January 9, 2014

OUTPERFORM

Reason for report:

COMPANY UPDATE

Marko Kozul, M.D.
(415) 905-7221
Marko.Kozul@Leerink.com

Irene Lau
(415) 905-7256
Irene.Lau@Leerink.com

LEERINK

ACCELERON PHARMA

Many 2014 Catalysts & Improving Upon ESAs in ESRD Drive Our New $52PT; Reit OP

• **Bottom Line:** We are rapidly nearing key catalysts for core pipeline programs across most quarters in 2014. As of YE13, we can add Sotatercept potential and data readouts for evaluation in End Stage Renal Disease (ESRD) hemodialysis patients experiencing bone mineral density and vascular calcification abnormalities. Future upside could also be further driven by potential combo with Sorafenib for Hepatocellular Carcinoma (HCC). Specifically, we anticipate: 1) in 1Q14, Phase II dose escalation 2nd-line Renal Cell Carcinoma (RCC) Axitinib combo data; 2) in 2Q14 (EHA), top-line Phase II Sotatercept/ACE-536 data in both MDS and β-Thalassemia and Phase II Part-1 ESRD data; 3) in 4Q14 (ASH), full Phase II Sotatercept/ACE-536 data in both MDS and β-Thal. and likely potential Phase II Dalantercept-Sorafenib combo HCC data. As a result, we are adding heavily risk-adjusted revenue potential in ESRD patient subsets to our model, which drives our new $52 price target (up from $35) and we reiterate our Outperform rating (OP).

• **Sotatercept potential in ESRD Hemodialysis subsets now adds to previous core program potential and 2014 data readouts.** This recently initiated trial aims to capitalize on Sotatercept's positive impact on bones by assessing potential benefit to bone mineral density and decreased vascular calcification, which is observed in ESRD patients on hemodialysis. This trial is not attempting to only show a Hg increase to treat ESRD associated anemia, which can be managed with Erythrocyte Simulating Agents (ESAs). While ~90% of all hemodialysis ESRD patients (total >600K in US) experience concurrent bone mineral density problems (leading to 4x increase in potential fractures/bone disease), for conservatism we assume Sotatercept might only benefit a small minority. Given a sliding scale of price sensitivity in the ESRD market, in our new model we assume only marginal Sotatercept premium over ESAs in only a minor subset of patients, with potential future proven benefit in bone mineral density and vascular calcification leading to significant revenue upside. While the randomized ESA active control portion of this trial (Part-2) is likely by 1H15, the PK and safety (Part-1) read will occur near term in 1H14. Until further data readouts in ESRD, we are currently modeling a heavily discounted high teens probability of success.

• **A Dalantercept-Sorafenib combo HCC trial with potential late 2H14 preliminary data could represent further 2014 upside.** Near term and building upon the experience in RCC, XLRN plans to initiate this 1st-line combo trial in HCC. Sorafenib was approved based on a second interim analysis showing a statistically significant 2.8-month overall survival (OS) benefit (10.7 mos.) vs. placebo (7.9 mos.) and 2.7-month Time to Progression benefit (5.5 mos.) vs. placebo (2.8 mos.). Preliminary response data from the Dalancercept combo trial will be available by YE14 with maturing PFS data in 2015. We believe HCC could provide a further large market opportunity currently not in our model.

Key Stats:	**(NASDAQ:XLRN)**
S&P 600 Health Care Index:	**1,289.05**
Price:	**$41.26**
Price Target:	$52.00
Methodology:	DCF analysis
52 Week High:	$43.70
52 Week Low:	$15.00
Shares Outstanding (mil):	2.4
Market Capitalization (mil):	$99.0
Book Value/Share:	$16.68
Cash Per Share:	$16.29
Dividend (ann):	$0.00
Dividend Yield:	0.0%

Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2012A	--	--	--	--	$15.3	--	--	--	--	($1.44)	NM
2013E	$15.0A	$26.4A	$4.3A	$18.0	$63.7	$0.13A	$0.64A	($0.66)A	$0.13	$0.25	NM
2014E	--	--	--	--	$40.0	--	--	--	--	($0.49)	NM

Source: Company Information and Leerink Partners LLC Research
Revenue in MM, GAAP EPS presented

INVESTMENT THESIS

We rate XLRN Outperform. We believe XLRN shares are poised to appreciate near/longer term driven by progress with CELG-partnered compounds Sotatercept/ACE-536 and proprietary Dalantercept (ACE-041). XLRN has multiple significant data read-out catalysts during almost every quarter until YE14. Pivotal Catalysts through 2014: 1) Preliminary Dalantercept Phase II RCC data in 1Q14; 2) Top-line Sotatercept and ACE-536 Phase II MDS and β-Thal. (4 trials) data at EHA in 2Q14; 3) Final Sotatercept and ACE-536 Phase II MDS and β-Thal. (4 trials) data at ASH in 4Q14; 4) Initiate pivotal MDS and/or β-Thal. trials by YE14. MEDACorp KOLs are very bullish and encouraged by emerging pipeline data and science. We assume probability of success in the low 30%s for Sotatercept/ACE-536 in MDS, 40% for β-Thal., 20% in end-stage renal disease (ESRD) patients on hemodialysis, and low 30%s for Dalantercept in 2nd-line RCC.

Change in Estimates

Our valuation is increased from $35 to $52 by including probability adjusted royalty revenue from ESRD patients on hemodialysis at 20%. XLRN has initiated a Phase II study in December 2013 to assess safety and efficacy of sotatercept in treating anemia and its potential to control conditions like mineral and bone disorder associated with chronic kidney disease. Our 2014 EPS changed from ($0.52) to ($0.49).

Milestones

Product	Partner	Indication	Phase	Timing	Milestone
ACE-536	CELG	MDS + β-Thal.	Ph. II	1Q14	Initiate Phase II Expansion Cohort for β-Thal.
				2Q14	**Phase II dose escalation data for MDS and β-Thal. at EHA-2014**
				4Q14	**Final Phase II in MDS and β-Thal. data**
				YE14	Initiate Phase III trial for MDS and/or β-Thal.
				2018	Approval and launch
Sotatercept (ACE-011)				1Q14	Initiate Phase II Expansion Cohort for β-Thal.
				2Q14	**Phase II dose escalation MDS + β-Thal. data at EHA-2014**
				4Q14	**Final Phase II in MDS + β-Thal. data**
				2018	Approval and launch
				YE14	Initiate Phase III trial for MDS and/or β-Thal.
	CELG	ESRD	Ph. II	**1H14**	**Part-1 top-line data**
				1H15	**Part-2 top-line data**
Dalantercept (ACE-041)	Proprietary	Oncology	Ph. II	**1Q14**	**Dose escalation Phase II RCC combo data trial (full at ASCO-2014)**
					GOG Ovarain Cancer single agent trial Go-No-Go to Part-2 of trial
				1Q14	Initiate Phase II (Part-2, N=112) RCC randomized trial (PFS endpoint)
				1H14	Initiate Phase II combo (sorafenib) trial in HCC
				YE14	Preliminary Phase II combo (sorafenib) data in HCC
				2014	Phase II data in SCCHN
				2018	Approval and launch in RCC
New TGF-β Candidates		Muscle	PC	2014	Advance Muscle Loss candidate into clinic (ACE-083)
		Fibrosis	PC	2015	Advance Fibrosis (i.e., PAH) candidate into clinic

Source: Company reports, Leerink Partners estimates.

Phase II Sotatercept Intravenous (IV)/Subcutaneous (SC) End-Stage Kidney Disease Patients on Hemodialysis	
Purpose:	Determine optimal administration route, dose level, and safety of IV or SC sotatercept for maintaining hemoglobin levels in ESRD hemodialysis subjects
# Pts:	**Part-1:** N=60 **Part-2:** N=230 19 international sites (as of 1.8.14)
Design:	Interventional, 2x Part, randomized, open label, treatment trial
Trial Arms:	**Note:** Patients in both parts of study must first be on stable dose of ESA to maintain Hg levels and switched to treatment with sotatercept after an ESA treatment free period of ~5 days **Part-1:** Staggered dose group escalation ▪ **Arm-1 (IV):** ACE-011 IV starting at **0.1mg/kg (gp-1)**, then **0.2mg/kg (gp-2)** and **0.3mg/kg (gp-3)** every 14 days for total of 8 doses and followed for 4 months after last dose ▪ **Arm-2 (SC):** ACE-011 SC starting at **0.13mg/kg (gp-1)**, then **0.26mg/kg (gp-2)**, and **0.4mg/kg (gp-3)** every14 days for total of 8 doses and followed for 4 months after last dose **Part-2:** Parallel group, randomized vs. active control (ESA)
Primary Endpoint:	**Part-1:** ▪ **Pharmacokinetics:** C-max, T-max, AUC 28days [Time Frame: 28 days] and T-1/2,z [211 days] ▪ **Adverse Events:** [Time Frame: 211 days] [Designated as safety issue], TEAEs **Part-2:** ▪ **Change in mean hemoglobin concentration from baseline** ▪ **Ability of sotatercept to maintain hemoglobin levels within target range after switching from ESA to sotatercept**
Secondary Endpoints:	▪ Efficacy [Time Frame: 113 days] ▪ Change in mean hemoglobin (Hg) concentration between baseline and day-113 ▪ Bone Turnover biomarkers for remodeling and mineral metabolism for 211 days ▪ Change in serum bone biomarker concentrations between baseline and end of study (day-211)
Start:	October-2013
Data:	October-2015
Status:	Recruiting (as of 1.8.14)
Sponsors:	**CELG**
Clin.Trial.ID:	NCT01999582, **ACE-011-REN-002, 2012-003788-23**

Source: Company reports, Leerink Partners estimates.

VALUATION

We arrive at a new 12-month price target of XLRN shares of $52 a share (previously $35) based on the inclusion of probability adjusted royalty revenue from ESRD patients on hemodialysis at 20%. Our valuation is based on a discounted cash flow analysis. XLRN shares are poised to appreciate near/longer term driven by progress with CELG-partnered compounds Sotatercept/ACE-536 and proprietary Dalantercept (ACE-041). We apply a discount rate of 10% and a terminal growth rate of 1%, which translates to an 11x terminal multiple, which we believe is comparable to biotechnology companies in a similar development stage.

RISKS TO VALUATION

An investment in XLRN is fundamentally a high-risk, high-reward investment, in our opinion. XLRN may face significant clinical, regulatory, and commercial risks for pipeline products. Most important is clinical risk for Phase II Sotatercept and ACE-536 trials in MDS and β-Thal. as well as Dalantercept/Axitinib in RCC. There is also competitive risk from emerging MDS, β-Thal. and RCC therapies. Finally, XLRN may face financing risk beyond 1H15.

XLRN P&L ($000s, except per share data)	2012A	1Q13A	2Q13A	3Q13A	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
Revenues																			
Sotatercept/ACE-536 WW Revenue in MDS to CELG											$66,089	$141,589	$227,505	$324,937	$435,091	$559,283	$698,955	$855,680	$1,031,180
Probability of Success											*32%*	*32%*	*32%*	*32%*	*32%*	*32%*	*32%*	*32%*	*32%*
Risk Adjusted Sotatercept/ACE-536 WW Revenue											$21,148	$45,308	$72,801	$103,980	$139,229	$178,971	$223,666	$273,818	$329,978
Risk Adjusted Sotatercept/ACE-536 WW Royalties in MDS											**$4,230**	**$9,515**	**$16,016**	**$23,915**	**$32,023**	**$42,953**	**$55,916**	**$68,454**	**$82,494**
Sotatercept/ACE-536 WW Revenue in NTD β-Thal. to CELG											$3,659	$60,642	$127,092	$226,546	$339,098	$466,097	$609,020	$767,222	$904,639
Probability of Success											*40%*	*40%*	*40%*	*40%*	*40%*	*40%*	*40%*	*40%*	*40%*
Risk Adjusted Sotatercept/ACE-536 WW Revenue in NTD β-Thal.											$1,464	$24,257	$50,837	$90,619	$135,639	$186,439	$243,608	$306,889	$361,856
Risk Adjusted Sotatercept/ACE-536 WW Royalties in NTD β-Thal.											**$293**	**$4,851**	**$10,676**	**$19,936**	**$29,841**	**$42,881**	**$58,466**	**$73,653**	**$90,464**
Dalantercept WW Revenue in 2nd-line RCC											$68,061	$131,647	$210,325	$298,864	$398,173	$509,233	$633,101	$770,918	$877,863
Probability of Success											*32%*	*32%*	*32%*	*32%*	*32%*	*32%*	*32%*	*32%*	*32%*
Risk Adjusted Dalantercept WW Revenue in 2nd-line RCC											**$21,780**	**$42,127**	**$67,304**	**$95,637**	**$127,415**	**$162,954**	**$202,592**	**$246,694**	**$280,916**
Sotatercept US Revenue in ESRD Patients on Hemodialysis													$301,866	$819,107	$1,418,781	$1,915,379	$2,064,199	$2,220,226	$2,383,756
Probability of Success													*20%*	*20%*	*20%*	*20%*	*20%*	*20%*	*20%*
Risk Adjusted Sotatercept US Revenue in ESRD Patients on Hemodialysis													$60,373	$163,821	$283,756	$383,076	$412,840	$444,045	$476,751
Risk Adjusted Sotatercept US Royalties in ESRD Patients on Hemodialysis													**$12,075**	**$36,041**	**$65,264**	**$91,938**	**$103,210**	**$111,011**	**$119,188**
Collaboration Revenue						-	-												
License and milestone (Risk Adjusted beyond approval)	$9,696	$12,515	$22,891	$638	$15,000	$51,044	$40,000	-	$40,000	$25,000	$22,400	$6,400	-	$6,400	-	$6,400	$6,400	$6,400	$6,400
Cost-Sharing, Net	$5,558	$2,497	$3,537	$3,632	$3,000	$12,666													
Contract Manufacturing	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Collaboration Revenue				$4,270		$4,270													
Total Revenue	**$15,254**	**$15,012**	**$26,428**	**$4,270**	**$18,000**	**$63,710**	**$40,000**	**-**	**$40,000**	**$25,000**	**$48,702**	**$62,893**	**$106,071**	**$181,929**	**$254,543**	**$347,127**	**$426,584**	**$506,213**	**$579,462**
Costs and Expenses																			
Probability Adjusted Dalantercept COGS	-	-	-	-	-	-	-	-	-	-	$3,267	$6,319	$10,096	$9,564	$12,742	$16,295	$20,259	$24,669	$28,092
Research and Development	$35,319	$8,780	$8,911	$8,143	$9,500	$35,334	$38,867	$42,754	$47,030	$51,733	$25,866	$27,160	$28,518	$29,943	$31,441	$33,013	$34,663	$36,396	$38,216
SG&A (Risk Adjusted from Time of Dalantercept Launch)	$8,824	$3,096	$3,365	$3,011	$3,950	$13,422	$14,764	$16,241	$17,865	$19,651	$26,051	$28,656	$30,949	$32,496	$34,121	$35,827	$37,618	$39,499	$41,474
Total Costs and Expenses	**$44,143**	**$11,876**	**$12,276**	**$11,154**	**$13,450**	**$48,756**	**$53,632**	**$58,995**	**$64,894**	**$71,384**	**$55,184**	**$62,135**	**$69,562**	**$72,003**	**$78,303**	**$85,135**	**$92,541**	**$100,565**	**$107,782**
Operating Income (EBIT)	**($28,889)**	**$3,136**	**$14,152**	**($6,884)**	**$4,550**	**$14,954**	**($13,632)**	**($58,995)**	**($24,894)**	**($46,384)**	**($6,482)**	**$758**	**$36,509**	**$109,925**	**$176,240**	**$261,991**	**$334,044**	**$405,648**	**$471,680**
Y/Y growth																			
Other Income (Expenses)	($2,255)	($1,066)	($356)	($11,629)	-	($13,051)	-	-	-	-	-	-	-	-	-	-	-	-	-
Interest Income	$91	$12	$8			$20													
Interest Expense	($1,529)	($435)	($726)	-	($726)	($1,887)	($1,278)	($521)	-	-	-	-	-	-	-	-	-	-	-
Income Before Taxes	**($32,582)**	**$1,647**	**$13,078**	**($18,513)**	**$3,824**	**$36**	**($14,909)**	**($59,515)**	**($24,894)**	**($46,384)**	**($6,482)**	**$758**	**$36,509**	**$109,925**	**$176,240**	**$261,991**	**$334,044**	**$405,648**	**$471,680**
Provision for Taxes							-	-	-	-	-	-	-	-	-	90,057	113,575	137,920	160,371
Tax Rate							0%	0%	0%	0%	0%	0%	0%	0%	0%	34%	34%	34%	34%
Net income	**($32,582)**	**$1,647**	**$13,078**	**($18,513)**	**$3,824**	**$36**	**($14,909)**	**($59,515)**	**($24,894)**	**($46,384)**	**($6,482)**	**$758**	**$36,509**	**$109,925**	**$176,240**	**$171,934**	**$220,469**	**$267,727**	**$311,309**
Change in fair value of warrants	$2,258	$1,067	$433	-	-	$1,500													
EPS (LPS) Basic	**($1.44)**	**$0.13**	**$0.64**	**($0.66)**	**$0.13**	**$0.25**	**($0.49)**	**($1.81)**	**($0.75)**	**($1.38)**	**($0.19)**	**$0.02**	**$1.05**	**$3.14**	**$4.99**	**$4.82**	**$6.11**	**$7.35**	**$8.46**
Basic Shares (000)	21,062	20,954	20,954	28,100	28,381	6,138	30,665	32,971	33,301	33,634	33,971	34,310	34,653	35,000	35,350	35,703	36,060	36,421	36,785

Source: Leerink Swann estimates and company reports.
Note: Basic and Diluated shares outstanding are pro forma for IPO priced 9/18/13.
NTD=non-transfusion dependent.

DCF Calcuation

Discount rate	*10%*
Terminal Growth Rate	*1%*
Valuation ($M)	$1,649
Valuation / Share	**$52**

Source: Leerink Swann estimates.

XLRN DCF Valuation/Share Sensitivity Analysis

Terminal Growth Rate \ Discount Rate	8.0%	9.0%	10.0%	11.0%	12.0%
0.0%	$68	$57	$48	$41	$36
1.0%	$75	$62	**$52**	$44	$38
2.0%	$85	$68	$56	$47	$40
3.0%	$98	$77	$62	$51	$43
4.0%	$118	$88	$69	$56	$47

Source: Leerink Swann estimates.

Disclosures Appendix

Analyst Certification

I, Marko Kozul, M.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

We arrive at a new 12-month price target of XLRN shares of $52 a share (previously $35) based on the inclusion of probability adjusted royalty revenue from ESRD patients on hemodialysis at 20%. Our valuation is based on a discounted cash flow analysis. XLRN shares are poised to appreciate near/longer term driven by progress with CELG-partnered compounds Sotatercept/ACE-536 and proprietary Dalantercept (ACE-041). We apply a discount rate of 10% and a terminal growth rate of 1%, which translates to an 11x terminal multiple, which we believe is comparable to biotechnology companies in a similar development stage.

Risks to Valuation

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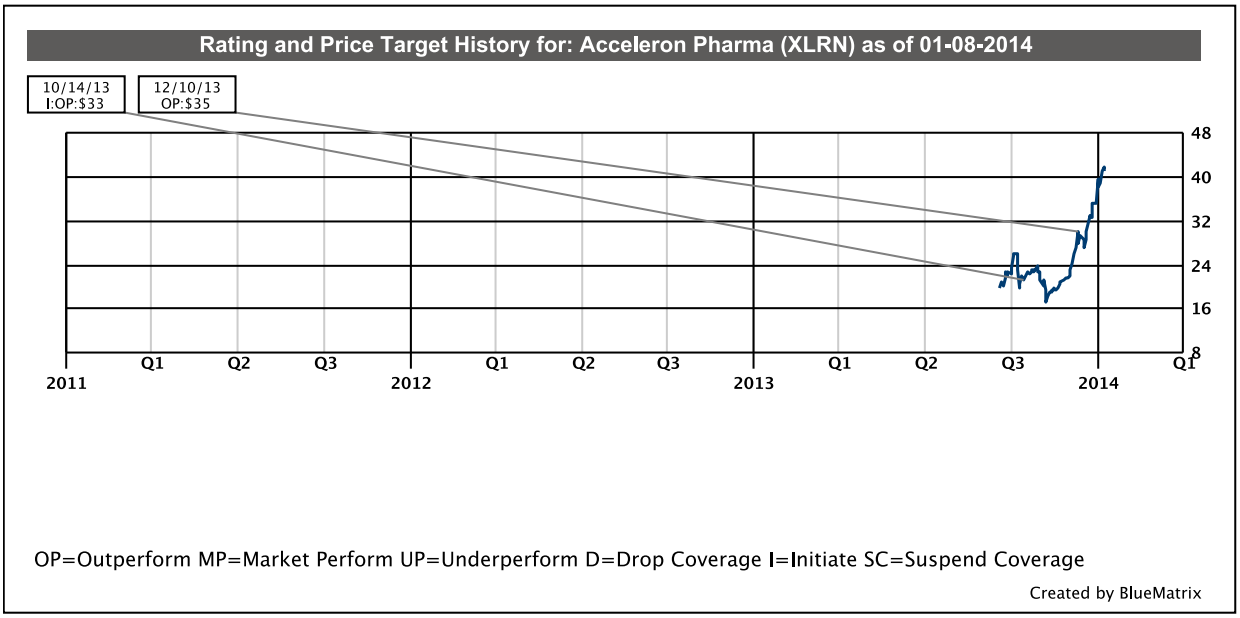

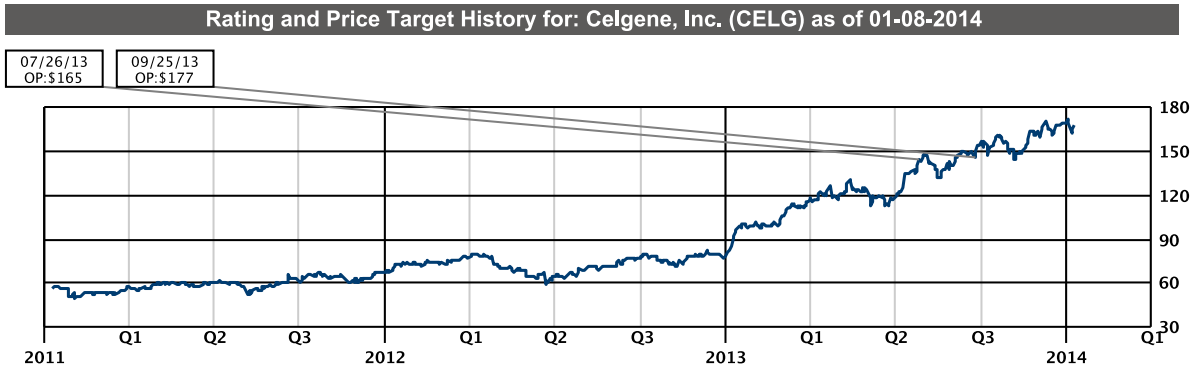

Leerink Swann initiated coverage of CELG with an Outperform rating on February 7, 2003. On June 11, 2013, Leerink Swann began a transition to specific price targets for the stocks under its coverage, replacing valuation ranges.

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 09/30/13				
			IB Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [OP]	111	64.90	27	24.00
HOLD [MP]	60	35.10	0	0.00
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.

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Important Disclosures

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In the past 12 months, the Firm has received compensation for providing investment banking services to Acceleron Pharma .

Leerink Partners LLC makes a market in Acceleron Pharma and Celgene, Inc.

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

Leerink Partners LLC has acted as the manager for a public offering of Acceleron Pharma in the past 12 months.

Leerink Partners 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
	Jonathan Chang, Ph.D.	(617) 918-4015	jonathan.chang@leerink.com
	Irene Lau	(415) 905-7256	irene.lau@leerink.com
	Paul Matteis	(617) 918-4585	paul.matteis@leerink.com
	Gena Wang, Ph.D., CFA	(212) 277-6073	gena.wang@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 Services	**Ana Gupte, Ph.D.**	(212) 277-6040	ana.gupte@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

New York
299 Park Avenue, 21st floor
New York, NY 10171
(888) 778-1653

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