

Cerulean Pharma Inc. (CERU)

Initiating Coverage at Market Outperform

MARKET DATA

Price	\$6.75
52-Week Range:	\$6.10 - \$8.06
Shares Out. (M):	14.3
Market Cap (\$M):	\$96.5
Average Daily Vol. (000):	47.0
Cash (M):	\$56
Cash/Share:	\$3.90
Enterprise Value (M):	\$190
LT Debt (M):	\$3

Source: Thomson Reuters and JMP Securities LLC

FY DEC	2013A	2014E	2015E
Revenue (\$M) 1Q	--	\$0.0	\$0.0
2Q	--	\$0.0	\$0.0
3Q	--	\$0.0	\$0.0
4Q	--	\$0.0	\$0.0
FY	\$0.0	\$0.0	\$0.0
EPS 1Q	--	(\$0.41)	(\$0.39)
2Q	--	(\$0.39)	(\$0.43)
3Q	--	(\$0.43)	(\$0.47)
4Q	--	(\$0.47)	(\$1.69)
FY	(\$2.17)	(\$1.69)	(\$1.74)

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE



MARKET OUTPERFORM | Price: \$6.75 | Target Price: \$14.00

INVESTMENT HIGHLIGHTS

Initiating coverage of Cerulean Pharma Inc. with a Market Outperform rating and 12-month price target of \$14, based on the synthesis of our DCF, standardized CAGR, and comparable company valuation methodologies. Cerulean Pharma (CERU) is a development-stage, oncology-focused drug development company, leveraging its nanopharmaceutical delivery technology platform to produce potent, tumor-targeted, anti-cancer medicines. In our view, Cerulean's combination of a compelling and differentiated Phase II asset with a seasoned and successful management team, makes for an attractive oncology play. CRLX101, the company's lead pipeline candidate, is a novel take on topoisomerase inhibitors that mixes in nanoparticle delivery with the targeted inhibition of hypoxia sensing transcription factor HIF1 α . Cerulean recently raised gross proceeds of \$59.5MM in its IPO on April 10, 2014 (JMP acted as co-manager) to fund the program through to the start of Phase III development.

CRLX101-novel twist on a well-known, effective class of drug. Cerulean's lead development candidate, CRLX101, is a nanoparticle formulation of camptothecin—a well-known potent inhibitor of topoisomerase-I. However, its development has been limited by poor tolerability at higher doses as a free compound. By formulating the molecule as a nanoparticle and shifting its distribution profile, Cerulean has managed to boost tumoral uptake and cell kill while maintaining acceptable tolerability. Building on preclinical evidence showing an ability to destabilize HIF1 α , Cerulean has steered CRLX101 development toward tumors where HIF1 α upregulation is associated with resistance, focusing on combinations with Avastin. We believe current Phase Ib/II data showing 27% ORR in multiple-refractory RCC represents validating, proof-of-concept clinical activity with the CRLX101 plus Avastin combination boding well for a planned randomized Phase II trial set to begin in 3Q14.

Nanoparticle platform adaptable to a diversity of payloads, optimized by design to target and destroy tumors. Cerulean refers to its nanoparticle technology as "dynamic", as each of its pipeline assets has two portals of entry into tumors. The technology, developed via a combination of efforts from MIT and CalTech, facilitates passage of the payload through the loose junctions of blood vessels inside tumors. Their size is also designed to keep them from traversing into normal tissue. Once in the tumor, these dynamic nanoparticles are actively taken up into the tumor to deposit their payload. Because of the high internal pressure of the tumor, very little of the drug escapes once it has crossed the vessel wall. In addition, size also helps the nanoparticles avoid the cell's pumping mechanisms responsible for detoxification. The delivery platform is adaptable to a diversity of small molecule payloads, in addition to camptothecin, including docetaxel (comprising a second development candidate,

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CRLX301), gemcitabine, methotrexate and tofacitinib. The company has also adapted its technology in order to more efficiently deliver RNA molecules, such as siRNA.

Establishing a 12-month price target of \$14 per share. Cerulean shares have traded off slightly since its IPO pricing at \$7 on April 10, we suspect suffering in kind from some of the sector pullback in the biotech space in recent weeks. We would anticipate that as CRLX101 programs begin to gain greater traction with investors and clinical investigators alike, that CERU has the potential to realize appreciable gains in the mid- to longer-term related to successful read-outs from ongoing Phase I combination trials in ovarian cancer and neoadjuvant rectal cancer toward the end of 2014, data from the flagship randomized Phase II RCC in mid-2015. Based on a synthesis of our valuation methodologies (DCF: \$11.49; CAGR: \$14.75; Coms: \$29.57), we assign a 12-month price target of \$14 per share.

INVESTMENT THESIS – CANCER SINGS THE CERULEAN BLUES

We are initiating coverage of Cerulean Pharma Inc. (CERU) with a Market Outperform rating and \$14 price target. Cerulean is walking a well-worn path in cancer drug development (sometimes successful, although frequently not) of taking a highly active, yet flawed (often because of tolerability, PK/PD parameter, or both) compound and optimizing its properties to boost tumor cell kill while sparing healthy tissue. We liken the Cerulean story to that of BIND Therapeutics (BIND, MO, \$30 PT) and Nektar Therapeutics (NKTR, NC) both of which are developing modified delivery formulations of well-known anti-cancer therapies, docetaxel and irinotecan, respectively. Perhaps the best-known recent example of this approach is that of Abraxane, the nanoparticle, albumin-bound incarnation of paclitaxel (Taxol) for the treatment of breast, lung, and pancreatic cancer.

Celgene (CELG, MO, \$205 PT) acquired Abraxis BioScience in 2010 for approximately \$2.9 billion plus contingent value rights when Abraxane was generating roughly \$350MM in sales and was indicated for use strictly in breast cancer. We estimate that Abraxane will generate over \$900MM in sales for Celgene during FY14. In the past 24 months, Abraxane has added indications for both NSCLC and pancreatic cancer to its label, while seeing appreciable use in disease contexts where taxane therapy is indicated. We expect sales of Abraxane to eclipse the \$1 billion in revenue mark sometime between FY14 and FY15. A similar approach is being taken by Nektar, a company that boasts a market cap of approximately \$1.5 billion. A similar path to value creation is possible for CERU should it execute on its business plan for the development of CRLX101 (and, eventually, CRLX301) for the indications and over the timelines we expect.

FIGURE 1. Cerulean Development Pipeline

Product Candidate	Indication	Preclinical	Phase I	Phase II	Phase III
CRLX101 (camptothecin)	Relapsed RCC	Phase Ib / II			
	Relapsed Ovarian Cancer	Phase II			
	Neoadjuvant Rectal Cancer	Phase Ib / II			
CRLX301 (docetaxel)	Solid tumors	Preclinical			

Source: JMP Securities LLC and Company reports

FIGURE 2. Upcoming Catalysts

Timing	Candidate	Catalysts
June 1-3	CRLX101	Updated single-arm, Avastin combo data in RCC at ASCO
July 2014	CRLX101	Initiation of randomized Phase II RCC study plus Avastin (~100 pts)
4Q14	CRLX101	Read-out from single Avastin combo in ovarian cancer
4Q14	CRLX101	Read-out from single-arm neoadjuvant rectal cancer IST (UNC)
4Q14	CRLX301	Initiation of Phase I trial in advances solid tumors
1Q15	CRLX101	Potential initiation of randomized Phase II neoadjuvant rectal cancer study (~100 p
1Q15	CRLX101	Potential initiation of pivotal ovarian Phase II trial in combination with Avastin
2H15	CRLX301	Phase I read-outs (PK, MTD, and preliminary efficacy)
4Q15	CRLX101	Read-out from randomized RCC Phase II in combo with Avastin

Source: Company reports

VALUATION

We derive our twelve-month price target of \$14 based on the synthesis of a discounted cash flow (DCF) analysis, our standardized CAGR methodology, and a relative valuation against a set of comparable stage biotechnology platform companies (Figure 3).

FIGURE 3. 12-month Price Target Synthesis

Synthesis of Valuation Approaches	
Approach	Valuation
DCF Analysis	\$11.49
CAGR	14.75
Comparables	29.57
Price Target	\$14.00

Source: JMP Securities LLC and Company reports

Our DCF valuation model projects sales of both CRLX101 and CRLX301 sales from the treatment of various solid tumor indications, plus royalty income, while subtracting cost of goods sold, projected operating expenses, and tax. In discounting net cash flows to year-end 2014, we have applied a blended, risk-adjusted discount rate of 38.7%, which takes into account both candidates' stage of development, likelihood of success, and relative contribution to peak revenue estimates. A terminal value for the company, calculated by applying a 2% long-term growth rate (which we believe is justified given the proprietary nature of Cerulean's dynamic nanoparticle technology), was similarly discounted to a present day valuation. Present value of free cash flows, together with a terminal value, were added to arrive at a residual value for the company. Finally, estimated cash and long-term debt were added and subtracted, respectively, to arrive at an equity valuation of \$191MM. Divided by our estimated 2014 year-end outstanding share count, we derive a per share valuation of \$11.49. Our DCF assumptions are detailed further in Figure 4.

FIGURE 4. Discounted Cash Flow Analysis

Discounted Cash Flow Model	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
CRLX101 Revenue	-	-	-	-	49.8	164.9	278.0	421.5	558.9	693.2	832.2	882.6
Ex-US Royalties	-	-	-	-	-	7.7	27.8	50.3	76.1	101.3	123.0	132.9
CRLX301 Revenue	-	-	-	-	-	105.6	221.2	341.1	501.2	623.6	673.3	697.4
Ex-US Royalties	-	-	-	-	-	-	15.8	32.3	49.8	71.0	86.0	90.8
Collaboration Revenue	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenues	\$ -	\$ -	\$ -	\$ -	\$ 49.8	\$ 278.2	\$ 542.7	\$ 845.2	\$ 1,186.0	\$ 1,489.2	\$ 1,714.6	\$ 1,803.6
Cost of product sales				0.0	6.0	18.1	27.8	42.1	55.9	69.3	83.2	88.3
COGS as % of revenue					12%	12%	11%	12%	12%	12%	12%	12%
Gross Profit	0.0	0.0	0.0	0.0	43.9	260.0	514.9	803.0	1,130.1	1,419.8	1,631.3	1,715.4
R&D expense	14.4	21.6	35.6	71.3	89.1	102.5	115.8	129.7	142.6	156.9	172.6	189.9
R&D as a % of revenue					179%	37%	21%	15%	12%	11%	10%	11%
SG&A expense	10.1	11.6	12.9	47.3	63.9	83.0	103.8	124.6	139.5	153.5	168.8	185.7
SG&A as a % of revenue					128%	30%	19%	15%	12%	10%	10%	10%
Total operating expenses	24.5	33.2	48.5	118.6	153.0	185.5	219.6	254.2	282.2	310.4	341.4	375.5
% Margin					307%	67%	40%	30%	24%	21%	20%	21%
Operating income (EBIT)	(24.5)	(33.2)	(48.5)	(118.6)	(109.1)	74.5	295.3	548.8	847.9	1,109.5	1,289.9	1,339.8
Taxes	0.0	0.0	0.0	0.0	0.0	11.2	59.1	137.2	254.4	388.3	451.5	468.9
Tax rate	0%	0%	0%	0%	0%	15%	20%	25%	30%	35%	35%	35%
After tax operating income	(24.5)	(33.2)	(48.5)	(118.6)	(109.1)	63.3	236.2	411.6	593.6	721.2	838.5	870.9
Discount year	0.00	1.00	2.00	3.00	4.00	5.00	6.00	7.00	8.00	9.00	10.00	11.00
Discount factor	1.0	1.4	1.9	2.7	3.7	5.1	7.1	9.9	13.7	19.0	26.4	36.7
PV	(24.5)	(23.9)	(25.2)	(44.4)	(29.5)	12.3	33.1	41.6	43.2	37.9	31.7	23.8
Residual value of cash flow	\$141											
+Cash and Cash equivalents	56											
Company value	197											
-Long-term debt on 12/31/13	6											
Value of equity	\$191											
Fully diluted shares outstanding on 12/31/14	16.60											
Price/share	\$11.49											
Blended discount rate	38.7%											
Terminal growth rate	2%											
										Terminal Value		
										64.7		

Blended Discount Factor Calculation			
Product	Risk Level	Dis. Factor	Sales in 2025
CRLX101	Phase II	30%	\$ 1,015
CRLX301	IND	50%	788
Total			\$ 1,804
Blended Discount Rate		38.7%	

Source: JMP Securities LLC and Company reports

We also arrived at a valuation based on our standardized CAGR methodology. We begin by calculating the profitable biotech PEG ratio (0.64), based on the mean 2014 P/E (15.6) and a mean forward CAGR of 24.2%. Based on a projected EPS for 2020 and a discount rate of 38.7%, we arrive at a valuation of \$14.75 per share. Our assumptions are detailed in Figure 5.

FIGURE 5. CAGR Valuation Model and Sensitivity Analysis

CAGR Valuation		Sensitivity Analysis					
Comparables		Discount Rate					
Biotech Group P/E (2014)	15.6	CAGR	35.7%	37.2%	38.7%	40.2%	41.7%
Biotech Group Forward CAGR ('14- '16)	24.2%						
Valued Company		12.4%	\$7.60	\$7.12	\$6.67	\$6.25	\$5.86
Year used for discounting	2020	17.4%	\$10.67	\$9.99	\$9.36	\$8.78	\$8.23
Price Target Year	2014	22.4%	\$13.75	\$12.87	\$12.06	\$11.30	\$10.60
5-year EPS CAGR	27.4%	27.4%	\$16.82	\$15.74	\$14.75	\$13.83	\$12.97
EPS in the discounting year	\$ 5.99	32.4%	\$19.89	\$18.62	\$17.45	\$16.36	\$15.34
Discount Rate	38.7%	37.4%	\$22.96	\$21.50	\$20.14	\$18.88	\$17.71
# Years for Discounting	6	42.4%	\$26.04	\$24.37	\$22.84	\$21.41	\$20.08
Target Price	\$14.75						

Source: JMP Securities LLC and Company reports

Finally, by taking the mean market cap valuation from a peer group of platform biotechnology companies, we derive a comparable valuation for CERU shares of \$29.57 (Figure 6).

FIGURE 6. Comparable Company Valuation

Comparable	Ticker	Price	Market Cap	Cash	Debt	EV
BIND Therapeutics Inc	BIND	\$9.13	\$150	\$52	\$3	\$102
Curis Incorporated	CRIS	\$2.15	\$185	\$10	\$28	\$203
Endocyte Inc	ECYT	\$6.62	\$274	\$53	\$0	\$221
Exelixis	EXEL	\$3.32	\$646	\$104	\$335	\$878
Infinity Pharmaceuticals Inc	INFI	\$9.16	\$445	\$68	\$0	\$377
Merrimack Pharmaceuticals Inc	MACK	\$6.43	\$664	\$65	\$103	\$702
Nektar Therapeutics	NKTR	\$11.47	\$1,456	\$39	\$203	\$1,620
Sunesis Pharmaceuticals Inc	SNSS	\$5.18	\$312	\$15	\$9	\$306
Synta Pharmaceuticals Corp	SNTA	\$4.03	\$364	\$48	\$14	\$330
Sorrento Therapeutics Inc	SRNE	\$9.30	\$214	\$32	\$4	\$187
Threshold Pharmaceuticals Inc	THLD	\$3.99	\$237	\$7	\$0	\$230
Verastem Inc	VSTM	\$8.01	\$207	\$19	\$0	\$188
Ziopharm Oncology Inc	ZIOP	\$3.43	\$346	\$68	\$0	\$277
Average			\$423			\$432
Cerulean Pharma Inc	CERU	\$6.94	\$99	\$5	\$3	\$97

Comparable Valuation **\$29.57**

Source: JMP Securities LLC and Company reports

INVESTMENT RISKS

Clinical. Drug development is an inherently risky business. Like all clinical trials, CRLX101 clinical development carries some risk of failure. CRLX101 may fail to maintain acceptable tolerability or to demonstrate meaningful enough efficacy to warrant further development through large Phase III trials or regulatory approval.

Regulatory and commercial. The ability of Cerulean or its potential partners to market its drugs depends upon those drugs obtaining approval from the FDA and foreign regulatory agencies. Failure to achieve approval or delays in the timelines to approval could negatively impact the company's share price.

Competitive. Oncology drug development is an increasingly competitive field and Cerulean faces considerable competition from companies with development-stage drug candidates, utilizing similar delivery formulation technology, as well as from companies with marketed products seeking to expand the number of indications approved for use. Some of these companies may possess greater R&D and commercial resources than Cerulean or its potential partners.

Financial. Following the IPO, we estimate that Cerulean will complete 1Q14 with approximately \$56MM in cash and cash equivalents—adequate resources to support current trials, the launch of a randomized Phase II trial of CRLX101 plus Avastin in 3rd/4th-line RCC, and company operations into 2H15. In the event current dose-finding studies in ovarian and neoadjuvant rectal cancer yield positive data and Cerulean elects to further development in these indications (a likely scenario, in our view), we anticipate that Cerulean will seek additional equity financing in the form of a secondary offering during 2015, thereby exposing existing shareholders to some degree of dilution risk.

COMPANY OVERVIEW

Cerulean Pharma Inc. (CERU) is a Cambridge, MA-based, clinical-stage nanopharmaceutical company that is developing dynamic, tumor-targeted medicines with the aim of maximizing the uptake of drug by tumor cells while preserving healthy tissue across various solid tumor malignancies. The company's lead pipeline candidate, CRLX101, is a nanopharmaceutical formulation of camptothecin - a highly active anti-cancer agent, and highly toxic when delivered as a free compound. CRLX101 is entering randomized Phase II testing for the treatment of 3rd/4th line renal cell carcinoma in combination with Avastin. CRLX101 is also being developed for the treatment of recurrent ovarian carcinoma and rectal cancer in the neoadjuvant setting.

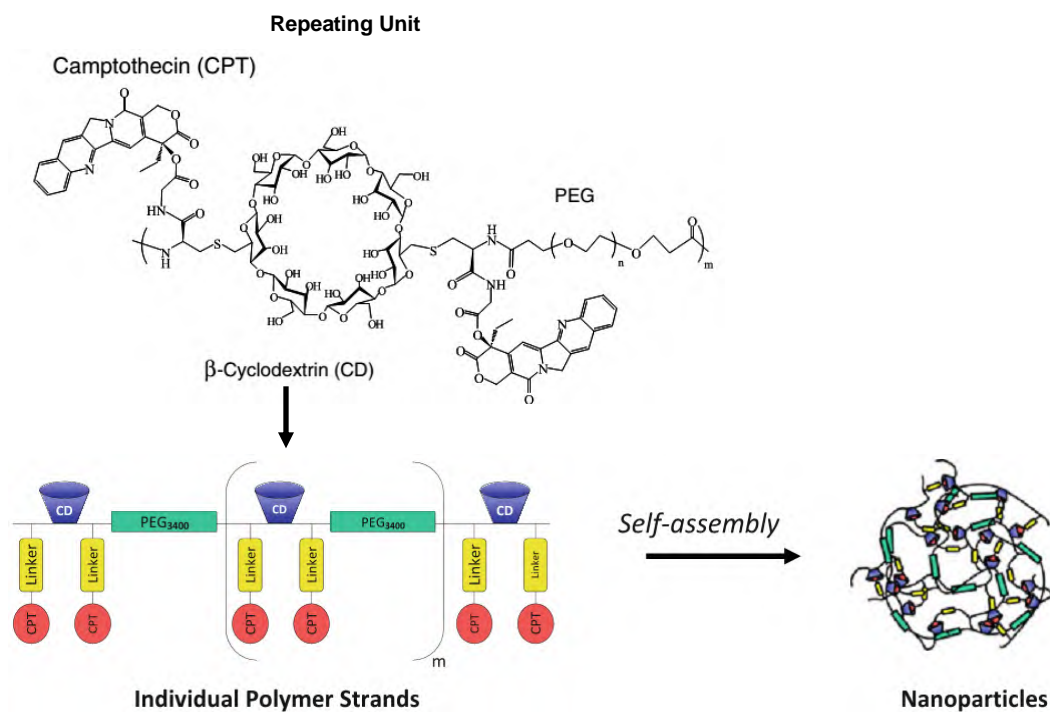
CRLX101 – DOUBLING UP ON THE CHANCES FOR SUCCESS USING A NANOPARTICLE APPROACH TO SOLID TUMOR THERAPY

The value proposition behind the Cerulean business model is straightforward, that of building a better mouse trap and then getting it to market. In this instance, the trap is represented by the highly active, but unwieldy and poorly tolerated topoisomerase inhibitor, camptothecin, and the mouse, a broad array of solid tumor indications where chemotherapy comprises the standard of care. Cerulean's platform utilizes a unique, proprietary, nanoparticle conjugation and assembly methodology to meet the preeminent challenge to delivering cytotoxic chemotherapy: maximizing tumor exposure while minimizing the impact to normal tissue and the overall health of the patient.

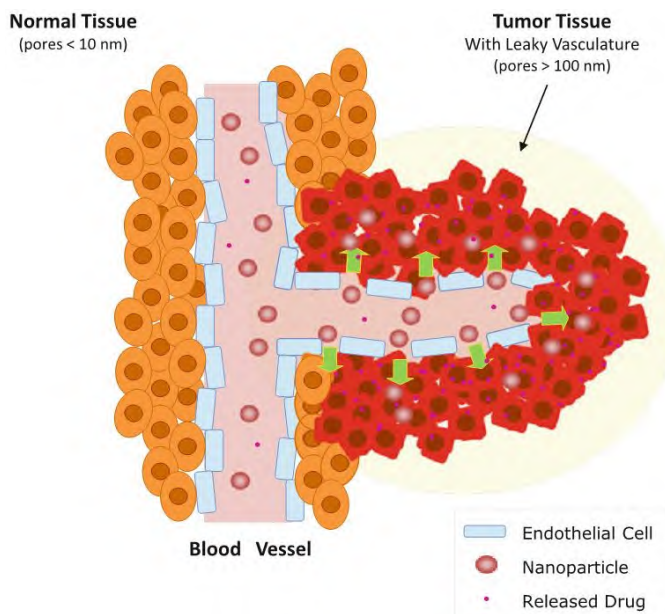
While Cerulean's lead clinical program is focused on camptothecin, its delivery technology is adaptable to nearly any small molecule active pharmaceutical ingredient (API) or RNA-based molecule. However, current target markets with CRLX101 represent a compelling and potentially lucrative commercial opportunity. Our estimates suggest CRLX101 could produce upwards of ~\$1bn in sales in the U.S and \$2bn worldwide by 2023.

Overview of CERU nanopharmaceutical delivery platform. Forming the basis of Cerulean's product candidates is its self-assembling nanopharmaceutical delivery technology. These particles consist of repeating polymer units, individually comprising an API (camptothecin in the case CRLX101) covalently linked, using a glycine linker, to a hydrophobic beta cyclodextrin, followed by a hydrophilic chain of polyethylene glycol (PEG) (Figure 7). Synthesis of the poly-cyclodextrin-PEG (poly-CDP) backbone follows a relatively simple four-step process, while conjugation to the active payload requires an additional two steps, resulting in an overall manufacturing process that is highly scalable to produce multi-kilogram batches.

The poly-CDP particles self-assemble in aqueous conditions into highly stable nanoparticles approximately 300kDa in molecular weight and between 20-30nm in diameter - large enough to evade permeation of intact vasculature in normal tissue, and small enough to traverse the leaky vasculature of tumor cells (Figure 8). Conjugation to poly-CDP increase camptothecin solubility by approximately three orders of magnitude, while preventing spontaneous inactivation of the molecule at physiologic pH through the opening of the lactone ring. Sustained release of API, once deposited, upon reaching its intended target tissue is achieved by pH-dependent hydrolysis of the glycine linker.

FIGURE 7. CRLX101 Composition and Polymer Self-Assembly

Source: Svenson S et al, *J Controlled Release*, 2011 and Weiss G, *Invest New Drugs*, 2012.

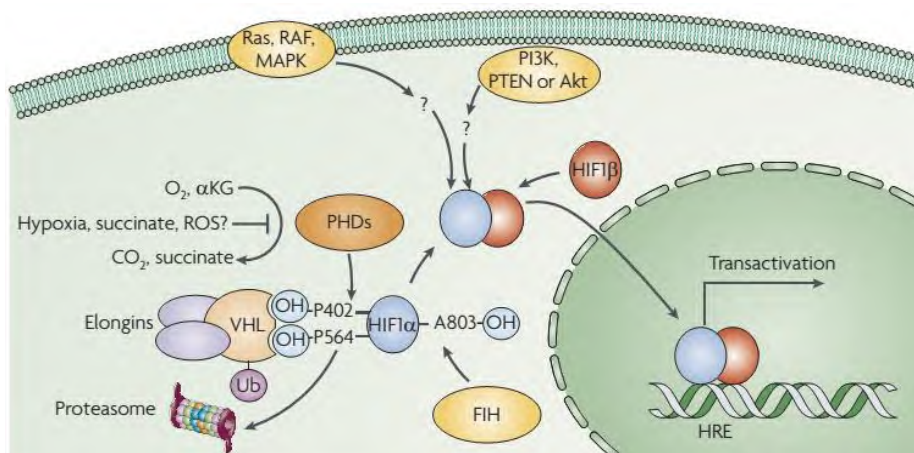
FIGURE 8. CRLX101 Nanoparticles Designed to Enhance Tumor Permeability

Source: Weiss G, *Invest New Drugs*, 2012.

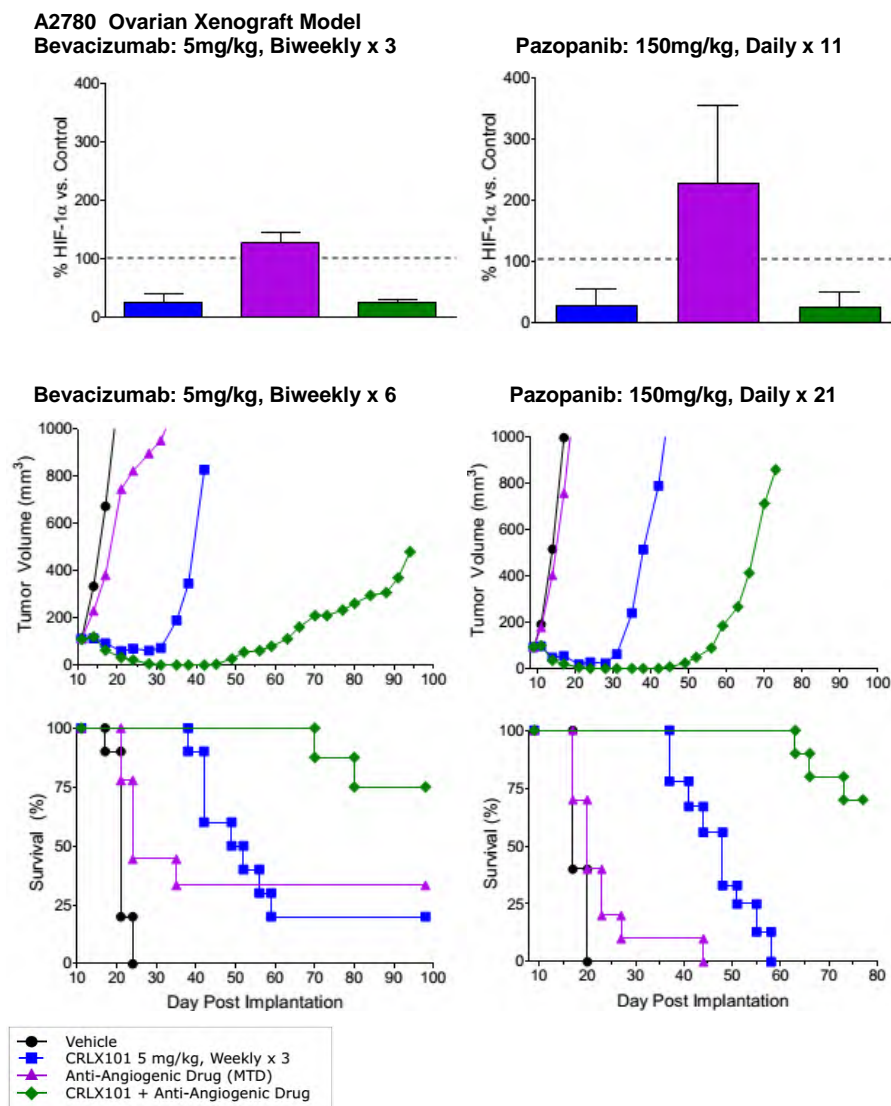
CRLX101 preclinical data suggest a dual mechanism of action and unique synergy with anti-angiogenic therapy. As a topoisomerase (TOPO)-I inhibitor, the primary mechanism behind the anti-tumor activity of camptothecin is well understood. In brief, TOPO-I facilitates the unwinding of the double helix during DNA synthesis. Inhibiting TOPO-I activity induces global DNA damage that prompts checkpoint activation and ultimately leads to cell death (apoptosis). Camptothecin derivative molecules, irinotecan (Camptosar) and (to a lesser extent) topotecan (Hycamtin), have well-established positioning as backbone chemotherapy in the treatment of various solid tumor malignancies including colon, pancreatic, ovarian, cervical, and small cell lung cancer.

In addition to TOPO-I inhibition, however, preclinical data indicates the camptothecin mediated antitumor activity is achieved, in part, through the degradation of hypoxia-inducible factor-1 α (HIF1 α). HIF α is well-established as an oxygen-sensing transcription factor that becomes stabilized and thereby upregulated in tumor cells proliferating under hypoxic stress (Figure 9). HIF1 α stabilization is linked to the upregulation of over 100 genes regulating cell survival and promoting angiogenesis. As evidence of this phenomenon (shown in Figure 10), preclinical studies using an aggressive ovarian cancer mouse xenograft model show that an induction of HIF1 α follows treatment with anti-VEGF therapies, Avastin (bevacizumab) and Votrient (pazopanib), correlating with tumor insensitivity to these agents. Co-treatment with CRLX101 reverses the induction HIF1 α and enhances the level of tumor growth inhibition (TGI), and, in turn, animal survival, above the level achieved by either single-agent CRLX101 or anti-VEGF therapy alone. While difficult to concretely discern the direct impact of HIF1 α inhibition from the overall effect of TOPO-1 inhibition by CRLX101, these data are consistent with prior data, published by Burkitt et al., (Mol Cancer Ther, 2009) showing specific gene knockdown of HIF1 α and HIF2 α to be synergistic with anti-VEGF therapy in a colorectal cancer xenograft model.

FIGURE 9. Mechanism of HIF α Stabilization Under Hypoxic Stress



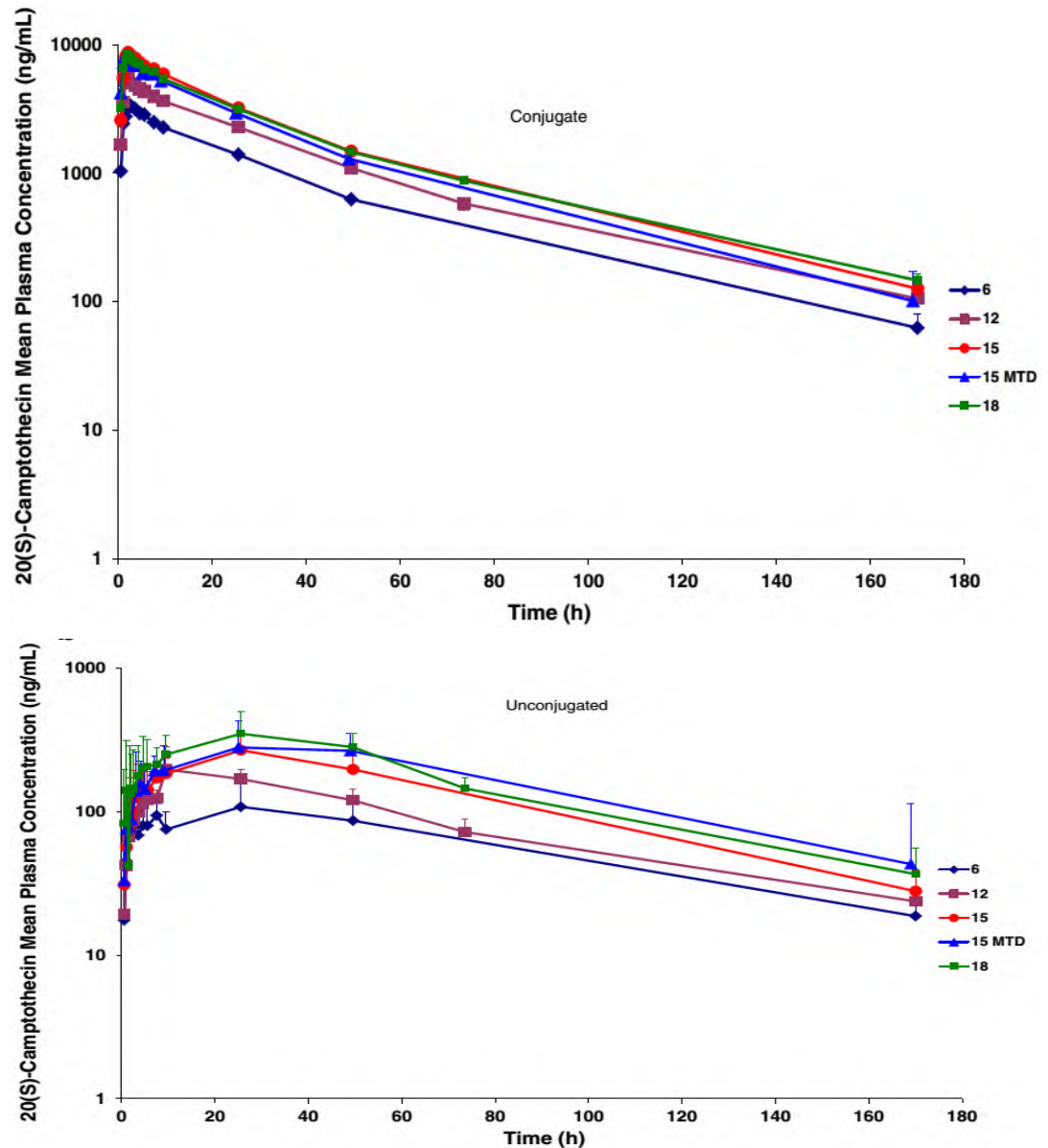
Source: Denko N, *Nature Reviews Cancer*, 2008.

FIGURE 10. CRLX101 Reverses Anti-VEGF Induction of HIF1 α , Enhancing TGI

Source: Company presentation

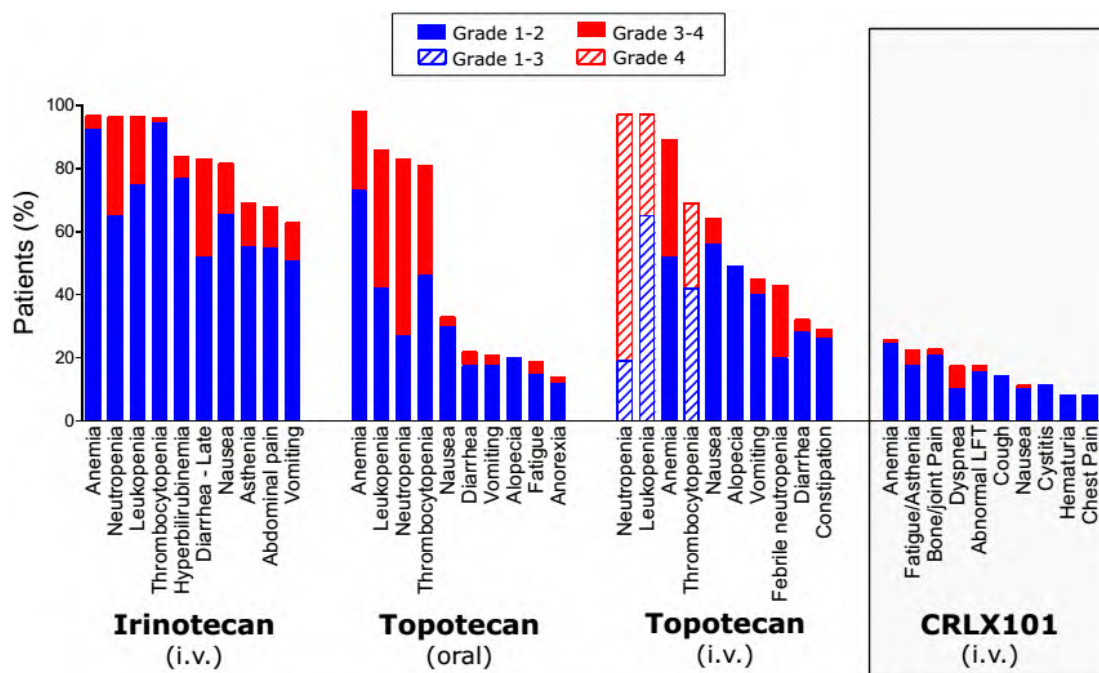
CRLX101 PK and safety data point to long half-life and well-managed toxicity profile. Initial clinical testing of CRLX101 was conducted in Phase I/IIa single-arm, open-label, dose-escalation study in patients with advanced solid tumor malignancies. CRLX101 was administered as a 60-minute infusion with varying dose and frequency, ultimately arriving at a maximum tolerated dose (MTD) of 15mg/m² once every two weeks (Q2W). Importantly, Phase I PK analysis recapitulated those observed preclinically of rapid systemic exposure of the poly-conjugated nanoparticle followed by a delayed, extended release of unconjugated camptothecin (Figure 11). Among the 36 patients treated in the Phase IIa trial at the MTD of 15mg/m² Q2W (the dose rolled forward to subsequent studies), the average half-life of unconjugated drug was 46.5 hours with an AUC of 32.4 h.mg/L, appreciably greater than the reported half-life and AUC of 21 hours and 0.47 h.mg/L, respectively, of irinotecan, allowing for greater uptake by dividing tumors over time.

FIGURE 11. Mean Plasma Concentration of CPD-conjugated and -unconjugated CRLX101 Delivered Camptothecin



Source: Weiss G, *Invest New Drugs*, 2012.

With respect to safety, CRLX101 was generally found to be safe and well tolerated. Similar to most cytotoxic chemotherapy, the most commonly observed adverse events in the Phase II expansion were primarily Grade 1/2 fatigue, anemia, and neutropenia. Of note, these events occur at levels far below those observed with irinotecan or topotecan (see Figure 12 for a comparison of adverse event profiles). Similar treatment-related adverse events were observed in a Phase IIb analysis of CRLX101 in NSCLC (described below). The relatively benign toxicity profile of CRLX101 lends itself to combinability with other targeted therapies to enhance antitumor outcomes.

FIGURE 12. Comparative Safety of CRLX101 versus Existing TOPO-I Inhibitors

* The label for IV topotecan categorizes non-hematological AEs as (a) grade 1-2 and (b) grade 3-4, but it categorizes hematological AEs as (a) grade 1-3 and (b) grade 4, so these AEs are shown with diagonal stripes.

Source: Company presentation

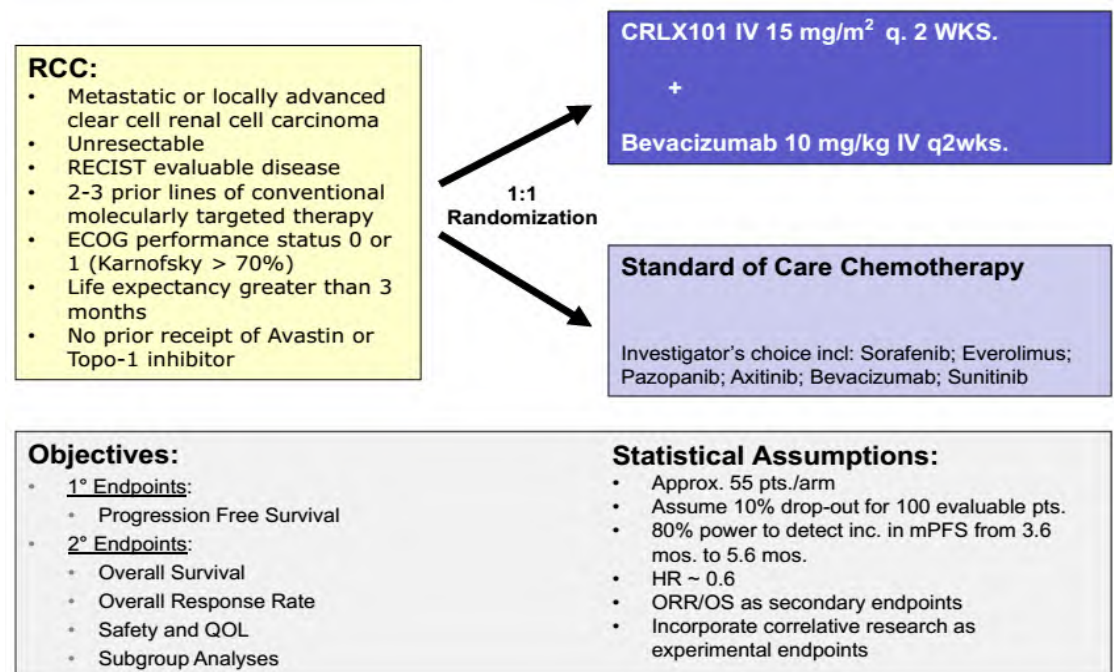
Setbacks in NSCLC Phase II were more a matter of protocol execution than of activity. Following the completion of Phase I analysis, Cerulean initially sought to develop CRLX101 as monotherapy for the treatment of second-/third-line non-small cell lung cancer (NSCLC). To that end, a large (157 patient) Phase II trial was conducted using 2:1 randomized trial design comparing CRLX101 to a control arm of best supportive care (BSC). Of note, the trial recruited exclusively from sites in Russia and the Ukraine. Ultimately, the trial was deemed a failure: median overall survival (OS) for patients receiving CRLX101 was 6.3 months compared to 11.9 months for patients treated with BSC ($p=0.14$).

Several factors are purported to have contributed to an overperformance by the control arm that yielded an OS outcome nearly double that of historical BSC or marketed EGFR-TKI therapy in similar refractory settings (median historical OS of 4.5 – 7.5 months). First, perhaps due to the open-label trial design and negative expectations associated with randomization to BSC, a higher early withdrawal rate was experienced with BSC compared to CRLX101 (16% vs. 5% withdrawal from study within the first cycle). This factor is believed to have contributed to an enrichment for patients with more slowly progressing disease in the PFS and OS analyses. A second imbalance was observed in the proportion of patients going on to receive subsequent therapy (40% on BSC vs. 28% on CRLX101). Notwithstanding these factors, however, CRLX101 was unlikely to have outperformed BSC in a more rigorously executed trial. While the NSCLC study proved useful in expanding the CRLX101 patient safety database and confirming its anti-tumor activity as single agent (6.2% ORR including one CR), Cerulean concluded CRLX101 was better adapted to indications where HIF1 α played a putative role in pathogenesis and drug resistance, potentially through combinations with anti-VEGF therapy.

Pilot combination studies with Avastin yield encouraging results along with a development path forward in RCC. The aforementioned paradigm is particularly relevant in clear cell renal cell carcinoma (ccRCC) where VHL is frequently inactivated resulting in a direct depression of HIF1 α through reduced turnover. In order to explore this hypothesis, Cerulean collaborated with investigators at the University of Pennsylvania in an investigator-sponsored Phase I study evaluating CRLX101 in combination with Avastin in patients with advanced or metastatic RCC and previously treated with at least one prior TKI therapy (median of two prior therapies). Interim trial results were presented at ASCO GU in February (updated March 25, 2014), showing 3 of 11 (27%) confirmed partial responses and good tolerability when administered at the RP2D of 15mg/m² Q2W in combination with standard regimen Avastin. Although these data are preliminary and based on low patient numbers, nevertheless, they are encouraging given that the objective response rate, thus far, is higher than those of current second-line TKI therapies sorafenib (Nexavar; BAYRY, NC) and axitinib (Inlyta; PFE, NC) which have historically ranged between 12-23% ORR, and lower still in patients treated with two or more prior therapies.

Based on these data, Cerulean is conducting a large, randomized, Phase II study of CRLX101 plus Avastin in third/fourth-line RCC versus physician's choice of standard of care (including any single-agent therapies such as Nexavar, Inlyta, Afinitor, Votrient, Avastin and Sutent; Figure 13). The trial will enroll between 110 to 120 patients recruited from 15-20 centers using 1:1 randomization, without the allowance for crossover following tumor progression. Initiating in 2H14, Cerulean expects to have meaningful results in 2H15, targeting a PFS HR<0.7 and a favorable OS trend as the threshold for advancing the program to Phase III. Assuming a positive Phase II outcome, the company anticipates having Phase III data ready for NDA submission in 1H18, enabling market launch toward the end of 2018.

FIGURE 13. Overview of Phase II RCC Trial in Combination with Avastin

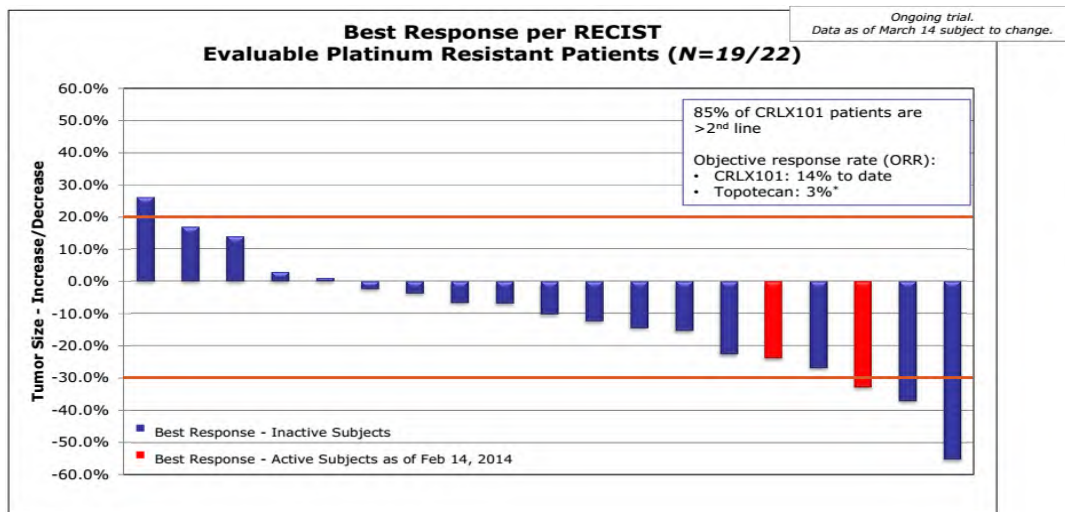


Source: Company presentation

Similarly encouraging opportunities in recurrent ovarian cancer. As a second indication for later-stage clinical development of CRLX101, Cerulean's program in refractory resistant ovarian cancer is similarly supported by both preclinical and clinical evidence suggesting hypersensitivity to combined angiogenic and HIF1 α inhibition. Data from the recently published Phase III AURELIA study of Avastin plus chemotherapy (Doxil, Taxol, or topotecan) in platinum-resistant ovarian cancer showed statistically significant improvement in objective response and PFS, as well as a favorable OS trend compared to single-agent chemotherapy. As described previously, preclinical work using aggressive ovarian cancer models posit HIF1 α upregulation as a mechanism of resistance to Avastin, implying that combination therapy of CRLX101 with Avastin as a potentially successful, survival prolonging regimen.

Adding to the rationale for combined therapy, CRLX101 has already benefited by encouraging single-agent results from a single-arm Phase II IST conducted at Massachusetts General and affiliated Harvard teaching hospitals during 2012 and 2013. Among the 29 total patients enrolled in the trial, 22 had patient history of platinum-resistance (recurrence from first-line therapy within six months). Of the 19 evaluable patients at the most recent follow-up (March 25, 2014), three (16%) achieved RECIST responses, while 15 (79%) maintained stable disease (Figure 14). On the heels of these results and demonstrated tolerability from the combination RCC study, a single-arm, ~43-patient Phase II IST of CRLX101 plus Avastin in second-/third-line, platinum-resistant ovarian cancer is now underway (first patient enrolled in February). Cerulean expects to present objective response data by YE14, targeting $\geq 20\%$ ORR as the threshold for advancing to an adaptive randomized Phase II/III trial beginning in 2015 (easily surmountable, in our view, given the single-agent activity and the 27.5% response rate achieved by Avastin combination therapy in AURELIA). Assuming clinical success, Cerulean anticipates market launch in ovarian cancer potentially as soon as 1H18.

FIGURE 14. CRLX101 Monotherapy Activity in Platinum Resistant Ovarian Cancer

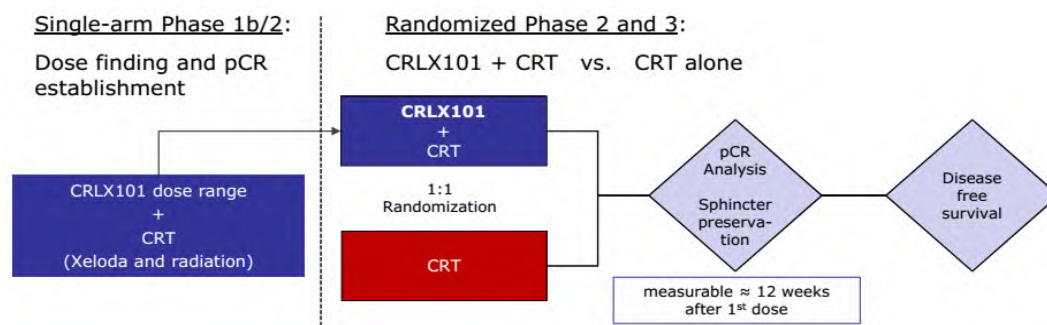


Source: Company presentation

Unmet need in neoadjuvant rectal cancer (RC) offers rapid path to registration. Rounding out its development strategy with CRLX101, Cerulean has taken aim at improving outcomes for patients with local, resectable rectal cancer whose disease has not yet metastasized beyond the lymph nodes. Current standard of care for such patients employs the use of neoadjuvant chemoradiation (CRT) with either Xeloda (capecitabine) or 5-FU as a means of achieving pathologic complete response (pCR) prior to surgical resection. Achievement of pCR is highly correlated with higher long-term disease-free and overall survival rates. Ionizing radiotherapy kills tumor cells by inducing single-strand DNA damage, which, if not repaired, induces apoptosis. Topoisomerase I activity is a central component to the resolution of such damage, and thus, from a mechanism perspective, the addition of a camptothecin-like molecule to standard chemoradiotherapy has the potential to further reduce tumor burden.

Building on this hypothesis, Cerulean, in collaboration with investigators at University North Carolina Chapel Hill, is conducting a two-part Phase Ib/II IST of CRLX101 in combination with Xeloda-based chemoradiation, first to establish safety and the RP2D of the combination regimen before transitioning to a 1:1 randomized trial, in order to determine potential clinical benefit over Xeloda chemotherapy alone using pCR as the primary clinical endpoint. Cerulean anticipates initial Phase I safety and single-arm preliminary efficacy data by YE14 and randomized pCR data by late 2015. Assuming meaningful results, Cerulean anticipates filing for accelerated approval on the basis of current FDA guidance recommending pCR as an acceptable endpoint for breast cancer neoadjuvant therapy.

FIGURE 15. Overview of Neoadjuvant Rectal Cancer Development Program



Source: Company presentation

Defining the commercial opportunity with CRLX101. In valuing the commercial opportunity for CRLX101, we developed incidence-driven market models for each of the three intended development indications – RCC, ovarian cancer, and rectal cancer – further segmented by geography. Beginning with RCC in the U.S., we arrive at an estimated addressable combined third/fourth-line patient population, of ~15,000, at the time of market launch, which we forecast will occur in 2018. Our model anticipates an initial median duration of 4.5 months, with modest incremental growth in duration of therapy year-over-year. We expect steady growth in market penetration, arriving at 50% peak penetration in 2024. Our model also anticipates migrating use to second-line RCC beginning in 2019, duration of use of approximately 7.6 months, and increasing annual market share approaching 20%. Our RCC market models for Europe and Japan are similarly segmented and follow similar market penetration dynamics; however, with staggered launch years of 2019 and 2020, respectively. Our model assumes ex-U.S. sales are led by a global commercial partner, delivering a straight line 15% royalty to Cerulean.

For ovarian cancer, we model an addressable recurrent population of ~13,000 patients in the U.S. at the time of label expansion in 2018 and moderate market adoption approaching 30% peak penetration in 2024. Likewise for rectal cancer, we model an addressable U.S. neoadjuvant population of ~30,000 patients receiving a six-week course of therapy prior to surgery, with approximately half going on to receive a second round in the absence of post-surgical progression. We model similar market projections for Europe and Japan, anticipating label expansions in 2020 and 2021, respectively.

This assumption may ultimately prove conservative, particularly if combination therapy with CRLX101 is successfully demonstrated to be more effective than current standard regimens. All told, we forecast CRLX101 sales of \$1.1bn in 2021 (\$600MM in the U.S.) and \$2.2bn in 2023 (\$1bn in U.S.) primarily generated through use in the treatment of RCC and ovarian cancer. A summary of projected CRLX101 revenue by geography and indication is provided in Figure 16, while detailed market model assumptions in RCC, ovarian, and RC in the U.S. are presented in Figures 17 to 19.

FIGURE 16. Summary of CRLX101 Revenues by Indication and Geography

CRLX101 Revenue Summary	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
WW Sales	\$ -	\$ 50	\$ 216	\$ 463	\$ 757	\$ 1,066	\$ 1,369	\$ 1,652	\$ 1,768
US	-	50	165	278	421	559	693	832	883
Ex-US Sales	-	-	51	185	335	507	676	820	886
Effective royalty rate			15%	15%	15%	15%	15%	15%	15%
Royalty Revenue to CERU	\$ -	\$ -	\$ 8	\$ 28	\$ 50	\$ 76	\$ 101	\$ 123	\$ 133
Breakdown by Geography and Indication									
US	\$ -	\$ 50	\$ 165	\$ 278	\$ 421	\$ 559	\$ 693	\$ 832	\$ 883
RCC	-	19	82	135	196	260	330	408	433
Ovarian	-	31	67	110	156	208	247	281	299
RC	-	-	15	33	69	91	116	143	151
EU	\$ -	\$ -	\$ 51	\$ 166	\$ 268	\$ 393	\$ 497	\$ 587	\$ 628
RCC	-	-	19	80	125	173	219	265	267
Ovarian	-	-	32	66	102	138	174	197	213
RC	-	-	-	20	41	83	104	125	147
JPN	\$ -	\$ -	\$ -	\$ 19	\$ 67	\$ 114	\$ 179	\$ 233	\$ 258
RCC	-	-	-	5	23	37	53	69	71
Ovarian	-	-	-	14	30	48	67	87	91
RC	-	-	-	-	14	29	59	77	96

Source: JMP Securities LLC and Company reports

FIGURE 17. CRLX101 Renal Cell Carcinoma (RCC) Market Model, U.S.

US									
CRLX101 RCC (\$MM)	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Incidence RCC, US	68,966	69,656	70,352	71,056	71,766	72,484	73,209	73,941	74,680
% Growth	1%	1%	1%	1%	1%	1%	1%	1%	1%
% pts with advanced RCC (stage IV metastatic)	25%	25%	25%	25%	25%	25%	25%	25%	25%
% pts receiving targeted front-line TKI Tx	85%	85%	85%	85%	85%	85%	85%	85%	85%
% pts failing front-line Tx	80%	80%	80%	80%	80%	80%	80%	80%	80%
Second-line RCC population	11,724	11,841	11,960	12,079	12,200	12,322	12,446	12,570	12,696
CRLX101 Second-Line RCC									
Market Penetration			5%	10%	15%	20%	20%	20%	20%
Duration of Therapy (months)			7.6	7.7	7.8	7.8	7.8	7.8	7.8
Total patient months, second-line			4,545	9,301	14,274	19,223	19,415	19,609	19,805
CRLX101 3rd/4th-Line RCC									
% patients failing 2L TKI Tx	75%	75%	75%	75%	75%	75%	75%	75%	75%
3rd-Line RCC population	8,793	8,881	8,970	9,060	9,150	9,242	9,334	9,427	9,522
% patients failing 3L TKI Tx	70%	70%	70%	70%	70%	70%	70%	70%	70%
4th-Line RCC population	6,155	6,217	6,279	6,342	6,405	6,469	6,534	6,599	6,665
Total 3rd/4th-Line RCC Population	14,948	15,098	15,249	15,401	15,555	15,711	15,868	16,027	16,187
Market Penetration		5%	15%	20%	25%	30%	40%	50%	50%
Duration of Therapy (months)		5.5	5.6	5.8	6.0	6.0	6.0	6.0	6.0
Total patient months, 3rd/4th-line		4,152	12,809	17,866	23,333	28,280	38,083	48,080	48,561
Total patient months on therapy		4,152	17,354	27,167	37,607	47,502	57,498	67,689	68,366
Cost of therapy (per month)		\$ 4,500	\$ 4,725	\$ 4,961	\$ 5,209	\$ 5,470	\$ 5,743	\$ 6,030	\$ 6,332
% price increase			5%	5%	5%	5%	5%	5%	5%
CRLX101 RCC Sales, US		\$ 19	\$ 82	\$ 135	\$ 196	\$ 260	\$ 330	\$ 408	\$ 433
% growth			339%	64%	45%	33%	27%	24%	6%

Source: JMP Securities LLC and Company reports

FIGURE 18. CRLX101 Ovarian Cancer Market Model, U.S.

US									
CRXL101 Ovarian (\$MM)	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Ovarian cancer incidence, US	23,281	23,549	23,819	24,093	24,370	24,651	24,934	25,221	25,511
% Growth	1.2%	1.2%	1.2%	1.2%	1.2%	1.2%	1.2%	1.2%	1.2%
% Stage III-IV disease	80%	80%	80%	80%	80%	80%	80%	80%	80%
% relapse after 1L Tx	70%	70%	70%	70%	70%	70%	70%	70%	70%
Addressable 2L Ovarian Cancer pts	13,037	13,187	13,339	13,492	13,647	13,804	13,963	14,124	14,286
Market penetration		5%	10%	15%	20%	25%	28%	30%	30%
Duration on therapy (months)		10.5	10.7	11.0	11.0	11.0	11.0	11.0	11.0
OC patient months on Tx		6,923	14,273	22,262	30,024	37,962	43,006	46,608	47,144
Cost per cycle of therapy		\$ 4,500	\$ 4,725	\$ 4,961	\$ 5,209	\$ 5,470	\$ 5,743	\$ 6,030	\$ 6,332
% price increase			5%	5%	5%	5%	5%	5%	5%
CRLX101 Ovarian Sales, US (\$MM)		\$ 31	\$ 67	\$ 110	\$ 156	\$ 208	\$ 247	\$ 281	\$ 299
% Growth			116%	64%	42%	33%	19%	14%	6%

Source: JMP Securities LLC and Company reports

FIGURE 19. CRLX101 Rectal Cancer (RC) Market Model, U.S.

US									
CRLX101 RC (\$MM)	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
RC incidence, US	41,978	42,398	42,822	43,250	43,682	44,119	44,560	45,006	45,456
% Growth	1%	1%	1%	1%	1%	1%	1%	1%	1%
% with resectable disease at Dx (Stage I-III)	80%	80%	80%	80%	80%	80%	80%	80%	80%
% eligible for surgery	85%	85%	85%	85%	85%	85%	85%	85%	85%
Addressable presurgery neoadjuvant RC population	28,545	28,830	29,119	29,410	29,704	30,001	30,301	30,604	30,910
Presurgical Neoadjuvant									
Market Penetration			5%	10%	20%	25%	30%	35%	35%
Presurgery RC patients on Tx			1,456	2,941	5,941	7,500	9,090	10,711	10,819
Cycles on therapy			1.5	1.5	1.5	1.5	1.5	1.5	1.5
Presurgical months on therapy			2,184	4,411	8,911	11,250	13,635	16,067	16,228
Post-surgical Neoadjuvant									
% maintained remission post surgery			50%	50%	50%	50%	50%	50%	50%
Addressable post-surgical neoadjuvant RC population			14,559	14,559	14,559	14,559	14,559	14,559	14,559
Market Penetration			5%	10%	20%	25%	30%	35%	35%
Post surgical RC patients on Tx			728	1,456	2,912	3,640	4,368	5,096	5,096
Cycles on therapy			1.5	1.5	1.5	1.5	1.5	1.5	1.5
Post surgical months on therapy			1,092	2,184	4,368	5,460	6,552	7,644	7,644
Total patient months on therapy			3,276	6,595	13,279	16,710	20,187	23,711	23,872
Cost per cycle of therapy			\$ 4,725	\$ 4,961	\$ 5,209	\$ 5,470	\$ 5,743	\$ 6,030	\$ 6,332
% price increase				5%	5%	5%	5%	5%	5%
CERU-014 CRPC Sales, US (\$MM)			\$ 15	\$ 33	\$ 69	\$ 91	\$ 116	\$ 143	\$ 151
% Growth				111%	111%	32%	27%	23%	6%

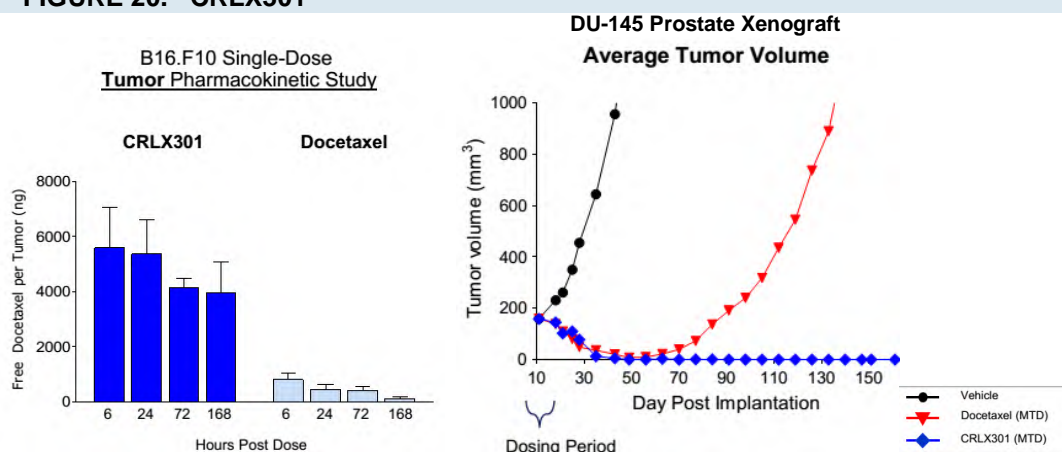
Source: JMP Securities LLC and Company reports

CRLX301 – CERULEAN’S ANSWER TO BETTER TAXANE CHEMOTHERAPY

CRLX301, Cerulean’s second pipeline candidate, is a nanopharmaceutical analog containing docetaxel as the API. Docetaxel (Taxotere) is a microtubule stabilizing agent that ultimately triggers cell death in dividing tissue and is approved for chemotherapeutic use in breast, non-small cell lung, and hormone refractory prostate cancers, as well as gastric adenocarcinoma and squamous cell carcinoma of the head and neck.

Like CRLX101, CRLX301 comprises of poly-CDP polymer units chemically linked to docetaxel via a glycine linker. Preclinical PK studies in mice, rats and dogs to date indicate similarly prolonged plasma distribution of docetaxel when delivered as CRLX301 versus free chemotherapy, resulting in, depending on the model, up to 500-fold greater plasma concentrations of docetaxel over time and up to 10-fold greater tumor up take. Preclinical efficacy studies suggest greater anti-tumor activity compared to free docetaxel at equal quantity dosing (Figure 20).

FIGURE 20. CRLX301



Source: Company reports

Having completed GLP toxicology studies, Cerulean is gearing up to begin Phase I clinical testing during the second half of 2014, initially at Australian centers ahead of an IND submission and engaging additional sites in the U.S. The Phase I trial will initially establish safety and maximum tolerated dosing in patients with advanced solid tumor malignancies before transitioning to a Phase IIa extension study exploring anti-tumor activity in two or three, as yet unspecified, tumor types.

Although we are favorably disposed to this approach to cancer drug development and believe CRLX301 stands as good a chance as any of demonstrating efficacy over standard docetaxel, our valuation for CRLX301 is hampered by limited visibility as to target indications for development. However, we believe it reasonable to assume a strategy that direct competes with Taxotere for market share in large target markets, specifically second-line NSCLC and metastatic hormone resistance prostate cancer. Anticipating market launch toward the end of 2019, while assuming similar initial pricing that of CRLX101 and fairly model penetration, we forecast combined US sales of \$700MM from both indications in 2025. A summary of projected CRLX301 revenue and detailed market models in NSCLC and CRPC are provided in Figures 21 and 22.

FIGURE 21. Summary of CRLX301 Revenues by Indication and Geography

CRLX301 Revenue Summary	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
WW Sales	\$ -	\$ -	\$ 106	\$ 326	\$ 557	\$ 833	\$ 1,097	\$ 1,247	\$ 1,303
US	-	-	106	221	341	501	624	673	697
Ex-US Sales	-	-	-	105	215	332	474	573	605
Effective royalty rate			15%	15%	15%	15%	15%	15%	15%
Royalty Revenue to CERU	\$ -	\$ -	\$ -	\$ 16	\$ 32	\$ 50	\$ 71	\$ 86	\$ 91
Breakdown by Geography and Indication									
US	\$ -	\$ -	\$ 106	\$ 221	\$ 341	\$ 501	\$ 624	\$ 673	\$ 697
NSCLC	-	-	59	123	171	266	344	385	400
CRPC	-	-	47	98	170	235	280	288	297
EU	\$ -	\$ -	\$ -	\$ 105	\$ 215	\$ 332	\$ 474	\$ 573	\$ 605
NSCLC	-	-	-	49	101	137	209	265	293
CRPC	-	-	-	56	115	195	265	309	312

Source: JMP Securities LLC and Company reports

FIGURE 22. CRLX301 NSCLC and CRPC Market Models, U.S.

US									
CRLX301 (\$MM)	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Lung Cancer									
Incidence NSCLC, US	196,407	199,353	202,343	205,379	208,459	211,586	214,760	217,981	221,251
% of patients with Stage III-IV disease	60.0%	59.8%	59.5%	59.3%	59.0%	58.8%	58.5%	58.3%	58.0%
# of Stage III or IV NSCLC Patients	117,844	119,114	120,394	121,687	122,991	124,307	125,635	126,974	128,326
2nd Line NSCLC									
% of 1L patients treated with platinum-based chemotherapy	80%	80%	80%	80%	80%	80%	80%	80%	80%
% of 1L patients progressing to 2nd line	90%	90%	90%	90%	90%	90%	90%	90%	90%
Addressable 2nd line patient population	84,848	85,762	86,684	87,615	88,553	89,501	90,457	91,421	92,394
Market Penetration			3%	6%	8%	12%	15%	15%	15%
2nd line patients treated with CRLX301			2,601	5,257	7,084	10,740	13,569	13,713	13,859
Cycles on therapy			5.0	5.1	5.2	5.2	5.2	5.7	5.7
Total patient months on therapy			13,003	26,810	36,484	55,634	70,556	77,480	78,997
Cost per cycle of therapy			\$ 4,500	\$ 4,590	\$ 4,682	\$ 4,775	\$ 4,871	\$ 4,968	\$ 5,068
% price increase				2%	2%	2%	2%	2%	2%
NSCLC Sales, US (\$MM)			\$ 59	\$ 123	\$ 171	\$ 266	\$ 344	\$ 385	\$ 400
Prostate Cancer									
CRPC prevalence, US	801,282	809,295	817,388	825,561	833,817	842,155	850,577	859,083	867,673
% metastasis from 2nd line NM-CRPC prevalence population	4%	4%	4%	4%	4%	4%	4%	4%	4%
# of prevalence patients with metastatic disease	32,051	32,372	32,696	33,022	33,353	33,686	34,023	34,363	34,707
CRPC incidence, US	254,071	256,612	259,178	261,770	264,387	267,031	269,702	272,399	275,123
% metastatic disease at diagnosis	4%	4%	4%	4%	4%	4%	4%	4%	4%
# of incidence patients with metastatic disease	10,163	10,264	10,367	10,471	10,575	10,681	10,788	10,896	11,005
1st line mCRPC population	42,214	42,636	43,063	43,493	43,928	44,367	44,811	45,259	45,712
% treated with taxane chemotherapy	90%	90%	90%	90%	90%	90%	90%	90%	90%
Addressable mCRPC population	37,993	38,373	38,756	39,144	39,535	39,931	40,330	40,733	41,141
Market Penetration			3%	6%	10%	13%	15%	15%	15%
mCRPC patients with CRLX301			1,163	2,349	3,954	5,191	6,050	6,110	6,171
Cycles on therapy			9.0	9.1	9.2	9.5	9.5	9.5	9.5
Total patients months on therapy			10,464	21,373	36,373	49,314	57,470	58,045	58,625
Cost per cycle of therapy			\$ 4,500	\$ 4,590	\$ 4,682	\$ 4,775	\$ 4,871	\$ 4,968	\$ 5,068
% price increase				2%	2%	2%	2%	2%	2%
CRPC Sales, US (\$MM)			\$ 47	\$ 98	\$ 170	\$ 235	\$ 280	\$ 288	\$ 297

Source: JMP Securities LLC and Company reports

INTELLECTUAL PROPERTY

CRLX101 and Cerulean's nanopharmaceutical technology platform is supported by a robust, multi-layer set of international patent estates, with the potential to grant regulatory exclusivity out to 2029. These include two patent estates of up to 13 U.S. patents covering CRLX101 composition of matter, manufacturing methods, and drug delivery. A third estate covers methods of use across cancer and inflammatory disorders, alone or in combination with other therapies, with patent expiration between 2030 and 2034. Corresponding patents have been granted by foreign major market territories including Europe, Japan, China, Canada, Australia, and Brazil, among others, with similar expiration timelines ranging from 2019 to 2031.

COMPETITIVE LANDSCAPE

From a competitive perspective, Cerulean faces competition from a number of marketed chemotherapeutic products and developing therapeutic nanoparticle technologies. These include marketed and generic versions of topoisomerase I inhibitors irinotecan (Camptosar) and topotecan (Hycamtin). These agents have been approved for use since the late nineties for the treatment of colorectal, ovarian, cervical, and small cell lung cancer. Nektar's (NKTR, NC) etirinotecan pegol is a novel, pegylated macromolecule version of irinotecan, designed to enhance the drug's pharmacokinetic profile and, as a consequence, antitumor activity. Nektar's lead development program with etirinotecan is a Phase III trial in metastatic breast cancer, and while none of the current development indications overlap with CRLX101, it may limit the breadth of potential development opportunities. CRLX101 also faces some level of competition from Abraxane (Celgene), an albumin-stabilized nanoparticle formulation of paclitaxel. While not formally approved for use in the treatment of ovarian cancer, Abraxane does receive appreciable use in the indication. This factor, combined with physician comfort with Abraxane as adjuvant breast cancer therapy, could present market risks to CRLX101 in its currently secondary development indications of recurrent ovarian cancer and neoadjuvant rectal cancer.

More specifically, within the nanoparticle encapsulation space, Cerulean faces competition from BIND therapeutics and privately held Intezyne, both of which are leveraging amphiphilic nanoparticle encapsulation technologies to maximize the efficient delivery of chemotherapeutics. Both Accurin technology platform from BIND and the IVECT (Intezyne's Versatile Encapsulation and Crosslinking Technology) platform from Intezyne make use of an inert bi-philic polymer shell to encapsulate an API without the need for covalent chemical modification. BIND's lead development candidate, BIND-014, a nanoparticle version of docetaxel, is currently in Phase II development for the treatment of NSCLC and CRPC, while Intezyne's IT-141, polymer encapsulated formulation of SN-38 (the active ingredient in irinotecan), which is currently in preclinical IND-enabling studies and is anticipated to begin Phase I development during 2014.

SUMMARY AND CONCLUSION

In our view, Cerulean Therapeutics embodies much of what investors found attractive about Abraxis: a differentiated chemotherapy that maintains or increases its antitumor activity, but has a superior tolerability profile, making it more amenable to combination regimens. On balance, we believe CERU bears a favorable risk/upside potential profile, rooted in the known antitumor activity of camptothecin, as well as the regulatory and commercial paths forward for CRLX101 in its intended indications. Within the next 18 months, we expect to have multiple meaningful top-line read-outs from late-stage clinical trials with CRLX101, as well as Phase I data from CRLX301. Provided the data are positive, these events could be expected to bring CERU's market cap in line with comparable platform technologies (e.g., BIND, ECT, MACK, NKTR, SRNE) that trade at an average market cap of ~\$500MM - a significant premium to CERU's present valuation. In our opinion, all necessary elements for success have come together in Cerulean. Thus, we are initiating coverage with a Market Outperform rating and \$14 price target.

APPENDIX A - BIOGRAPHIES

Senior Management

Oliver S. Fetzer, Ph.D., President and Chief Executive Officer. Dr. Fetzer has served as Cerulean's President and Chief Executive Officer and as a member of the board of directors since 2009. From July 2004 until September 2007, Dr. Fetzer served as Senior Vice President, Corporate Development and Research & Development at Cubist Pharmaceuticals, Inc. From January 2003 to July 2004, he served as Cubist Pharmaceuticals' Senior Vice President, Corporate Development and Chief Business Officer and, from July 2002 until January 2003, he served as its Senior Vice President, Business Development. Before his time at Cubist Pharmaceuticals, Inc., commencing in 1993, Dr. Fetzer held various positions of increasing responsibility at the Boston Consulting Group (BCG), a global leading management consulting firm, including Consultant, Project Leader, Principal, and Partner and Managing Director. Since December 2005, Dr. Fetzer has served on the board of directors of Auxilium Pharmaceuticals, Inc. and since April 2011 on the board of Tecan Group AG. Dr. Fetzer received a B.S. in Biochemistry from the College of Charleston, his Ph.D. in Pharmaceutical Sciences from the Medical University of South Carolina and an M.B.A. from Carnegie Mellon University.

Edward Garmey, M.D., Chief Medical Officer and Senior Vice President. Dr. Garmey has served as Cerulean's Chief Medical Officer and Senior Vice President since 2011. Prior to joining Cerulean, Dr. Garmey held a variety of positions at ArQule, Inc., a clinical-stage biotechnology company, including Vice President for Clinical Development since 2008, and as Clinical Development Liaison from 2007 to 2008. From 2006 to 2007, Dr. Garmey served as Medical Director at GPC Biotech, a German biopharmaceutical company and now a subsidiary of Agennix AG, where he helped oversee global clinical development studies. Dr. Garmey received his A.B. from Harvard University and his M.D. from New York University. He is a member of the Scientific Advisory Board for the Harvard-MIT Broad Institute's Cancer Vaccine Initiative, and he serves on the Board of Visitors of Hearth, a Boston-based non-profit organization dedicated to the elimination of homelessness among the elderly.

Christopher D. T. Guiffre, J.D., Senior Vice President and Chief Business Officer. Mr. Guiffre has served as Cerulean's Senior Vice President and Chief Business Officer since 2012. Prior to that, Mr. Guiffre held a number of senior executive positions at various biopharmaceutical companies. From 2010 to 2012, he served as President and Chief Executive Officer of Alvos Therapeutics, Inc.; from 2008 to 2009, he served as Chief Business Officer at Hydra Biosciences, Inc.; and from 2001 to 2008, he served as a senior executive at Cubist Pharmaceuticals, Inc., most recently as Senior Vice President, General Counsel and Secretary. From 1997 to 2001, Mr. Guiffre held several positions at Renaissance Worldwide, Inc., including Vice President, General Counsel and Clerk. Prior to that, he was an Associate at Bingham, Dana & Gould LLP (now known as Bingham McCutchen LLP). Mr. Guiffre received a B.S. degree from Babson College, a J.D. from Boston College Law School, and an M.B.A. from Boston College Carroll School of Management.

Karen Roberts, Senior Vice President, Finance and Administration. Ms. Roberts has served as Cerulean's Senior Vice President, Finance and Administration since 2010. Prior to joining Cerulean, from 2001 to 2009, Ms. Roberts served as Vice President, Finance and Administration of Elixir Pharmaceuticals, Inc., a biopharmaceutical company where she was the senior financial executive responsible for all aspects of finance, accounting and administration. From 1998 to 2001, Ms. Roberts served in a number of roles, including Corporate Controller and Chief Accounting Officer and Vice President, Finance, at Frontline Group, Inc., a provider of business performance improvement services and products. Prior to that, Ms. Roberts served as Director of Finance at Dyax Corp., a biotechnology company, and as Corporate Controller and Director, Financial Administration at T Cell Sciences, Inc., a biopharmaceutical company.

Scott Eliasof, Ph.D., VP, Research. Dr. Eliasof has led Cerulean's research team since 2007 and has served as vice president of research since 2011. Previously, he was the director of the Chemical Biology Platform at the Broad Institute, directing a multi-disciplinary team of professional scientists and technicians in the fields of synthetic chemistry, analytical chemistry, high-throughput screening, computational science, and software engineering. This interdisciplinary organization is closely affiliated with the laboratory of Stuart Schreiber from Harvard University and is one of the largest and oldest academic screening centers in the country. Prior to joining the Broad Institute, Dr. Eliasof worked at Millennium Pharmaceuticals, where he managed scientific teams in cell biology, molecular biology, neuroscience, and bioinformatics for a large-scale genomics-based drug discovery program. Earlier in his career, Dr. Eliasof was at Neurocrine Biosciences, where he played a key role in the exploration of glutamate transporters in the field of stroke and neurological disorders. Dr. Eliasof earned his B.S. from MIT in Electrical Engineering, Ph.D. from the University of California at Berkeley in Neuroscience, and completed his post-doctoral fellowship at the Vollum Institute in Portland, Oregon.

Marc Wolfgang, VP, Pharmaceutical Sciences and Manufacturing. Mr. Wolfgang has led Cerulean's analytical team since 2007 and has served as vice president of pharmaceutical sciences and manufacturing since 2011. Previously, he was senior director of quality at Momenta Pharmaceuticals, where he was responsible for building the quality affairs and quality control functions, including the establishment of an in-house cGMP testing laboratory. Prior to joining Momenta, he held various CMC related positions ranging from analytical development, QA/QC, production technology, and regulatory affairs at Millennium Pharmaceuticals, Biogen, and Boehringer Ingelheim. Mr. Wolfgang earned degrees in Biology and Chemistry from Pennsylvania State University and Montclair State University.

Source: Company website

Board of Directors

Alan L. Crane, Chairman of the Board of Directors. Mr. Crane is one of Cerulean's co-founders and has served as a member of the board of directors since 2006 and as chairman since 2009. From its founding until 2009, Mr. Crane served as Cerulean's Chief Executive Officer. Currently, he is a general partner at Polaris Venture Partners and was a Venture Partner at Polaris from 2002 until 2009. From 2002 until 2006, Mr. Crane was President and Chief Executive Officer of Momena Pharmaceuticals, Inc. Prior to this, he was Senior Vice President of Global Corporate Development at Millennium Pharmaceuticals, Inc. Mr. Crane serves on the boards of privately held life sciences companies Visterra, Inc., T2 Biosystems, Inc., Ocular Therapeutix, Inc., Seventh Sense Biosystems, Inc., Caloric Pharmaceuticals, Inc., XTuit Pharmaceuticals, Inc. and Vaccinex, Inc. Previously, he served on the boards of Sirtris Pharmaceuticals, Inc. (acquired by Glaxo SmithKline), Adnexus Therapeutics, Inc. (acquired by Bristol Myers Squibb), and Hydra Biosciences. Mr. Crane received his B.A., M.A. and M.B.A. from Harvard University.

Oliver S. Fetzner, Ph.D., Director, President and Chief Executive Officer

Paul A. Friedman, M.D., Director. Dr. Friedman has served as a director since January 2014. From 2001 to January 2014, he was Chief Executive Officer of Incyte Corporation, a public biotechnology company, and he served as President of Incyte from 2004 to January 2014. From 1998 until 2001, Dr. Friedman was President of DuPont Pharmaceuticals Research Laboratories, a wholly owned subsidiary of DuPont Pharmaceuticals Company (formerly The DuPont Merck Pharmaceutical Company), from 1994 to 1998 he served as President of Research and Development of The DuPont Merck Pharmaceutical Company, and from 1991 to 1994 he served as Senior Vice President at Merck Research Laboratories. Prior to his work at Merck and DuPont, Dr. Friedman was an Associate Professor of Medicine and Pharmacology at Harvard Medical School. Dr. Friedman is a Diplomate of the American Board of Internal Medicine and a Member of the American Society of Clinical Investigation. Dr. Friedman is a director of Incyte, public biopharmaceutical companies Auxilium Pharmaceuticals, Inc. and Durata Therapeutics, Inc. and private biopharmaceutical company Gliknik, Inc. Dr. Friedman was a director of Bausch & Lomb Incorporated from 2004 until its acquisition in 2007 and was a director of Sirtris Pharmaceuticals, Inc. from March 2008 until its acquisition in June 2008. Dr. Friedman received his A.B. from Princeton University and his M.D. from Harvard Medical School.

Steven E. Hall, Ph.D., Director. Dr. Hall has served as a member of Cerulean's board of directors since 2010. Dr. Hall has served as a venture partner at Lilly Ventures, the venture capital arm of Eli Lilly and Company, since 2009. Prior to joining Lilly Ventures, from 2003 to 2008, Dr. Hall was Senior Vice President, Research and Development, at Serenex, Inc., a biotechnology company (acquired by Pfizer), where he was also a co-founder. From 1994 to 2003, Dr. Hall held multiple positions, including Site Director, Sphinx Labs, Eli Lilly. Dr. Hall is the author of more than 40 papers and 60 patents. He received his B.S. in chemistry from Central Michigan University and his Ph.D. in organic chemistry from Massachusetts Institute of Technology. Dr. Hall currently sits on the boards of privately held life sciences companies FORMA Therapeutics, Inc., Esanex, Inc., Nimbus Discovery, LLC and Hydra Biosciences, Inc., and on the board of crowdsourcing service provider InnoCentive, Inc.

William T. McKee, Director. Mr. McKee has served as a director since January 2014. Mr. McKee served as Chief Operating Officer and Chief Financial Officer at EKR Therapeutics, Inc., a private specialty pharmaceutical company, from 2010 until 2012 when EKR was sold to Cornerstone Therapeutics Inc., a public pharmaceutical company. Until 2010, Mr. McKee served as the Executive Vice President and Chief Financial Officer of Barr Pharmaceuticals, LLC, a subsidiary of Teva Pharmaceutical Industries Limited, a generic pharmaceutical company, and the successor entity to Barr Pharmaceuticals, Inc., a public specialty pharmaceutical company, which was acquired by Teva in 2008. Mr. McKee was also Executive Vice President and Chief Financial Officer of Barr prior to its acquisition by Teva, after having served in positions of increasing responsibility at Barr from 1995 until its acquisition. Prior to joining Barr, Mr. McKee served as Director of International Operations and Vice President-Finance at Absolute Entertainment, Inc., a private developer and marketer of entertainment software, from 1993 until 1994. From 1990 until 1993, Mr. McKee worked at Gramkow & Carnevale, CPA's, an accounting firm, and from 1983 until 1990, he worked at Deloitte & Touche. Mr. McKee serves on the board of directors of Auxilium Pharmaceuticals, Inc., a public specialty biopharmaceutical company. Mr. McKee received his B.B.A. from the University of Notre Dame.

William H. Rastetter, Ph.D., Director. Dr. Rastetter has served as a director since January 2014. He is a Co-Founder of Receptos, Inc., a biopharmaceutical company, where he has been a director and Chairman of the Board since May 2009 and was Acting Chief Executive Officer from May 2009 to November 2010. Dr. Rastetter served as a Partner at the venture capital firm of Venrock Associates from 2006 to February 2013. Prior to his tenure with Venrock, Dr. Rastetter was Executive Chairman of Biogen Idec, from the merger of the two companies (Biogen and Idec Pharmaceuticals) in 2003 through the end of 2005. He joined Idec Pharmaceuticals in 1986 and served as Chairman and Chief Executive Officer. Prior to Idec, he was Director of Corporate Ventures at Genentech, Inc. and served as well in a scientific capacity at Genentech. Dr. Rastetter also serves as the Chairman of public life sciences companies Illumina, Inc., Neurocrine Biosciences, Inc. and Fate Therapeutics Inc. and as a director of Regulus Therapeutics, Inc., a public biopharmaceutical company. Dr. Rastetter has held various faculty positions at the Massachusetts Institute of Technology and Harvard University and is an Alfred P. Sloan Fellow. Dr. Rastetter holds a B.S. in Chemistry from the Massachusetts Institute of Technology and received his M.A. and Ph.D. in Chemistry from Harvard University.

Ram Sasisekharan, Ph.D., Director. Dr. Sasisekharan is one of Cerulean's co-founders and has served as a consultant and as a member of the board of directors since 2006. Dr. Sasisekharan has been a Professor of Biological Engineering at the Massachusetts Institute of Technology since 1996 and is Director of the Harvard-MIT Division of Health Sciences & Technology and Edward Hood Taplin Professor of Biological Engineering & Health Sciences & Technology and also a member of the Koch Institute for Integrative Cancer Research. Dr. Sasisekharan founded Momena Pharmaceuticals, Inc. and Visterra, Inc., and he serves on the board of directors of Visterra, Inc. Dr. Sasisekharan's research on complex polysaccharides has led to over 125 publications and over 50 patents, including the core technologies of Momena Pharmaceuticals, Inc. He has won both the Burroughs Wellcome and Beckman Foundation Young Investigator Awards and was the recipient of the 1998, 1999, 2000 and 2001 CaPCure Awards from the CaPCure Foundation. Dr. Sasisekharan serves on the steering committee of the Consortium for Functional Glycomics. Dr. Sasisekharan received his B.S. in Physical Sciences from Bangalore University, his M.S. in Biophysics from Harvard University and his Ph.D. in Medical Sciences from Harvard Medical School.

Robert I. Pepper, M.D., Director. Dr. Pepper served as a member of Cerulean's board of directors since 2006. Dr. Pepper has over 25 years of experience building and operating leading research and development operations. Dr. Pepper co-founded Third Rock Ventures, L.P. in March 2007 and focuses on the formation, development and scientific strategy of its portfolio companies, as well as actively identifying and evaluating new investments. Prior to joining Third Rock Ventures, L.P., from 2003 to 2007, Dr. Pepper served as President of Research and Development at Millennium Pharmaceuticals, Inc. Before joining Millennium Pharmaceuticals, Inc. in 1994, he served as principal investigator in the laboratory of tumor biology at Massachusetts General Hospital Cancer Center. Dr. Pepper is also a founder and former member of the scientific advisory board of Cell Genesys/Abgenix. Dr. Pepper holds an A.B. in biochemistry from Princeton University and an M.D. from Harvard Medical School. Dr. Pepper serves as an adjunct faculty member at Harvard Medical School and Massachusetts General Hospital and is an advisory board member of several leading healthcare institutions, including the Partners HealthCare Center for Personalized Genetic Medicine, Harvard Medical School and Tufts Medical School. Dr. Pepper is a board member of private life sciences companies Alcresta, Inc., Allena Pharmaceuticals, Inc., Constellation Pharmaceuticals Inc. and Kala Pharmaceuticals, Inc. as well as public biopharmaceutical company bluebird bio Inc., and is also on the board of overseers at Tufts University.

Source: Company website

FIGURE 23. Cerulean Pharma (CERU) Income Statement

Income Statement (\$MM)	2013A	1Q14E	2Q13A	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Product Sales and Royalties:																	
CRLX101																	
US Sales							-	-	-	49.8	164.9	278.0	421.5	558.9	693.2	832.2	882.6
ROW Royalties							-	-	-	-	7.7	27.8	50.3	76.1	101.3	123.0	132.9
CRLX301																	
US Sales							-	-	-	-	105.6	221.2	341.1	501.2	623.6	673.3	697.4
ROW Royalties							-	-	-	-	-	15.8	32.3	49.8	71.0	86.0	90.8
Total Product Sales and Royalties	0.0	-	-	-	-	-	-	-	-	49.8	278.2	542.7	845.2	1,186.0	1,489.2	1,714.6	1,803.6
Collaboration Revenue	0.0					-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	0.0	-	-	-	-	-	-	-	-	49.8	278.2	542.7	845.2	1,186.0	1,489.2	1,714.6	1,803.6
Cost of Goods Sold										6.0	18.1	27.8	42.1	55.9	69.3	83.2	88.3
Gross Profit	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	43.9	260.0	514.9	803.0	1,130.1	1,419.8	1,631.3	1,715.4
Operating Expenses:																	
Research and Development	9.7	3.0	3.5	3.8	4.1	14.400	21.6	35.6	71.3	89.1	102.5	115.8	129.7	142.6	156.9	172.6	189.9
General and administrative	6.2	1.6	2.5	2.8	3.2	10.100	11.6	12.9	47.3	63.9	83.0	103.8	124.6	139.5	153.5	168.8	185.7
Total operating expenses	15.9	4.6	6.0	6.6	7.3	24.500	33.2	48.5	118.6	153.0	185.5	219.6	254.2	282.2	310.4	341.4	375.5
Operating income (loss)	(15.9)	(4.6)	(6.0)	(6.6)	(7.3)	(24.500)	(33.2)	(48.5)	(118.6)	(109.1)	74.5	295.3	548.8	847.9	1,109.5	1,289.9	1,339.8
Other income (expense):																	
Interest income	0.0	0.0	0.0	0.0	0.0	0.0											
Interest expense	(1.5)	(0.4)	(0.4)	(0.4)	(0.5)	(1.7)											
Decrease in value of preferred stock warrant liability	0.2	0.1	0.1	0.1	0.1	0.3											
Total other income, net	(1.3)	(0.4)	(0.4)	(0.4)	(0.5)	(1.7)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pretax net income (loss)	(17.143)	(5.0)	(6.4)	(7.0)	(7.8)	(26.223)	(33.2)	(48.5)	(118.6)	(109.1)	74.5	295.3	548.8	847.9	1,109.5	1,289.9	1,339.8
Income tax benefit (provision)						0.0	0.0	0.0	0.0	0.0	(11.2)	(59.1)	(137.2)	(254.4)	(388.3)	(451.5)	(468.9)
Tax Rate						0%	0%	0%	0%	0%	15%	20%	25%	30%	35%	35%	35%
Comprehensive income (loss)	(17.1)	(5.0)	(6.4)	(7.0)	(7.8)	(26.223)	(33.2)	(48.5)	(118.6)	(109.1)	63.3	236.2	411.6	593.6	721.2	838.5	870.9
Accretion of redeemable convertible preferred stock	0.0																
Net income (loss) attributable to common stockholders	(17.143)	(5.0)	(6.4)	(7.0)	(7.8)	(26.2)	(33.2)	(48.5)	(118.6)	(109.1)	63.3	236.2	411.6	593.6	721.2	838.5	870.9
Basic EPS to common shareholders	\$ (2.17)	\$ (0.41)	\$ (0.39)	\$ (0.43)	\$ (0.47)	\$ (1.69)	\$ (1.74)	\$ (2.21)	\$ (4.82)	\$ (3.72)	\$ 1.97	\$ 7.19	\$ 12.26	\$ 17.29	\$ 20.55	\$ 23.39	\$ 23.79
Diluted EPS to common shareholders	\$ (2.17)	\$ (0.41)	\$ (0.39)	\$ (0.43)	\$ (0.47)	\$ (1.69)	\$ (1.74)	\$ (2.21)	\$ (4.82)	\$ (3.72)	\$ 1.64	\$ 5.99	\$ 10.23	\$ 14.47	\$ 17.25	\$ 19.68	\$ 20.07
Basic shares outstanding	7.9	12.1	16.4	16.5	16.6	15.5	19.1	21.9	24.6	29.4	32.1	32.8	33.6	34.3	35.1	35.8	36.6
Diluted shares outstanding	7.9	12.1	16.4	16.5	16.6	15.5	19.1	21.9	24.6	29.4	38.7	39.5	40.2	41.0	41.8	42.6	43.4

Source: JMP Securities LLC, Company reports

JMP FACTS AND DISCLOSURES

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Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months.

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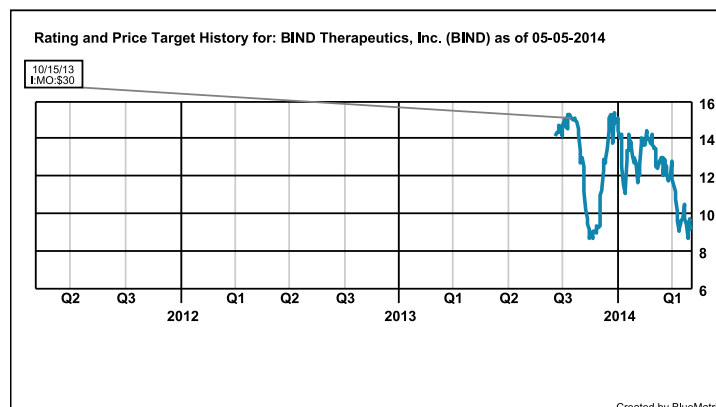
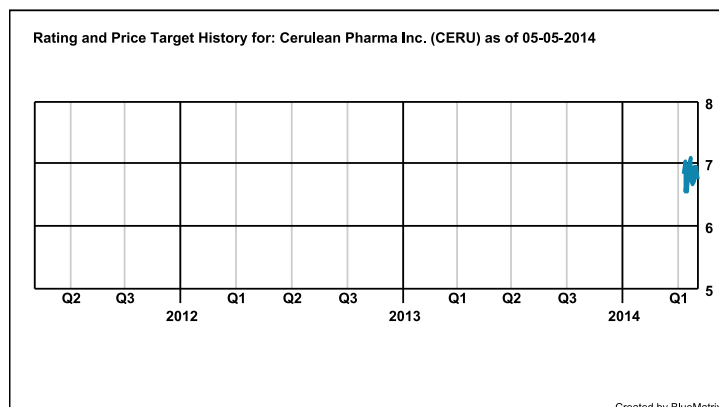
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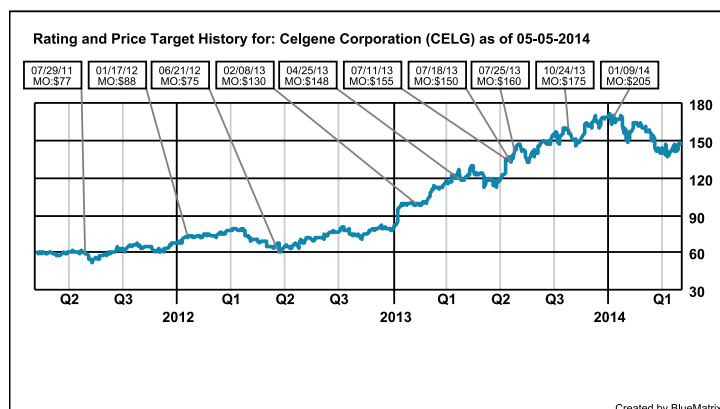
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JMP Rating	Regulatory Equivalent	# Co's Under Coverage	% of Total	Regulatory Equivalent	# Co's Under Coverage	% of Total	# Co's Receiving IB Services in Past 12 Months	% of Co's With This Rating
MARKET OUTPERFORM	Buy	253	58.03%	Buy	253	58.03%	101	39.92%
MARKET PERFORM	Hold	135	30.96%	Hold	135	30.96%	17	12.59%
MARKET UNDERPERFORM	Sell	5	1.15%	Sell	5	1.15%	0	0%
COVERAGE IN TRANSITION		43	9.86%		43	9.86%	0	0%
TOTAL:		436	100%		436	100%	118	27.06%

Stock Price Chart of Rating and Target Price Changes:

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar quarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.





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