Puma Biotechnology, Inc.

May 9, 2013

1Q13 Update, First Neratinib Neo-Adjuvant Data Expected Mid-Year

On 5/9, after the close, Puma reported 1Q13 results. No new/major program updates were announced. **The company reiterated plans to initiate a phase III trial of lead drug neratinib, for HER2+ metastatic breast cancer, later this quarter** and suggested that data from multiple ongoing trials will read out this year. We expect Puma to have at least 2 phase III trials ongoing by year-end.

The first phase III 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. The trial has an SPA; co-primary endpoints will be progression-free survival (PFS) and overall survival (OS). If PFS data show a neratinib benefit, Puma plans to file for Accelerated Approval, with an expectation of full approval pending positive OS results.

The company plans to initiate a phase III trial to evaluate the combination of neratinib and the mTOR inhibitor temsirolimus in the 4th line metastatic setting in 2H13. In addition, a phase II trial in patients with brain metastases is expected to readout in 4Q13, with a phase III decision to follow.

Data from two potentially important phase II trials in the neoadjuvant setting are expected this year. Results from two arms of the multi-arm I-SPY 2 trial – neratinib/paclitaxel vs. Herceptin/paclitaxel- are expected mid-year. Data from a second study evaluating neratinib/paclitaxel vs. Herceptin/ paclitaxel vs. neratinib/Herceptin/paclitaxel are expected in 4Q13. If successful, phase III neoadjuvant trials could begin in 2014.

The company also briefly reported that enrollment in phase II trials in mutated NSCLC and HER2-negative breast cancer were ongoing. We believe preliminary data from each could be available by year-end. Puma ended 1Q13 with $119M in cash ($4.13/share); we estimate 2013 op-ex of $78M.

FYE – Dec.	2012A	2013E		2014E	
EPS	**Current**	**Previous**	**Current**	**Previous**	**Current**
1Q	-$0.59A	-$0.70E	-$0.41A	$1.70E	$1.70E
2Q	-$0.74A	-$0.75E	-$0.75E	-$0.85E	-$0.85E
3Q	-$1.29A	-$0.74E	-$0.74E	-$0.78E	-$0.78E
4Q	-$0.83A	-$0.72E	-$0.72E	-$0.75E	-$0.75E
Year	-$3.42A	-$2.91E	-$2.63E	-$0.68E	-$0.68E
P/E	-8.2x		-10.6x		-41.1x
Mean EPS Estimate	-$3.03		-$2.28		-$1.89
Revenue (mil.)	**Current**	**Previous**	**Current**	**Previous**	**Current**
1Q	$0.0A	$0.0E	$0.0A	$100.0E	$100.0E
2Q	$0.0A	$0.0E	$0.0E	$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	$0.0A	$0.0E	$0.0E	$100.0E	$100.0E
EV/EBITDA	0.0x		NA		NA
Operating Margin	NA	NA	NA	NA	NA

PBYI

Price (May 8, 2013)	$27.97
Mkt. Cap. (mil.)	$802.1

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	$34.65-$11.00
Shares Out. (mil.)	28.7
Float (mil.)	16.0
Avg. Daily Vol. (000)	90
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	$4.50
Free Cash Flow/Share	NA
Net Cash/Share	$4.13
Shareholders' Equity (mil.)	$118.3
Est. 5-Year EPS Growth	NA
Convertible	No
Key Indices	

EPS Est. Changes	2013	2014
04/02/13	-$2.91	-$0.68
11/15/12	-$3.26	NA
06/14/12	-$1.27	

Comments

Puma Biotechnology – Pipeline

Product	Mechanism of Action	Indication	Status	Partner
Neratinib	HER1/2/4 inhibitor	Breast cancer	Phase III	None
		NSCLC	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 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 4Q13
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. Further data expected 2013.
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 expected 2H13
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, data expected mid-2013
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	240mg daily neratinib dosing + 8mg weekly Torisel	Primary endpoint: PFS	NA	Initiated 1Q13, potential data 2H13
Neratinib phase II trial in patients with breast cancer mutation	Phase II Study of Neratinib in Metastatic HER2 Non-amplified But HER2 Mutant Breast Cancer. Expected to enroll 29 patients.	Mutated HER2-negative breast cancer.	240mg daily	Primary endpoint: overall response. Secondary endpoint: PFS.	NA	Initiated 1Q13, potential data 2H13

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 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 2H13 pending positive data from ongoing phase I/II combo trial. SPA planned.

Source: SunTrust Robinson Humphrey and Puma Biotechnology, Inc.

Puma Biotechnology – Upcoming Milestones

Product	Event	Expected
Neratinib	Initiate phase III trial, neratinib/capecitabine vs lapatinib/capecitabine, 3rd-line and later HER2+ metastatic breast cancer (MBC)	2Q13
	Initiate phase III trial, neratinib/Torisel combo in HER2+ MBC, 4th-line	2H13
	NIH I-SPY 2 trial in first-line breast, neoadjuvant setting: neratinib/paclitaxel vs Herceptin/paclitaxel vs neratinib/Herceptin/paclitaxel; top-line data	Mid-2013
	NCI/NSABP first-line breast, neoadjuvant combos: neratinib/paclitaxel vs Herceptin/paclitaxel vs neratinib/Herceptin/paclitaxel; top-line data	2H13
	Top-line data, phase II trial, neratinib/Torisel combo in HER2+ MBC, 4th-line	2H13
	Top-line data, phase II trial, single-agent, HER2+ MBC w/brain metastases	4Q13
	Top-line data, phase II trial, neratinib/Torisel combo in NSCLC patients with HER2-activating mutations	2H13
	Top-line data, phase II trial, metastatic breast cancer w/mutant HER2	2H13
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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	2012A	1Q13A	2Q13E	3Q13E	4Q13E	2013E	1Q14E	2Q14E	3Q14E	4Q14E	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	-	-	-	100,000	75,000	55,188	13,058	20,729	33,717	43,091
Total operating revenue	**-**	**-**	**-**	**-**	**-**	**-**	**100,000**	**-**	**-**	**-**	**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	49,554	9,532	19,242	19,287	19,332	67,393	29,424	28,334	26,155	25,065	108,978	87,182	75,195	63,916	70,307	77,338	85,072
General and administrative	24,762	2,274	2,770	2,697	2,725	10,466	4,653	4,481	4,136	3,964	17,234	38,777	51,573	52,604	54,708	56,897	59,173
Depreciation and amortization	265	-	49	49	49	147	49	49	49	49	196	196	350	357	364	371	379
Total operating expenses	**74,580**	**11,806**	**22,061**	**22,033**	**22,106**	**78,006**	**34,126**	**32,864**	**30,340**	**29,078**	**126,408**	**129,961**	**146,190**	**164,384**	**202,383**	**248,039**	**292,199**
Income (Loss) from operations	**(74,580)**	**(11,806)**	**(22,061)**	**(22,033)**	**(22,106)**	**(78,006)**	**65,874**	**(32,864)**	**(30,340)**	**(29,078)**	**(26,408)**	**($25,684)**	**19,752**	**79,282**	**164,613**	**224,952**	**285,285**
Other income (expense)	100	26	(25)	(25)	(25)	(49)	(25)	(25)	(25)	(25)	(100)	(100)	(65)	650	1,470	3,525	5,225
Pretax income (loss)	**(74,480)**	**(11,780)**	**(22,086)**	**(22,058)**	**(22,131)**	**(78,055)**	**65,849**	**(32,889)**	**(30,365)**	**(29,103)**	**(26,508)**	**(25,784)**	**19,687**	**79,932**	**166,083**	**228,477**	**290,510**
Income tax provision (benefit)	-	-	-	-	-	-	-	-	-	-	-	-	-	3,197	36,538	54,834	75,533
Net income (loss)	**($74,480)**	**($11,780)**	**($22,086)**	**($22,058)**	**($22,131)**	**($78,055)**	**$65,849**	**($32,889)**	**($30,365)**	**($29,103)**	**($26,508)**	**($25,784)**	**$19,687**	**$76,734**	**$129,545**	**$173,642**	**$214,977**
Diluted earnings per share	**($3.42)**	**($0.41)**	**($0.75)**	**($0.74)**	**($0.72)**	**($2.63)**	**$1.70**	**($0.85)**	**($0.78)**	**($0.75)**	**($0.68)**	**($0.54)**	**$0.41**	**$1.57**	**$2.62**	**$3.48**	**$4.26**
Basic common shares outstanding	21,726	28,677	29,327	29,977	30,627	29,652	38,627	38,747	38,867	38,987	38,807	47,987	48,467	48,951	49,441	49,935	50,434
Diluted common shares outstanding	21,726	28,677	29,327	29,977	30,627	29,652	38,627	38,747	38,867	38,987	38,807	47,987	48,467	48,951	49,441	49,935	50,434
Ratios and Margins																	
Gross Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	87.0%	83.6%	80.5%	79.0%	76.0%	74.4%
R&D as percent of revenue	NM	NM	NM	NM	NM	NM	29.4%	NM	NM	NM	NM	83.6%	45.3%	26.2%	19.2%	16.4%	14.7%
G&A as percent of revenue	NM	NM	NM	NM	NM	NM	4.7%	NM	NM	NM	17.2%	37.2%	31.1%	21.6%	14.9%	12.0%	10.2%
Operating margin	NM	NM	NM	NM	NM	NM	65.9%	NM	NM	NM	NM	NM	11.9%	32.5%	44.9%	47.6%	49.4%
Pretax margin	NM	NM	NM	NM	NM	NM	65.8%	NM	NM	NM	NM	NM	11.9%	32.8%	45.3%	48.3%	50.3%
Profit margin	NM	NM	NM	NM	NM	NM	65.8%	NM	NM	NM	NM	NM	11.9%	31.5%	35.3%	36.7%	37.2%
Tax rate	NM	NM	NM	NM	NM	NM	0.0%	NM	NM	NM	NM	NM	0.0%	4.0%	22.0%	24.0%	26.0%

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.

Important Disclosures

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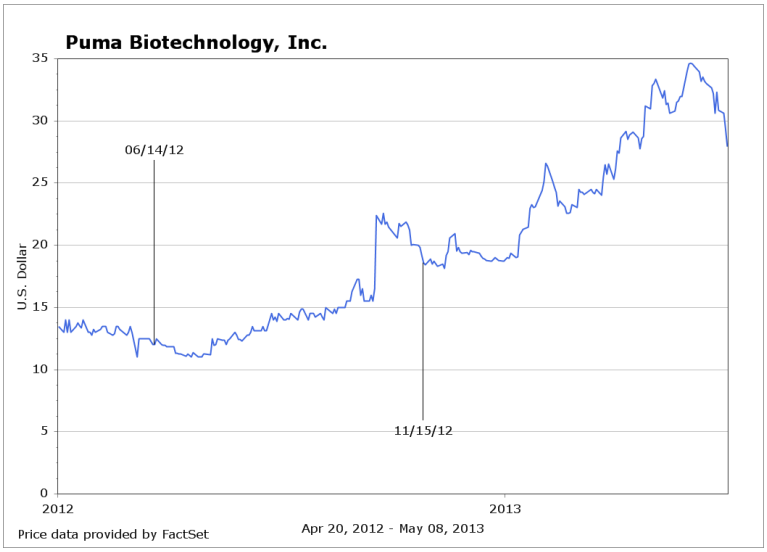

Rating And Price Target History (PBYI)			
Date	**Rating**	**Target**	**Closing**
06/14/2012	Buy	$19.00	$12.00
11/15/2012	Neutral		$18.59

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 05/09/2013:

Coverage Universe		
Rating	**Count**	**Percent**
Buy	164	46
Hold/Neutral	184	52
Sell/Reduce	9	3

Investment Banking Clients Past 12 months		
Rating	**Count**	**Percent***
Buy	50	14
Hold/Neutral	30	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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