Puma Biotechnology, Inc.

February 20, 2013

Receives SPA for Neratinib Phase III Trial in 3rd-Line HER2+ MBC

This morning, Puma announced an agreement with the FDA on a Special Protocol Assessment (SPA) for a phase III trial of lead drug neratinib in patients with ≥3rd-line HER2-positive (HER2+) metastatic breast cancer. The trial is expected to begin late-1Q/early-2Q, essentially in-line with prior 1Q guidance. We view the SPA as an incremental positive as it clarifies trial design issues, but expect minimal impact on shares as the news was largely expected.

The planned trial will be a randomized, controlled, international study comparing neratinib + capecitabine to Tykerb + capecitabine in 600 patients who have failed a minimum of two prior therapies. This size is larger than our prior 400 patient estimate. Co-primary endpoints will be progression-free survival (PFS) and overall survival (OS). **If PFS data show a neratinib benefit, the company plans to file for Accelerated Approval, with an expectation of full approval pending positive OS results.** The company also announced that discussions with EU regulatory authorities had been consistent with FDA commentary. Thus, upon successful completion, an EU filing is also planned.

Prior phase II data for neratinib compare favorably to Tykerb in a similar setting. Results from a neratinib/capecitabine combination study in previously treated HER2+ metastatic disease demonstrated response rates of 57% to 64%, with PFS of 36 to 40 weeks. By comparison, Tykerb in a similar population demonstrated a 24% response rate and 28 week PFS. Head-to-head studies have not been performed. While this cross-trial comparison favors neratinib, we note that PFS differences often compress in final OS data.

We also expect Puma in 2013 to initiate a phase III trial of neratinib in HER2+ breast cancer that has metastasized to the brain, and a study in combination with temsirolimus in the 4th-line setting. A potentially important 2Q catalyst could be preliminary results from a phase II brain metastases trial, at ASCO.

FYE – Dec.	2012E	2013E		2014	
EPS	**Current**	**Previous**	**Current**	**Previous**	**Current**
1Q	-$0.59A	-$0.98E	-$0.98E	NA	NA
2Q	-$0.74A	-$0.90E	-$0.90E	NA	NA
3Q	-$1.29A	-$0.72E	-$0.72E	NA	NA
4Q	-$1.01E	-$0.72E	-$0.72E	NA	NA
Year	-$3.63E	-$3.26E	-$3.26E	NA	NA
P/E	-6.9x		-7.7x		NA
Mean EPS Estimate	-$2.24		-$1.71		NA
Revenue (mil.)	**Current**	**Previous**	**Current**	**Previous**	**Current**
1Q	$0.0A	$0.0E	$0.0E	NA	NA
2Q	$0.0A	$0.0E	$0.0E	NA	NA
3Q	$0.0A	$0.0E	$0.0E	NA	NA
4Q	$0.0E	$0.0E	$0.0E	NA	NA
Year	$0.0E	$0.0E	$0.0E	NA	NA
EV/EBITDA	0.0x		NA		NA
Operating Margin	NA	NA	NA	NA	NA

PBYI

Price (Feb. 20, 2013)	$24.95
Mkt. Cap. (mil.)	$500.0

Biotechnology

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

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Market Data:	
52-Week Range	$27.95-$10.00
Shares Out. (mil.)	20.0
Float (mil.)	16.0
Avg. Daily Vol. (000)	60
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	$1.40
Free Cash Flow/Share	NA
Net Cash/Share	$2.05
Shareholders' Equity (mil.)	$9.0
Est. 5-Year EPS Growth	NA
Convertible	No
Key Indices	

EPS Est. Changes	2012	2013
11/15/12	-$3.63	-$3.26
08/15/12	-$2.33	NA
06/14/12	-$1.77	-$1.27

Comments

Puma Biotechnology – Pipeline

Product	Mechanism of Action	Indication	Status	Partner
Neratinib	HER1/2/4 inhibitor	Breast cancer	Phase III	None
		NSCLC	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, Inc.

Puma Biotechnology – Summary of Planned Clinical Trials

Drugs	Design	Entry Criteria	Treatment	Endpoints	Notes
Neratinib phase III combo trial with chemotherapy	Randomized, multicenter (approximately 150 sites) global study versus lapatinib in approximately 600 patients.	HER2+ metastatic disease; previously treated with 2 or more prior lines of therapy	Neratinib + capecitabine vs lapatinib + capecitabine	Co-primary endpoints: PFS and OS.	Expected to begin 2Q13. SPA agreement reached with FDA 1Q13. One successful trial sufficient for NDA
Neratinib phase III trial in patients with brain metastases	Expect randomized, neratinib + capecitabine vs lapatinib + capecitabine; expected to enroll 400 patients.	HER2+ metastatic disease with CNS lesions; patients must have brain metastases	Expect standard 240mg daily neratinib dosing	Primary endpoint PFS in patients with CNS metastases	Potential initiation 2Q13. SPA planned.
Neratinib phase III trial in 4th-line metastatic disease, combo with temsirolimus	Expected to enroll 300 patients.	HER2+ metastatic disase in ≥3rd-line disease.	Expect standard 240mg daily neratinib dosing + 8mg weekly Torisel vs. comparator arm TBD	Primary endpoint PFS	Potential initiation 1H13 pending positive data from ongoing phase I/II combo trial. SPA planned.
Neratinib phase II trial alone and in combo with Torisel in mutated NSCLC	2 arms: neratinib +/- Torisel; 20 patients in each arm; successful arm will continue and enroll an additional 60-80 patients	NSCLC patients with documented activating HER2 mutations on exon-20	Expect standard 240mg daily neratinib dosing + 8mg weekly Torisel	Expect primary endpoint PFS	Expected to begin 1Q13.
Neratinib phase II trial in patients with breast cancer mutation	Expected to enroll 15 patients stage 1, additional cohort stage 2	Breast cancer mutation; details expected Oct/Nov	TBD.	NA	Expected to begin 1Q13. Mutation data presented at San Antonio Breast Cancer Symposium 4Q12

Source: SunTrust Robinson Humphrey and Puma Biotechnology, Inc.

Puma Biotechnology– Summary of 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 40 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 expected at ASCO 2013
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 at San Antonio Breast Cancer Symposium, 4Q12
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 2013
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 2013

Source: SunTrust Robinson Humphrey and Puma Biotechnology, Inc.

Puma Biotechnology – Upcoming Milestones

Product	Event	Expected
Neratinib	Initiate phase II trial, metastatic breast cancer w/mutant HER2	1Q13
	Initiate phase III trial, neratinib/capecitabine vs lapatinib/capecitabine, 3rd-line and later HER2+ metastatic breast cancer (MBC)	2Q13
	Initiate phase II trial, neratinib/Torisel combo in NSCLC patients with HER2-activating mutations	1Q13
	Initiate phase III trial, neratinib/Torisel combo in HER2+ MBC, 4th-line	1H13
	NCI/NSABP first-line breast, neoadjuvant combos: neratinib/paclitaxel vs Herceptin/paclitaxel vs neratinib/Herceptin/paclitaxel; top-line 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
	Top-line data, phase II trial, single-agent, HER2+ MBC w/brain metastases	2Q13
	Initiate phase III trial, neratinib/capecitabine vs lapatinib capecitabine, HER2+ w/brain metastases	2Q13
Neratinib I.V.	File IND	2013

Source: SunTrust Robinson Humphrey and Puma Biotechnology, Inc.

SunTrust Robinson Humphrey

Puma Biotechnology, Inc. -- Statement of Operations

Amounts in thousands, except per-share figures

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	1Q12A	2Q12A	3Q12A	4Q12E	2012E	1Q13E	2Q13E	3Q13E	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Global neratinib sales	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**$29,276**	**$143,178**	**$312,222**	**$475,825**	**$626,591**	**$773,788**
Revenue																	
Neratinib revenue	-	-	-	-	-	-	-	-	-	-	-	$29,276	$110,754	$230,607	$346,267	$439,273	$534,393
Collaborative revenues	-	-	-	-	-	-	-	-	-	-	100,000	75,000	55,188	13,058	20,729	33,717	43,091
Total operating revenue	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**$100,000**	**$104,276**	**$165,942**	**$243,666**	**$366,997**	**$472,990**	**$577,484**
Operating expenses:																	
Cost of Goods Sold	-	-	-	-	-	-	-	-	-	-	-	3,806	19,072	47,507	77,004	113,433	147,576
Research & development	10,568	13,006	17,779	17,525	58,879	17,296	19,242	19,287	19,332	75,157	108,978	87,182	75,195	63,916	70,307	77,338	85,072
General and administrative	1,235	1,702	8,025	2,761	13,723	2,579	2,770	2,697	2,725	10,771	17,234	38,776	51,572	52,603	54,707	56,895	59,171
Depreciation and amortization	49	69	69	49	236	49	49	49	49	196	196	196	350	357	364	371	379
Total operating expenses	**11,852**	**14,777**	**25,873**	**20,335**	**72,837**	**19,924**	**22,061**	**22,033**	**22,106**	**86,124**	**126,408**	**129,960**	**146,189**	**164,383**	**202,382**	**248,038**	**292,198**
Income (Loss) from operations	**(11,852)**	**(14,777)**	**(25,873)**	**(20,335)**	**(72,837)**	**(19,924)**	**(22,061)**	**(22,033)**	**(22,106)**	**(86,124)**	**(26,408)**	**(25,683)**	**19,753**	**79,283**	**164,615**	**224,953**	**285,286**
Other income (expense)	26	23	14	(20)	43	(25)	(25)	(25)	(25)	(100)	(100)	(100)	(65)	650	1,470	3,525	5,225
Pretax income (loss)	**(11,826)**	**(14,755)**	**(25,859)**	**(20,355)**	**(72,795)**	**(19,949)**	**(22,086)**	**(22,058)**	**(22,131)**	**(86,224)**	**(26,508)**	**(25,783)**	**19,688**	**79,933**	**166,085**	**228,478**	**290,511**
Income tax provision (benefit)	-	-	-	-	-	-	-	-	-	-	-	-	-	3,197	36,539	54,835	75,533
Net income (loss)	**($11,826)**	**($14,755)**	**($25,859)**	**($20,355)**	**($72,795)**	**($19,949)**	**($22,086)**	**($22,058)**	**($22,131)**	**($86,224)**	**($26,508)**	**($25,783)**	**$19,688**	**$76,735**	**$129,546**	**$173,643**	**$214,978**
Diluted earnings per share	**($0.59)**	**($0.74)**	**($1.29)**	**($1.01)**	**($3.63)**	**($0.98)**	**($0.90)**	**($0.72)**	**($0.72)**	**($3.26)**	**($0.62)**	**($0.46)**	**$0.34**	**$1.29**	**$2.13**	**$2.80**	**$3.40**
Basic common shares outstanding	20,040	20,040	20,040	20,155	20,069	20,275	24,495	30,515	30,635	26,480	40,941	56,351	56,914	57,483	58,058	58,639	59,225
Diluted common shares outstanding	20,040	20,040	20,040	20,155	20,069	20,275	24,495	30,515	30,635	26,480	42,441	56,351	58,414	59,583	60,774	61,990	63,229

Source: Puma Biotechnology, Inc. and SunTrust Robinson Humphrey

Investment Thesis

We believe Puma Biotechnology represents a promising potential long-term opportunity in the cancer space. The company's lead program, Neratinib, for HER2+ breast cancer, has demonstrated 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.

Our $19 price target is based on a 35x multiple of our probability-adjusted, diluted 2017 EPS estimate of $0.95, discounted four years at 15%. Our probability-adjustment assumes a 67% probability of approval applied to diluted 2017E EPS of $1.29. A 35x multiple is in line with emerging, newly profitable biopharmaceuticals companies, which can traded at EPS multiples ranging from 25x to 45x or higher.

Risks to our target include failure of neratinib to successfully achieve the primary endpoint of ongoing and future clinical trials, as well as any unexpected potential safety concerns that would impact the development of neratinib for breast or gastric cancers.

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.

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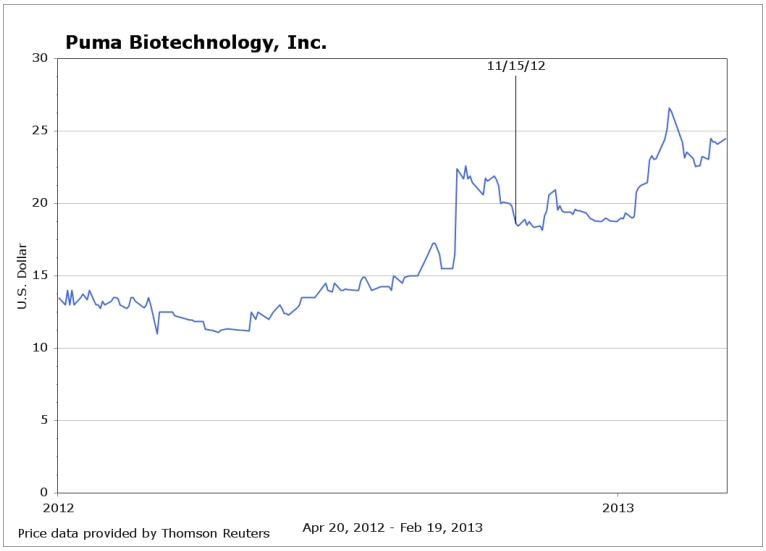

Rating And Price Target History (PBYI)

Date	Rating	Target	Closing
06/14/2012	Buy	$19.00	$0.00
11/15/2012	Neutral		$18.59

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%
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SunTrust Robinson Humphrey ratings distribution as of 02/20/2013:

Coverage Universe		
Rating	**Count**	**Percent**
Buy	149	43
Hold/Neutral	187	54
Sell/Reduce	10	3

Investment Banking Clients Past 12 months		
Rating	**Count**	**Percent***
Buy	48	14
Hold/Neutral	26	8
Sell/Reduce	1	0

*Percentage of Investment Banking clients in Coverage Universe by rating

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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

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