October 27, 2014

**OUTPERFORM** 

Michael Schmidt, Ph.D. (617) 918-4588 Michael.Schmidt@Leerink.com

Jonathan Chang, Ph.D.

(617) 918-4015

Jonathan.Chang@Leerink.com

Reason for report: **FLASH NOTE** 



#### CERULEAN PHARMA INC.

CEO Resignation a Surprise; New Veteran Board Members Strengthen Leadership

- Bottom Line: This evening, CERU announced that CEO Oliver Fetzer has resigned as President and CEO to pursue other opportunities. Former INCY (OP) CEO Paul Friedman, currently a board member, will become Executive Chairman. Chris Guiffre CERU's Chief Business Officer will assume the position of Chief Operating Officer. In addition, CERU announced the appointment of Dr. David Parkinson to its Board of Directors; he also will join a newly formed Clinical Advisory Committee of the Board, which will consist of Dr. Parkinson, Dr. Susan Kelley and Dr. Paul Friedman. A search for CEO successor is ongoing, and there are no changes to CERU's product development plans. We are maintaining our Outperform Rating ahead of several clinical data readouts for CRLX-101 in 2015. CERU currently trades with an enterprise value of only \$24M. With \$64M cash on hand at the end of 2Q14 and upcoming data points in 2015, we believe the company is well positioned to execute on its strategy.
- CEO resignation a surprise to us. Oliver Fetzer served as CERU's CEO since 2009 and took the company public earlier this year. The search for a new CEO will start immediately, and we believe the company's well-connected board should be instrumental in recruiting a capable and experienced CEO successor.
- Industry veterans form impressive Clinical Advisory Committee of the Board which will assist management. CERU today also announced the appointment of Dr. David Parkinson to its Board of Directors, effective as of October 29, 2014. Dr. Parkinson is an oncology industry veteran (BIIB, AMGN [MP], NVS [OP]) and past chairman of the Food & Drug Administration (FDA) Biologics Advisory Committee. With Dr. Parkinson's appointment, CERU has formed a Clinical Advisory Committee of the Board, which will consist of Dr. Parkinson, Dr. Susan Kelley and Dr. Paul Friedman. Dr. Kelly joined CERU's Board on October 8th and was previously the Chief Medical Officer of the Multiple Myeloma Research Foundation and Therapeutic Area Head/Oncology at Bayer where she led development and approval of Nexavar.
- · We are maintaining our Outperform Rating ahead of clinical data readouts for CRLX-101 in 2015. We continue to believe that CERU's lead product CRLX-101 has an attractive mechanism of action (MOA) that could overcome several limitations of approved agents. Recall, CRLX-101 is a nanoparticle formulation of camptothecin, a potent inhibitor of topoisomerase 1 (topo 1). We believe CRLX-101 addresses a validated target, but toxicities have limited broad adoption of approved topo 1 inhibitors, topotecan and irinotecan. We believe CRLX-101 also down-regulates HIF-1α, an "undruggable" cancer target implicated in angiogenesis, and we believe CRLX-101's dual MoA makes it particularly useful as part of a combination therapy regimen.
- In our view, key de-risking upcoming data points are: (1) single arm data in platinum-resistant 2nd/3rd line ovarian cancer in combination w/ Avastin in 1Q15, (2) single arm Phase II data in neoadjuvant rectal cancer in combination w/ radiation and Xeloda in 1Q15, and (3) randomized

Key Stats:	(NASDAQ:CERU)
S&P 600 Health Care Index:	1,342.30
Price:	\$4.14
52 Week High:	\$8.06
52 Week Low:	\$3.35
Shares Outstanding (mil):	20.1
Market Capitalization (mil):	\$83.2



controlled Phase II data in 4Q15 in 3rd line RCC w/ Avastin. The ovarian and rectal cancer data will inform randomized Phase II-go decisions for these indications. CRLX301. the company's second product candidate is expected to enter the clinic in 4Q14, with Phase I data expected in 4Q15.



# **Disclosures Appendix Analyst Certification**

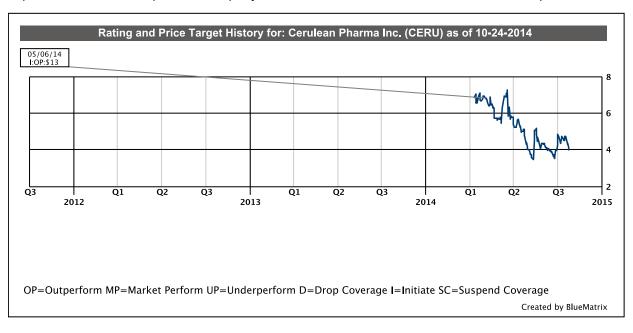
I, Michael Schmidt, Ph.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

#### **Valuation**

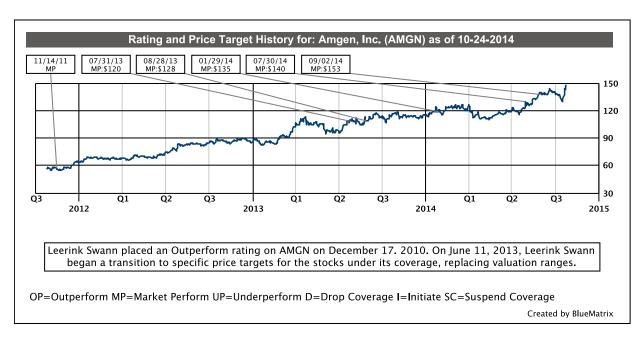
We estimate a \$13 per share price target in 12 months for CERU, reflecting a \$260M market capitalization based on a discounted cash flow analysis. We use a 16% WACC as the discount rate, which we view as appropriate for CERU. We use probability weighted revenue assumptions. We model ~\$1.0Bn peak US CRLX101 sales in 2030E across three lead indications in 3rd line renal cell cancer, platinum-resistant ovarian cancer, and neoadjuvant rectal cancer.

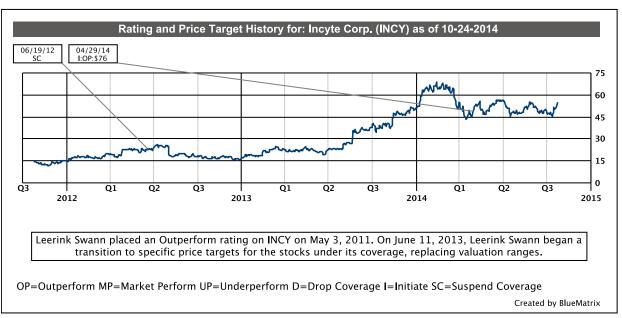
#### **Risks to Valuation**

CERU faces significant clinical and regulatory risks since its main value driver is currently in multiple early stage investigator-sponsored clinical trials. Like many other developmental stage Biopharma companies, CERU faces manufacturing, competitive, commercial, regulatory, and safety risks, as well as risks to its intellectual property. Specifically, CERU faces regulator uncertainty on whether pCR will be accepted by the FDA as an approvable endpoint for a potential future neoadjuvant rectal cancer trial. CERU also faces financial risk and may need to raise dilutive capital near term. We expect the company's current cash balance to be sufficient to fund operations until late 2015.

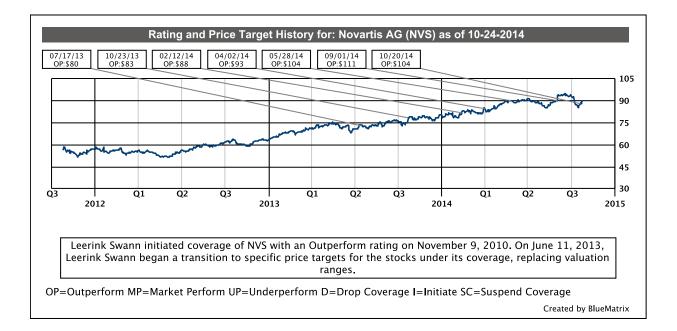














	Distribution of Ratings/Investment Banking Services (IB) as of 09/30/14 IB Serv./Past 12 Mos.					
Rating	Count	Percent	Count	Percent		
BUY [OP]	138	69.30	51	37.00		
HOLD [MP]	61	30.70	2	3.30		
SELL [UP]	0	0.00	0	0.00		

### **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 Cerulean Pharma Inc. .

Leerink Partners LLC makes a market in Cerulean Pharma Inc., Amgen, Inc. and Incyte Corp.

Leerink Partners LLC is willing to sell to, or buy from, clients the common stock of Novartis AG on a principal basis.

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

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

Leavink Dentmans II O F it. December							
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				
7.0000.000	7.1100 017.tva.11a.11, 017.t	(017) 010 1011	andela variati e le crimine 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				
	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				
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				
Medical Devices, Cardiology	Danielle Antalffy	(212) 277-6044	danielle.antalffy@leerink.com				
3,	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				
Healthcare Technology	David Larsen, CFA	(617) 918-4502	david.larsen@leerink.com				
& Distribution	Christopher Abbott	(617) 918-4010	chris.abbott@leerink.com				
Digital Health	Steve 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 Assistant	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