



INSTITUTIONAL RESEARCH

HEALTHCARE & BIOTECHNOLOGY

COMPANY UPDATE

Member FINRA/SIPC

Toll Free: 866-928-0928 ♦ www.DawsonJames.com ♦ 925 Federal Highway, 6th Floor ♦ Boca Raton, FL 33432

May 31, 2011

Advanced Life Sciences Holdings Inc. (OTCBB/ADLS)

Neutral **Terminating Coverage**

ALS is developing therapies for infectious diseases, cancer and respiratory illness

Vernon T. Bernardino
Senior Research Analyst
(212) 551-3601
vbernardino@dawsonjames.com

INVESTMENT HIGHLIGHTS

We are terminating coverage on the shares of Advanced Life Sciences (ALS) Holdings Inc. at this time in order to focus research resources in other areas. Our most recent rating on these shares was Neutral.

Current Price **\$0.05**
Price Target **N/A**

MARKET DATA		05/31/11
Stock Symbol	ADLS	
Market	Nasdaq OTC BB	
52 Wk Low-High	\$0.03	- \$2.70
Market Cap. (MM)	\$0.5	
Shares Out (MM)	10.8	
3-Month Avg. Daily Vol (000s)	117.8	
Enterprise Value (MM)	\$8.9	
Insider Ownership	1.7%	
Institutional Ownership	30.0%	

BALANCE SHEET METRICS		(12/30/10)
Cash (MM)	\$0.2	
Long-Term Debt (MM)	\$8.5	

EARNINGS DATA			
FY - 12/31	2008A	2009A	2010A
Full Year EPS (diluted)	(\$0.59)	(\$0.16)	(\$0.06)
Revenue (MM)	\$0.2	\$2.8	\$0.8



Source: Reuters, FactSet.

VALUATION

Advanced Life Sciences Holdings, Inc. (OTCBB: ADLS) is a biopharmaceutical company engaged in the discovery, development and commercialization of novel drugs in the therapeutic areas of infection, cancer and respiratory diseases. Comparable companies that focus on anti-infective therapeutics and medical countermeasures against biological and chemical weapons currently trade at a mean enterprise value (EV) ranging from \$614 MM to \$913 MM.

INVESTMENT RISKS

The key risks are:

- **Development Risk** Although Restanza previously has demonstrated safety and efficacy in two Phase III trials, and has demonstrated superiority in one of two of these trials versus clarithromycin, there is no guarantee that it will be successful in achieving the primary endpoint of the planned trial (i.e., superiority versus azithromycin). Further, we anticipate the cost to conduct the planned third Phase III trial with Restanza ranges from \$8MM to \$10 MM. As a result, ALS currently does not have the capital resources to initiate the planned Phase III clinical trial, and would need to raise capital or establish a collaboration with a partner to further develop Restanza.
- **Regulatory Risk** ALS has been granted a Special Protocol Assessment (SPA) for the design of the company's planned Phase III trial with Restanza in CABP. The SPA provides limited assurance that if the agreed upon clinical trial protocols are followed, the clinical trial endpoints are achieved and there is a favorable risk benefit profile, the data may serve as the primary basis of an efficacy claim in support of an NDA. The FDA, however, continues to conduct work on finalizing its draft guidance for clinical trials in CABP. It was the FDA's debate on the appropriate parameters for a non-inferiority clinical trial design for CABP that derailed the positive results achieved with the company's earlier NDA submission in 2008.
- **Commercialization Risk** Given its prior experience with the successful completion of two Phase III trials with Restanza, we believe ALS is capable of conducting the successful completion of a third Phase III trial. However, the company has no prior experience commercializing an antibacterial product, and thus, establishing a collaboration with an experienced partner would help mitigate commercialization risk.
- **Financial Risk** ALS faces several near-term financial challenges. In ALS' 4Q10 and FY10 results reported March 24, 2011, the company had \$159,596 in cash on hand as of December 31, 2010, and what we estimate was a burn rate of \$1.6 MM per quarter, net of impairment charges. Further, the company's revolving line of credit has \$8.1 MM outstanding with \$2.5 MM of the outstanding loan balance classified as a current liability. ALS is in discussions with its bank to defer prepayment to sometime in 2011. As a result, the company is not likely to use its cash reserves to further advance its R&D programs near-term and will primarily use its capital resources to service its debt obligations.
- **Market Risk** We believe ALS near-term will need to raise capital, however, at current stock prices tapping the capital markets would be significantly dilutive to shareholders.

IMPORTANT DISCLOSURES:

Price Chart



Price target and ratings changes over the past 3 years:

Initiated – November 23, 2010 – Target N/A

Analyst Certification: The analyst(s) whose name appears on this research report certifies that 1) all of the views expressed in this report accurately reflect his personal views about any and all of the subject securities or issuers discussed; and 2) no part of the research analyst's compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst in this research report; and 3) All Dawson James employees, including the analyst(s) responsible for preparing this research report, may be eligible to receive non-product or service specific monetary bonus compensation that is based upon various factors, including total revenues of Dawson James and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.

Dawson James has received investment banking compensation from the companies mentioned in this report and may actively seek compensation for investment banking services in the future. Dawson James does not make a market in this security. Neither the research analyst whose name appears on this report nor any member of his household is an officer, director or advisory board member of the company. Dawson James did not receive any other compensation from the company in the previous 12 months. The Firm and/or its directors and employees may own securities of the company(s) in this report and may increase or decrease holdings in the future, but the Firm as a whole does not beneficially own 1% or more of any class of common equity securities of the subject company.

Ratings definitions: **1) Buy:** the stock is expected to appreciate and produce a total return of at least 20% over the next 12-18 months; **2) Neutral:** the stock is fairly valued for the next 12-18 months; and **3) Sell:** the stock is expected to decline at least 20% over the next 12-18 months and should be sold.

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Buy	22	85%	8	31%
Neutral	4	15%	3	75%
Sell	0	0%	0	0%
Total	26	100%	11	42%

Information about valuation methods and risks can be found in the "VALUATION" and "RISKS" sections of this report.

DAWSON JAMES SECURITIES, INC., Member SIPC, FINRA, (the "Firm") does not make a market in these securities. The Firm may perform or seek to perform investment banking services for these companies in the future. Analysts receive no direct compensation in connection with the firm's investment banking business. All Dawson James employees, including the analyst(s) responsible for preparing this research report, may be eligible to receive non-product or service specific monetary bonus compensation that is based upon various factors, including total revenues of Dawson James and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report. The Firm, its officers, directors, analysts or employees may affect transactions in and have long or short positions in the securities (or options or warrants with respect thereto) mentioned herein. Although the statements of fact in this report have been obtained from and are based upon recognized statistical services, issuer reports or communications, or other sources that the Firm believes to be reliable, we cannot guarantee their accuracy. All opinions and estimates included in this report constitute the analyst's judgment as of the date of this report and are subject to change without notice. The Firm may effect transactions as principal or agent in the securities mentioned herein. The securities discussed or recommended in this report may be unsuitable for investors depending on their specific investment objectives and financial position. This report is offered for informational purposes only, and does not constitute an offer or solicitation to buy or sell any securities discussed herein in any jurisdiction where such would be prohibited. Additional information is available upon request.