August 7, 2013

OUTPERFORM

Reason for report:

EARNINGS

Howard Liang, Ph.D.
(617) 918-4857
Howard.Liang@Leerink.com

Gena Wang, Ph.D.
(212) 277-6073
Gena.Wang@Leerink.com

LEERINK SWANN

HEALTHCARE EQUITY RESEARCH

PUMA BIOTECHNOLOGY, INC.

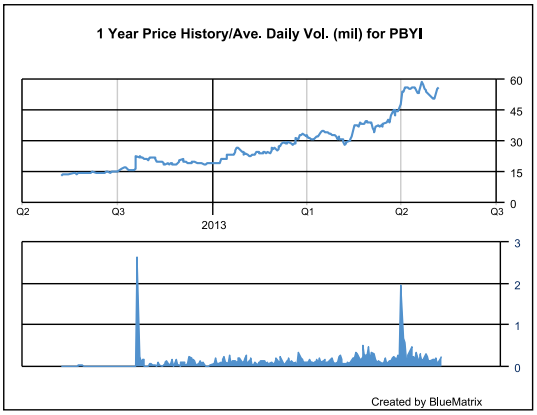
Busy Newsflow Ahead in 2H:13

• **Bottom Line:** PBYI reported 2Q:13 earnings yesterday and provided an update on pipeline development where the company is on track to announce results from a series of studies in breast cancer and lung cancer. Key upcoming catalysts, in our view, include neratinib neoadjuvant Phase II data (I-SPY 2 in Aug/Sept '13 and FB-7 in later 2013), where the pathologic complete response (pCR) data could provide support for a pivotal program and another shot on goal for PBYI. Phase II data in later 2013 from HER2-negative HER2 mutant patients with either NSCLC or breast cancer may form a foundation for a new targeted therapy that could be applicable to a broader population of other tumor types (basket study to start imminently). We believe PBYI remains well positioned as a sought-after late-stage cancer story with a differentiated candidate that has a good probability of success, in our view. We are increasing our valuation from $44 to $70 by recognizing neratinib opportunities in HER2-mutated patients as well as by assuming higher pricing for neratinib, which in our view remains reasonable.

• **Pipeline continues to progress.** After receiving a Special Protocol Assessment (SPA) from the FDA and a Scientific Advice (SA) from the EU, PBYI initiated the Phase III trial evaluating neratinib/Xeloda vs. Tykerb/Xeloda in third-line HER2-positive breast cancer. Additionally, the combination therapy of neratinib/temsirolimus in fourth-line HER2+ metastatic breast cancer (mBC) could lead to a Phase III initiation later this year. In addition to the neoadjuvant breast cancer therapy and fourth-line mBC therapy, neratinib is also being evaluated in a Phase II trial in combination with Torisel in fourth-line HER2+ mBC with data anticipated later in 2013 and followed by Phase III initiation. The Phase II trial in patients with HER2 negative HER2 mutated NSCLC is ongoing with initial data anticipated later in 2013. Data from the Phase II trial in Her2+ mBC with brain mets are on track to be reported later in 2013.

• **Model update.** PBYI reported R&D expenses were $10.4M vs. our estimate of $6.5M. Total G&A costs were $2.3M vs. our estimate of $7.6M. GAAP EPS was ($0.44) vs. our estimate of ($0.52). The company ended the quarter with $108M cash, which by our estimate is sufficient to support operations well to 2015. We are updating our model to reflect these changes and our 2013 EPS changes from ($2.02) to ($1.73).

Key Stats:	**(NASDAQ:PBYI)**
S&P 600 Health Care Index:	**1,112.48**
Price:	**$55.91**
Price Target:	$70.00
Methodology:	Probability-weighted DCF analysis, 10% discount rate
52 Week High:	$59.02
52 Week Low:	$12.55
Shares Outstanding (mil):	28.7
Market Capitalization (mil):	1,604.6
Book Value/Share:	(11.28)
Cash Per Share:	$3.75
Dividend (ann):	$0.00
Dividend Yield:	0.0%
Shares Outstanding (mil): Pro Forma	
Cash Per Share: Pro Forma	



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2012A	0.0	0.0	0.0	0.0	0.0	($0.59)	($0.74)	($1.29)	($0.83)	($3.42)	NM
2013E - New	**0.0A**	**0.0A**	**0.0**	**0.0**	**0.0**	**($0.41)A**	**($0.44)A**	**($0.44)**	**($0.44)**	**($1.73)**	**NM**
2013E - Old	0.0A	0.0A	0.0	0.0	0.0	($0.48)	($0.52)	($0.51)	($0.51)	($2.02)	NM
2014E - New	**--**	**--**	**--**	**--**	**0.0**	**--**	**--**	**--**	**--**	**($1.83)**	**NM**
2014E - Old	--	--	--	--	0.0	--	--	--	--	($2.31)	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 - 10 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 (MP). HER2+ breast cancer is a large market with over $5B in current sales of Roche's Herceptin (>$5B), and GSK's (MP) 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.

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PBYI Upcoming Milestones

Timing	Event
Neratinib oral (irreversable HER2/ERBb2 inhibitor)	
Aug/Sept	I-SPY 2 data from Phase II neoadjuvant trial in HER2(+) breast cancer
Late 2013	FB-7 data from Phase II neoadjuvant trial in HER2(+) breast cancer
Late 2013	Initial data from Phase II trial with Torisel in HER2 mutated NSCLC. Trial may qualified for accelerated approval
Late 2013	Data from Phase II trial with Torisel in 4th line HER2(+) MBC; Initiate Phase III trial
Late 2013	Data from Phase II trial in HER2(+) MBC that metastasized to the brain
Late 2013	Initial Phase II data from HER2-negative HER2 mutations breast cancer
Late 2013	Initiate Phase II basket study in solid tumors with a HER2 mutation

MBC - metastatic breast cancer
Source: Company reports and Leerink Swann LLC

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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.
	Phase III	Combination with chemo in 2nd/3rd line HER2(+) MBC.
	Phase II	Combination with chemo 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, results in 2013
NSCLC	Phase II	Combination with Torisel in HER2 mutated NSCLC 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	
PB357 (irreversable HER2/ERBb2 inhibitor)		
	Preclinical	Back up for PB272, explore additional development

Source: Company reports and Leerink LLC

VALUATION

We are increasing our valuation for PBYI from $44 to $70 based on increased recognition of neratinib opportunities in HER2-mutated patients as well as by assuming higher pricing for neratinib which in our view remains reasonable. We include neratinib indication in HER2-mutant NSCLC, and increase the probability of success from 20% to 50% and peak penetration from 15% to 30% based on enhanced conviction. We are increasing our assumptions for pricing for neratinib (from 25% to 33% premium to Tykerb) but we believe these assumptions of $37k per patient in relapsed / refractory metastatic setting, $18k per patient in neoadjuvant setting, and $74k per patient in HER2-mutated patients remain reasonable. Incorporating these changes and maintaining the other assumptions in our DCF model, we derive a $70 valuation for PBYI. We believe a 10% discount rate is appropriate given probability weighted sales projection.

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. The current pro forma cash is estimated at ~$108M, and we expect current cash to support operation well through 2015. There is likely a need for additional financing before becoming cash-flow positive.

PBYI Income Statement ($000)	2010A	2011A	2012A	Mar-13A	Jun-13A	Sep-13E	Dec-13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Neratinib US sales - pw			0					0	0	0	79,535	165,258	293,155	498,682	701,638
Neratinib Ex.-US sales - pw			0					0	0	0	0	55,675	148,732	293,155	498,682
Neratinib Ex.-US Royalties - pw									0	0	0	11,135	29,746	58,631	99,736
Collaborative revenues		0	0	0	0	0	0	0							
Total Revenue	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**79,535**	**176,393**	**322,901**	**557,313**	**801,375**
COGS (including royalty paid to PFE)	0	0	0					0	0	0	19,884	55,233	110,472	197,959	300,080
% of revenue - oral			*25%*					*25%*	*25%*	*25%*	*25%*	*25%*	*25%*	*25%*	*25%*
% of revenue - IV			*25%*					*25%*	*25%*	*25%*	*25%*	*25%*	*25%*	*25%*	*25%*
R&D		826	49,636	9,500	10,400	10,300	10,300	39,300	42,897	46,850	48,180	49,550	50,502	22,573	11,425
R&D from operations			46,641	8,500	9,100	9,000	9,000	35,600	39,160	43,076	44,368	45,699	46,613	18,645	7,458
R&D Neratinib			40,711	8,500	9,100	9,000	9,000	35,600	39,160	43,076	44,368	45,699	46,613	18,645	7,458
R&D other			5,930	0	0	0	0	0	0	0					
R&D legacy trials			8,400	300	300	300	300	1,200	1,440						
R&D stock option expense		38	3,894	700	1,000	1,000	1,000	3,700	3,737	3,774	3,812	3,850	3,889	3,928	3,967
SG&A	7	9,320	24,814	2,300	2,300	2,500	2,500	9,600	11,330	40,225	69,950	79,398	83,367	86,817	90,411
SG&A from operations		9,290	5,747	1,800	1,900	2,000	2,000	7,700	9,240	35,000	59,500	68,425	71,846	74,720	77,709
SG&A stock option expense and other		30	19,067	500	400	500	500	1,900	2,090	5,225	10,450	10,973	11,521	12,097	12,702
Depreciation and Amortization	0	11	0	0	0	0	0	0	0	0	0	0	0	0	0
Total expenses	**7**	**10,157**	**74,450**	**11,800**	**12,700**	**12,800**	**12,800**	**48,900**	**54,227**	**87,075**	**138,014**	**184,180**	**244,341**	**307,349**	**401,916**
Operating Income	**(7)**	**(10,157)**	**(74,450)**	**(11,800)**	**(12,700)**	**(12,800)**	**(12,800)**	**(48,900)**	**(54,227)**	**(87,075)**	**(58,479)**	**(7,787)**	**78,560**	**249,963**	**399,459**
Other Income (expense)	0	0	0					0	0	0	0	0	0	0	0
Interest/Investment Income (expense), Net	0	(76)	98	0	100	10	10	120	0	0	0	0	0	0	0
Interest/Investment Income	0	4	98	0	100	10	10	120	0	0	0	0	0	0	0
Interest Expense, Net	0	(80)	0	0	0	0	0	0	0	0	0	0	0	0	0
Net Income Before Taxes	(7)	(10,233)	(74,352)	(11,800)	(12,600)	(12,790)	(12,790)	(49,980)	(54,227)	(87,075)	(58,479)	(7,787)	78,560	249,963	399,459
Tax rate								*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Income Taxes		0	0	0	0	0	0	0	0	0	0	0	0	0	0
Net Income before preferred stocks	(7)	(10,233)	(74,352)	(11,800)	(12,600)	(12,790)	(12,790)	(49,980)	(54,227)	(87,075)	(58,479)	(7,787)	78,560	249,963	399,459
Stock Based Compensation	0	0	22,962	1,200	1,400	1,500	1,500	5,600	5,827	8,999	14,262	14,823	15,410	16,025	16,669
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)**	**(74,352)**	**(11,800)**	**(12,600)**	**(12,790)**	**(12,790)**	**(49,980)**	**(54,227)**	**(87,075)**	**(58,479)**	**(7,787)**	**78,560**	**249,963**	**399,459**
GAAP EPS	**(0.00)**	**(1.32)**	**(3.42)**	**(0.41)**	**(0.44)**	**(0.44)**	**(0.44)**	**(1.73)**	**(1.83)**	**(2.70)**	**(1.68)**	**(0.22)**	**1.89**	**5.85**	**9.09**
Non-GAAP Net Income			**(51,390)**	**(10,300)**	**(10,900)**	**(10,990)**	**(10,990)**	**(43,180)**	**(46,960)**	**(78,076)**	**(44,217)**	**7,035**	**93,970**	**265,988**	**416,128**
Non-GAAP EPS			**(2.48)**	**(0.36)**	**(0.38)**	**(0.38)**	**(0.38)**	**(1.49)**	**(1.59)**	**(2.42)**	**(1.27)**	**0.17**	**2.26**	**6.22**	**9.47**
Basic Shares Outstanding	4,000	7,747	21,726	28,677	28,677	28,963	29,253	28,892	29,621	32,222	34,897	35,600	36,317	37,049	37,796
Diluted Share Outstanding	4,000	8,178	25,749	31,107	31,407	31,707	32,007	31,557	32,757	35,957	39,157	40,357	41,557	42,757	43,957

Note: pw - probability weighted

Sources: Company reports, Leerink Swann LLC

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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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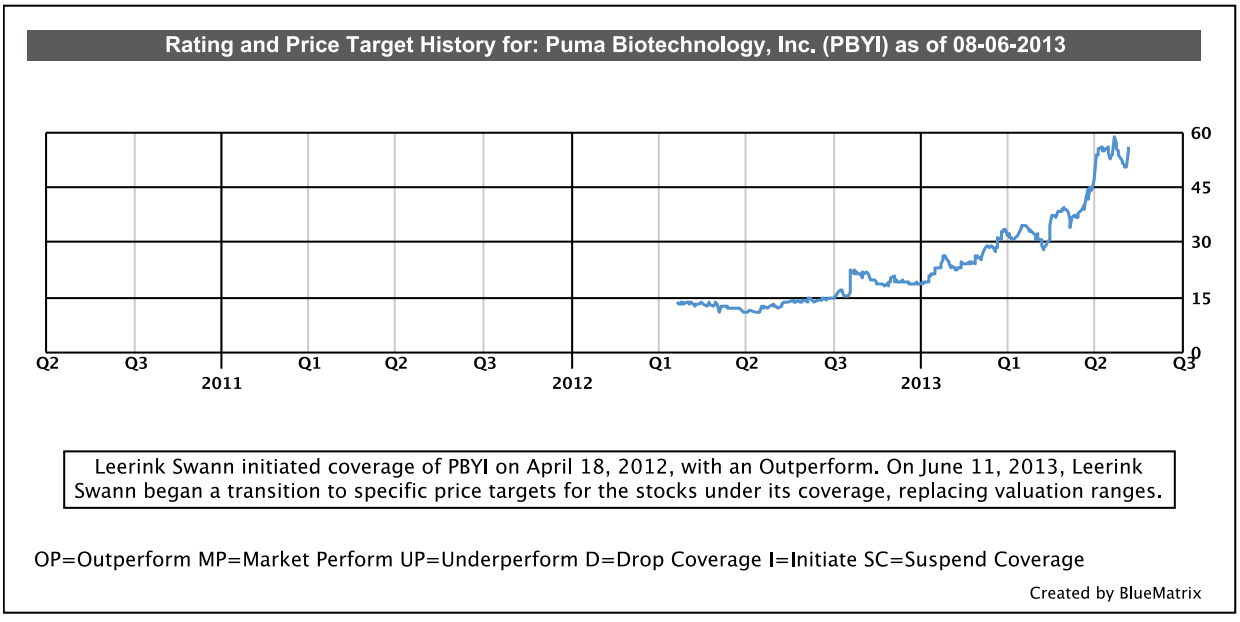

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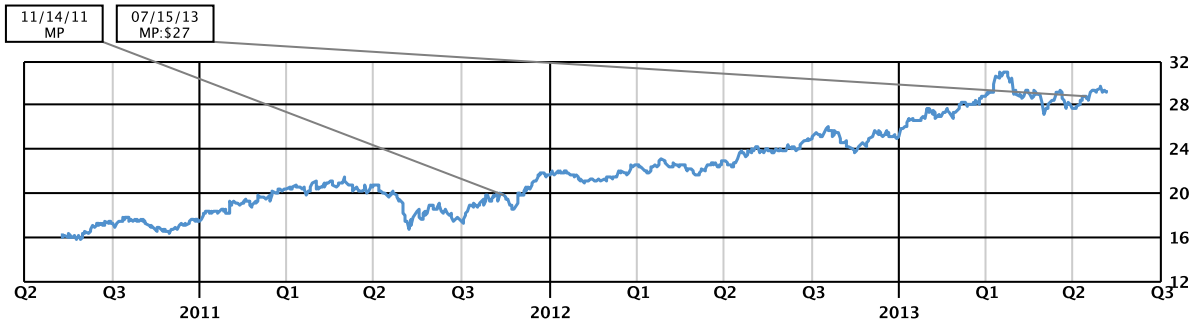
Rating and Price Target History for: Pfizer Inc. (PFE) as of 08-06-2013



Leerink Swann placed an Outperform rating on PFE on Feb. 12, 2009. On June 11, 2013, Leerink Swann began a transition to specific price targets for the stocks under its coverage, replacing valuation ranges.

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 06/30/13				
			IB Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [OP]	103	62.80	30	29.00
HOLD [MP]	61	37.20	2	3.00
SELL [UP]	0	0.00	0	0.00

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.

Important Disclosures

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Like all Firm employees, analysts receive compensation that is impacted by, among other factors, overall firm profitability, which includes revenues from, among other business units, the Private Client Division, Institutional Equities, and Investment Banking. Analysts, however, are not compensated for a specific investment banking services transaction.

Leerink Swann Consulting LLC, an affiliate of Leerink Swann LLC, is a provider of evidence-based strategy and consulting to the healthcare industry.

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 and 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 and Pfizer Inc.

Leerink Swann LLC has acted as a co-manager for a public offering of Puma Biotechnology, Inc. in the past 12 months.

Leerink Swann LLC Equity Research

Director of Equity Research	**John L. Sullivan, CFA**	(617) 918-4875	john.sullivan@leerink.com
Associate Director of Research	**Alice C. Avanian, CFA**	(617) 918-4544	alice.avanian@leerink.com
Healthcare Strategy	**John L. Sullivan, CFA**	(617) 918-4875	john.sullivan@leerink.com
	Alice C. Avanian, CFA	(617) 918-4544	alice.avanian@leerink.com
Biotechnology	**Howard Liang, Ph.D.**	(617) 918-4857	howard.liang@leerink.com
	Joseph P. Schwartz	(617) 918-4575	joseph.schwartz@leerink.com
	Marko Kozul, M.D.	(415) 905-7221	marko.kozul@leerink.com
	Michael Schmidt, Ph.D.	(617) 918-4588	michael.schmidt@leerink.com
	Irene Lau	(415) 905-7256	irene.lau@leerink.com
	Gena Wang, Ph.D.	(212) 277-6073	gena.wang@leerink.com
	Paul Matteis	(617) 918-4585	paul.matteis@leerink.com
Life Science Tools and Diagnostics	**Dan Leonard**	(212) 277-6116	dan.leonard@leerink.com
	Justin Bowers, CFA	(212) 277-6066	justin.bowers@leerink.com
Pharmaceuticals/Major	**Seamus Fernandez**	(617) 918-4011	seamus.fernandez@leerink.com
	Ario Arabi	(617) 918-4568	ario.arabi@leerink.com
Specialty Pharmaceuticals, Generics	**Jason M. Gerberry, JD**	(617) 918-4549	jason.gerberry@leerink.com
	Christopher W. Kuehnle, JD	(617) 918-4851	chris.kuehnle@leerink.com
Medical Devices, Cardiology & Orthopedics	**Danielle Antalffy**	(212) 277-6044	danielle.antalffy@leerink.com
	Richard Newitter	(212) 277-6088	richard.newitter@leerink.com
	Robert Marcus, CFA	(212) 277-6084	robert.marcus@leerink.com
	Ravi Misra	(212) 277-6049	ravi.misra@leerink.com
Healthcare Technology & Distribution	**David Larsen, CFA**	(617) 918-4502	david.larsen@leerink.com
	Christopher Abbott	(617) 918-4010	chris.abbott@leerink.com
Sr. Editor/Supervisory Analyst	**Mary Ellen Eagan, CFA**	(617) 918-4837	maryellen.eagan@leerink.com
Supervisory Analysts	Robert Egan		bob.egan@leerink.com
	Amy N. Sonne		amy.sonne@leerink.com
Research Assistant	Paul Matteis	(617) 918-4585	paul.matteis@leerink.com
	George Villarina	(212) 277-6012	george.villarina@leerink.com

New York
1251 Avenue of Americas, 22nd Floor
New York, NY 10020
(888) 347-2342

Boston
One Federal Street, 37th Floor
Boston, MA 02110
(800) 808-7525

San Francisco
201 Spear Street, 16th Floor
San Francisco, CA 94105
(800) 778-1164