

# Catalyst Roundup: A Review of Select Catalysts from Last Quarter's Outlook Report

Biomedtracker's quarterly Outlook Reports detail important upcoming catalysts not to miss.

Here's a look at the outcome of two catalysts featured in the Q2 2018 Outlook Report.

Drug:  
**Zemdri for Complicated Urinary Tract Infections (cUTI); Bloodstream Infection (BSI)**  
Achaogen (AKAO)

Catalyst Occurred:  
**PDUFA for NDA - First Review**  
June 26, 2018

## FDA DECISION

- cUTI: Approved
- BSI: Complete Response Letter (CRL)

"In line with the FDA Advisory panel vote, Zemdri was approved for cUTI but received a CRL for its NDA for the BSI indication which was submitted under the new, limited population for antibacterial and antifungal drugs (LPAD) pathway...The label excludes data from the CARE trial and does not discuss the use of Zemdri for CRE infections.

"With regards to the CRL for the BSI indication, it is possible that there will be additional work in this indication using combination therapies."

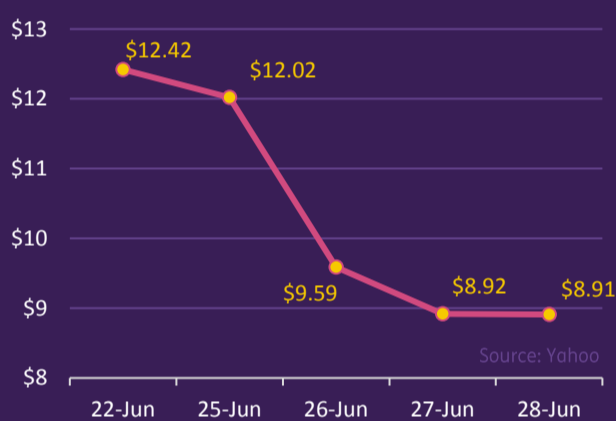
## BIOMEDTRACKER ANALYSES

Change to Likelihood of Approval (LOA) for BSI: **-28%**

LOA before decision	LOA after decision
73%	45%
(15% Below Avg.)	(16% Below Avg.)

Due to the CRL, the development phase regressed to Phase III for the BSI indication, resulting in the larger drop in LOA.

## AKAO: 5-DAY STOCK PERFORMANCE



## NOTABLE UPCOMING CATALYSTS

Market Launch for cUTI: July 2018  
EU MAA Filing: 2018

Drug:  
**ALXN1210 for Paroxysmal Nocturnal Hemoglobinuria (PNH)**  
Alexion Pharmaceuticals (ALXN)

Catalyst Occurred:  
**Phase III SWITCH - Top-Line Results**  
April 26, 2018

## TRIAL RESULTS

- Met Primary Endpoint of Change in LDH levels
- Met Four Key Secondary Endpoints

"ALXN1210's once every eight weeks dosing reinforces its clinical attractiveness and provides it with a competitive advantage over Soliris' biweekly dosing. This is likely to be favored both by patients and payers who would likely benefit from reduced infusion costs."

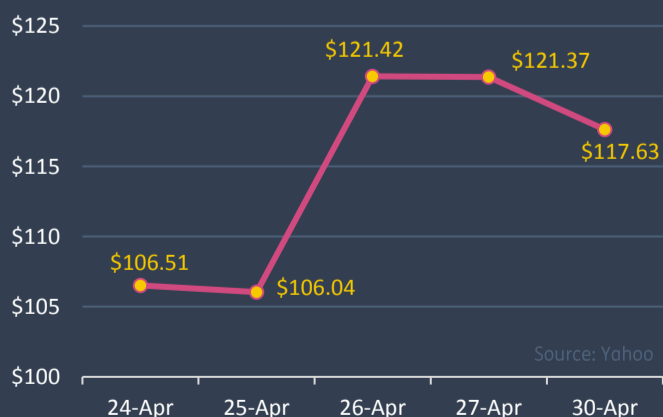
"Non-inferiority to Soliris was achieved on all endpoints. This is likely to help promote the transition from Soliris to ALXN1210, and boost ALXN1210 uptake."

## BIOMEDTRACKER ANALYSES

Change to Likelihood of Approval (LOA): **+4%**

LOA before results	LOA after results
65%	69%
(6% Above Avg.)	(10% Above Avg.)

## ALXN: 5-DAY STOCK PERFORMANCE



## NOTABLE UPCOMING CATALYSTS

PDUFA for BLA: February 19, 2019

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Biomedtracker's  
Q3 2018 Outlook Report