

Overview

Advanced Life Sciences is a biopharmaceutical company engaged in the discovery, development and commercialization of drugs in the areas of infection, oncology and respiratory disease. The Company's lead product candidate, cethromycin, is a novel once-a-day oral antibiotic developed for the treatment of respiratory tract infections.

OTC BB: ADLS.OB
Market Cap: \$21M at 4-15-09
52 Week Range: \$0.14-\$1.45
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Advanced Life Sciences has assembled a promising pipeline of clinical and preclinical candidates using its internal discovery platform of medicinal chemistry and structural biology, coupled with in-licensing promising new products. The Company has three product candidates that are either in clinical development or approved to begin clinical development.

Development Pipeline

	Discovery	Preclinical	Phase I	Phase II	Phase III	Commercialization
Product Portfolio (Indication)	Infectious Disease					
	<i>Cethromycin</i> (Community Acquired Pneumonia)					
	<i>Cethromycin</i> (Biodefense)	<i>Pre-NDA Animal Studies</i>				
	Oncology					
	<i>ALS-357</i> (Melanoma)					
	Respiratory Disease					
	<i>ALS-886</i> (ARDS)					

Cethromycin Program

With increasing worldwide resistance rates to current macrolide and penicillin antibiotics there is a growing medical need for new antibiotics. Cethromycin was created to address this need and Advanced Life Sciences is focusing its resources on its development and commercialization. In late 2007, we completed two successful pivotal Phase III trials for the treatment of mild-to-moderate community-acquired pneumonia (CAP) in adults. After confirming the cardiac safety of cethromycin in a thorough QT study, we compiled and recently announced the submission of a New Drug Application (NDA) to the Food & Drug Administration (FDA) in CAP. In December 2008, the FDA accepted and filed the cethromycin NDA with a target PDUFA date of July 31, 2009.

In addition to its potential utility in CAP, cethromycin is also being developed to treat airborne bacterial bioterror agents such as anthrax, tularemia and plague. As resistance to the first-line treatments grows, there is a medical need for new therapeutics that work differently than existing agents to treat anthrax infection. Our collaboration with USAMRIID has produced promising results in anthrax, and a recent primate study confirmed cethromycin's efficacy in preventing anthrax infection. This study, along with the data from our recently awarded Defense Threat Reduction Awareness (DTRA) contract, could potentially support a future sNDA submission for the treatment of anthrax and other biodefense-related pathogens.

About Community Acquired Pneumonia

CAP is defined as a lower respiratory tract infection caused by pathogens such as *Streptococcus pneumoniae* and *Haemophilus influenzae* that is not acquired in a hospital or long term care facility. Resistance rates to these key pathogens are reaching alarming levels. When the infection is acquired, the lungs' air sacs fill with liquid, making it difficult for oxygen to penetrate through the lungs. If CAP is not treated properly, it can result in death, especially to people with weakened immune systems, such as the elderly. Macrolides and penicillins are currently the first-line treatments for respiratory tract infections such as CAP.

- The sixth leading cause of death in the US
- An estimated 5.6 million cases of CAP occur annually in the US, resulting in approximately 10 million physician visits and 1.1 million hospitalizations
- The estimated total annual cost of healthcare for CAP in the US is \$8.4 billion, with prescribed antibiotics accounting for \$2 billion annually
- The cost of hospitalized CAP patients unresponsive to penicillins or macrolides is \$15,000 per patient versus \$200 office visit with effective prescription
- The cost of collateral damage in the form of Clostridium difficile associated disease (CDAD) is \$1 billion in the US and growing

Commercialization and Partnering Plan for Cethromycin

The Company has reached a commercialization agreement with Wyeth for the marketing and promotion of cethromycin in the Asia Pacific region. We plan to partner with companies in other major global markets in our effort to target primary care physicians and patients around the world.

Recently Accomplished Milestones

March 2009	Department of Defense (DoD) exercised its full option to award the Company \$3.8 million under the previously announced contract to develop cethromycin as a broad-spectrum medical countermeasure
February 2009	Announced Anti-Infective Drugs Advisory Committee (AIDAC) meeting in June 2009 to discuss the New Drug Application (NDA) for cethromycin
December 2008	FDA accepted cethromycin NDA
September 2008	Signed commercialization agreement with Wyeth for cethromycin in Asia Pacific region
September 2008	Submitted NDA for cethromycin in CAP
June 2008	Article in Journal of Antimicrobial Chemotherapy supporting role for cethromycin as potential treatment for infections caused by CA-MRSA

Management Team

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