

Wednesday, February 12, 2014  
10:25 AM

## Main document changes and comments

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aldox

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Aldox

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The company was founded in 1985. Current President and Chief Executive Officer Steven A. Kriegsman has been involved with CytRx [since 2000](#). During Mr. Kriegsman's time at CytRx the company has pursued several opportunities, focusing on RNA interference technology in the mid 2000's, but spun out their RNA assets into what has since become Galena Biopharma. Today, CytRx is headquartered in Los Angeles, and the

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based on linker technologies to enhance the efficacy of chemotherapeutic drugs. Aldoxorubicin is the first drug in the pipeline and consists of an acid-sensitive linker attached to the chemotherapy drug doxorubicin. The linker allows 3.5 times the standard dose of doxorubicin to be given to the patient at each cycle.

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aldox

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FDA approval process

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clinical development stage with Aldox

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no less than six different

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multiple indications

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applications of aldox

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pivotal

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which will begin this quarter

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The company received a "Special Protocol Assessment" from the FDA which means there is agreement that this trial can be used to file for marketing approval.

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The drug

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also in

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wrapping up

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Last week,CytRx announced the start of		
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with Aldox.		
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, and a 18 patient Phase Ib trial for rare forms of STS		
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B		
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Combining an existing chemo drug with a linker molecule that causes it to bind		
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Using		
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with		
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to deliver an anti-cancer drug to the tumor		
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facilitates a higher dose with less toxicity. This concept		
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427		
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447		
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the first nine months of 2013		
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2012		
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proven		
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known		
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but with some additional advantages.		
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to an well tested drug concept.		
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Aldox requires an acidic environment to release the drug from the linker. This is a key feature since it does not release the drug in healthy,non-acidic tissues. This allows 3.5 times the standard dose of doxorubicin to be given to the patient at each cycle. Further, CytRx has reported that they can treat for longer than six cycles which is the		

current maximum for doxorubicin due to toxicity.

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As a result, the fact that CytRx has already performed strongly in FDA trials should never have been much of a surprise in the first place

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in clinical trials,

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ultimately resulting in

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as the company's compounds move through the process

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in the future.

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potential

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The market is enormous (over \$1 billion), the disease is very deadly, and the

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The		
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since doxorubicin is the current standard of care		
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p		
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conservatively		
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and		
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spending in this area is a high priority as		
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with poor treatment options available today		
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GMB		
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GBM		
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allows for the drug		
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can		
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in animal models

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, the picture below shows the difference

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uptake of

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aldox

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Aldox

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in the brain of a

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GBM animal

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GBM see picture below

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if possible, the medical term for which is resection,

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adhering to the highest

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receiving

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Both Roche and Merck have made major attempts at GBM drugs, with



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the		
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was recently		
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by equivocal		
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for its		
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survival		
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Despite this, Roche is <a href="#">projecting</a> enormous sales volume of roughly \$7 billion at peak.		
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promising		
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advanced		
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the most		
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other than aldox		
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Aldox		
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doxorubicin which is		
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known		
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which limits its use to approximately 20% of GBM patients that have a specific		
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mutation. The

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enough, [roughly](#) \$500 million

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multi-billion dollar opportunity for an effective drug

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products in the pipeline

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opportunities with Aldox

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products

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indications

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world wide

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worldwide

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per patient

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will likely

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could

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