

BioRunUp

Analyst Report

ALXA – Alexa Pharmaceuticals

FDA Catalyst

Catalyst Date: PDUFA October 11th, 2010

Drug: AZ-004 for the Rapid Treatment of Agitation

BioRunUp Rating: Buy

Summary:

ALXA's drug AZ-004 has a PDUFA date of 10/11/10. We feel that ALXA will benefit from being one of the first of a series of FDA Approvals in October. We expect its run to continue into early October, and with dilution out of the way we expect to see ALXA spike into the \$5 range. We do not recommend holding through approval.

Drug Information:

AZ-004 (*Staccato* loxapine) is Alexza's lead program, which is being developed for the rapid treatment of agitation in schizophrenic or bipolar disorder patients. Alexza has submitted a New Drug Application submission in December 2009, and has a Prescription Drug User Fee Act (PDUFA) goal date of October 11, 2010. In February 2010, Alexza established a partnership with Biovail Laboratories International SRL, a subsidiary of Biovail Corporation, to develop and commercialize AZ-004 in the U.S. and Canada.

Potential Drug Market:

Episodes of acute agitation occur often in the 2.4 million schizophrenia and 5.7 million bipolar disorder patients in the U.S. Management estimates that 90% of these patients will experience an episode of acute agitation during their lifetime.

Industry sources expect Alexza to charge about \$50 per dose and expect first year sales to be around \$45M

Financial Information:

On August 5th, 2010 Alexza announced that it entered into definitive agreements with a select group of institutional investors to raise approximately \$18.0 million in gross proceeds in a registered direct offering through the sale of common stock and warrants. Alexza estimates that net proceeds from the offering will be approximately \$16.4 million, after deducting placement agents' commissions and estimated offering expenses. The Company intends to use the net proceeds from the sale of the securities primarily for general corporate purposes, including clinical trial, research and development, general and administrative and manufacturing expenses.

We do not expect any further dilution before the PDUFA date

Updates:



Price

\$3.62

Run-Up Target

\$5.25

52 Week Range: 1.93 - 3.92

Avg Volume: 805K

Market Cap: 192M

EPS: -2.94

Cash on Hand: \$19.9M

Shares Out: 53M

Institutional Holders: 29%

Company Description:

Alexza Pharmaceuticals, Inc. (Alexza) is a pharmaceutical company focused on the research, development, and commercialization of products for the acute treatment of central nervous system (CNS) conditions. The Company's product candidates are based on its technology, the Staccato system. The Staccato system vaporizes an excipient-free drug to form a condensation aerosol that, when inhaled, allows for systemic drug delivery. Alexza has five other product candidates in various stages of clinical development.