August 22, 2012

OUTPERFORM

Reason for report:

COMPANY UPDATE

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LEERINK SWANN

HEALTHCARE EQUITY RESEARCH

PUMA BIOTECHNOLOGY, INC.

Management Update Highlights Increasing Number of Shots on Goal

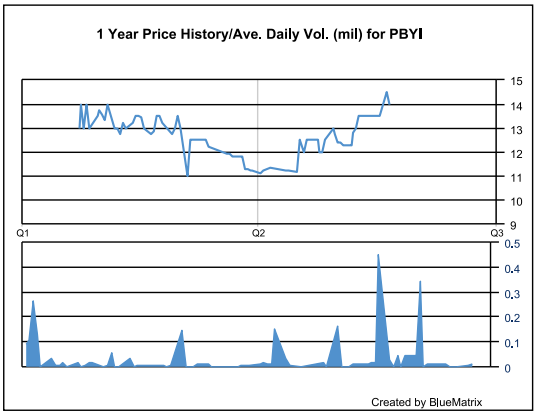
• Bottom Line: We recently hosted investor meetings with senior management of PBYI and are encouraged by the significant recent progress of lead candidate neratinib (pan-HER tyrosine kinase inhibitor) as well as potential new opportunities beyond HER2-overexpressing breast cancer. Specifically there is now greater visibility for the Phase III program with two Phase III trials in HER2-overexpressing metastatic breast cancer (mBC). Additionally, recent data suggest neratinib may have an opportunity in two new indications---NSCLC with HER2 mutation and breast cancer with undisclosed new mutation, both of which could rapidly develop into pivotal programs by YE:12. We look for a catalyst-rich 2H:12 and beyond, with potential to maximize neratinib commercial opportunities in multiple cancer settings. Our valuation remains $20.

• Intriguing new opportunities for neratinib. PBYI for the first time disclosed neratinib development in breast cancer patients with an undisclosed new mutation that is present in 2% of total breast cancer population. Initial look at the data from the preclinical and Phase I studies is anticipated in the upcoming San Antonio Breast Cancer Symposium (SABCS, Dec 4-8, 2012). PBYI expects to initiate a Phase II trial in 4Q:12 which could evolve into a registration trial for accelerated approval. In addition, based on recent data (summary follows), PBYI plans to initiate a Phase II trial for a combination therapy with Torisel in HER2 mutated NSCLC patients with initial data anticipated in 1Q:13. Although still early, we see these as very interesting opportunities for neratinib.

• Greater visibility of registration programs. Based on promising single-arm Phase II data from three studies in 2nd/3rd line HER2 (+) mBC as single agent (vs. Tykerb), combo with vinorelbine (vs. Hercaptin + vinorelbine), and combo with capecitabine (vs. Tykerb + capecitabine), PBYI plans to initiate a randomized Phase III trial in chemo combination in 2H:12. Interim Phase II data from combination with Torisel in 4th line mBC support a potential randomized pivotal trial in 2H:12.

• Key upcoming data include Torisel combination update and brain met data. Upcoming data include: (1) Phase II data from neratinib/Torisel in 4th line HER2(+) mBC in 4Q:12; (2) preclinical and Phase I data in breast cancer with a new mutation in SABCS; (3) Phase II data from mBC with brain metastases in 1H:13; and (4) Phase II data from two neoadjuvant trials in 1H:13. We believe data in mBC patients with brain metastases could be especially interesting because this is a setting not amenable by current agents including both HER2-antibody based agents as well as Tykerb.

Key Stats:	**(NASDAQ:PBYI)**
S&P 600 Health Care Index:	**837.98**
Price:	**$14.00**
52 Week High:	$14.50
52 Week Low:	$10.00
Shares Outstanding (mil):	20.0
Market Capitalization (mil):	280.0
Book Value/Share:	(16.19)
Cash Per Share:	$2.05
Dividend (ann):	$0.00
Dividend Yield:	0.0%
Valuation:	$20



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2011A	--	--	--	--	0.0	--	--	--	--	($1.32)	NM
2012E - New	**0.0A**	**0.0A**	**0.0**	**0.0**	**0.0**	**($0.59)A**	**($0.74)A**	**($0.39)**	**($0.38)**	**($2.10)**	**NM**
2012E - Old	0.0A	0.0A	0.0	0.0	0.0	($0.24)	($0.31)	($0.50)	($0.55)	($1.62)	NM
2013E - New	**--**	**--**	**--**	**--**	**0.0**	**--**	**--**	**--**	**--**	**($1.40)**	**NM**
2013E - Old	--	--	--	--	0.0	--	--	--	--	($1.90)	NM

Source: Company Information and Leerink Swann LLC Research
Revenues in $MM; 2011 GAAP EPS, 2012 PF EPS; 2013 GAAP EPS

Please refer to pages 7 - 11 for Important Disclosures, Price Charts and Analyst Certification.

INVESTMENT THESIS

We rate Puma Biotechnology shares Outperform. Puma is a cancer-focused biotechnology company with an in-licensing model founded by the same management team that successfully executed the same strategy with Cougar Biotechnology. Lead agent neratinib, a pan-HER tyrosine kinase inhibitor, is a late-stage compound for breast cancer currently in Phase II, after the rolling back of a Phase III program following the transfer of the asset from Pfizer. HER2+ breast cancer is a large market with over $5B in current sales of Roche's Herceptin (>$5B), and GSK's Tykerb (>$450M), another tyrosine kinase inhibitor (TKI) against HER2. Although Tykerb sales are currently relatively modest, it has been only approved for the metastatic setting and most of the Herceptin sales appear to come from the adjuvant setting. Based on MEDACorp breast cancer key opinion leader feedback, we believe neratinib has the potential to be the best-in-class TKI against HER2. It appears to have superior efficacy compared to Tykerb. Its safety has been demonstrated in a large database of more than 3,000 patients. The adverse event of diarrhea associated with neratinib, while frequent, appears transient and manageable. Neratinib is currently in Phase II studies in combination with Herceptin, including two studies in the neoadjuvant (before surgery) setting. The FDA has stated that it intends to issue a guidance document that allows the use of pathological complete response as a surrogate endpoint for accelerated approval. I-SPY 2, which involved neratinib, was mentioned in the FDA statement. Therefore, we believe there is potential for a rapid registration path in the neoadjuvant setting. In addition, the combination of neratinib with mTOR inhibitor Torisel (PFE) has shown intriguing early data and has a compelling pre-clinical rationale. We see this combination as another interesting path to move forward for neratinib. Additional data on this as well as a Herceptin combination could be available during 2012, potentially providing catalysts for the stock. Although HER2+ market is becoming increasingly crowded, we believe HER2 TKIs will continue to have a role. There have been consistent clinical data as well as a preclinical rationale that HER2 TKIs adds to the activity of Herceptin and we believe there is an opportunity for neratinib to be combined with Herceptin. With the advent of pertuzumab and T-DM1 (both Roche), HER2+ breast cancer has clearly become more crowded but because of non-overlapping mechanism of action, we believe neratinib could potentially be combined with the HER2-antibody based agents or used sequentially. We believe there is significant commercial opportunity that is more than sufficient for the size of Puma.

Early data from HER mutated NSCLC preliminary but promising. PBYI presented Phase I data from a dose-ranging, 59-patient study of neratinib + Torisel in NSCLC at 2011 ASCO and 2012 IASLC. Data from the study suggested 2 partial response and 3 stable disease from 6 evaluable HER2 mutated NSCLC patients who were treated with 120-240mg daily oral dose of neratinib and 15-75mg weekly IV of Torisel. The median time to progression in these five patients was 23.6 weeks. Although preliminary, we believe these data indicate initial clinical evidence of effect and are supportive to the preclinical observation of synergistic effect by both mTOR and HER2 inhibition.

Model update. PBYI reported financial results on August 14, 2012. Total operating expenses were $14.8M, higher than our estimated of $6.5M, partially due to $3M transition costs incurred to pay back licensor PFE (MP). Total SG&A were $1.7M, slightly higher than our estimate of $1.5M. Management anticipates significant reduction in 2H:12 R&D costs due to a capped-cost structure associated with the licensor PFE (i.e., PFE is expected to pay costs beyond a capped amount, which is not disclosed). The company ended the quarter with $41M cash. Based on guided quarterly cash burn of $7-8M, we expect current cash to support operation well into 2H:13. We are updating our model to reflect these changes.

PBYI Upcoming Milestones

Timing	Event
Neratinib oral (irreversable HER2/ERBb2 inhibitor)	
2H:12	Initiate Phase III trial w/chemo in 2nd/3rd-line HER2(+) MBC
2H:12	Data from Phase II trial with Torisel in 4th line HER2(+) MBC; Initiate Phase III trial
2H:12	Data from Phase II trial in HER2(+) MBC that metastasized to the brain
2H:12	Submit an IND filing for IV formulation of Neratinib
4Q:12	Initiate Phase II trial with Torisel in HER2 mutated NSCLC. Trial may qualified for accelerated approval
4Q:12	Initiate Phase II trial in breast cancer pts with newly identified mutations. Trial may qualified for accelerated approval.
1Q:13	Initial Phase II data from combination with Torisel in HER2 mutated NSCLC
2013	Data from Phase II neoadjuvant trial in HER2(+) breast cancer

MBC - metastatic breast cancer

Source: Company reports and Leerink Swann LLC

PBYI Product Pipeline

Indication	Status	Comments
Neratinib (PB272)-Oral (irreversable HER2/ERBb2 inhibitor)		
Metastatic Breast Cancer (MBC)	Phase II	Phase I/II trial of Torisel + Neratinib in HER2 (+) in triple-negative breast cancer, n=65; enrollment ongoing. Potential to initiate pivotal in 2H:12
	Phase II	Combination with chemo in 2nd/3rd line HER2(+) MBC. Phase III to be initiated in 2H:12.
	Phase II	Combination with chemo in as neoadjuvant. NSABP and I-SPY2 trials with pathological CR as endpoint. 3-arm: taxol + Herceptin, taxol + neratinib, taxol + neratinib + Herceptin
	Phase II	Single agent in MBC with brain metastatics, Phase II initiated in Jan, 2012, potential results in 2H:12/1H:13
NSCLC	Phase II	Combination with Torisel in HER2 mutated NSCLC to be initiated in 4Q:12. Initial data anticipated in 2013. Trial may qualified for accelerated approval.
Neratinib (PB272)-IV (irreversable HER2/ERBb2 inhibitor)		
Advanced Cancer	Preclinical	Submit IND in 2H:12
PB357 (irreversable HER2/ERBb2 inhibitor)		
	Preclinical	Back up for PB272, explore additional development

Source: Company reports and Leerink LLC

VALUATION

Our valuation for PBYI remains $20, but we are slightly modifying our revenue projection and NPV methodology. We include neratinib sales projection in HER2 (+) MBC with brain metastases given anticipated Phase II data timeline of 1H:13. We project an initial launch of neratinib in MBC patients as well as neoadjuvant therapy in Stage 0-III patients in 2015 with modest sales of $8M (probability weighted). We project sales in 2018 in additional indications including neoadjuvant maintenance therapy, adjuvant therapy and MBC with brain metastases. We assign 30% probability of success for the MBC with brain metastases and 65% for the rest. Based on current patent expiry of 2025 in both the U.S. and EU, we project out neratinib sales till 2027 (with an estimated 2-year expansion). We also project one-year delay for each indication in the EU market with a rapid increase from 50% to 100% of prior year U.S. revenue. Assuming PBYI forms an ex-U.S. commercial partner at approximately 20% royalty, we anticipate royalty revenue and milestone payments roughly offset estimated 10-20% royalty and $187.5M that PBYI needs to pay to PFE. Using a 10% discount rate (we view it appropriate since we use probability-weighted sales), with no valuation assigned to the terminal value of oral neratinib and other pipeline candidate, together with estimated cash and share count by YE:13, we derive a $20 valuation for PBYI.

Our previous $20 valuation was derived from a DCF analysis which included probability-weighted (at 65%) projected neratinib sales in breast cancer in the U.S. and royalty on probability-weighted (at 65%) estimated neratinib sales in breast cancer outside the U.S. from 2015 to 2030, the expected patent expiry for neratinib. We used a discount rate of 11% per year.

RISKS TO VALUATION

HER2+ breast cancer market has become more crowded with advancement of pertuzumab, T-DM1, Tovok (Boerhinger Ingelheim) in addition to approved agents Herceptin and Tykerb, all of which are ahead of neratinib in development.

Differentiation vs. currently marketed agent remains to be firmly established. The perception of superior efficacy of neratinib relative to Tykerb is based on cross-trial comparisons, and remains to be demonstrated in a randomized study.

Financing risks. Puma currently has a cash position of $41M as of 2Q:12, which is expected to support operations through mid to 2H:13, by our estimate. There is likely a need for additional financing before becoming cash-flow positive.

PBYI Income Statement ($000)	2010A	2011A	Mar-12A	Jun-12A	Sep-12E	Dec-12E	2012E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Neratinib US sales - pw							0	0	0	7,980	43,482	91,464	155,233	241,955	319,977
Neratinib Ex.-US sales - pw							0	0	0	0	3,990	30,438	82,318	155,233	241,955
Neratinib Ex.-US Royalties - pw									0	0	798	6,088	16,464	31,047	48,391
Collaborative revenues		0	0	0	0	0	0								
Total Revenue	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**7,980**	**44,280**	**97,551**	**171,696**	**273,001**	**368,368**
COGS (including royalty paid to PFE)	0	0	0	0	0	0	0	0	0	1,995	11,868	30,475	59,388	99,297	140,483
R&D		826	10,568	13,006	5,983	5,977	35,534	24,920	31,929	36,938	32,147	28,017	22,967	10,976	11,286
SG&A	7	9,320	1,235	1,702	1,674	1,698	6,309	6,869	8,812	12,043	51,186	55,234	59,603	62,005	64,503
Depreciation and Amortization	0	11	49	69	125	125	368	383	398	414	431	448	466	485	504
Total expenses	**7**	**10,157**	**11,852**	**14,777**	**7,782**	**7,800**	**42,211**	**32,171**	**41,139**	**51,391**	**95,633**	**114,174**	**142,423**	**172,762**	**216,776**
Operating Income	**(7)**	**(10,157)**	**(11,852)**	**(14,777)**	**(7,782)**	**(7,800)**	**(42,211)**	**(32,171)**	**(41,139)**	**(43,410)**	**(51,352)**	**(16,623)**	**29,273**	**100,239**	**151,592**
Other Income (expense)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Interest/Investment Income (expense), Net	0	(76)	26	23	21	20	89	0	0	0	0	0	0	0	0
Net Income Before Taxes	(7)	(10,233)	(11,826)	(14,755)	(7,761)	(7,780)	(42,122)	(32,171)	(41,139)	(43,410)	(51,352)	(16,623)	29,273	100,239	151,592
Income Taxes		0	0	0	0	0	0	0	0	0	0	0	0	0	0
Net Income before preferred stocks	(7)	(10,233)	(11,826)	(14,755)	(7,761)	(7,780)	(42,122)	(32,171)	(41,139)	(43,410)	(51,352)	(16,623)	29,273	100,239	151,592
Preferred Dividends	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
GAAP Net Income to Common Stocks	**(7)**	**(10,233)**	**(11,826)**	**(14,755)**	**(7,761)**	**(7,780)**	**(42,122)**	**(32,171)**	**(41,139)**	**(43,410)**	**(51,352)**	**(16,623)**	**29,273**	**100,239**	**151,592**
GAAP EPS	**(0.00)**	**(1.32)**	**(0.59)**	**(0.74)**	**(0.39)**	**(0.38)**	**(2.10)**	**(1.40)**	**(1.44)**	**(1.37)**	**(1.59)**	**(0.51)**	**0.75**	**2.51**	**3.68**
Basic Shares Outstanding	4,000	7,747	20,040	20,040	20,140	20,241	20,115	23,001	28,503	31,608	32,245	32,895	33,558	34,234	34,924
Diluted Share Outstanding	4,000	8,178	21,193	21,433	21,733	22,033	21,598	25,283	31,483	35,183	36,383	37,583	38,783	39,983	41,183

Note: pw - probability weighted

Sources: Company reports, Leerink Swann LLC

Disclosures Appendix

Analyst Certification

I, Howard Liang, Ph.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

Valuation

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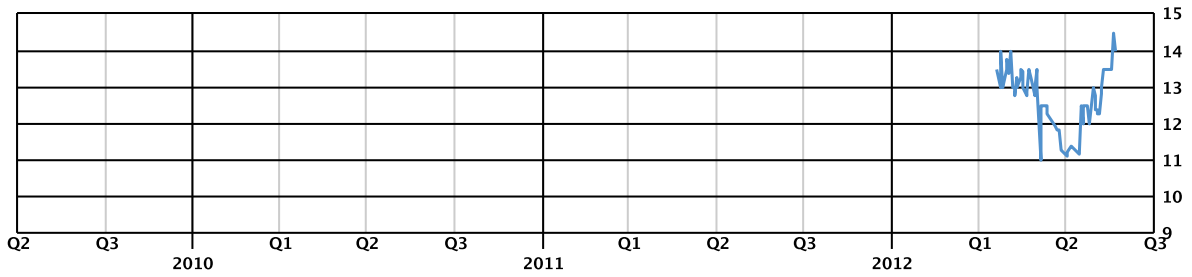
LEERINK SWANN

Rating and Price Target History for: Puma Biotechnology, Inc. (PBYI) as of 08-21-2012

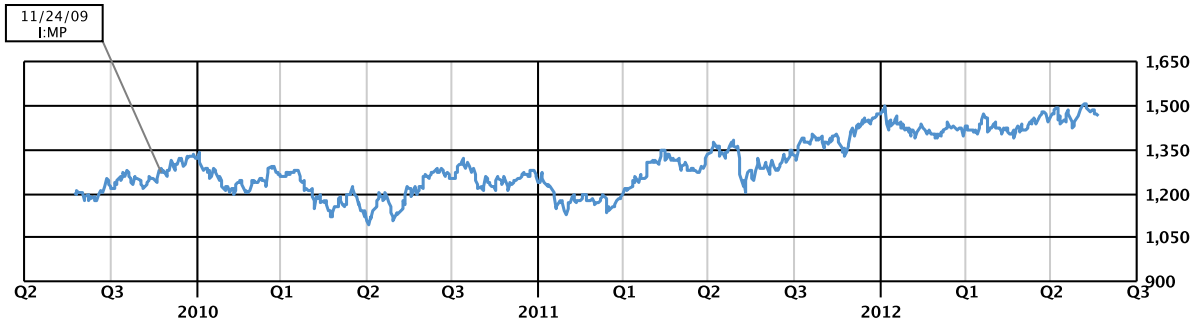


Leerink Swann initiated coverage of PBYI on April 18, 2012 with an Outperform.

OP=Outperform MP=Market Perform UP=Underperform D=Drop Coverage I=Initiate SC=Suspend Coverage

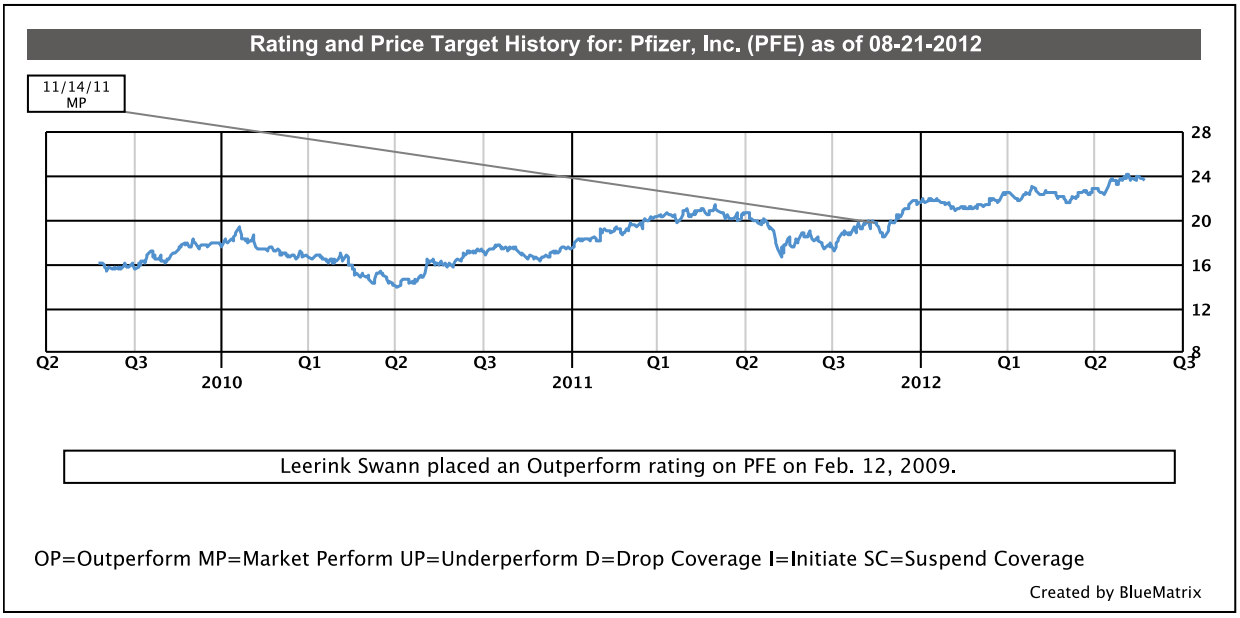
Created by BlueMatrix

Rating and Price Target History for: GlaxoSmithKline plc (GSK LN) as of 08-21-2012



OP=Outperform MP=Market Perform UP=Underperform D=Drop Coverage I=Initiate SC=Suspend Coverage

Created by BlueMatrix


Rating and Price Target History for: Pfizer, Inc. (PFE) as of 08-21-2012
11/14/11
MP
28
24
20
16
12
8
Q2
Q3
2010
Q1
Q2
Q3
2011
Q1
Q2
Q3
2012
Q1
Q2
Q3
Leerink Swann placed an Outperform rating on PFE on Feb. 12, 2009.
OP=Outperform MP=Market Perform UP=Underperform D=Drop Coverage I=Initiate SC=Suspend Coverage
Created by BlueMatrix

Distribution of Ratings/Investment Banking Services (IB) as of 06/30/12				
			IB Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [OP]	92	57.1	23	25.0
HOLD [MP]	69	42.9	4	5.8
SELL [UP]	0	0.0	0	0.0

Explanation of Ratings

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

Market Perform (Hold/Neutral): We expect this stock to perform in line with its benchmark over the next 12 months.

Underperform (Sell): We expect this stock to underperform its benchmark over the next 12 months.The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than $2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over $2 billion.

From October 1, 2006 through January 8, 2009, the relevant benchmarks for the above definitions were the Russell 2000® Health Care Index for issuers with a market capitalization of less than $2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over $2 billion.

Definitions of Leerink Swann Ratings prior to October 1, 2006 are shown below:

Outperform (Buy): We expect this stock to outperform its benchmark by more than 10 percentage points over the next 12 months.

Market Perform (Hold/Neutral): We expect this stock to perform within a range of plus or minus 10 percentage points of its benchmark over the next 12 months.

Underperform (Sell): We expect this stock to underperform its benchmark by more than 10 percentage points over the next 12 months.

For the purposes of these definitions, the relevant benchmark were the Russell 2000® Health Care Index for issuers with a market capitalization of less than $2 billion and the S&P 500® Index for issuers with a market capitalization over $2 billion.

Important Disclosures

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In the past 12 months, the Firm has received compensation for providing investment banking services to Puma Biotechnology, Inc.

Leerink Swann LLC makes a market in Puma Biotechnology, Inc.

Leerink Swann LLC is willing to sell to, or buy from, clients the common stock of GlaxoSmithKline plc on a principal basis.

Leerink Swann LLC is willing to sell to, or buy from, clients the common stock of Pfizer, Inc. on a principal basis.

In the past 12 months, an affiliate of the Firm, Leerink Swann Consulting LLC, has received compensation for providing non-securities services to: GlaxoSmithKline plc.

In the past 12 months, an affiliate of the Firm, Leerink Swann Consulting LLC, has received compensation for providing non-securities services to: Pfizer, Inc.

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