

## UBS Investment Research

### Puma Biotechnology

#### Fast PhIII Path & Positive News at SABCS

##### ■ What's changed? PhII combo data with Torisel & new HER2 mutations

Updated combo data for neratinib + Torisel demonstrated ~50% ORR (all PRs) at the MTD (240mg neratinib QD + 2mg weekly Torisel) and median PFS of 4.2mo in 4<sup>th</sup> line metastatic HER2+ pts. Add'l, data was presented on new mutations for HER2+ disease (spec., V777L, G309A, D796H, V842I & L755S). In these mutations, neratinib has IC<sub>50</sub>s of ~2nm (lapatinib ~400-1,000nm), an indication of sig. neratinib activity. A PhII (NCT01670877) is underway for this ~4,000 pt pop.

##### ■ Our analysis: 4<sup>th</sup> line Torisel combo provides fast path to market

From mgt., we learned PhII combo data was presented to FDA at an end-of-PhII mtg. FDA written notes outline PhIII: (1) Primary endpoints of ORR and OS, but **ORR (assessed at wk 12) can be used for accelerated approval**; (2) 3 arms: neratinib+Torisel, neratinib alone, or physician's choice. Mgt. plans to work with FDA on an SPA and initiate PhIII in ~2Q13. With 4<sup>th</sup> line SOC ORRs at ~10%, the 50% PhII neratinib ORR provides sig. confidence in an accelerated pathway and, in our opinion, is highly indicative that neratinib could be on the market in 2014.

##### ■ Impact on the stock: Greater potential for upside in 2013

The updates from San Antonio provide more confidence that there are multiple upside drivers in 2013 with a reasonable chance of success. We can now add the 4<sup>th</sup> line PhIII and the HER2 mutations PhII to the already long list of PhIIs in CNS disease, neoadjuvant, HER mutated lung cancer and PhIII start as key 2013 events.

##### ■ 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	-	-	-7.1	-14.2	-9.4
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\$19.38 on 07 Dec 2012 19:38 EST

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## Global Equity Research

Americas

Biotechnology

12-month rating **Buy**  
**Unchanged**

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

Price **US\$19.38**

RIC: PBVI.N BBG: PBVI US

9 December 2012

#### Trading data

52-wk range	US\$22.60-11.00
Market cap.	US\$0.53bn
Shares o/s	27.5m (COM)
Free float	95%
Avg. daily volume ('000)	32
Avg. daily value (m)	US\$0.7

#### Balance sheet data 12/12E

Shareholders' equity	US\$0.13bn
P/BV (UBS)	3.2x
Net Cash (debt)	US\$0.13bn

#### Forecast returns

Forecast price appreciation	+39.3%
Forecast dividend yield	0.0%
Forecast stock return	+39.3%
Market return assumption	5.2%
Forecast excess return	+34.1%

#### 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)	(0.61)
12/12E	(2.98)	(2.92)
12/13E	(1.03)	(2.24)

#### Performance (US\$)



Source: UBS

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# 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

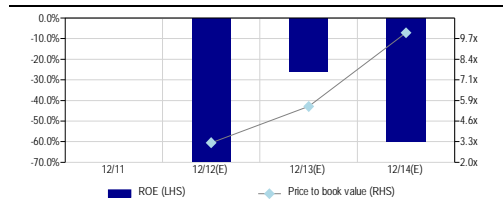
Source: Company accounts, UBS estimates. (UBS) valuations are stated before goodwill-related charges and other adjustments for abnormal and economic items at the analysts' judgement. Note: For some companies, the data represents an extract of the full company accounts.

## Company profile

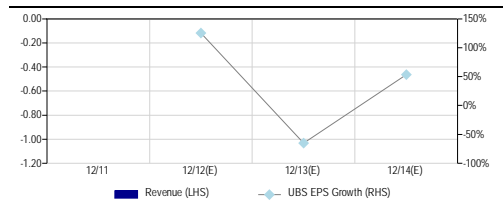
Puma is a biotechnology company, focused on the development of small molecules for the treatment of cancer. Its key development compound is an agent for HER2+ disease called neratinib. Neratinib is currently being studied in metastatic breast cancer, CNS disease, neoadjuvant breast cancer and lung cancer. 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	-	-	-	3.2	5.5	10.1
EV/revenue (core)	-	-	-	-	-	-
EV/EBITDA (core)	-	-	-	-7.1	-14.2	-9.4
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	-	-	534	534	534
+ 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	-	-	444	422	460

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	-	-	-	(20.1)	(26.4)	(16.1)

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\$19.38 on 07 Dec 2012 19:38 EST Market cap(E) may include forecast share issues/buybacks.

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## ■ Puma Biotechnology

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.

## ■ 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 <sup>1</sup>	IB Services <sup>2</sup>
Buy	Buy	50%	31%
Neutral	Hold/Neutral	41%	31%
Sell	Sell	9%	20%
UBS Short-Term Rating	Rating Category	Coverage <sup>3</sup>	IB Services <sup>4</sup>
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 30 September 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.

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**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).

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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
<b>Puma Biotechnology</b> <sup>2, 4, 5, 6, 16</sup>	PBYI.N	Buy	N/A	US\$19.38	07 Dec 2012

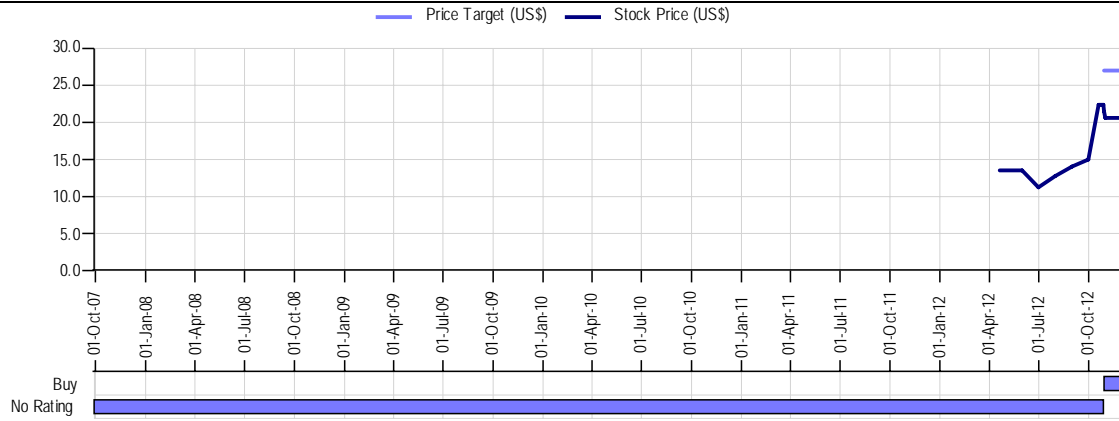
Source: UBS. All prices as of local market close.

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Unless otherwise indicated, please refer to the Valuation and Risk sections within the body of this report.

## Puma Biotechnology (US\$)



Source: UBS; as of 07 Dec 2012



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