

# **UBS Investment Research First Read: Puma Biotechnology**

# Perjeta Highlights Opportunity/Competition

#### ■ What's changed? Roche's Perjeta granted priority review in neoadjuvant

Based on the NEOSHPERE (n=417) and TRYPHAENA (n=225), Perjeta was granted priority review (PDUFA 10/31/2013). Perjeta demonstrated a pCR rate of 45.8% vs 29% for Herceptin + chemo (p=0.014). The PhIII APHINITY study (n=4,800) will be the confirmatory study.

#### ■ Our analysis: Demonstrates pCR path valid; highlights competition

The good news is that Roche has validated both that neoadjuvant products can file under the new pCR endpoint and that accelerated approval is possible – both points made by Puma mgt. The bad news is that Roche will have ~1.5 yrs of runway before neratinib could enter the neoadjuvant market. That said, the market will need to be developed and Roche will clearly help the market to reach its potential. Right now, the biggest question for us is if neratinib will have to run a non-inferiority study vs. Perjeta or can continue with superiority vs. Herceptin.

#### **■** Impact on the stock: A mixed bag

On the one hand, validation of the opportunity is good. And we only have 2022E WW neoadjuvant sales of ~\$300M in our model (at 50% probability of success) which leaves more than enough room for competition in the ~\$2B pot. market. That said, we believe most investors (incl. ourselves) were skeptical of Roche's ability to file on NEOSPHERE and thus today's news is somewhat unexpected and will likely lead to pressure on PBYI as the first-to-market optionally is now gone.

#### ■ Valuation: We maintain our Buy and \$49 PT

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

12/11	12/12	12/13E	12/14E	12/15E
0	0	0	0	19
(10)	(74)	(47)	(53)	(47)
(10)	(74)	(46)	(51)	(44)
(1.32)	(3.42)	(1.58)	(1.64)	(1.27)
0.00	0.00	0.00	0.00	0.00
5-yr hist av.	12/12	12/13E	12/14E	12/15E
-	-	-	-	-240.7
-	>500	366.9	308.1	296.7
-	-3.4	-26.8	-24.4	-27.5
-	NM	NM	NM	NM
-	0.0	0.0	0.0	0.0
	0 (10) (10) (1.32) 0.00	0 0 (10) (74) (10) (74) (1.32) (3.42) 0.00 0.00 5-yr hist av. 12/12 >500 3.4 - NM	0 0 0 0 (10) (74) (47) (10) (74) (46) (1.32) (3.42) (1.58) (0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.	0 0 0 0 0 0 0 (10) (74) (47) (53) (10) (74) (46) (51) (1.32) (3.42) (1.58) (1.64) 0.00 0.00 0.00 0.00 0.00 0.00 0.00 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' ludgement.

Valuations: based on an average share price that year, (E): based on a share price of US\$47.48 on 01 Jul 2013 19:41 EDT

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# **Global Equity Research**

Americas

Biotechnology

12-month rating

Buy

Unchanged

12m price target

US\$49.00

Unchanged

Price

US\$47.48

RIC: PBYI.N BBG: PBYI US

2 July 2013

#### Trading data

52-wk range	US\$47.48-11.10
Market cap.	US\$1.36bn
Shares o/s	28.7m (COM)
Free float	95%
Avg. daily volume ('000)	48
Avg. daily value (m)	US\$1.9

#### Balance sheet data 12/13E

Shareholders' equity	US\$0.09bn
P/BV (UBS)	16.0x
Net Cash (debt)	US\$0.11bn

#### Forecast return

FUIECast returns	
Forecast price appreciation	+3.2%
Forecast dividend yield	0.0%
Forecast stock return	+3.2%
Market return assumption	5.4%
Forecast excess return	-2.2%

#### EPS (UBS, US\$)

	12/	13E	12/12
	UBS	Cons.	Actual
Q1	(0.41)	(0.41)	(0.59)
Q2E	(0.39)	(0.52)	(0.73)
Q3E	(0.39)	(0.55)	(1.29)
Q4E	(0.39)	(0.58)	(0.83)
12/13E	(1.58)	(2.05)	
12/14E	(1.64)	(2.07)	

#### Performance (US\$)



Source: UBS

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# **Puma Biotechnology**

				40/44	40/40	10/105	0/ 1	40/445	0/ 1	40/455	0/ 1
Income statement (US\$m) Revenues		<u> </u>	<u> </u>	12/11 0	12/12	12/13E 0	% ch	12/14E 0	% ch	12/15E 19	% ch
Operating expenses (ex depn)	-	-	-	-	-	-	_	-	-	(66)	-
EBITDA (UBS)	-			(10)	(74)	(46)	-37.6	(52)	13.2	(47)	-11.2
Depreciation	-	-	-	0	0	0	5.0	0	5.0	0	5.0
Operating income (EBIT, UBS)	-	-	-	(10)	(74)	(47)	-37.4	(53)	13.2	(47)	-11.1
Other income & associates	-	-	-	0	0	0	-	0	-	0	-
Net interest	-	-	-	0	0	0	104.1	2	<i>850.0</i>	3	73.7
Abnormal items (pre-tax)	-	-	-	0	0	0	-	0	-	0	-
Profit before tax	-	-	-	(10)	(74)	(46)	-37.6	(51)	9.6	(44)	-14.3
Tax	-	-	-	0	0	0	-	0	-	0	-
Profit after tax	-	-	-	(10)	(74)	(46)	-37.6	(51)	9.6	(44)	-14.3
Abnormal items (post-tax)	-	-	-	0	0	0	-	0	-	0	-
Minorities / pref dividends	-	-	-	(10)	(7.1)	0	- 27 /	(51)	- 07	0	- 11.2
Net income (local GAAP) Net Income (UBS)				(10) (10)	(74) (74)	(46) (46)	-37.6 -37.6	(51) (51)	9.6 9.6	(44) (44)	-14.3 -14.3
Net Income (OBS)	-	-	-	(10)	(74)	(40)	-37.0	(31)	7.0	(44)	-14.3
Tax rate (%)	-	-	-	0	0	0	-	0	-	0	-
Pre-abnormal tax rate (%)	-	-	-	0	0	0	-	0	-	0	-
Dor oboro (LIC¢)				10/11	12/12	10/10	0/ 04	12/145	0/ ah	12/155	0/ ah
Per share (US\$) EPS (local GAAP)	-	-	-	12/11 (1.32)	12/12 (3.42)	12/13E (1.58)	<b>% ch</b> -53.9	12/14E (1.64)	% ch 4.3	12/15E (1.27)	% ch -23.0
EPS (UBS)	-	-	-	(1.32)	(3.42)	(1.58)	-53.9 -53.9	(1.64)	4.3	(1.27)	-23.0
Net DPS	-	-	-	0.00	0.00	0.00	-	0.00	-	0.00	20.0
Cash EPS	-	-	-	(1.32)	(3.41)	(1.57)	-54.0	(1.63)	4.3	(1.26)	-23.1
BVPS	-	-	-	2.71	4.68	2.97	-36.5	1.36	-54.2	2.46	80.3
Balance sheet (US\$m)	-	-	-	12/11	12/12	12/13E	% ch	12/14E	% ch	12/15E	% ch
Cash and equivalents	-	-	-	53	137	106	-23.0	60	-43.7	100	68.5
Other current assets	-	-	-	0 54	12 149	1 107	-91.8 -28.3	1	-43.3	1 101	<i>0.0</i> <i>67.4</i>
Total current assets Net tangible fixed assets	-	-	-	5 <del>4</del> 1	2	3	-28.3 41.2	<b>61</b> 4	-43.3 32.5	5	07.4 27.4
Net intangible fixed assets	_	-	-	0	0	0	41.2	0	32.3	0	27.4
Investments / other assets		_	-	1	1	1	0.0	1	0.0	1	0.0
Total assets				55	152	111	-27.1	66	-40.7	108	63.7
Trade payables & other ST liabilities	-	_	_	1	22	22	0.2	22	0.2	21	-2.7
Short term debt	-	-	-	0	0	0	-	0	-	0	-
Total current liabilities	-	-	-	1	22	22	0.2	22	0.2	21	-2.7
Long term debt	-	-	-	0	0	0	-	0	-	0	-
Other long term liabilities	-	-	-	0	1	1	0.0	1	0.0	1	0.0
Total liabilities	-	-	-	1	23	23	0.2	23	0.2	22	-2.5
Equity & minority interests	-	-	-	54	130	88	-31.9	43	<i>-51.3</i>	85	99.0
Total liabilities & equity	-	-	-	55	152	111	-27.1	66	-40.7	108	63.7
Cash flow (US\$m)	-		-	12/11	12/12	12/13E	% ch	12/14E	% ch	12/15E	% ch
Net income	=	-	-	(10)	(74)	(46)	-37.6	(51)	9.6	(44)	-14.3
Depreciation	-	-	-	0	0	0	5.0	0	5.0	0	5.0
Net change in working capital	-	-	-	0	10	11	2.1	0	- <i>99.5</i>	(1)	-
Other (operating)	-	-	-	8	20	5	-74.5	6	10.0	6	10.0
Net cash from operations	-	-	-	(2)	(44)	(30)	-30.8	(45)	47.7	(38)	-16.0
Capital expenditure	-	-	-	0	(1)	(1)	10.0	(1)	10.0	(1)	10.0
Net (acquisitions) / disposals	=	-	-	0	0	0	-	0	-	0	-
Other changes in investments	-	-	-	(1)	0	0	- 4.2	0	10.0	0	10.0
Cash from investing activities Increase/(decrease) in debt	-	-	-	(1)	(1)	(1)	-4.3	(1)	10.0	(1)	10.0
Share issues / (repurchases)	-	-	-	0 57	0 129	0	-	0	-	0 80	-
Dividends paid	-	-	-	0	0	0	-	0	-	0	-
Other cash from financing	-	-	-	0	0	0	-	0	-	0	-
Cash from financing activities	-			57	129	0	-100.0	0	0.0		177777.8
•							.55.5		0.0		
Cash flow chge in cash & equivalents	-	-	•	53	84	(32)	-	(46)	-	41	-
FX / non cash items	-	-	-	-	0	0	-	0	-	0	-
Bal sheet chge in cash & equivalents	-	-	-	-	84	(32)	-	(46)	-	41	-
Core EBITDA	-	_	-	(10)	(74)	(46)	-37.6	(52)	13.2	(47)	-11.2
Maintenance capital expenditure	-	-	-	0	(1)	(1)	10.0	(1)	10.0	(1)	10.0
Maintenance net working capital	-	-	-	0	0	0	-	0	-	0	-
Operating free cash flow, pre-tax	-	-	-	(10)	(75)	(47)	-36.9	(54)	13.1	(48)	-10.7

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.

# **Global Equity Research**

Americas

Biotechnology

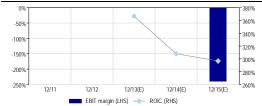
12-month rating	Buv

12m price target US\$49.00

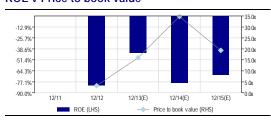
# Company profile

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

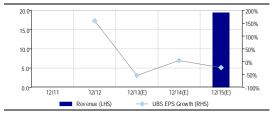
# Profitability



# ROE v Price to book value



### **Growth (UBS EPS)**



# **Puma Biotechnology**

Valuation (x)	5Yr Avg	12/11	12/12	12/13E	12/14E	12/15E
P/E (local GAAP)	=	-	NM	NM	NM	NM
P/E (UBS)	-	-	NM	NM	NM	NM
P/CEPS	-	-	NM	NM	NM	NM
Net dividend yield (%)	=	-	0.0	0.0	0.0	0.0
P/BV	-	-	3.2	16.0	34.8	19.3
EV/revenue (core)	-	-	-	-	-	NM
EV/EBITDA (core)	-	-	-3.4	-26.8	-24.4	-27.5
EV/EBIT (core)	-	-	NM	NM	NM	NM
EV/OpFCF (core)	-	-	NM	NM	NM	NM
EV/op. invested capital	-	-	NM	NM	NM	NM
Enterprise value (US\$m)		12/11	12/12	12/13E	12/14E	12/15E
Average market cap		-	344	1,362	1,362	1,362
+ minority interests		0	0	0	0	0
+ average net debt (cash)		(10)	(95)	(122)	(83)	(80)
+ pension obligations and other		Ó	0	0	0	0
- non-core asset value		0	0	0	0	0
Core enterprise value		-	249	1,240	1,279	1,282
Growth (%)	5Yr Avg	12/11	12/12	12/13E	12/14E	12/15E
Revenue		-	-	-	-	-
EBITDA (UBS)	-	-	NM	-37.6	13.2	-11.2
EBIT (UBS)	-	-	NM	-37.4	13.2	-11.1
EPS (UBS)	=	-	159.3	-53.9	4.3	-23.0
Cash EPS	=	-	158.7	-54.0	4.3	-23.1
Net DPS	=	-	-	-	-	-
BVPS	-	-	72.5	-36.5	-54.2	80.3
Margins (%)	5Yr Avg	12/11	12/12	12/13E	12/14E	12/15E
EBITDA / revenue	-	-	-	-	-	NM
EBIT / revenue	-	-	-	-	-	-240.7
Net profit (UBS) / revenue	-	-	-	-	-	NM
Return on capital (%)	5Yr Avg	12/11	12/12	12/13E	12/14E	12/15E
EBIT ROIC (UBS)	-	-	NM	NM	NM	NM
ROIC post tax	-	-	NM	NM	NM	NM
Net ROE	-	-	(81.1)	(42.9)	(78.4)	(68.7)
Coverage ratios (x)	5Yr Avg	12/11	12/12	12/13E	12/14E	12/15E
EBIT / net interest	=	-	-	-	-	-
Dividend cover (UBS EPS)	-	-	-	-	-	-
Div. payout ratio (%, UBS EPS)	=	-	-	-	-	-
Net debt / EBITDA	-	5.3	1.9	2.3	1.1	2.2
Efficiency ratios (x)	5Yr Avg	12/11	12/12	12/13E	12/14E	12/15E
Revenue / op. invested capital	-	-	0.0	0.0	0.0	NM
Revenue / fixed assets	-	-	0.0	0.0	0.0	4.2
Revenue / net working capital	<u> </u>		0.0	0.0	0.0	NM
Investment ratios (x)	5Yr Avg	12/11	12/12	12/13E	12/14E	12/15E
OpFCF / EBIT	-	1.0	1.0	1.0	1.0	1.0
Capex / revenue (%)	- -	-	1.0	-	-	7.3
Capex / depreciation	- -	NM	4.0	4.2	4.4	4.6
Capital structure (%)	5Yr Avg	12/11	12/12	12/13E	12/14E	12/15E
	STEAVY			NM		NM
1 ' '		(00.0)				
Net debt / total equity	-	(98.2) NM	NM NM		NM NM	
' '	-	(98.2) NM	NM (38.3)	NM (9.8)	NM (6.5)	NM (6.2)

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

Valuations: based on an average share price that year, (E): based on a share price of US\$47.48 on 01 Jul 2013 19:41 EDT 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	
Buy	Buy	45%	36%	
Neutral	Hold/Neutral	45%	36%	
Sell	Sell	11%	19%	
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%	

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

Source: UBS. Rating allocations are as of 31 March 2013.

#### **UBS Investment Research: Global Equity Rating Definitions**

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

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

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

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

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**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
Puma Biotechnology <sup>2, 4, 6, 16</sup>	PBYI.N	Buy	N/A	US\$47.48	01 Jul 2013

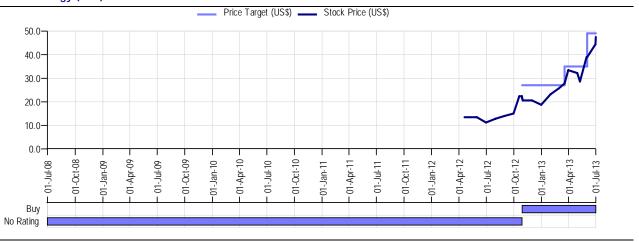
Source: UBS. All prices as of local market close.

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

# Puma Biotechnology (US\$)



Source: UBS; as of 01 Jul 2013

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