

Puma Biotechnology, Inc.

3Q12 Update - Neratinib to Enter Phase III. Downgrade to Neutral.

On 11/14, Puma reported 3Q results. The company continues preparations for phase III trials of lead drug neratinib (breast cancer), expected to begin 4Q12/1H13. We expect the program to include two to three studies, with Special Protocol Assessments planned for certain trials. We are changing our rating on the shares to Neutral from Buy; our \$19 price target is unchanged.

We expect an update of prior data from an ongoing phase II combination study of neratinib with temsirolimus at the San Antonio Breast Cancer Conference (SABC) in December. Prior data demonstrated a 60% response rate with this combination (n=15). Based on the decision to initiate a phase III study with the combination, we expect the SABC data to hold up.

Puma reiterated plans to initiate in 4Q12/1Q13 a phase III combination trial of neratinib and chemotherapy (capecitabine) in patients who failed prior HER2 therapy. We expect the comparator to be lapatinib and enrollment of 400.

A trial in NSCLC patients with HER2-activating mutations is expected to begin in 4Q12/1Q13. The company previously indicated that this study would 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, found in approximately 2% - 4% of NSCLC patients.

Puma also plans to initiate a phase II trial in metastatic breast cancer patients who possess mutant, non-amplified HER2. This trial will begin in 4Q12; data possible in 2013. The targeted mutation exists in up to 2% breast cancers.

Our move to Neutral is based on PBYI's considerable appreciation, up close to 60% from mid-June (vs. +5% for the NBI index); plus the timelines to phase III catalysts. We expect performance in line with the sector over near/medium term.

Near / medium term.					
FYE – Dec.	2011A	2012E		2013E	
EPS	Current	Previous	Current	Previous	Current
1Q	NA	-\$0.59A	-\$0.59A	-\$0.41E	-\$0.98E
2Q	NA	-\$0.74A	-\$0.74A	-\$0.35E	-\$0.90E
3Q	-\$0.09A	-\$0.49E	-\$1.29A	-\$0.28E	-\$0.72E
4Q	-\$1.24A	-\$0.51E	-\$1.01E	-\$0.28E	-\$0.72E
Year	-\$1.32A	-\$2.33E	-\$3.63E	-\$1.27E	-\$3.26E
P/E	-14.6x		-5.3x		-5.9x
Mean EPS Estimate	-\$1.32		-\$2.24		-\$1.71
Revenue (mil.)	Current	Previous	Current	Previous	Current
1Q	NA	\$0.0A	\$0.0A	\$0.0E	\$0.0E
2Q	NA	\$0.0A	\$0.0A	\$0.0E	\$0.0E
3Q	\$0.0A	\$0.0E	\$0.0A	\$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

November 14, 2012

PBYI

Price (Nov. 14, 2012) \$19.21
Mkt. Cap. (mil.) \$385.0

Biotechnology

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

Brian Lian, Ph.D.

212-319-3728

brian.lian@suntrust.com

Market Data:

52-Week Range \$23.25-\$10.00
Shares Out. (mil.) 20.0
Float (mil.) 16.0
Avg. Daily Vol. (000) 44
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
08/15/12 -2.33 NA
06/14/12 -1.77 -1.27
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 (SABC) and the 2013 ASCO conference. The SABC presentation 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 ASCO presentation will likely highlight results from the ongoing trial in metastatic breast cancer patients with brain metastases. This trial is expected to mature in time for a full, potentially oral, presentation. The following tables outline Puma's ongoing and planned clinical trials, including the recently described studies in HER2 mutant NSCLC and breast cancer.

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, 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
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.

Financial Update

Puma finished 3Q with \$162M in cash (\$5.67/share), pro forma for a 4Q12 equity offering. We currently estimate a 2013 net loss of approximately \$86M.

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 disease 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 4Q12/1Q13.
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 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
		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 – Upcoming Milestones

Product	Event	Expected
Neratinib	Follow-up data, Torisel ph.II combo trial, HER2+ and triple negative breast, multiple priors	4Q12
	Initiate phase II trial, metastatic breast cancer w/mutant HER2	4Q12
	Initiate phase III trial, neratinib/capecitabine vs lapatinib/capecitabine, 2nd-line and later HER2+ breast MBC	4Q12/1Q13
	Initiate phase II trial, neratinib/Torisel combo in NSCLC patients with HER2-activating mutations	4Q12/1Q13
	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; 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
	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
	Neratinib I.V. File IND	2013

Source: SunTrust Robinson Humphrey and Puma Biotechnology, Inc.

Puma Biotechnology – Statement of Operations



Puma Biotechnology, Inc. -- Statement of Operations

Amounts in thousands, except per-share figures

Brian Lian, Ph.D.

212-319-3728

	2010A	2011A	1Q12A	2Q12A	3Q12A	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	10,588	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
General and administrative	7	9,320	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
Depreciation and amortization	-	11	49	69	69	49	236	49	49	49	49	196	196	196	350	357	364
Total operating expenses	7	10,157	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
Income (Loss) from operations	(7)	(10,157)	(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
Other income (expense)	-	(76)	26	23	14	(20)	43	(25)	(25)	(25)	(25)	(100)	(100)	(100)	(65)	650	1,470
Pretax income (loss)	(7)	(10,233)	(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
Income tax provision (benefit)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net income (loss)	(7)	(10,233)	(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
Diluted earnings per share	(\$0.00)	(\$1.32)	(\$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
Basic common shares outstanding	4,000	7,747	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
Diluted common shares outstanding	4,000	7,747	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

Source: Puma Biotechnology, Inc. and SunTrust Robinson Humphrey

Ratios and Margins

Gross Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	87.0%	83.6%	80.5%	79.0%
R&D as percent of revenue	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	83.6%	45.3%	26.2%	19.2%
G&A as percent of revenue	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	17.2%	37.2%	31.1%	21.6%	14.9%
Operating margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	11.9%	32.5%	44.9%
Pretax margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	11.9%	32.8%	45.3%
Profit margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	11.9%	31.5%	35.3%
Tax rate	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	0.0%	4.0%	22.0%

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

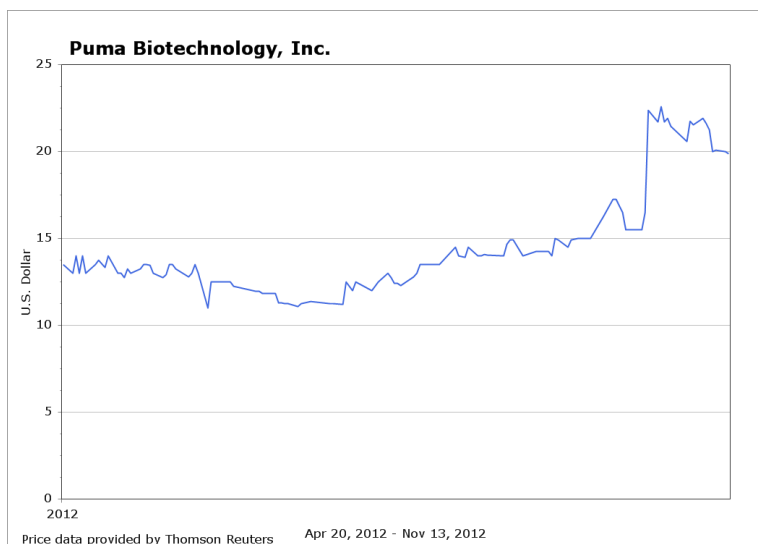
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Important Disclosures

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

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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				
<i>Total return (capital gain/loss + dividends) expected over the next 12 months</i>				
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 11/15/2012:

Coverage Universe			Investment Banking Clients Past 12 months		
Rating	Count	Percent	Rating	Count	Percent*
Buy	154	46	Buy	36	11
Hold/Neutral	184	54	Hold/Neutral	25	7
Sell/Reduce	0	0	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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SunTrust Robinson Humphrey, Research Department, 3333 Peachtree Road N.E., Atlanta, GA 30326-1070