, and proliferation. As a result, HER2 positive breast cancer is characterized by more aggressive tumor growth, increased metastatic activity, earlier relapse, and a poorer prognosis compared with HER2 negative. Neratinib, by inhibiting HER2, thus represents an important potential therapeutic for cancers where HER2 amplification plays a role in disease progression.

Puma is initially developing neratinib for metastatic breast and gastric cancers that have failed to respond to, or have progressed following, other treatments. The company is evaluating various combinations of neratinib with both chemotherapeutic and targeted agents. We believe the market opportunity for neratinib could be substantial. Approximately 100K to 120K HER2+ breast cancer patients are diagnosed each year in the U.S. and EU combined. Currently approved HER2-targeting agents include Herceptin (trastuzumab, Roche) and Tykerb (lapatinib, GSK), which registered $4.85B and $372M, respectively, in global 2011 sales. We believe neratinib, based on preliminary data, could become a leading agent for second/third-line breast cancer, with further potential growth from the adjuvant, neoadjuvant, and gastric cancer settings. In addition, an investigator-sponsored phase II trial evaluating neratinib's effect on breast cancer that has metastasized to the brain is ongoing. Positive data could ultimately lead to neratinib being positioned as the oral therapy of choice in regimens for CNS metastases. Our model assumes market entry in late-2015, with worldwide sales growth to approximately $680M from breast cancer by 2020. We assume gastric cancer is a more modest opportunity, with worldwide sales of approximately $88M by 2020.

Over the next several quarters, Puma plans to complete ongoing trials of neratinib in HER2+ breast cancer, and could be in a position to initiate a pivotal program in 4Q12/1Q13. A potential phase III trial would utilize a combination of neratinib with the mTOR inhibitor temsirolimus in $\geq 3^{rd}$-line metastatic breast cancer. A phase I/II study of this regimen is ongoing. Preliminary results have been promising; final data are expected 2H12. If successful, such a strategy could lead to an NDA by 1H15. Puma also plans to initiate phase II trials in 2^{nd}-line and later metastatic breast cancer, combining neratinib with chemotherapy. In addition a phase II study in HER2+ gastric cancer is planned for 2012. As no drugs are currently approved for 2^{nd}-line HER2+ gastric cancer, we believe positive results could lead to increased investor interest and a potentially expedited path to market. We expect data from these trials, as well as follow-up results from ongoing studies, to generate catalysts over the next 12 to 24 months.

In our view, previous phase II data for neratinib have demonstrated encouraging efficacy, suggesting a profile that may be preferable to GSK's lapatinib, as well as various chemotherapeutic agents used in the metastatic setting. As a single agent, neratinib has demonstrated a 24% overall response rate (ORR) in HER2+ metastatic breast cancer, vs. an approximately 7% ORR reported historically for single agent lapatinib. In combination with the chemotherapeutic agent vinorelbine in metastatic disease, neratinib has demonstrated a 56% ORR, which compares favorably to historical vinorelbine combination data for both Herceptin and lapatinib, which have demonstrated ORRs of 27% and 26%, respectively. A phase II combination study of neratinib with capecitabine demonstrated a 63% ORR, vs. historical ORRs of 24% and 48% for combinations of capecitabine with lapatinib or Herceptin, respectively, in comparable settings. We believe the evidence to date, while preliminary and non-randomized, suggests neratinib has efficacy that is at least comparable to that of other targeted agents in the metastatic breast setting.

Neratinib may have several important competitive advantages vs. existing agents. Due to its irreversible mechanism of action, neratinib may lead to more durable activity compared with the reversible mechanisms of Herceptin/lapatinib. This could lead to a more effective disruption of HER2 signaling, and improved tumor control. In addition, neratinib has shown activity against various mutants, including the EGFR vIII and T790M mutants. While difficult to predictably translate into clinical activity, this broadened spectrum represents an encouraging profile due to the common loss of activity among EGFR inhibitors induced by T790M, and the importance of EGFR vIII in CNS tumors. Notably, lapatinib has little activity vs. T790M. We believe the EGFR vIII activity could be important in reducing the propensity for brain metastases in breast cancer patients. Finally, neratinib, by binding to the intracellular domain of HER2/EGFR, retains activity against truncated HER2 receptors, thereby obviating one potential resistance mechanism to antibody-based therapies such as Herceptin, pertuzumab, and trastuzumab-DM1. We believe these characteristics, combined with the efficacy signals outlined above, suggest an improved and differentiated therapeutic profile vs. competitive agents. In our view, these may improve neratinib's chances for success in randomized trials against other HER2-targeting agents.

We expect Puma to seek a partner for neratinib ex-U.S. and potentially launch the drug alone in the U.S. Alternatively, with sufficiently attractive data, a larger partner could find M&A a preferable approach to unlocking neratinib's value. As a reminder, Puma's current management team shares many key members with that of the former Cougar Biotechnology (CGBR). CGRB developed abiraterone, for prostate cancer, and was acquired in 2009 by JNJ for approximately $1B. Like CGRB, Puma was founded by Alan Auerbach, and employs many former members of CGRB's team, including Charles Eyler, SVP, Finance, who was formerly CGRB's CFO, and Richard Phillips, SVP, Regulatory Affairs, who also held this position with CGRB. In our view, given the team's agnostic approach to maximizing shareholder value, partnering and M&A each represent possible options.

Upcoming Catalysts

Key near-term catalysts for Puma shares include initial data from a phase I combination trial of neratinib, Herceptin, and paclitaxel, expected at ASCO in June. These results will be important as the majority of the enrolled patients have previously been treated with Herceptin/paclitaxel.

Key follow-up data from an ongoing phase I/II combination trial of neratinib and temsirolimus (Torisel) in refractory HER2+ breast cancer could be available at the San Antonio Breast Cancer conference, 4Q12. Preliminary phase II data were presented at the San Antonio Breast Cancer conference in 2011, demonstrating a 60% response rate (n=15) in a heavily pretreated population. Further positive data could pave the way for a pivotal program in 4th-line metastatic and triple-negative breast cancer. Such a trial could begin 4Q12/1H13.

An investigator-sponsored phase II trial of neratinib in metastatic breast cancer patients with brain metastases was initiated in 1Q12. With rapid enrollment, we believe preliminary data could be available at the San Antonio 2012 or ASCO 2013 conferences. Due to the modest 6% overall response rate observed for lapatinib in this setting, a strong signal could lead to increased interest in neratinib for patients at elevated risk for CNS metastases.

Finally, enrollment will continue in two key randomized studies in neoadjuvant breast cancer, one conducted in collaboration with the National Surgical Adjuvant Breast and Bowel Project (NSABP) and another conducted by the NIH and referred to as the I-SPY 2 TRIAL (Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging and Molecular Analysis 2). Both studies are critically important in evaluating the benefit of adding neratinib to existing regimens in the neoadjuvant setting. We expect data in the 2013 timeframe.

Two trials that could generate meaningful results longer term include a phase II trial in metastatic HER2+ gastric cancer, expected to begin later this year, and a phase I trial using an IV formulation of neratinib, an IND for which is planned for 2012. Based on GSK's extensive ongoing phase III program for lapatinib in both first and second-line HER2+ metastatic gastric cancer, we believe the rationale for neratinib is attractive. The GSK data could become an important peripheral catalyst for Puma shares. Both phase III trials are fully enrolled but GSK has not provided guidance on data releases. The following table highlights key near-term events for Puma.

Puma Biotechnology – Upcoming Milestones

Product	Event	Expected
Neratinib	Follow-up data, Torisel ph.II combo trial, HER2+ and triple negative breast, multiple priors	4Q12
	NCI/NSABP first-line breast, neoadjuvant combos: neratinib/paclitaxel vs Herceptin/paclitaxel vs neratinib/Herceptin/paclitaxel; topline data	2013
	NIH I-SPY 2 trial in first-line breast, neoadjuvant setting: neratinib/paclitaxel vs Herceptin/paclitaxel vs neratinib/Herceptin/paclitaxel; topline data	2013
	Initiate phase II trial, neratinib/capecitabine vs lapatinib/capecitabine, 2nd-line and later HER2+ breast MBC	2H12
	Initiate phase II trial, neratinib/vinorelbine vs Herceptin/vinorelbine, 2nd-line and later HER2+ breast MBC	2H12
	Topline data, phase II trial, single-agent, HER2+ MBC w/brain metastases	2H12
	Initiate phase II trial, HER2+ gastric cancer	2H12
	Initiate phase III trial, neratinib/Torisel combo in HER2+ MBC; 4th-line or triple negative	2H12/1H13
Neratinib I.V.	File IND	2012

Source: SunTrust Robinson Humphrey and Puma Biotechnology

Valuation

Probability-Adjusted Valuation Suggests $19 per Share

Our 12- to 18-month price target for Puma is $19. This is based on a 35x multiple of our probability-adjusted, diluted 2017 EPS estimate of $0.94, discounted four years at 15%. We believe a 15% discount rate is appropriate given the probability adjustment applied to neratinib in its two most important indications, HER2+ metastatic breast and gastric cancers. We assume Puma enters a partnership prior to marketing approval, retaining U.S. rights. Ex-U.S., we assume a royalty in the high-teens to low-20s.

Our revenue model assumes approval in HER2+ metastatic breast cancer as a first indication, in 2H15. We model marketing approval for HER2+ gastric cancer in 2017. We assume EU marketing authorization with an approximately one-year lag for each indication. We expect neratinib to be utilized in adjuvant, neoadjuvant, and later-line metastatic breast cancer settings. The exhibit below highlights our share value calculation and includes a sensitivity analysis to evaluate share prices under various EPS multiple and discount rate scenarios. The revenue builds in both indications are discussed on page 14 and our income statement is found at the back of this report.

Puma Biotechnology, Inc. – Probability-Adjusted Valuation

Product Candidate	Probability of Approval	Potential 2017 Revenue (1)	Approximate Net Margin	Royalty Revenue (1)	Total EPS Contribution	Weighted EPS Contribution
Neratinib, breast	67%	$223	30%	$12	$1.37	$0.92
Neratinib, gastric	50%	$8	30%	$1	$0.06	$0.03
Total Revenue to Puma		**$231**	**-**	**-**	**$1.42**	**$0.94**

Notes: (1) Assumes PBYI launches alone in U.S., partners ex-U.S. for tiered royalty up to 25%.

	2017E EPS:	$0.94					
	Discounted Years	4.0		Discount Rate			
EPS Multiple	5%	10%	15%	20%	25%	30%	35%
10	8	6	5	5	4	3	3
15	12	10	8	7	6	5	4
20	16	13	11	9	8	7	6
25	19	16	14	11	10	8	7
30	23	19	16	14	12	10	9
35	27	23	**$18.90**	16	14	12	10
40	31	26	22	18	15	13	11
45	35	29	24	20	17	15	13

Source: SunTrust Robinson Humphrey

EPS Multiple Valuation Suggests Approximately $20 per Share

We also performed an EPS multiple valuation to derive an estimate of Puma's share value. Applying a 35x multiple to our 2017 EPS estimate of $1.37 and discounting four years at 25% results in a theoretical equity value of $19.71. We believe a 35x multiple and 25% discount rate are appropriate as they reflect the typical multiple for a rapidly growing, profitable biotechnology firm, and adequately risk-adjust future earnings. We prefer the probability-adjusted method as it allows a handicapped estimate of neratinib's chance of approval in each relevant indication. Our EPS multiple approach is shown below.

Puma Biotechnology – EPS Multiple Valuation

Multiple of 2017E EPS	
2017E EPS	$1.37
Multiple	35
Value	$48
Discount	25%
Years	4
Discounted value	**$19.71**

Sales Multiple Method: $10

As an alternative to the probability-adjusted approach, we applied a sales multiple approach to estimate Puma's share value. In our experience, this method is a less reliable means of assessing share value. Applying a 6x multiple to our 2017 revenue estimate of $244 million and discounting 4 years at 25% results in an equity value of $10.37, below both EPS multiple methods shown above. We believe a 6x multiple may be conservative given the growth prospects for neratinib and the higher multiples enjoyed by other emerging oncology companies early in product launch cycles. The exhibit below shows the calculation.

Puma Biotechnology – Sales Multiple Valuation

Multiple of 2017E Sales	
2017E sales	$244
Discount	25%
Years	4
Shares out in 2017	58
Discounted value	$1.73
Multiple	6
Value per share	**$10.37**

Pipeline Overview

Puma is developing a portfolio of small molecule therapies for cancer. The company's lead program, neratinib, is a novel, irreversible pan-inhibitor of the ErbB family of tyrosine kinases. The drug was previously being developed by Pfizer for multiple solid tumor indications. Puma licensed exclusive, global rights to the program following Pfizer's 2011 oncology portfolio review. The ErbB kinases are known to play an important role in tumor growth, aggressiveness, and survival. Neratinib has completed multiple phase I and II trials, demonstrating promising antitumor efficacy as both a single agent and in combination with various cytotoxic chemotherapeutics.

Neratinib possesses multiple characteristics that could lead to strong uptake in the breast and gastric cancer settings. We view the compound's impressive efficacy, including among patients who progressed following exposure to other HER2+ based regimens, and encouraging safety profile as creating the potential for significant sales in multiple breast cancer settings. If approved, we expect this profile to drive demand in metastatic HER2+ disease as well as in the adjuvant and neoadjuvant settings. In addition, earlier-stage programs include an intravenous formulation of neratinib, expected to enter phase I in 2H12/1H13, and a second pan-ErbB inhibitor,

PB357, which has previously completed phase I studies. As the bulk of Puma's equity value is tied to neratinib, the following pipeline discussion will focus on plans and progress with that program.

Puma Biotechnology - Pipeline

Product	Mechanism of Action	Indication	Status	Partner
Neratinib	HER1/2/4 inhibitor	Breast cancer	Phase II	None
		Gastric cancer	To enter phase II	None
Neratinib I.V.	HER1/2/4 inhibitor	Breast/gastric	Preclinical	None
PB357	HER1/2/4 inhibitor	Cancer	Phase I	None

Source: SunTrust Robinson Humphrey and Puma Biotechnology

Neratinib, A Novel Small Molecule ErbB Inhibitor for HER2+ Cancers

Current status and plans

At least 14 studies of neratinib are currently ongoing. In our view, the most important of these are the four phase II trials in HER2+ breast cancer: two neoadjuvant studies, one investigator-sponsored study in patients with CNS metastases, and a combination study with temsirolimus in 2nd-line and later metastatic disease. In our view, the CNS metastases and temsirolimus combination trials are the most interesting of the four, as they could generate data in 2H12 that could lead to initiation of pivotal studies in the late-2012/early-2013 timeframe. We view the two neoadjuvant studies as important for establishing neratinib's utility in earlier settings, thereby expanding the drug's potential role across the entire therapeutic paradigm. If positive, neratinib could potentially be used prior to surgery, post-surgery, in patients at risk of CNS metastases, and in patients relapsing following treatment with Herceptin, lapatinib, or various chemotherapeutic regimens.

We believe the CNS metastases study will generate key data in support of the thesis that neratinib, by readily crossing the blood-brain-barrier, could demonstrate efficacy in a key subset of breast cancer largely untreated by Herceptin. Approximately one-third of metastatic breast cancer patients experience brain metastases, and Herceptin does not penetrate the blood-brain-barrier. In addition, prior data with lapatinib demonstrated the drug's promising activity in reducing the frequency of metastatic lesions. However, we believe lapatinib's sub-10% single agent ORR leaves room for improvement. Assuming neratinib's impressive preliminary activity holds in the ongoing study, we believe it is reasonably likely to generate data at least comparable to that reported for lapatinib.

The temsirolimus combination study could potentially lead to initiation of a pivotal program in late-stage metastatic disease by early-2013. The combined inhibition of EGFR and Her2, via neratinib, and mTOR, via temsirolimus, should serve to attenuate two common signaling pathways involved in tumor growth and metastasis. We believe preliminary data (discussed later) demonstrate encouraging signs of efficacy in heavily pre-treated patients. In the first 15 evaluable patients, the combination resulted in a 60% ORR. While early, we believe this provides important preliminary evidence of the combination's promise.

Thus, while multiple additional studies are being conducted by various independent groups, in our view these four are the most important in determining the future regulatory path. The following table summarizes the key ongoing trials of neratinib in breast cancer.

Puma Biotechnology – Overview of Key Ongoing Clinical Trials

Drugs	Design	Entry Criteria	Treatment	Endpoints	Notes	Key dates
Neratinib phase II trial in patients w/brain metastases	Open label, two cohort, single site trial, expected to enroll 45 patients	HER2+ metastatic disease. Cohort 1: new or progressive CNS lesions, including patients who progressed after 1 line of therapy for CNS disease. Cohort 2: CNS lesions amenable to surgery, may have received prior therapy for CNS lesions.	240mg daily	Primary endpoint: Overall response rate in CNS by composite response criteria. Secondary endpoint: PFS, OS, CNS response by MacDonald criteria, safety and tolerability	Conducted by the Dana Farber Breast Cancer Consortium	Initiated 1Q12, data possible 4Q12
Neratinib phase I/II combo trial with temsirolimus	Phase I/II trial to explore MTD of combo; single arm, two cohort trial, expected to enroll up to 65 patients	HER2+ metastatic disease w/progression on Herceptin OR triple negative disease. Cohort 1: HER2 amplified. Cohort 2: triple negative	240mg daily neratinib + escalating temsirolimus doses (8mg, 15mg, 25mg)	Primary endpoint, phase II: ORR in both cohorts. Secondary endpoints: 6mo PFS and response rates, correlation of PTEN and PI3K mutational changes with response	Triple negative patients did not achieve PR or SD for ≥6 months (n=5)	Initiated 2010, preliminary data presented 4Q11, follow-up data possible 2H12
Neratinib phase II combo trial with Herceptin, paclitaxel	Phase II trial to compare combos; three arms: taxol/Herceptin, taxol/neratinib, taxol/Herceptin/neratinib in up to 120 patients in the **neoadjuvant setting**	HER2+ locally advanced disease.	Arm 1: 80mg/m2 taxol + 4mg/8mg/kg Herceptin + 60mg/m2 doxorubicin + 600mg/m2 cyclophosphamide. Arm 2: replaces Herceptin w/neratinib. Arm 3: contains Herceptin and neratinib.	Primary endpoint: pathologic CR rate in breast and lymph nodes. Secondary endpoints: pCR in breast tissue, clinical CR, recurrence-free survival, OS	Conducted in collaboration with NSABP. Original protocol only compared Herceptin w/neratinib. Third arm added 2012.	Initiated 2010, data possible 2H12
Neratinib phase II combo trial with Herceptin, paclitaxel	Multi-arm phase II trial in up to 800 patients designed to utilize biomarkers to guide treatment decisions. Among agents being assessed: neratinib, ABT-888, AMG 386, AMG 479. **Neoadjuvant setting**	Invasive breast cancer, regional metastases allowed, no-prior cytotoxic therapies.	Three most important arms: neratinib + taxol, Herceptin + taxol, neratinib + Herceptin + taxol	Primary endpoint: pathologic CR rates. Secondary endpoints: 3 and 5 year relapse-free and overall survival, pCR predictions based on exploratory markers	Conducted by NIH (I-SPY 2 TRIAL)	Initiated in 2010, enrollment ongoing, potential data 2H12

Source: SunTrust Robinson Humphrey, Puma Biotechnology, ClinicalTrials.gov

Planned trials to focus on combos, CNS metastases, gastric cancers

Puma is planning to conduct multiple trials, potentially including a pivotal program over the next 12 to 18 months. The first trial we expect the company to initiate will be a phase II study in the second/third-line HER2+ metastatic setting. Details have not yet been disclosed, but we expect the trial to be a randomized study with neratinib added to various chemotherapeutic regimens, such as capecitabine, paclitaxel, and vinorelbine. Previous data, outlined below, demonstrated neratinib's promise when combined with each of these agents. The company has indicated plans to initiate this study in the mid-2012 timeframe. We would anticipate data 12 to 18 months later.

A potential phase III program evaluating the combination of neratinib with temsirolimus in heavily pretreated patients could begin in late 2012 or early 2013. We view this study as potentially the most rapid path for neratinib to reach the market. Temsirolimus is currently approved for advanced kidney cancer and works via inhibition of the mammalian target of rapamycin (mTOR), leading to disruption of the PI3K/AKT pathway, which results in G1 arrest and reduced cell proliferation. As discussed above, the preliminary signal from an ongoing phase I/II study has shown the combination to be potent and well-tolerated, with a preliminary ORR of approximately 60% in late-stage disease. Positive follow-up results, expected 2H12, could lead to initiation of a pivotal program in late-stage metastatic breast cancer.

In addition, a larger phase II program evaluating the efficacy of neratinib in patients with CNS metastases is planned for 2H12/1H13. As discussed previously, an ongoing trial in this setting is being conducted by the Dana

Farber Breast Cancer Consortium. We expect Puma to apply the preliminary findings from this study in the design of the upcoming trial. Preliminary data from the Dana Farber trial could be available by year-end; a company-sponsored trial could follow, though Puma has not provided detailed guidance.

Finally, a phase II trial in HER2+ gastric cancer is expected to begin this year. As no agents are currently approved for 2nd-line HER2+ metastatic gastric cancer, we believe positive results would likely lead to a phase III program. As a reminder, GSK is currently conducting two phase III trials of lapatinib in HER2+ gastric cancer, and both studies are fully enrolled. Positive data from these trials could bode well, in our view, for neratinib's potential efficacy in gastric cancer. The following table summarizes the planned trials Puma has outlined for neratinib over the upcoming 12-18 months.

Puma Biotechnology – Overview of Planned Neratinib Trials

Drugs	Design	Entry Criteria	Treatment	Endpoints	Notes
Neratinib phase II combo trial with chemotherapy	TBD. Expect randomized multicenter combination study w/various chemotherapeutic agents.	HER2+ metastatic disease; previously treated with ≥1 prior line of therapy	TBD. Expect neratinib + capecitabine vs lapatinib + capecitabine as well as neratinib + vinorelbine vs herceptin + vinorelbine	NA	Expected to begin mid-2012.
Neratinib phase II trial in patients with brain metastases	TBD. Expect randomized, controlled trial, potentially neratinib + capecitabine vs lapatinib + capecitabine	HER2+ metastatic disease with CNS lesions	TBD. Expect standard 240mg daily neratinib dosing	NA	Potential initiation 2H12/1H13.
Neratinib phase III trial in 4th-line metastatic disease, combo with temsirolimus	TBD.	HER2+ metastatic disase in ≥3rd-line disease.	TBD. Expect standard 240mg daily neratinib dosing + 8mg weekly Torisel	NA	Potentially 4Q12 pending positive data from ongoing phase I/II combo trial.
Neratinib phase II trial in HER2+ gastric cancer	TBD.	HER2+ gastric cancer, expected to enroll ≥ 2nd-line disease.	Expect standard 240mg daily neratinib	NA	Expected to begin 2012.

Source: SunTrust Robinson Humphrey and Puma Biotechnology

Prior Data Demonstrate Promising Efficacy in Multiple Settings

According to ClinicalTrials.Gov, at least 32 trials of neratinib have been completed or are in progress, including studies in refractory solid tumors, non-small cell lung cancer, and breast cancer. The majority of the prior clinical data has been collected by Pfizer, Wyeth, and various cancer cooperative groups. We believe the most relevant of the prior studies are the phase II trials conducted in HER2+ breast cancer, as this is the primary focus of Puma's near-term development efforts. The following discussion will therefore focus on the breast data.

The totality of prior neratinib data demonstrate an impressive efficacy signal, from both single-agent and combination regimens. Below we summarize three key combination studies as well as a phase II single-agent trial. Where possible, we also show comparable data from trials of existing agents, primarily Herceptin (trastuzumab) and Tykerb (lapatinib). While cross-trial comparisons are unreliable and not a recommended means of evaluating data, in the absence of randomized trial results they may provide a high-level view of relative activity.

Single Agent Activity in HER2+ Breast Cancer

Neratinib has demonstrated impressive efficacy as a single agent in patients who have progressed following treatment with Herceptin. Pfizer/Wyeth previously conducted a single agent phase II trial of neratinib in HER2+

metastatic breast cancer, evaluating two cohorts; one with no prior Herceptin exposure, and a second with prior exposure. Among patients with prior Herceptin exposure, most (91%) had been treated for metastatic disease, and a majority (77%) had been treated with a cytotoxic regimen in the metastatic setting. In the prior exposure cohort, the observed overall response rate (ORR) was 24% and median progression-free survival (PFS) was 39.6 weeks. Among patients without prior Herceptin exposure, the results were even more impressive, demonstrating a 56% ORR and 52.4 week PFS. We believe this compares favorably to single agent activity reported for lapatinib. As the following table shows, in a slightly more heavily pretreated population, lapatinib-treated patients experienced a 7% ORR and 8.1 week median PFS. Despite the caveats associated with cross-trial comparisons, we believe the qualitative signal suggests neratinib's promise in previously-treated metastatic disease.

Summary of Phase II Trial Evaluating Neratinib as a Single-Agent in Advanced HER2+ Breast Cancer

Neratinib arm	Evaluable patients	ORR (RECIST)	Median duration of response	Median PFS, weeks	16-Week PFS rate (primary endpoint)	Median overall survival
Prior trastuzumab treatment (1)	63	24%	39.3 wks	22.3 wks	59%	NR
No prior trastuzumab	64	56%	52.4 wks	39.6 wks	78%	NR
Lapatinib single agent (2)	145	7%	-	8.1 wks	-	39.0 wks

Source: (1) J.Clin.Oncol. 28:1301-1307, 2010; 91% had received prior trastuzumab for metastatic disease; 77% had received prior cytotoxic therapy for metastatic disease. (2) J Clin Oncol 26: 2008 (May 20 suppl; abstr 1015); www.gsk-clinicalstudyregister.com, study EGF104900; 100% had received prior trastuzumab + cytotoxic therapy for metastatic disease.

Combination Studies Demonstrate Safety, Tolerability, Efficacy

Neratinib has been evaluated in multiple phase II combination trials with chemotherapeutic and targeted agents for breast cancer. Pfizer in 2010 presented the results of a phase II trial of neratinib in combination with paclitaxel in HER2+ metastatic breast cancer. Two subsets were evaluated, patients who were first-line metastatic and those who had received up to three prior cytotoxic regimens for metastatic disease. The trial was non-randomized and the goal was to assess the safety and tolerability of the combination in solid tumors, then evaluate the combo's MDT in the two settings.

The neratinib/paclitaxel combination results showed encouraging safety, tolerability and preliminary efficacy. Full doses of both agents were utilized in the phase II portion of the study, 240mg neratinib, daily, and 50mg/m2 paclitaxel on days one, eight, and 15 of a 28-day cycle. While the size of the trial was modest (n=99), we believe the results demonstrate at least comparable efficacy with a phase III trial of the lapatinib/paclitaxel combination, previously reported by GSK. First-line patients experienced similar response rates, at 70% and 69% for neratinib and lapatinib, respectively, when combined with paclitaxel. However, PFS and clinical benefit rates appear to favor neratinib. As shown in the following table, the median PFS data for neratinib in both the first line and more refractory subgroups were consistent, at 57.0 weeks and 55.6 weeks, respectively. This compares favorably to the 42.0 week PFS data from the phase III combination trial of lapatinib and paclitaxel. The key takeaways, in our view, are that neratinib's efficacy is consistent in first-line and more heavily pretreated populations, and that PFS data in the first-line setting appear to be at least in-line with first-line data reported for lapatinib, when the same paclitaxel combination is employed. The following table summarizes the key findings of the neratinib/paclitaxel combination.

Summary of Phase II Trial Evaluating the Combination of Neratinib + Paclitaxel in Metastatic HER2+ Breast Cancer

Part 2: Neratinib 240mg daily + 80mg/m2 paclitaxel day 1, 8, 15 of 28 day cycle (1)	Evaluable patients	ORR (RECIST)	Median duration of response	Median PFS, weeks	Clinical benefit response rate (3)	Median overall survival
Overall population	99	72%	NR	57.0 wks	82%	NR
First-line setting	33	70%	NR	57.0 wks	82%	NR
≥ Second-line setting	66	74%	NR	55.6 wks	82%	NR
Lapatinib + paclitaxel, first-line setting (2)	222	69%	40.3 wks	42.0 wks	75%	27.8 mos

Source: (1) Poster P3-14-04, 33rd Annual San Antonio Breast Cancer Symposium, 2010.
(2) www.gsk-clinicalstudyregister.com, study EGF104535. (3) ORR + stable disease of at least 24 wks.

Pfizer also completed a phase I/II trial evaluating neratinib in combination with the cytotoxic agent vinorelbine in HER2+ metastatic breast cancer. Patients in this trial were required to have been previously treated with at least one Herceptin-based regimen for metastatic disease, as well as one to two cytotoxic regimens. Two key groups of patients were those who were naïve to prior lapatinib therapy, and with those with prior exposure. The results demonstrated encouraging efficacy in both subsets. Importantly, the median PFS in patients with no prior lapatinib therapy was approximately 44.1 weeks, which is impressive given that this population had received multiple prior therapies for metastatic disease. This compares favorably to PFS data from lapatinib in combination with vinorelbine in ≥2nd-line metastatic disease (see table below). Similarly, the neratinib/vinorelbine combination demonstrated promising ORR and PFS outcomes compared with combination data for Herceptin and vinorelbine, in patients previously exposed to a Herceptin regimen for metastatic disease.

In our view, the primary takeaways from this study are that prior treatment with antibody or kinase inhibitor-based therapies does not preclude therapeutic benefit from neratinib, despite the fact that each approach modulates the same signaling pathway. The following table highlights the phase II portion of the neratinib + vinorelbine trial and includes relevant data from studies of lapatinib and Herceptin in broadly similar settings.

Summary of Phase II Trial Evaluating the Combination of Neratinib + Vinorelbine in HER2+ MBC

Part 2: Neratinib 240mg + vinorelbine 15mg/m2 day 1, 8 of 21-day cycle (1)	Evaluable patients	ORR (RECIST)	Stable disease ≥24 weeks	Duration of response	Median PFS, weeks
Overall population	68	56%	18%	NR	-
Prior lapatinib treatment	12	50%	25%	-	-
No prior lapatinib	56	57%	9%	-	44.1 wks
Trastuzumab + vinorelbine in ≥ 2 line MBC (2)	26	27%	-	-	TTP 28.7 wks
Lapatinib + vinorelbine in ≥ 2 line MBC (3)	19	26%	-	-	20 wks

Source: (1) Poster P3-14-05, 33rd Annual San Antonio Breast Cancer Symposium, 2010
(2) J Clin Oncol 28:15s, 2010 (suppl; abstr 1113); subset with prior trastuzumab exposure for metastatic disease. (3) J Clin Oncol 29: 2011 (suppl; abstr e13079).

Pfizer also conducted a phase I/II trial of neratinib and capecitabine in HER2+ metastatic breast cancer. As with the trials above, this study was intended to evaluate the safety, tolerability, and preliminary efficacy of the combination. All patients had been previously treated with Herceptin in the metastatic setting, as well as with a taxane in the adjuvant, neoadjuvant, or metastatic setting. We believe the data show consistency with the above results, indicating neratinib's efficacy in patients previously exposed to HER2+ regimens. In addition, the data again suggest favorable activity compared with both lapatinib and Herceptin, in qualitatively similar settings. We believe that the ORR data, duration of responses, and median PFS data all demonstrate neratinib's promise in pretreated populations. The following table summarizes the capecitabine combination data as well as comparable trial results from lapatinib and Herceptin.

Summary of Phase II Trial Evaluating the Combination of Neratinib + Capecitabine in HER2+ MBC

Part 2: Neratinib 240mg + capecitabine 750mg/m2 BID, days 1-14 of 21-day cycle (1)	Evaluable patients	ORR (RECIST)	Median duration of response	Median PFS, weeks	Stable disease ≥24 weeks
Overall population	68	63%	-	-	9%
Prior lapatinib treatment	7	57%	48.3 wks	35.9 wks	14%
No prior lapatinib	61	64%	46.3 wks	40.3 wks	8%
Lapatinib + capecitabine in ≥2nd line MBC (2)	198	24%	-	28.3 wks	-
Trastuzumab + capecitabine in ≥2nd line MBC (3)	78	48%	16.9 wks	35.4 wks	-

Source: (1) Abstract P1-12-09, 34th Annual San Antonio Breast Cancer Symposium, 2011.
(2) N.Engl.J.Med 2006; 355:2733-43. Breast Cancer Res Treat (2008) 112:533-543. Tykerb label.
(3) J. Clin. Oncol. 27(12) 1999-2006. 70% had prior trastuzumab + taxane for metastatic disease; 26% had prior trastuzumab with or without or other chemotherapy for metastatic disease.

At the 2012 ASCO conference, Puma announced encouraging preliminary data from an NCI-supported phase I study evaluating the triplet combination of neratinib, paclitaxel, and Herceptin in refractory HER2+ metastatic breast cancer. In this ongoing trial, dose escalation of neratinib resulted in the observation of a dose-limiting toxicity (Grade 3 diarrhea) at the maximum planned dose of 240mg, once daily. The company expects to ultimately be able to administer neratinib at or near the full dose used in other combinations, potentially utilizing a 200mg dose. The observation of diarrhea in this combo is not surprising, given the known tendency for kinase inhibitors to induce this effect, as well as lapatinib's established poor tolerability in this same triplet (dose reductions of up to 50% required). We believe the important takeaways are the improved relative tolerability reported for neratinib, along with the impressive observed anti-tumor activity. Among 15 evaluable patients, six responses were reported, including one CR. As this population had been exposed to an average of four prior therapies, including taxane and Herceptin-based regimens, we believe the observed activity is impressive. Puma plans to further evaluate data from this trial as plans for registration studies evolve.

Competitive Landscape

Multiple drugs are currently in development for HER2+ breast cancer. As the following table shows, most of these belong to one of four primary categories; new formulations of existing drugs, biosimilar versions of marketed therapies, small molecules, and immunotherapies. We believe the relative lack of orally-available options creates an opportunity for neratinib to be utilized in various combinations, with or without antibody-based therapies. Of the small molecules in development, Afatinib is most advanced, currently in a global phase III program for first and second-line metastatic breast cancer. In our view, the preliminary data for neratinib discussed above are more promising than currently available data from many of these drug candidates. For example, preliminary data from a phase II trial of afatinib in HER2+ metastatic breast cancer demonstrated an ORR in the low-20% range (J Clin Oncol 27:15s, 2009 (suppl; abstr 1023)). Other oral agents listed below have yet to complete substantive phase II programs in HER2+ metastatic breast cancer. Thus, in our view, the landscape for a daily oral therapy is relatively open.

Summary of Competitive Landscape for HER2 Targeting Agents

Drug	Status	Company (originator)
Pertuzumab	Approved	Roche
Trastuzumab subcutaneous	BLA filed	Roche
Afatinib	Phase-III	Boehringer-Ingleheim
Cancer vaccine E75	Phase-III	Galena
Trastuzumab biosimilar	Phase-III	Celltrion
Trastuzumab biosimilar	Phase-III	Shanghai CP Guojian
Trastuzumab emtansine (T-DM1)	Phase-III	Roche/Immunogen
AC 480	Phase-II	Ambit (BMS)
AE 37	Phase-II	Antigen Express
Anti-CD3-anti-HER2/neu-activated T cells	Phase-II	Transtarget
AZD 8931	Phase-II	AstraZeneca
BMS 690514	Phase-II	BMS
HER2-antigen specific cancer immunotherapeutic	Phase-II	GSK
Lapuleucel-T	Phase-II	Dendreon
Varlitinib	Phase-II	ASLAN (Array)

Source: AdisInsight

We believe the recent approval of Roche's Perjeta (pertuzumab) and the presentation of phase III data from the EMELIA study of trastuzumab emtansine (T-DM1) change the landscape for early therapy in metastatic breast cancer. Moving forward, we expect first-line therapy to consist of Herceptin + Perjeta, followed by T-DM1 second-line, assuming it ultimately receives marketing clearance, likely in the 2013 time frame. In our view, neratinib and combinations thereof would therefore see utilization in third-line settings. If data support its benefit over lapatinib, we expect neratinib to become the preferred oral agent for HER2+ regimens following various permutations of the three agents listed above. Thus, while the landscape has changed with the approval of Perjeta and presentation of strongly positive T-DM1 data, our view of the neratinib opportunity remains enthusiastic.

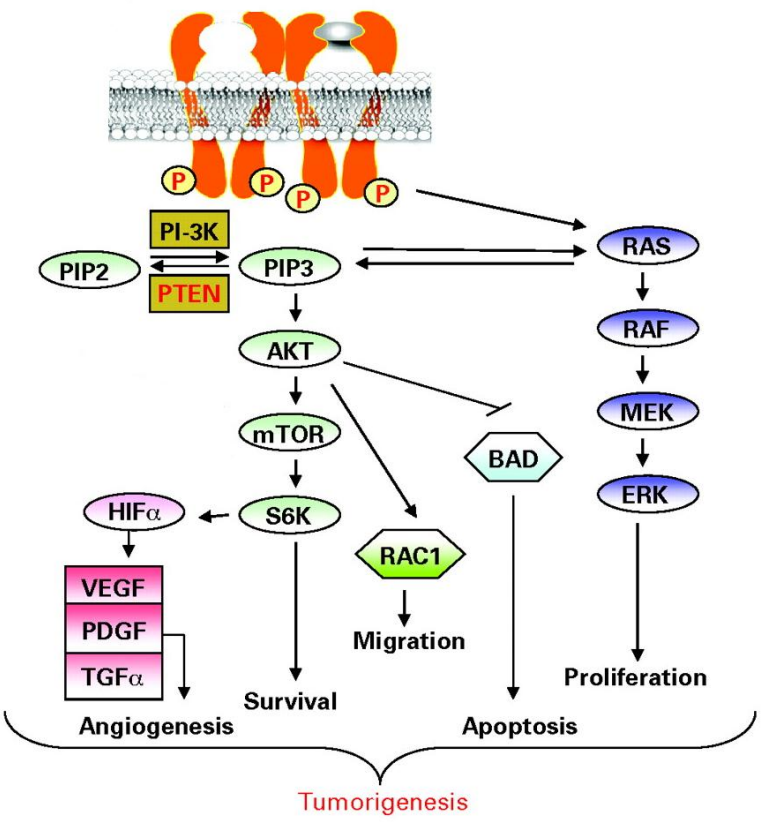
Importance of HER2 Signaling in Cancer

Uncontrolled signaling via the HER2 cascade is a well-documented pathway to tumorigenesis. Under normal conditions, the HER2 receptor forms dimers with other ErbB receptors, such as EGFR and HER3, to create a signaling complex. The complex becomes activated via phosphorylation of multiple tyrosine sites within the intracellular domain. The resulting activated kinase then induces multiple transduction pathways, the most important of which are the AKT and MAPK (MEK) pathways. Therefore, when uncontrolled signaling occurs, as in cancer transformation, hyperactivation of these pathways results in an upregulation of protein synthesis, which leads to increased proliferation, angiogenesis, migration, and survival. Due to the central role of HER2 in the dimerization and subsequent signaling processes, it is a critically important target for drug development.

Antibody therapies such as Herceptin target the extracellular domain of HER2, leading to disruption of intracellular signaling. Small molecule therapeutics such as neratinib and lapatinib target the intracellular domain, binding at ATP-binding sites and preventing phosphorylation and activation. In the schematic below, neratinib would bind in the areas marked with a P, and therefore block transduction of the initial signals leading to the AKT and MAPK pathways. An irreversible inhibitor such as neratinib, by permanently disabling the HER2 cascade, thus makes for an attractive drug development candidate.

The following diagram summarizes the process. Dimerized HER2 receptor complexes are shown at the top, in red. Intracellular phosphorylation sites are designated with a P, and the downstream outcomes of each cascade are highlighted at the bottom. Of note is the importance of AKT/mTOR in cell migration and survival. This illustrates the rationale behind Puma's ongoing phase II combination study evaluating neratinib with the mTOR inhibitor Torisel. Synergistic efficacy could potentially lead to improved antitumor responses vs. each single agent alone.

Schematic of HER2/EGFR/HER3 Signaling Cascade



Source: JCO March 1, 2010 vol. 28 no. 7 1091-1096

Market Opportunity in Breast and Gastric Cancers

We believe the market opportunity for neratinib, pending successful phase III development, could be substantial. Even if approval were only granted in ≥3rd-line HER2+ metastatic breast cancer, the available data would likely lead to utilization in a variety of settings. Adjuvant, second-line, and CNS-metastatic disease are all settings in which uptake could be reasonably assumed. As a reminder, approximately 30% of metastatic breast cancer patients experience brain metastases. While we do not specifically break this group out, we note that positive data in the ongoing phase II CNS metastases trial could lead to revisions to our model. In addition, we include neoadjuvant use in our model, as we assume FDA Guidance for this setting will be clarified before the potential launch of neratinib. We also include modest penetration into the HER2+ gastric cancer indication. While smaller than the breast market, gastric could generate meaningful incremental revenue.

We currently model a late-2015 market entry, followed by gradual market penetration into the settings outlined above. We expect Puma to partner the drug outside the U.S., in exchange for a royalty in the mid-teen to mid-20% range. We currently estimate revenue from breast indications to total approximately $300M in 2017, growing to approximately $685M in 2020. The following tables highlight our estimates in each of the HER2+ breast cancer settings, neoadjuvant, adjuvant, and second-line metastatic.

Neratinib Revenue Summary: HER2+ Neoadjuvant, Adjuvant, and Second-line Metastatic Breast Cancer Settings

Neoadjuvant breast						
Neoadjuvant breast (U.S.)	**2015E**	**2016E**	**2017E**	**2018E**	**2019E**	**2020E**
Breast cancer incidence	239,339	241,732	244,150	246,591	249,057	251,548
HER2+ segment	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%
Estimated HER2+ population	59,835	60,433	61,037	61,648	62,264	62,887
Metastatic at diagnosis	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%
Regional lymphnode involvement at diagnosis	33.0%	33.0%	33.0%	33.0%	33.0%	33.0%
Lymphnode involvement and metastatic population, annually	**22,737**	**22,965**	**23,194**	**23,426**	**23,660**	**23,897**
Penetration rate	1.0%	5.0%	10.0%	13.0%	15.0%	18.0%
Number of treated patients	227	1,148	2,319	3,045	3,549	4,301
Annual cost	34,800	35,844	36,919	38,027	39,168	40,343
Duration (yrs)	0.5	0.5	0.5	0.5	0.5	0.5
Total U.S. sales, neoadjuvant setting	**$3,956,272**	**$20,578,551**	**$42,815,733**	**$57,903,569**	**$69,504,326**	**$86,766,421**

Neoadjuvant breast						
Neoadjuvant breast (ex-U.S.)	**2015E**	**2016E**	**2017E**	**2018E**	**2019E**	**2020E**
Breast cancer incidence	241,732	244,150	246,591	249,057	251,548	254,063
HER2+ segment	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%
Estimated HER2+ population	60,433	61,037	61,648	62,264	62,887	63,516
Metastatic at diagnosis	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%
Regional lymphnode involvement at diagnosis	33.0%	33.0%	33.0%	33.0%	33.0%	33.0%
Lymphnode involvement and metastatic population, annually	**22,965**	**23,194**	**23,426**	**23,660**	**23,897**	**24,136**
Penetration rate	0.0%	2.0%	6.0%	8.0%	10.0%	12.0%
Number of treated patients	-	464	1,406	1,893	2,390	2,896
Annual cost	22,620	23,299	23,998	24,717	25,459	26,223
Duration (yrs)	0.5	0.5	0.5	0.5	0.5	0.5
Total ex-U.S. sales, neoadjuvant setting	**-**	**$5,403,927**	**$16,865,117**	**$23,393,042**	**$30,419,727**	**$37,974,770**

Source: SunTrust Robinson Humphrey

Adjuvant breast

Adjuvant breast (U.S.)	2015E	2016E	2017E	2018E	2019E	2020E
Breast cancer incidence	239,339	241,732	244,150	246,591	249,057	251,548
HER2+ segment	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%
Estimated HER2+ population	59,835	60,433	61,037	61,648	62,264	62,887
Metastatic at diagnosis	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%
Regional lymphnode involvement at diagnosis	33.0%	33.0%	33.0%	33.0%	33.0%	33.0%
Lymphnode involvement and metastatic population, annually	**22,737**	**22,965**	**23,194**	**23,426**	**23,660**	**23,897**
Penetration rate	2.0%	6.0%	12.0%	17.0%	20.0%	22.0%
Number of treated patients	455	1,378	2,783	3,982	4,732	5,257
Annual cost	34,800	35,844	36,919	38,027	39,168	40,343
Duration (yrs)	1	1	1	1	1	1
Total U.S. sales, adjuvant setting	**$15,825,090**	**$49,388,522**	**$102,757,759**	**$151,440,103**	**$185,344,870**	**$212,095,695**

Adjuvant breast

Adjuvant breast (ex-U.S.)	2015E	2016E	2017E	2018E	2019E	2020E
Breast cancer incidence	241,732	244,150	246,591	249,057	251,548	254,063
HER2+ segment	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%
Estimated HER2+ population	60,433	61,037	61,648	62,264	62,887	63,516
Metastatic at diagnosis	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%
Regional lymphnode involvement at diagnosis	33.0%	33.0%	33.0%	33.0%	33.0%	33.0%
Lymphnode involvement and metastatic population, annually	**22,965**	**23,194**	**23,426**	**23,660**	**23,897**	**24,136**
Penetration rate	0.0%	2.0%	5.0%	7.0%	10.0%	12.0%
Number of treated patients	-	464	1,171	1,656	2,390	2,896
Annual cost	22,620	23,299	23,998	24,717	25,459	26,223
Duration (yrs)	1	1	1	1	1	1
Total ex-U.S. sales, adjuvant setting	**-**	**$10,807,855**	**$28,108,529**	**$40,937,823**	**$60,839,454**	**$75,949,540**

Second-line breast

Second-line metastatic breast (U.S.)	2015E	2016E	2017E	2018E	2019E	2020E
Breast cancer incidence	239,339	241,732	244,150	246,591	249,057	251,548
HER2+ segment	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%
Estimated HER2+ population	59,835	60,433	61,037	61,648	62,264	62,887
Metastatic at diagnosis	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%
Regional lymphnode involvement at diagnosis	33.0%	33.0%	33.0%	33.0%	33.0%	33.0%
Lymphnode involvement and metastatic population, annually	**22,737**	**22,965**	**23,194**	**23,426**	**23,660**	**23,897**
Penetration rate	2.0%	8.0%	15.0%	22.0%	28.0%	34.0%
Number of treated patients	455	1,837	3,479	5,154	6,625	8,125
Annual cost	34,800	35,844	36,919	38,027	39,168	40,343
Duration (yrs)	0.6	0.6	0.6	0.6	0.6	0.6
Total U.S. sales, second-line setting	**$9,495,054**	**$39,510,818**	**$77,068,319**	**$117,588,786**	**$155,689,691**	**$196,670,554**

Second-line breast

Second-line breast (ex-U.S.)	2015E	2016E	2017E	2018E	2019E	2020E
Breast cancer incidence	241,732	244,150	246,591	249,057	251,548	254,063
HER2+ segment	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%
Estimated HER2+ population	60,433	61,037	61,648	62,264	62,887	63,516
Metastatic at diagnosis	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%
Regional lymphnode involvement at diagnosis	33.0%	33.0%	33.0%	33.0%	33.0%	33.0%
Lymphnode involvement and metastatic population, annually	**22,965**	**23,194**	**23,426**	**23,660**	**23,897**	**24,136**
Penetration rate	0.0%	5.0%	9.0%	13.0%	17.0%	20.0%
Number of treated patients	0	1,160	2,108	3,076	4,062	4,827
Annual cost	22,620	23,299	23,998	24,717	25,459	26,223
Duration (yrs)	0.6	0.6	0.6	0.6	0.6	0.6
Total ex-U.S. sales, second-line setting	**-**	**$16,211,782**	**$30,357,211**	**$45,616,432**	**$62,056,243**	**$75,949,540**

Source: SunTrust Robinson Humphrey

We also model incremental revenue from neratinib in HER2+ gastric cancer. Assuming positive phase III data and a 2016 launch, we estimate steady growth in both U.S. and ex-U.S. markets, reaching approximately $88M in total 2020 sales. The following revenue model summarizes our estimate of neratinib's sales in HER2+ gastric cancer.

Gastric						
Gastric cancer (U.S.)	**2015E**	**2016E**	**2017E**	**2018E**	**2019E**	**2020E**
Gastric and esophageal cancer incidence	37,600	37,976	38,356	38,739	39,127	39,518
HER2+ segment	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%
Estimated HER2+ population	9,400	9,494	9,589	9,685	9,782	9,879
Penetration rate	0.0%	0.5%	3.0%	7.0%	10.0%	13.0%
Number of treated patients	0	47	288	678	978	1,284
Annual cost	34,800	35,844	36,919	38,027	39,168	40,343
Duration (yrs)	0.8	0.8	0.8	0.8	0.8	0.8
Total U.S. sales, neoadjuvant setting	**-**	**$1,276,136**	**$7,965,386**	**$19,334,912**	**$28,734,441**	**$38,860,171**

Gastric						
Gastric cancer (ex-U.S.)	**2015E**	**2016E**	**2017E**	**2018E**	**2019E**	**2020E**
Gastric and esophageal cancer incidence	136,900	138,269	139,652	141,048	142,459	143,883
HER2+ segment	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%
Estimated HER2+ population	34,225	34,567	34,913	35,262	35,615	35,971
Penetration rate	0.0%	0.0%	1.0%	3.0%	5.0%	7.0%
Number of treated patients	0	0	349	1,058	1,781	2,518
Annual cost	22,620	23,299	23,998	24,717	25,459	26,223
Duration (yrs)	0.8	0.8	0.8	0.8	0.8	0.8
Total U.S. sales, neoadjuvant setting	**-**	**-**	**$6,283,687**	**$19,610,758**	**$34,001,785**	**$49,520,880**

Source: SunTrust Robinson Humphrey

As mentioned above, assuming approval in the HER2+ breast and gastric indications, we expect Puma to market the drug alone in the U.S. and enter a partnership for ex-U.S. markets. At this point, our model only assumes an EU partnership. Upside to our global revenue estimates could come from a Japanese or broader Asian partnership. For convenience, below is a summary breakout of U.S. and ex-U.S. sales in breast and gastric cancers, as well as our estimate of royalty revenue to Puma.

Summary of Neratinib Revenue Contributions, HER2+ Breast and Gastric cancers

	2015E	2016E	2017E	2018E	2019E	2020E
U.S. Sales, Breast	**$29,276,416**	**$109,477,890**	**$222,641,811**	**$326,932,458**	**$410,538,887**	**$495,532,669**
Ex-U.S. Sales, Breast	**-**	**$32,423,565**	**$75,330,857**	**$109,947,297**	**$153,315,423**	**$189,873,851**
U.S. Sales, Gastric	**-**	**$1,276,136**	**$7,965,386**	**$19,334,912**	**$28,734,441**	**$38,860,171**
Ex-U.S. Sales, Gastric	**-**	**-**	**$6,283,687**	**$19,610,758**	**$34,001,785**	**$49,520,880**
WW Revenue, Breast	**$29,276,416**	**$141,901,455**	**$297,972,667**	**$436,879,755**	**$563,854,310**	**$685,406,520**
WW Revenue, Gastric	**-**	**$1,276,136**	**$14,249,072**	**$38,945,669**	**$62,736,226**	**$88,381,051**
WW Revenue, all indications	**$29,276,416**	**$143,177,591**	**$312,221,740**	**$475,825,424**	**$626,590,536**	**$773,787,571**
Total U.S. sales	**$29,276,416**	**$110,754,026**	**$230,607,196**	**$346,267,370**	**$439,273,328**	**$534,392,840**
Total ex-U.S. sales	**-**	**$32,423,565**	**$81,614,543**	**$129,558,054**	**$187,317,208**	**$239,394,731**
Royalty on ex-U.S. sales	16.0%	16.0%	16.0%	16.0%	18.0%	18.0%
Total royalty revenue to Puma	**-**	**$5,187,770**	**$13,058,327**	**$20,729,289**	**$33,717,097**	**$43,091,052**

Source: SunTrust Robinson Humphrey

Partnership Overview

Pfizer License: Up to $187M in Milestones, Royalty 10% - 20%

Puma licensed neratinib from Pfizer in 2Q11, in exchange for up to $187M in development and sales-based milestones. In addition, Pfizer is eligible to receive a tiered royalty on sales, ranging from approximately 10% to

20%. We believe the majority of the milestone payments occur at sales levels in the $500M or above range. In our model, we assume a 10% royalty on initial sales, growing by 1% for each $100M in incremental revenue, to a total of approximately 20% at sales >$1B. While many ongoing studies were initiated by Pfizer, the company will transfer responsibility of ongoing trials to Puma in 1H12. The two companies will share development costs for ongoing studies, with Puma's contribution capped at an undisclosed level. Puma will be responsible for the conduct and funding of any new trials.

The overall agreement covers IP related to the development, manufacture, and commercialization of oral and IV formulations of neratinib, as well as the phase I drug candidate PB357. Given the back-ended nature of the milestones, we believe the license provides attractive economics to Puma and allows the company to dedicate the majority of financial resources to developing the asset, rather than paying for it. In our view, this affords the greatest opportunity for success, after which both parties share in the economic gains.

Summary of Key Neratinib IP

The following table highlights key expiries for neratinib. We expect the company to receive a two- to three-year Hatch Waxman extension on various of these patents. Therefore, we expect neratinib to have an approximately 10- to 12-year market opportunity before the first potential generic competition.

Drug	Patent	Expiry
Neratinib	Composition of matter	2025
	Methods of use in breast cancer	2025
	Polymorph	2028
	Family of structures, including neratinib	2019

Key Management

Name	Position	Previous
Alan Auerbach	CEO	CEO, Cougar Biotechnology; Biotechnology analyst, Wells Fargo; Research analyst, Seidler Companies
Charles Eyler	SVP, Finance, Treasurer	VP, Finance, Cougar Biotechnology; CFO, COO, Hayes Medical
Richard Phillips, Ph.D.	SVP, Regulatory Affairs, Quality Assurance, Pharmacovigilance	Global Regulatory Consultant, PPD; SVP, Regulatory Affairs, Cougar; Director, Regulatory Affairs, Amgen

Summary Balance Sheet

Puma ended 1Q12 with approximately $50M in cash and equivalents. We currently assume the company will burn approximately $25M in 2012, growing to the $30M-range in 2013 as Puma absorbs a greater share of ongoing clinical trial costs. As a result, we believe the company's cash on hand is sufficient to fund operations into the 2014 timeframe.

Assets	**3/31/12**
Cash, equivalents, and investment securities	$50,173
Prepaid expenses, receivables, other current assets	$538
PP&E	$1,057
Other assets	$1,054
Total Assets	$52,822

Liabilities and Shareholders' Equity	
Accounts payable, expenses, other current liab.	$9,483
Deferred rent	$744
Shareholders' Equity	$42,595
Total liabilities and shareholder's equity	$52,822

(Amounts in thousands)

SUNTRUST ROBINSON HUMPHREY

Puma Biotechnology, Inc. -- Statement of Operations

Amounts in thousands, except per-share figures

Brian Lian, Ph.D.
212-319-3728

	2010A	2011A	1Q12A	2Q12E	3Q12E	4Q12E	2012E	1Q13E	2Q13E	3Q13E	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E
Global neratinib sales	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**$29,276**	**$143,178**	**$312,222**	**$475,825**
Revenue																	
Neratinib revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	$29,276	$110,754	$230,607	$346,267
Collaborative revenues	-	-	-	-	-	-	-	-	-	-	-	-	100,000	75,000	55,188	13,058	20,729
Total operating revenue	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**$100,000**	**$104,276**	**$165,942**	**$243,666**	**$366,997**
Operating expenses:																	
Cost of Goods Sold	-	-	-	-	-	-	-	-	-	-	-	-	-	3,806	19,072	47,507	77,004
Research & development	-	826	10,568	5,325	5,250	5,525	26,668	5,609	5,690	5,715	5,740	22,754	32,993	37,942	40,978	43,027	47,329
General and administrative	7	9,320	1,235	2,350	2,570	2,761	8,916	2,579	2,770	2,697	2,725	10,771	17,234	38,776	51,572	53,119	55,243
Depreciation and amortization	-	11	49	49	49	49	196	49	49	49	49	196	196	196	350	357	364
Total operating expenses	**7**	**10,157**	**11,852**	**7,724**	**7,869**	**8,335**	**35,780**	**8,237**	**8,509**	**8,461**	**8,514**	**33,721**	**50,423**	**80,720**	**111,971**	**144,009**	**179,940**
Income (Loss) from operations	**(7)**	**(10,157)**	**(11,852)**	**(7,724)**	**(7,869)**	**(8,335)**	**($35,780)**	**(8,237)**	**(8,509)**	**(8,461)**	**(8,514)**	**(33,721)**	**49,577**	**23,557**	**53,970**	**99,656**	**187,056**
Other income (expense)	-	(76)	26	(20)	(20)	(20)	(34)	(25)	(25)	(25)	(25)	(100)	(100)	(100)	(65)	650	1,470
Pretax income (loss)	**(7)**	**(10,233)**	**(11,826)**	**(7,744)**	**(7,889)**	**(8,355)**	**(35,814)**	**(8,262)**	**(8,534)**	**(8,486)**	**(8,539)**	**(33,821)**	**49,477**	**23,457**	**53,905**	**100,306**	**188,526**
Income tax provision (benefit)	-	-	-	-	-	-	-	-	-	-	-	-	4,948	2,815	8,625	18,055	41,476
Net income (loss)	**($7)**	**($10,233)**	**($11,826)**	**($7,744)**	**($7,889)**	**($8,355)**	**($35,814)**	**($8,262)**	**($8,534)**	**($8,486)**	**($8,539)**	**($33,821)**	**$44,529**	**$20,642**	**$45,281**	**$82,251**	**$147,050**
Diluted earnings per share	**($0.00)**	**($1.32)**	**($0.59)**	**($0.38)**	**($0.39)**	**($0.41)**	**($1.77)**	**($0.40)**	**($0.35)**	**($0.28)**	**($0.28)**	**($1.27)**	**$1.04**	**$0.36**	**$0.77**	**$1.37**	**$2.41**
Basic common shares outstanding	4,000	7,747	20,040	20,155	20,270	20,385	20,213	20,505	24,725	30,745	30,865	26,710	41,174	56,585	57,151	57,723	58,300
Diluted common shares outstanding	4,000	7,747	20,040	20,155	20,270	20,385	20,213	20,505	24,725	30,745	30,865	26,710	42,674	56,585	58,651	59,824	61,021

Source: Puma Biotechnology, Inc. and SunTrust Robinson Humphrey

Investment Thesis

We believe Puma Biotechnology represents a compelling, undercovered story in the cancer space. The company's lead program, Neratinib, for HER2+ breast cancer, has demonstrated impressive efficacy as both a single agent and in combination with common regimens. We believe this drug candidate has the potential to ultimately become the oral therapy of choice in various combination cocktails for HER2+ disease.

Company Description

Puma Biotechnology is a development-stage biopharmaceutical company that acquires and develops innovative products for the treatment of various forms of cancer. The company is focused on in-licensing drug candidates that are undergoing or have already completed initial clinical testing for the treatment of cancer and then seek to further develop those drug candidates for commercial use.

Analyst Certification

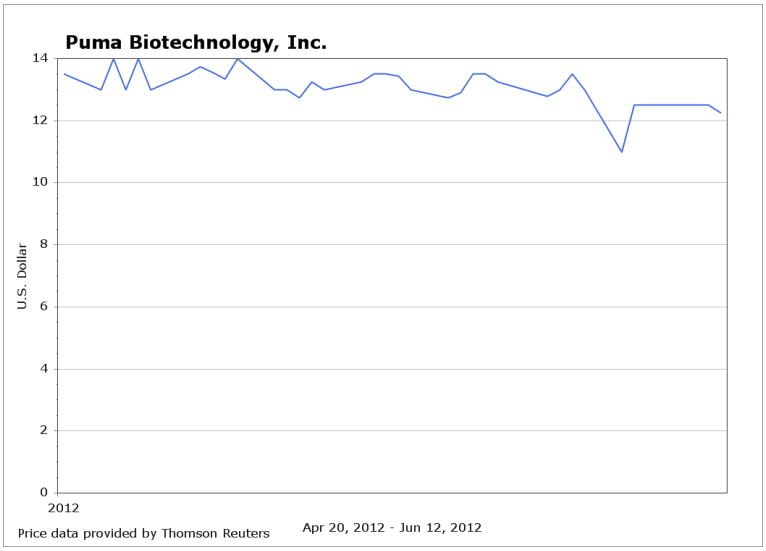
I, Brian Lian, Ph.D., hereby certify that the views expressed in this research report accurately reflect my personal views about the subject company(ies) and its (their) securities. I also certify that I have not been, am not, and will not be receiving direct or indirect compensation in exchange for expressing the specific recommendation(s) in this report.

Important Disclosures

- SunTrust Robinson Humphrey, Inc. makes a market in the following companies at the time of this report: Puma Biotechnology, Inc.

Analyst compensation is based upon quality of analysis, communication skills, stock price performance and the overall revenue and profitability of the firm, including investment banking revenue.

As a matter of policy and practice, the firm prohibits the offering of favorable research or a specific research rating as consideration or inducement for the receipt of business or compensation. In addition, analysts and associated persons preparing research reports are prohibited from owning securities in the subject companies.



Rating And Price Target History (PBYI)			
Date	**Rating**	**Target**	**Closing**

No changes made in the prior three years.

Definition of Ratings

SunTrust Robinson Humphrey assigns one of three ratings to stocks covered by our Research Department: **Buy, Neutral, or Reduce.**

In addition, we assign a risk rank to each stock based on a combination of fundamental and stock volatility factors:
Low = Low stock price volatility reflected by high predictability of financial results.
Moderate = Moderate stock price volatility reflected by medium predictability of financial results.
High = High stock price volatility reflected by inconsistent predictability of financial results.
Speculative = Greatest stock price volatility reflected by low predictability of financial results.
Venture = Recommended only for maximum risk oriented and well-diversified portfolios.

Our ratings are a function of the risk ranking (higher return expectations for higher risk) and the absolute expected total return (price appreciation plus dividends) that result in our estimated 12-month price target. Please refer to the grid below for additional detail.

Performance Definition Scale

Total return (capital gain/loss + dividends) expected over the next 12 months

Rating	Low Risk	Moderate Risk	High Risk	Speculative
Buy	Over 10%	Over 15%	Over 20%	Over 25%
Neutral	-5% to 10%	-5% to 15%	-10% to 20%	-10% to 25%
Reduce	-5% or Worse	-5% or Worse	-10% or Worse	-10% or Worse

SunTrust Robinson Humphrey assigns one of three ratings to industries/sectors covered by our Research Department: Overweight, Market Weight or Underweight. These terms are relative to the appropriate S&P 500 industries/sectors.

Deviations from expected price targets due to price movement and/or volatility will be reviewed by the analyst and research management on a timely basis. Price targets are only required on Buy rated stocks; the analyst may choose to have price targets on Neutral or Reduce rated stocks, but it is not required. Action taken by an investor should be based upon their personal investment objectives and risk tolerance compared to a stock's expected performance and risk ranking.

SunTrust Robinson Humphrey ratings distribution as of 06/14/2012:

Coverage Universe		
Rating	**Count**	**Percent**
Buy	139	44
Hold/Neutral	178	56
Sell/Reduce	0	0

Investment Banking Clients Past 12 months		
Rating	**Count**	**Percent***
Buy	30	9
Hold/Neutral	25	8
Sell/Reduce	0	0

*Percentage of Investment Banking clients in Coverage Universe by rating

Financial Definitions

Average Daily Volume = The cumulative number of shares traded over 200 days ÷ number of trading sessions in that period
Book Value/Share = Shareholders' equity ÷ shares outstanding
Debt/Cap. = Debt ÷ shareholders' equity + debt
Debt/EBITDA = Long-term debt ÷ earnings before interest, tax, depreciation, and amortization
Dividend/Yield = Annual dividend per share ÷ share price
Est. 5-Year EPS Growth = Expected 5-year CAGR from latest actual
Float = Number of shares outstanding available for public trading
Free Cash Flow/Share = Trailing four quarters cash flow from operations - yearly CAPEX ÷ shares outstanding
Long-Term Debt = Loans and financial obligations extending beyond one year
Net Cash/Share = Cash + liquid securities - total debt (short and long term) ÷ shares outstanding
ROE (last year actual) = Net income ÷ shareholders' equity

Shareholders' Equity = Share capital + retained earnings - treasury shares

Key Indices:
DJIA – Dow Jones
RUI – Russell 1000
RUT – Russell 2000
MID – S&P MidCap 400
SPX – S&P 500
SML – S&P SmallCap 600

Other Disclosures

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