

UBS Investment Research

Puma Biotechnology

Continued Positive Updates

■ What's changed? SPA complete for 3rd line HER2+ mBC

Mgt. has agreed with FDA and EMA on a trial plan for the PhIII study of neratinib plus Xeloda in 3rd line metastatic breast cancer (mBC), neratinib's lead indication. This study will take approximately 1 year to enroll and 9 months to produce data, suggesting filing in 2015. Mgt. will file on PFS for accelerated approval with OS as confirmatory (PFS and OS are co-primary endpoints).

■ Our analysis: SPA positions neratinib well; more key updates from mgt.

Overall, the SPA clarifies the regulatory hurdles and points to mgt.'s ability to design trials which pass the regulatory bar and are also favorable to neratinib. It also bodes well for the SPA for neratinib in 4th line mBC (neratinib + Torisel) which should be complete by mid-year. We also spoke with mgt. who updated us on (1) the HER2 mutated lung cancer study where ORR can be used for accelerated approval; and (2) neo-adjuvant with iSPY2 expected by summer 2013 and NSABP by late 2013 (see inside for key details for lung and neo-adjuvant).

■ Impact on the stock: 2013 and 2014 data heavy with upside potential

Both 2013 and 2014 continue to shape up as key value driving events for Puma. We continue to see solid chances in mBC with the opportunities in lung, neoadjuvant and CNS disease as all upside which could start to occur in 2H13. We continue to like the progress we see from mgt. and PBYI.

■ Valuation: We maintain our Buy and \$27 PT

Our PT is based on our sum-of-the-parts analysis.

Highlights (US\$m)	-	12/11	12/12E	12/13E	12/14E
Revenues	-	0	0	0	0
EBIT (UBS)	-	(10)	(64)	(31)	(50)
Net Income (UBS)	-	(10)	(64)	(30)	(48)
EPS (UBS, US\$)	-	(1.32)	(2.98)	(1.03)	(1.58)
Net DPS (UBS, US\$)	-	0.00	0.00	0.00	0.00
Profitability & Valuation	5-yr hist av.	12/11	12/12E	12/13E	12/14E
EBIT margin %	-	-	-	-	-
ROIC (EBIT) %	-	-	<-500	<-500	<-500
EV/EBITDA (core) x	-	-	-9.2	-18.8	-12.1
PE (UBS) x	-	-	NM	NM	NM
Net dividend yield %	-	-	0.0	0.0	0.0

Source: Company accounts, Thomson Reuters, UBS estimates. (UBS) valuations are stated before goodwill-related charges and other adjustments for abnormal and economic items at the analysts' judgement.

Valuations: based on an average share price that year, (E): based on a share price of US\$24.26 on 20 Feb 2013 18:41 EST

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Global Equity Research

Americas

Biotechnology

12-month rating **Buy**
Unchanged

12m price target **US\$27.00**
Unchanged

Price **US\$24.26**

RIC: PBYI.N BBG: PBYI US

20 February 2013

Trading data

52-wk range	US\$26.60-11.00
Market cap.	US\$0.67bn
Shares o/s	27.5m (COM)
Free float	95%
Avg. daily volume ('000)	15
Avg. daily value (m)	US\$0.3

Balance sheet data 12/12E

Shareholders' equity	US\$0.13bn
P/BV (UBS)	4.0x
Net Cash (debt)	US\$0.13bn

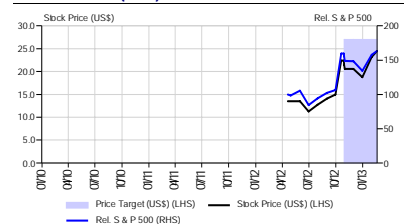
Forecast returns

Forecast price appreciation	+11.3%
Forecast dividend yield	0.0%
Forecast stock return	+11.3%
Market return assumption	5.3%
Forecast excess return	+6.0%

EPS (UBS, US\$)

	12/12E	12/11
	UBS	Cons. Actual
Q1	(0.59)	(0.59)
Q2	(0.73)	(0.74)
Q3	(1.29)	(1.29)
Q4E	(0.45)	(0.75)
12/12E	(2.98)	(3.34)
12/13E	(1.03)	(2.36)

Performance (US\$)



Source: UBS

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ANALYST CERTIFICATION AND REQUIRED DISCLOSURES BEGIN ON PAGE 5.

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Key New Info

■ **HER2 mutated lung cancer**

- The study will evaluate neratinib + Torisel versus neratinib alone (prior data was in combination with Torisel, but it is unclear if Torisel provides a significant advantage)
- The initial cohort will have 13 patients per arm. However, once the arm with the highest ORR is chosen (likely mid-2013), management will expand into a 40-50 patient expansion study. This study is in 2nd line NSCLC patients.
- Management recently met with FDA and FDA guided management to enroll an additional single-arm study with all comers (i.e., 1st and 2nd line patients). Once data is available from the expansion cohort of the 1st study and this second study, management can file on ORR. It will have to enroll a randomized study for confirmation. We would expect this second all comers study to begin in early 2014 with filing by late 2014 or early 2015. As a reminder this is the same path to market as Pfizer's crizotinib (Xalkori).

■ **Neo-adjuvant studies**

- **iSPY2 (NIH study)** – This study has two arms: Taxol plus herceptin and Taxol plus neratinib. The data from this study should be available by mid-2013. This study enrolled patients at a higher risk of recurrence, so the population is harder to treat. This data could inform data from the larger NSABP study.
- **NSABP** – This study has three arms: Taxol plus herceptin, Taxol plus neratinib and Taxol plus herceptin plus neratinib. Recall this design is identical to the neo-ALTTO study which included Tykerb instead of neratinib. Clearly depending upon the outcome of the iSPY2 study (recall Tykerb was inferior to herceptin in that study, but when all three agents were combined the Tykerb plus herceptin plus Taxol was superior to the arm containing herceptin plus Taxol), there is the potential for neratinib to produce significantly better results than Tykerb.

Puma Biotechnology

Income statement (US\$m)	-	-	-	12/11	12/12E	% ch	12/13E	% ch	12/14E	% ch
Revenues	-	-	-	0	0	-	0	-	0	-
Operating expenses (ex depn)	-	-	-	(10)	(63)	518.8	(30)	-52.7	(49)	65.6
EBITDA (UBS)	-	-	-	(10)	(63)	518.8	(30)	-52.7	(49)	65.6
Depreciation	-	-	-	0	(1)	9244.0	(1)	5.0	(1)	5.0
Operating income (EBIT, UBS)	-	-	-	(10)	(64)	528.0	(31)	-51.8	(50)	63.5
Other income & associates	-	-	-	0	0	-	0	-	0	-
Net interest	-	-	-	0	0	1554.7	1	1178.0	2	137.5
Abnormal items (pre-tax)	-	-	-	0	0	-	0	-	0	-
Profit before tax	-	-	-	(10)	(64)	522.7	(30)	-53.0	(48)	61.6
Tax	-	-	-	0	0	-	0	-	0	-
Profit after tax	-	-	-	(10)	(64)	522.7	(30)	-53.0	(48)	61.6
Abnormal items (post-tax)	-	-	-	0	0	-	0	-	0	-
Minorities / pref dividends	-	-	-	0	0	-	0	-	0	-
Net income (local GAAP)	-	-	-	(10)	(64)	522.7	(30)	-53.0	(48)	61.6
Net Income (UBS)	-	-	-	(10)	(64)	522.7	(30)	-53.0	(48)	61.6
Tax rate (%)	-	-	-	0	0	-	0	-	0	-
Pre-abnormal tax rate (%)	-	-	-	0	0	-	0	-	0	-
Per share (US\$)	-	-	-	12/11	12/12E	% ch	12/13E	% ch	12/14E	% ch
EPS (local GAAP)	-	-	-	(1.32)	(2.98)	125.8	(1.03)	-65.4	(1.58)	53.6
EPS (UBS)	-	-	-	(1.32)	(2.98)	125.8	(1.03)	-65.4	(1.58)	53.6
Net DPS	-	-	-	0.00	0.00	-	0.00	-	0.00	-
Cash EPS	-	-	-	(1.32)	(2.93)	122.5	(1.00)	-66.1	(1.55)	55.6
BVPS	-	-	-	2.71	6.01	121.6	3.54	-41.2	1.92	-45.7
Balance sheet (US\$m)	-	-	-	12/11	12/12E	% ch	12/13E	% ch	12/14E	% ch
Cash and equivalents	-	-	-	53	125	135.0	97	-22.4	51	-47.7
Other current assets	-	-	-	0	0	0.0	0	0.0	0	0.0
Total current assets	-	-	-	54	126	134.3	98	-22.4	51	-47.6
Net tangible fixed assets	-	-	-	1	3	293.2	5	83.9	7	51.2
Net intangible fixed assets	-	-	-	0	0	-	0	-	0	-
Investments / other assets	-	-	-	1	1	0.0	1	0.0	1	0.0
Total assets	-	-	-	55	129	133.7	104	-20.0	60	-42.4
Trade payables & other ST liabilities	-	-	-	1	1	1.5	1	1.6	1	1.7
Short term debt	-	-	-	0	0	-	0	-	0	-
Total current liabilities	-	-	-	1	1	1.5	1	1.6	1	1.7
Long term debt	-	-	-	0	0	-	0	-	0	-
Other long term liabilities	-	-	-	0	0	0.0	0	0.0	0	0.0
Total liabilities	-	-	-	1	1	0.8	1	0.9	1	1.0
Equity & minority interests	-	-	-	54	128	136.2	103	-20.2	59	-42.8
Total liabilities & equity	-	-	-	55	129	133.7	104	-20.0	60	-42.4
Cash flow (US\$m)	-	-	-	12/11	12/12E	% ch	12/13E	% ch	12/14E	% ch
Net income	-	-	-	(10)	(64)	522.7	(30)	-53.0	(48)	61.6
Depreciation	-	-	-	0	1	9244.0	1	5.0	1	5.0
Net change in working capital	-	-	-	0	0	-97.2	0	10.0	0	10.0
Other (operating)	-	-	-	8	8	4.5	4	-50.0	4	10.0
Net cash from operations	-	-	-	(2)	(55)	2324.7	(25)	-54.5	(43)	72.3
Capital expenditure	-	-	-	0	(3)	1088.9	(3)	10.0	(4)	10.0
Net (acquisitions) / disposals	-	-	-	0	0	-	0	-	0	-
Other changes in investments	-	-	-	(1)	0	-	0	-	0	-
Cash from investing activities	-	-	-	(1)	(3)	129.8	(3)	10.0	(4)	10.0
Increase/(decrease) in debt	-	-	-	0	0	-	0	-	0	-
Share issues / (repurchases)	-	-	-	57	130	-	0	-	0	-
Dividends paid	-	-	-	0	0	-	0	-	0	-
Other cash from financing	-	-	-	0	0	-	0	-	0	-
Cash from financing activities	-	-	-	57	130	127.8	0	-	0	-
Cash flow chge in cash & equivalents	-	-	-	53	72	-	(28)	-	(46)	-
FX / non cash items	-	-	-	-	0	-	0	-	0	-
Bal sheet chge in cash & equivalents	-	-	-	-	72	-	(28)	-	(46)	-
Core EBITDA	-	-	-	(10)	(63)	518.8	(30)	-52.7	(49)	65.6
Maintenance capital expenditure	-	-	-	0	(3)	1088.9	(3)	10.0	(4)	10.0
Maintenance net working capital	-	-	-	0	0	-	0	-	0	-
Operating free cash flow, pre-tax	-	-	-	(10)	(66)	532.7	(33)	-49.8	(53)	60.0

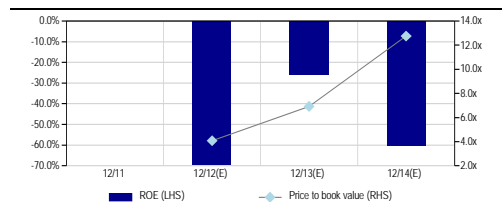
Source: Company accounts, UBS estimates. (UBS) valuations are stated before goodwill-related charges and other adjustments for abnormal and economic items at the analysts' judgement. Note: For some companies, the data represents an extract of the full company accounts.

Company profile

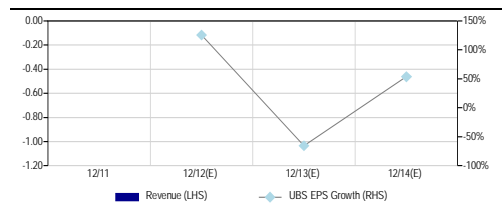
Puma is a biotechnology company, focused on the development of small molecules for the treatment of cancer. Its key development compound is an agent for HER2+ disease called neratinib. Neratinib is currently being studied in metastatic breast cancer, CNS disease, neoadjuvant breast cancer and lung cancer. We expect key data in 2013.

Profitability

ROE v Price to book value



Growth (UBS EPS)



Valuation (x)	5Yr Avg	-	12/11	12/12E	12/13E	12/14E
P/E (local GAAP)	-	-	-	NM	NM	NM
P/E (UBS)	-	-	-	NM	NM	NM
P/CEPS	-	-	-	NM	NM	NM
Net dividend yield (%)	-	-	-	0.0	0.0	0.0
P/BV	-	-	-	4.0	6.9	12.6
EV/revenue (core)	-	-	-	-	-	-
EV/EBITDA (core)	-	-	-	-9.2	-18.8	-12.1
EV/EBIT (core)	-	-	-	NM	NM	NM
EV/OpFCF (core)	-	-	-	NM	NM	NM
EV/op. invested capital	-	-	-	NM	NM	NM

Enterprise value (US\$m)	-	12/11	12/12E	12/13E	12/14E
Average market cap	-	-	668	668	668
+ minority interests	-	0	0	0	0
+ average net debt (cash)	-	(10)	(89)	(111)	(74)
+ pension obligations and other	-	0	0	0	0
- non-core asset value	-	0	0	0	0
Core enterprise value	-	-	579	557	594

Growth (%)	5Yr Avg	-	12/11	12/12E	12/13E	12/14E
Revenue	-	-	-	-	-	-
EBITDA (UBS)	-	-	-	NM	-52.7	65.6
EBIT (UBS)	-	-	-	NM	-51.8	63.5
EPS (UBS)	-	-	-	125.8	-65.4	53.6
Cash EPS	-	-	-	122.5	-66.1	55.6
Net DPS	-	-	-	-	-	-
BVPS	-	-	-	121.6	-41.2	-45.7

Margins (%)	5Yr Avg	-	12/11	12/12E	12/13E	12/14E
EBITDA / revenue	-	-	-	-	-	-
EBIT / revenue	-	-	-	-	-	-
Net profit (UBS) / revenue	-	-	-	-	-	-

Return on capital (%)	5Yr Avg	-	12/11	12/12E	12/13E	12/14E
EBIT ROIC (UBS)	-	-	-	NM	NM	NM
ROIC post tax	-	-	-	NM	NM	NM
Net ROE	-	-	-	(69.6)	(25.9)	(60.0)

Coverage ratios (x)	5Yr Avg	-	12/11	12/12E	12/13E	12/14E
EBIT / net interest	-	-	-	-	-	-
Dividend cover (UBS EPS)	-	-	-	-	-	-
Div. payout ratio (% UBS EPS)	-	-	-	-	-	-
Net debt / EBITDA	-	-	5.3	2.0	3.3	1.0

Efficiency ratios (x)	5Yr Avg	-	12/11	12/12E	12/13E	12/14E
Revenue / op. invested capital	-	-	-	0.0	0.0	0.0
Revenue / fixed assets	-	-	-	0.0	0.0	0.0
Revenue / net working capital	-	-	-	0.0	0.0	0.0

Investment ratios (x)	5Yr Avg	-	12/11	12/12E	12/13E	12/14E
OpFCF / EBIT	-	-	1.0	1.0	1.1	1.1
Capex / revenue (%)	-	-	-	-	-	-
Capex / depreciation	-	-	NM	3.0	3.1	3.3

Capital structure (%)	5Yr Avg	-	12/11	12/12E	12/13E	12/14E
Net debt / total equity	-	-	(98.2)	(97.7)	(94.9)	(86.8)
Net debt / (net debt + equity)	-	-	NM	NM	NM	NM
Net debt (core) / EV	-	-	-	(15.5)	(20.0)	(12.5)

Source: Company accounts, UBS estimates. (UBS) valuations are stated before goodwill-related charges and other adjustments for abnormal and economic items at the analysts' judgement.

Valuations: based on an average share price that year, (E): based on a share price of US\$24.26 on 20 Feb 2013 18:41 EST Market cap(E) may include forecast share issues/buybacks.

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■ Puma Biotechnology

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■ Statement of Risk

Key risks associated with a development-stage biotechnology company include: (a) the ability to finance the company through debt and equity issuances; (b) the outcome of clinical trials and regulatory approvals; and (c) the ability of management to bring its development projects to the market.

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UBS 12-Month Rating	Rating Category	Coverage ¹	IB Services ²
Buy	Buy	48%	34%
Neutral	Hold/Neutral	42%	35%
Sell	Sell	9%	18%
UBS Short-Term Rating	Rating Category	Coverage ³	IB Services ⁴
Buy	Buy	less than 1%	33%
Sell	Sell	less than 1%	0%

1:Percentage of companies under coverage globally within the 12-month rating category.

2:Percentage of companies within the 12-month rating category for which investment banking (IB) services were provided within the past 12 months.

3:Percentage of companies under coverage globally within the Short-Term rating category.

4:Percentage of companies within the Short-Term rating category for which investment banking (IB) services were provided within the past 12 months.

Source: UBS. Rating allocations are as of 31 December 2012.

UBS Investment Research: Global Equity Rating Definitions

UBS 12-Month Rating	Definition
Buy	FSR is > 6% above the MRA.
Neutral	FSR is between -6% and 6% of the MRA.
Sell	FSR is > 6% below the MRA.
UBS Short-Term Rating	Definition
Buy	Buy: Stock price expected to rise within three months from the time the rating was assigned because of a specific catalyst or event.
Sell	Sell: Stock price expected to fall within three months from the time the rating was assigned because of a specific catalyst or event.

KEY DEFINITIONS

Forecast Stock Return (FSR) is defined as expected percentage price appreciation plus gross dividend yield over the next 12 months.

Market Return Assumption (MRA) is defined as the one-year local market interest rate plus 5% (a proxy for, and not a forecast of, the equity risk premium).

Under Review (UR) Stocks may be flagged as UR by the analyst, indicating that the stock's price target and/or rating are subject to possible change in the near term, usually in response to an event that may affect the investment case or valuation.

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UBS Securities LLC: Matthew Harrison; Matthew Roden, PhD.

Company Disclosures

Company Name	Reuters	12-mo rating	Short-term rating	Price	Price date
Puma Biotechnology ^{2, 4, 5, 6, 16}	PBYI.N	Buy	N/A	US\$24.26	20 Feb 2013

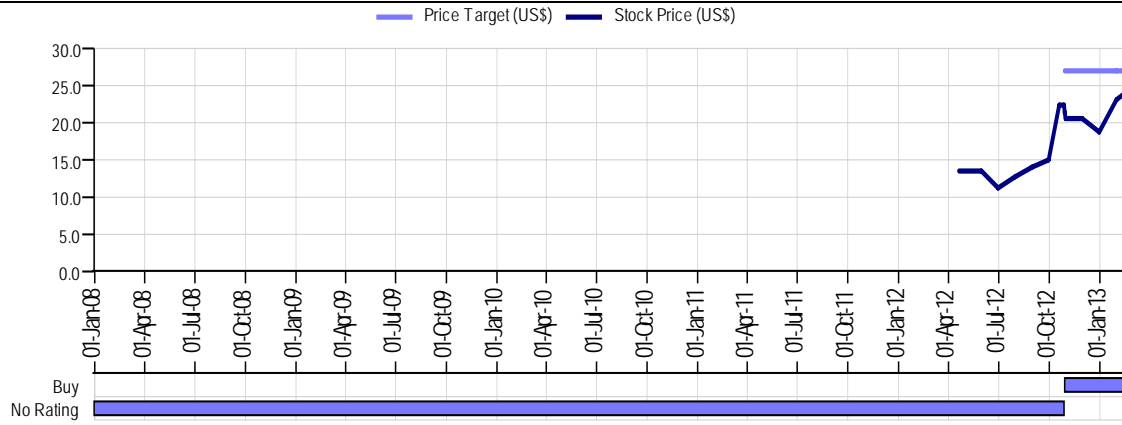
Source: UBS. All prices as of local market close.

Ratings in this table are the most current published ratings prior to this report. They may be more recent than the stock pricing date

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Puma Biotechnology (US\$)



Source: UBS; as of 20 Feb 2013

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