Puma Biotechnology, Inc.

August 15, 2012

PBYI

Price (Aug. 9, 2012)	$13.50
Mkt. Cap. (mil.)	$270.5

Biotechnology

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

New Neratinib Trials Highlighted in 2Q12 Results

We met with Puma management in NY to discuss the company's 8/14 announcement of new clinical plans for lead drug neratinib, for metastatic breast cancer. In addition to previously announced phase III plans, CEO Alan Auerbach outlined new trials in selected mutations in breast and non-small cell lung cancer (NSCLC). While early, we believe the potential to identify sensitive patient subsets could generate significant long-term upside.

A new trial in NSCLC patients with HER2-activating mutations is expected to begin in 4Q12. This trial will initially evaluate neratinib +/- the mTOR inhibitor temsirolimus in approximately 40 patients; a larger 60-80 patient cohort will follow. Initial results could be available in 2013. Targeted patients possess duplicating insertions for amino acids 776-779 on exon 20. Such mutations are found in approximately 2% - 4% of the 180K annual NSCLC diagnoses.

Puma also announced plans to initiate a phase II trial in metastatic breast cancer patients possessing an undisclosed HER2 mutation. This trial will begin in 4Q12, with data possible in 2013. The company estimates that the targeted mutation exists in up to 2% of the 230K annual breast cancer diagnoses.

The company believes positive results from either new study could facilitate an Accelerated Approval strategy akin to Pfizer's Xalkori, launched in 2011 for ALK+ NSCLC. As a reminder, ALK mutations exist in up to 5% of NSCLC diagnoses. The consensus estimate for 2015 Xalkori sales is $764M.

Separately, Puma also reported 2Q12 results after the close. The release reiterated plans to initiate three phase III trials in refractory metastatic breast cancer over the next three to nine mos. SPAs are planned for each (see pg 2).

We believe the expanding neratinib program opens high-value opportunities not reflected at current levels. We reiterate our Buy rating on the shares.

FYE – Dec.	2011A	2012E		2013E	
EPS	**Current**	**Previous**	**Current**	**Previous**	**Current**
1Q	NA	-$0.59A	-$0.59A	-$0.40E	-$0.41E
2Q	NA	-$0.38E	-$0.74A	-$0.35E	-$0.35E
3Q	-$0.09A	-$0.39E	-$0.49E	-$0.28E	-$0.28E
4Q	-$1.24A	-$0.41E	-$0.51E	-$0.28E	-$0.28E
Year	-$1.32A	-$1.77E	-$2.33E	-$1.27E	-$1.27E
P/E	-10.2x		-5.8x		-10.6x
Mean EPS Estimate	-$1.32		-$1.71		-$1.59
Revenue (mil.)	**Current**	**Previous**	**Current**	**Previous**	**Current**
1Q	NA	$0.0A	$0.0A	$0.0E	$0.0E
2Q	NA	$0.0E	$0.0A	$0.0E	$0.0E
3Q	$0.0A	$0.0E	$0.0E	$0.0E	$0.0E
4Q	$0.0A	$0.0E	$0.0E	$0.0E	$0.0E
Year	-$10.2A	$0.0E	$0.0E	$0.0E	$0.0E
EV/EBITDA	NA		0.0x		NA
Operating Margin	NA	NA	NA	NA	NA

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Market Data:

52-Week Range	$14.03-$10.00
Shares Out. (mil.)	20.0
Float (mil.)	16.0
Avg. Daily Vol. (000)	35
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.)	$28.0
Est. 5-Year EPS Growth	NA
Convertible	No
Key Indices	

EPS Est. Changes	2012	2013
06/14/12	-$1.77	-$1.27
NA	NA	NA
NA	NA	NA

Comments

Puma outlined plans to report top line data from two phase II trials at the upcoming San Antonio Breast Cancer Symposium and the 2013 ASCO conference. The first will be follow up data from the ongoing combination study of neratinib and temsirolimus in refractory metastatic breast cancer. Preliminary data were presented at the 2011 conference. The second study will likely include a preliminary overview of the ongoing trial in metastatic breast cancer patients with brain metastases. This trial is expected to mature in time for a full presentation at the ASCO conference in 2013. The following tables outline Puma's ongoing and planned clinical trials, including the recently described studies in HER2 mutant NSCLC and breast cancer. We continue to expect the company to generate data leading to no fewer than five potential NDA filing opportunities over the next 18 to 30 months.

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 to be submitted for San Antonio Breast Cancer Symposium, 4Q12; final 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 – Summary of Planned Clinical Trials

Drugs	Design	Entry Criteria	Treatment	Endpoints	Notes
Neratinib phase III combo trial with chemotherapy	Expect randomized multicenter combination study versus lapatinib in approximately 400 patients.	HER2+ metastatic disease; previously treated with 2 prior lines of therapy	Expect neratinib + capecitabine vs lapatinib + capecitabine	Primary endpoint PFS	Expected to begin 4Q12/1Q13. SPA planned. 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 4Q12. Expect to submit data for ASCO 2013.
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 4Q12. Mutation data to be submitted for San Antonio Breast Cancer Symposium 4Q12
Neratinib phase II trial in HER2+ gastric cancer	TBD.	HER2+ gastric cancer, expected to enroll ≥ 2nd-line disease.	Expect standard 240mg daily neratinib	NA	Timing NA

Source: SunTrust Robinson Humphrey and Puma Biotechnology, Inc.

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, Inc.

Puma Biotechnology – Upcoming Milestones

Product	Event	Expected
Neratinib	Follow-up data, Torisel ph.II combo trial, HER2+ and triple negative breast, multiple priors	4Q12
	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; 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	4Q12
	Topline 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
	Initiate phase II trial, HER2+ gastric cancer	2H12/1H13
Neratinib I.V.	File IND	2013

Source: SunTrust Robinson Humphrey and Puma Biotechnology, Inc.

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Puma Biotechnology, Inc. -- Statement of Operations

Amounts in thousands, except per-share figures

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	2011A	1Q12A	2Q12A	3Q12E	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	826	10,568	13,006	7,250	7,525	38,349	9,609	10,690	10,715	10,740	41,754	60,543	69,625	75,195	78,955	86,850	95,535	105,088
General and administrative	9,320	1,235	1,702	2,570	2,761	8,268	2,579	2,770	2,697	2,725	10,771	17,234	38,776	51,572	53,119	55,243	57,453	59,751
Depreciation and amortization	11	49	69	49	49	216	49	49	49	49	196	196	196	350	357	364	371	379
Total operating expenses	**10,157**	**11,852**	**14,777**	**9,869**	**10,335**	**46,833**	**12,237**	**13,509**	**13,461**	**13,514**	**52,721**	**77,973**	**112,402**	**146,188**	**179,937**	**219,461**	**266,792**	**312,794**
Income (Loss) from operations	**(10,157)**	**(11,852)**	**(14,777)**	**(9,869)**	**(10,335)**	**(46,833)**	**(12,237)**	**(13,509)**	**(13,461)**	**(13,514)**	**(52,721)**	**22,027**	**(8,126)**	**19,753**	**63,728**	**147,536**	**206,198**	**264,690**
Other income (expense)	(76)	26	23	(20)	(20)	8	(25)	(25)	(25)	(25)	(100)	(100)	(100)	(65)	650	1,470	3,525	5,225
Pretax income (loss)	**(10,233)**	**(11,826)**	**(14,755)**	**(9,889)**	**(10,355)**	**(46,825)**	**(12,262)**	**(13,534)**	**(13,486)**	**(13,539)**	**(52,821)**	**21,927**	**(8,226)**	**19,688**	**64,378**	**149,006**	**209,723**	**269,915**
Income tax provision (benefit)	-	-	-	-	-	-	-	-	-	-	-	2,193	(987)	3,150	11,588	32,781	50,334	70,178
Net income (loss)	**($10,233)**	**($11,826)**	**($14,755)**	**($9,889)**	**($10,355)**	**($46,825)**	**($12,262)**	**($13,534)**	**($13,486)**	**($13,539)**	**($52,821)**	**$19,734**	**($7,239)**	**$16,538**	**$52,790**	**$116,224**	**$159,390**	**$199,737**
Diluted earnings per share	**($1.32)**	**($0.59)**	**($0.74)**	**($0.49)**	**($0.51)**	**($2.33)**	**($0.60)**	**($0.55)**	**($0.44)**	**($0.44)**	**($1.99)**	**$0.46**	**($0.13)**	**$0.28**	**$0.88**	**$1.91**	**$2.57**	**$3.15**
Basic common shares outstanding	7,747	20,040	20,040	20,155	20,270	20,126	20,390	24,610	30,630	30,750	26,595	41,058	56,468	57,033	57,603	58,179	58,761	59,349
Diluted common shares outstanding	7,747	20,040	20,040	20,155	20,270	20,126	20,390	24,610	30,630	30,750	26,595	42,558	56,468	58,533	59,703	60,897	62,115	63,358

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.

Our $19 price target is based on a 35x multiple of our probability-adjusted, diluted 2017 EPS estimate of $0.94, discounted four years at 15%. 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.

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.

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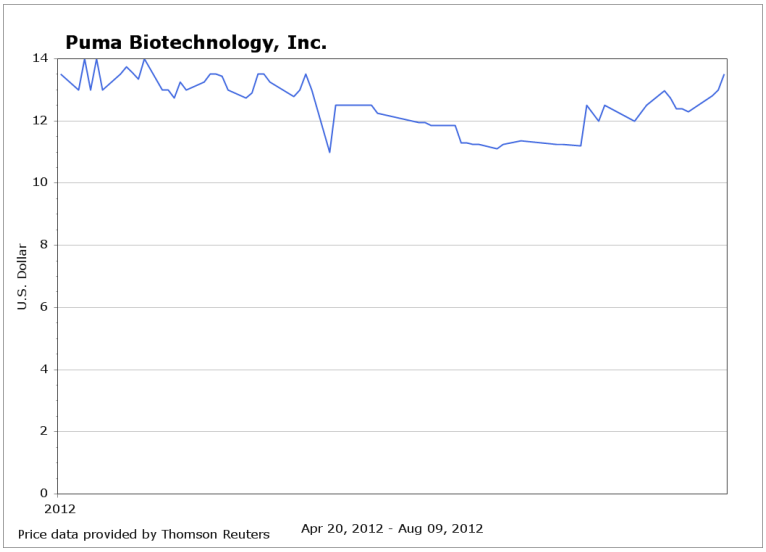

Rating And Price Target History (PBYI)			
Date	**Rating**	**Target**	**Closing**
06/14/2012	Buy	$19.00	$0.00

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 08/14/2012:

Coverage Universe		
Rating	**Count**	**Percent**
Buy	148	43
Hold/Neutral	196	57
Sell/Reduce	1	0

Investment Banking Clients Past 12 months		
Rating	**Count**	**Percent***
Buy	34	10
Hold/Neutral	26	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

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