#### **OUTPERFORM**

Jason M. Gerberry, JD (617) 918-4549 Jason.Gerberry@Leerink.com

**Derek C. Archila** (617) 918-4851

Derek.Archila@Leerink.com

Reason for report: **EARNINGS** 



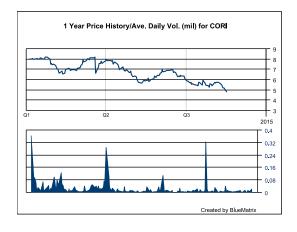
## **CORIUM INTERNATIONAL, INC.**

FY'4Q Update: Focus on CNS Pipeline + Upcoming PTH Data

- Bottom Line: This evening, CORI reported fiscal 4Q results -- sales of \$11.1m and a net loss of \$6.4m, which beat our sales and net loss estimates of \$9.8m and \$11m, respectively. The beat came from slightly lower opex and a 1x non-cash gain. Important FY'4Q updates included: (1) agreement with Capital Royalty Group resulting in ~\$10m in debt financing bringing CORI's cash position to ~\$46m upon closing; (2) incremental pipeline updates for the company's CNS portfolio including the likely launch of Ph. 1 clinical studies for its lead Alzheimer's (AD) program in 1H'15 -- CORI aspires to advance its CNS programs in-house & potentially build a commercial organization around them; (3) Ph. 2a PTH data remains on track to read out in 1H'15. We remain OP, but lower our price target to ~\$11/share (from \$12).
- Incremental updates on key development programs. On the CC, CORI provided updates on: (1) its lead AD program donepezil (Aricept), which showed encouraging pre-clinical PK data demonstrating sustained and reproducible blood levels. CORI expects to move the program into Ph. 1 in 1H'15; (2) memantine (Namenda) is set to enter formulation and PK studies "soon" and the company expects to begin clinical work in 2015 behind donepezil; (3) aripiprazole (Abilify) is also set to begin formulation studies and CORI expects to begin clinical work in late '15/ early '16; & (4) a new partnership with WHO on a transdermal polio vaccine program. Mgmt indicated there is broad utility for transdermal technology for vaccines, and this program may serve as a springboard for additional vaccine development.
- PTH Phase 2a data expected in 1H'15. On the FY'4Q update, mgmt commented that the MicroCor PTH (parathyroid hormone) program is still scheduled to read out Phase 2a data in 1H'15. Recall, MicroCor PTH is similar to LLY's (OP) Forteo for treatment of osteoporosis, a drug that generated annual US and international sales of \$510m and \$730m, respectively. Forteo is a once-daily subcutaneous injection with patent coverage through 2019. CORI's transdermal delivery system aims to achieve a similar dosing profile to Forteo but improve on the PK characteristics (faster onset and better tolerability).
- Mgmt expects FY'15 revenue growth to be flat. On the CC, mgmt guided FY'15 revenue to be in line with FY'14 revenue levels, noting growth in whitestrips will be balanced by decreasing revenues in the clonidine and fentanyl markets. In both g-clonidine and g-fentanyl, CORI's partners continue to face increasing competition in each respective market. In the clonidine patch market, ACT (OP) recently launched a generic competitor, which in FY'4Q captured ~6% of the market. According to IMS, TEVA (OP)/CORI's g-clonidine share was down from ~58% to ~53% during FY'4Q and we expect further share erosion with ACT likely to capture ~20-25% of the market by the end of FY'15.

Key Stats: (NASDAQ:CORI)

S&P 600 Health Care Index: 1,354.78 Price: \$4.76 Price Target: \$11.00 from \$12.00 Methodology: Sum-of-Parts DCF Analysis 52 Week High: \$8.49 52 Week Low: \$4.30 Shares Outstanding (mil): 18.0 Market Capitalization (mil): \$85.7 Book Value/Share: \$0.00 Cash Per Share: \$2.00 Dividend (ann): \$0.00 Dividend Yield: 0.0%



Sep Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2014A	\$10.5	\$10.7	\$10.2	\$11.1	\$42.4	(\$0.21)	\$0.33	(\$0.28)	(\$0.35)	(\$0.99)	NM
2015E - New	\$10.1	\$10.1	\$10.4	\$10.7	\$44.8	(\$0.35)	(\$0.40)	(\$0.42)	(\$0.25)	(\$1.23)	NM
2015E - Old					\$48.8					(\$0.97)	NM
2016E					\$64.9					(\$0.74)	NM

Source: Company Information and Leerink Partners LLC Research

Revenues in millions.

GAAP EPS.



### **INVESTMENT THESIS**

We rate CORI shares Outperform. CORI's current valuation largely reflects its base business -- a stable, transdermal patch mfg business. While CORI's pipeline gets little credit in the current valuation, we view the risk/reward as favorable keyed by Phase 3 Twirla, a contraceptive patch partnered with Agile Therapeutics. We view Twirla as a low development risk (75% POS) product with potential to reach \$400m in peak US sales. Beyond Twirla, CORI has several self-funded Phase 2 assets that have the potential to generate non-dilutive partnership dollars sometime in 2015. With its recent IPO proceeds, we believe CORI will be able to leverage its transdermal formulation expertise & secure better partnership terms, which should dramatically alter the margin profile of the company. Lastly, we are confident in CORI mgmt's ability to build a diversified transdermal-delivery spec pharma company based on its experience at Alza, a pioneer in transdermal and modified delivery drugs.

### **CHANGES TO MODEL**

EPS & Total Sales Forecasts (2013-19E) (\$MM, except per share data)

Total EPS Forecasts 2013-19E											
	2013	2014	2015E	2016E	2017E	2018E	2019E				
New	(6.24)	(0.99)	(1.23)	(0.74)	(0.52)	(0.17)	(0.02)				
Old	(2.40)	(0.99)	(0.97)	(0.74)	(0.52)	(0.17)	(0.02)				
Difference	(3.85)	0.00	(0.26)	-	-	-	-				
	Total Revenue Forecasts 2013-19E										
	2013	2014	2015E	2016E	2017E	2018E	2019E				
New	50	42	45	65	84	106	119				
Old	50	41	49	65	84	106	119				
Difference	-	1	(4)	-	-	-	-				

Source: Leerink Partners, LLC estimates, Company information

### **VALUATION**

Our  $\sim$ \$11 (from \$12) price target is based on a sum-of-the-parts valuation analysis: (1) base business =  $\sim$ \$6.22, based on 2.5x multiple on  $\sim$ \$45m F'15E revenue from base business products, (2) Twirla =  $\sim$ \$1.79, (3) Ph. II products =  $\sim$ \$2.07, (4) MicroCor =  $\sim$ 57c, and (5) net cash  $\sim$ 45c.

### **RISKS TO VALUATION**

Potential risks to CORI valuation include: (1) clinical failure of Twirla Ph. III; (2) incremental competitive headwinds in fentanyl and/or clonidine TDS markets; & (3) product recalls and/or cGMP issues relating to existing commercial products could negatively impact valuation.

CORI P&L Summary (Adj. Basis)

CORI P&L Summary (Adj. Basis)																	CAGR	CAGR
(Fiscal Year End Last Friday of September)	2012	2013	1Q 12/13	2Q 3/14	3Q 6/14E	4Q 9/14	2014	1Q 12/15E	2Q 3/15E	3Q 6/15E	4Q 9/15E	2015E	2016E	2017E	2018E	2019E	14-16E	14-19E
clonidinne TDS, partner TEVA (brand: Catapres TTS)	10.7	12.5	2.6	2.3	2.6	1.9	9.4	1.9	1.8	1.7	1.6	7.0	7.0	6.1	6.1	6.1	-14%	-8%
fentanyl TDS, partner Par (brand: Duragesic)	15.0	16.4	3.1	2.5	2.7	2.7	11.0	2.8	2.6	2.7	3.1	11.2	10.1	9.9	9.8	9.8	-4%	-2%
Crest White Strips, partner P&G	10.0	9.8	2.4	2.4	2.6	2.6	10.0	2.7	2.9	3.1	3.4	12.0	13.2	14.5	16.0	17.6	15%	12%
Total in-line patch sales	35.7	38.7	8.1	7.2	7.9	7.2	30.4	7.4	7.3	7.5	8.1	30.2	30.3	30.5	31.8	33.4	0%	2%
scopolamine TDS, partner TEVA (brand: Transderm Scop)	-	-	-	-	-	-	-	-	-	-	-	3.5	3.0	3.0	3.0	3.0	na	na
oxybutynin TDS, partner TEVA (brand: Oxytrol)	- 1	- 1	-	-	-	-	- 1	-	-	-	-	-					na	na
AG200-15 contraceptive patch, partner Agile	- 1	- 1	•	-	-	-		•	-	-	-	-	4.0	10.0	16.0	20.0	na	na
P&G OTC cosmetic product Corplex Tamsulosin	- 1	-	-	•	-	-	- 1	-	-	-	-	-	4.0	6.0	9.0	14.0	na na	na na
Alzheimer's TDS (505b2 path)			-		-	_		-			-	_	-	-	_	_	na	na
Parkinson't TDS (505b2 path)		-		-	-	-		-		-	-	-	-	-	-	-	na	na
Total pipeline patch product sales	-	-	-	-	-	-	-	-	-	-	-	3.5	11.0	19.0	28.0	37.0	na	na
hPTH (1-34) TDS	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	na	na
Product royalties	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	na	na
Contract Research & Development	6.8	10.8	2.1	3.3	2.0	1.7	9.0	2.2	2.3	2.4	2.1	9.0	16.0	20.0	24.0	26.0	33%	24%
License & Collaboration Revenue	0.3	0.8	0.3	0.2	0.3	0.4	1.2	0.5	0.5	0.5	0.5	2.0	7.7	14.3	21.7	23.0	151%	80%
Other revenues	- 1	-	-	-	-	1.8	1.8	-	-	-	-	-	-	-	-	-	-100%	-100%
Total Revenues	42.9	50.3	10.5	10.7	10.2	11.1	42.4	10.1	10.1	10.4	10.7	44.8	64.9	83.9	105.5	119.4	24%	23%
% Y/Y growth	na	17.3%	-17.1%	-20.3%	-22.2%	-0.3%	-15.6%	-4.0%	-5.8%	2.1%	-3.3%	5.5%	45.0%	29.2%	25.8%	13.2%		
Cost of product sales	24.4	24.8	5.2	5.0	4.6	5.4	20.2	5.7	6.3	6.9	7.6	26.5	31.4	36.7	43.9	51.4	25%	21%
Cost of contract R&D	10.2	11.9	3.5	3.9	3.8	4.2	15.4	3.7	3.6	3.3	(0.4)	10.2	20.8	27.5	34.3	36.8	16%	19%
COGS	34.6	36.7	8.8	8.9	8.4	9.6	35.6	9.4	9.9	10.2	7.1	36.6	52.1	64.1	78.1	88.2	21%	20%
% of net sales	80.7%	73.0%	83.7%	83.1%	82.0%	86.4%	83.9%	93.5%	98.0%	98.1%	66.6%	81.8%	80.3%	76.5%	74.0%	73.8%		
Gross Income	8.3	13.6	1.7	1.8	1.8	1.5	6.8	0.7	0.2	0.2	3.6	8.1	12.8	19.7	27.4	31.3	37%	36%
% of product sales	19.3%	27.0%	16.3%	16.9%	18.0%	13.6%	16.1%	6.5%	2.0%	1.9%	33.4%	18.2%	19.7%	23.5%	26.0%	26.2%		
G&A	4.6	6.5	1.8	1.2	3.5	2.5	9.1	2.3	2.5	2.7	2.7	10.2	10.4	10.5	10.6	10.6	7%	3%
% of net sales	11%	13%	17.3%	11.5%	34.4%	23.0%	21.4%	22.9%	24.8%	26.0%	25.2%	22.8%	16.0%	12.5%	10.0%	8.9%		
R&D	4.0	5.5	0.9	1.3	1.6	3.6	7.4	2.6	2.8	3.1	3.5	12.0	12.0	15.0	16.0	17.0	28%	18%
% of net sales	9.3%	10.9%	8.2%	11.8%	15.8%	32.7%	17.4%	25.9%	27.7%	29.8%	32.7%	26.8%	18.5%	17.9%	15.2%	14.2%		
Amortization	0.5	1	0.1	0.1	0.1	0.1	0.5	0.1	0.1	0.1	0.1	0.5	-		_	_	-100%	-100%
% of net sales	1.2%	1.1%	1.2%	1.2%	1.4%	1.3%	1.3%	1.3%	1.3%	1.3%	0.9%	1.1%	0.0%	0.0%	0.0%	0.0%		
Gain on equipment sale	(0)	(0)	(0)	(0)	(0)	(0)	(0)	1.570	1.570	1.570	0.576	1.170	0.070	0.070	0.070	0.070	-100%	-100%
% of net sales	-0.1%	-0.4%	-0.4%	-0.3%	-0.2%	-0.2%	-0.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	-10070	-10070
Operating Income	(0.8)	1.2	(1)	(1)	(3)	(5)	(10.1)	(4)	(5)	(6)	(3)	(15)	(10)	(6)	1	4	-2%	NA
% of net sales	-1.9%	2.4%	(.,	(.,	(0)	(0)	-23.7%	(-)	(0)	(0)	(0)	-32.6%	-14.8%	-6.9%	0.8%	3.1%		
Net financial expense	(4.6)	(15.1)	(1.0)	4.3	(1.6)	(1.6)	0.1	(2.0)	(2.0)	(2.0)	(2.0)	(8.0)	(4.0)	(4.0)	(4.0)	(4.0)		
Pretax Income	(5.5)	(13.9)	(2)	4	(5)	(6)	(9.9)	(6)	(7)	(8)	(5)	(22.6)	(13.6)	(9.8)	(3.2)	(0.3)	17%	na
% Pre-tax margin	-12.7%	-27.6%	-20.0%	33.0%	-48.9%	-57.5%	-23.4%	-63.5%	-71.6%	-74.4%	-44.0%	-50.4%	-21.0%	-11.6%	-3.0%	-0.3%		
Income Taxes (benefit)	(0)	0	-		-	0	0	-			-	-	_	-		_	-100%	-100%
% Tax rate	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%		
GAAP Net Income	(5.4)	(13.9)	(2.1)	3.5	(5.0)	(6.4)	(9.9)	(6.4)	(7.2)	(7.7)	(4.7)	(22.6)	(13.6)	(9.8)	(3.2)	(0.3)	NA	na
% of net sales	(5.4)	(.3.5)	-20.0%	33.0%	-48.9%	-57.5%	(5.5)	-63.5%	-71.6%	-74.4%	-44.0%	(22.5)	(10.0)	(0.0)	(0.2)	(0.0)		
Diluted GAAP EPS	(2.47)	(6.24)	(0.21)	0.33	(0.28)	(0.35)	(0.99)	(0.35)	(0.40)	(0.42)	(0.25)	(1.23)	(0.74)	(0.52)	(0.17)	(0.02)	NA	NA
% growth	nm	nm					nm					nm	nm	nm	nm	-90%		
Weighted Average Diluted Shares	2.2	2.2	10.1	10.7	17.6	18.0	10.0	18.1	18.2	18.3	18.7	18.3	18.5	18.8	19.2	19.6	36%	14%
% growth		1%	238%	155%	203%	-536%	352%	78%	70%	4%	4%	82%	1%	2%	2%	2% #		

Source: Company information, Leerink Research estimates.; Note: F2Q14 share ct may require adjustment after 10Q publishes

Sharecount based on what company reported, may not sum to FY due to rounding



# **Disclosures Appendix Analyst Certification**

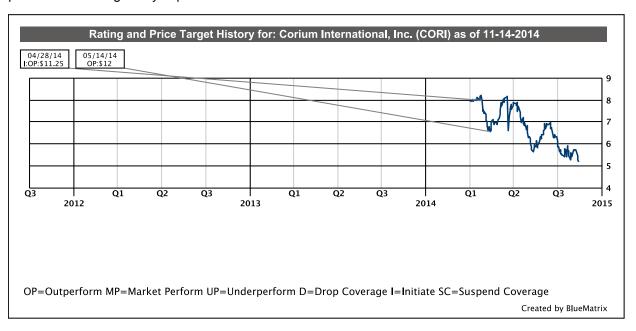
I, Jason M. Gerberry, JD, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

## **Valuation**

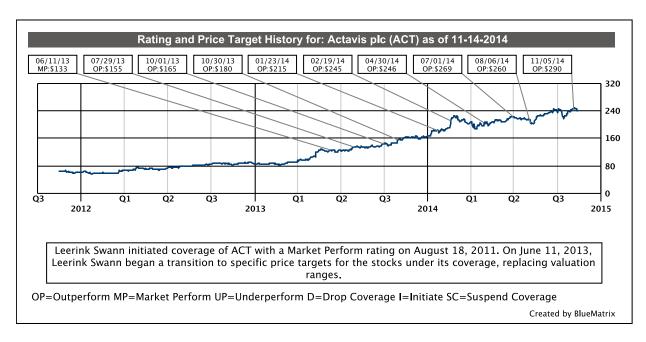
Our  $\sim$ \$11 (from \$12) price target is based on a sum-of-the-parts valuation analysis: (1) base business =  $\sim$ \$6.22, based on 2.5x multiple on  $\sim$ \$45m F'15E revenue from base business products, (2) Twirla =  $\sim$ \$1.79, (3) Ph. II products =  $\sim$ \$2.07, (4) MicroCor =  $\sim$ 57c, and (5) net cash  $\sim$ 45c.

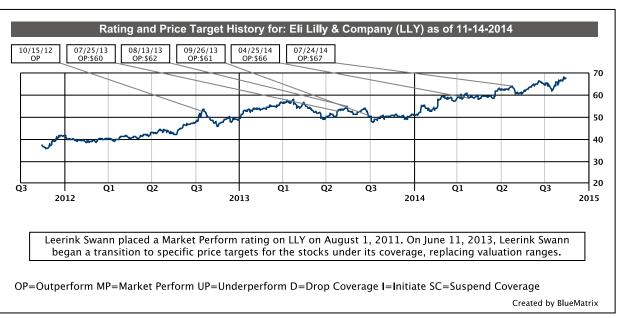
## **Risks to Valuation**

Potential risks to CORI valuation include: (1) clinical failure of Twirla Ph. III; (2) incremental competitive headwinds in fentanyl and/or clonidine TDS markets; & (3) product recalls and/or cGMP issues relating to existing commercial products could negatively impact valuation.

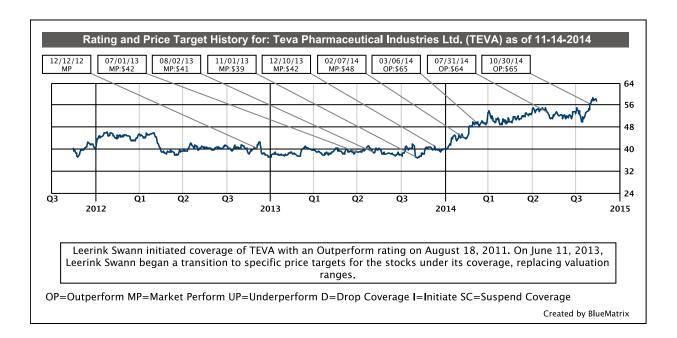














Distribution of Ratings/Investment Banking Services (IB) as of 09/30/14 IB Serv./Past Mo								
Rating	Count	Percent	Count	Percent				
BUY [OP] HOLD [MP]	138 61	69.30 30.70	51 2	37.00 3.30				
SELL [UP]	0	0.00	0	0.00				

## **Explanation of Ratings**

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

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

<u>Underperform (Sell):</u> 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**

This information (including, but not limited to, prices, quotes and statistics) has been obtained from sources that we believe reliable, but we do not represent that it is accurate or complete and it should not be relied upon as such. All information is subject to change without notice. This is provided for information purposes only and should not be regarded as an offer to sell or as a solicitation of an offer to buy any product to which this information relates. The Firm, its officers, directors, employees, proprietary accounts and affiliates may have a position, long or short, in the securities referred to in this report, and/or other related securities, and from time to time may increase or decrease the position or express a view that is contrary to that contained in this report. The Firm's salespeople, traders and other professionals may provide oral or written market commentary or trading strategies that are contrary to opinions expressed in this report. The Firm's proprietary accounts may make investment decisions that are inconsistent with the opinions expressed in this report. The past performance of securities does not guarantee or predict future performance. Transaction strategies described herein may not be suitable for all investors. Additional information is available upon request by contacting the Editorial Department at One Federal Street, 37th Floor, Boston, MA 02110.

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, Institutional Equities, and Investment Banking. Analysts, however, are not compensated for a specific investment banking services transaction. MEDACorp is a network of healthcare professionals, attorneys, physicians, key opinion leaders and other specialists accessed by Leerink and it provides information used by its analysts in preparing research.

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

Leerink Partners LLC makes a market in Corium International, Inc. and Teva Pharmaceutical Industries Ltd.



Leerink Partners LLC is willing to sell to, or buy from, clients the common stock of Actavis plc and Eli Lilly & Company on a principal basis.

Leerink Partners LLC has acted as the manager for a public offering of Corium International, Inc. in the past 12 months.

While IMS Health has been used as a source, the analysis contained herein has been arrived at independently by the firm and IMS is not responsible for the analysis or use of the data.

©2014 Leerink Partners LLC. All rights reserved. This document may not be reproduced or circulated without our written authority.

Leerink Partners LLC Equity Research								
	Leerink Partners L	LC Equity Resear	511					
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					
	7, 0.77	(011) 010 1011						
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					
	Michael Schmidt, Ph.D.	(617) 918-4588	michael.schmidt@leerink.com					
	Gena Wang, Ph.D., CFA	(212) 277-6073	gena.wang@leerink.com					
	Paul Matteis	(617) 918-4585	paul.matteis@leerink.com					
	Jonathan Chang, Ph.D.	(617) 918-4015	jonathan.chang@leerink.com					
	Richard Goss	(617) 918-4059	richard.goss@leerink.com					
Life Science Tools	Dan Leonard	(212) 277-6116	dan.leonard@leerink.com					
and Diagnostics	Justin Bowers, CFA	(212) 277-6066	justin.bowers@leerink.com					
and Diagnooned	oddin Bowolo, Olivi	(212) 211 0000	jacan need cheer made n					
Pharmaceuticals/Major	Seamus Fernandez	(617) 918-4011	seamus.fernandez@leerink.com					
•	Ario Arabi	(617) 918-4568	ario.arabi@leerink.com					
	Aneesh Kapur	(617) 918-4576	aneesh.kapur@leerink.com					
Specialty Pharmaceuticals	Jason M. Gerberry, JD	(617) 918-4549	jason.gerberry@leerink.com					
	Derek C. Archila	(617) 918-4851	derek.archila@leerink.com					
Medical Devices, Cardiology	Danielle Antalffy	(212) 277-6044	danielle.antalffy@leerink.com					
O Outhouse Page	Puneet Souda	(212) 277-6091	puneet.souda@leerink.com					
& Orthopedics	Richard Newitter	(212) 277-6088	richard.newitter@leerink.com					
	Ravi Misra	(212) 277-6049	ravi.misra@leerink.com					
Healthcare Services	Ana Gupte, Ph.D.	(212) 277-6040	ana.gupte@leerink.com					
nealtricare Services	Ana Gupte, Fil.D.	(212) 277-0040	ana.gupte@leennk.com					
Healthcare Technology	David Larsen, CFA	(617) 918-4502	david.larsen@leerink.com					
& Distribution	Christopher Abbott	(617) 918-4010	chris.abbott@leerink.com					
Digital Health	Steven Wardell	(617) 918-4097	steven.wardell@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					
Editorial	Cristina Diaz-Dickson	(617) 918-4548	cristina.diaz-dickson@leerink.com					
Research Associate	Carmen Augustine	(212) 277-6012	carmen.augustine@leerink.com					

**New York** 299 Park Avenue, 21<sup>st</sup> floor New York, NY 10171 (888) 778-1653 Boston One Federal Street, 37<sup>th</sup> Floor Boston, MA 02110 (800) 808-7525

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