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**ADMINISTRATIVE PROCEEDING**

**File No. 3-17293**

**In the Matter of**

**Advanced Life Sciences Holdings, Inc., *et al.*,**

**Respondents.**

# ADVANCED LIFE SCIENCES' BRIEF IN SUPPORT OF THE PETITION FOR REVIEW OF THE INITIAL DECISION AS TO ADVANCED LIFE SCIENCES HOLDINGS, INC.

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We have received the Initial Decision Release No. 1065 Administrative Proceeding File No. 3-17293 regarding Advanced Life Sciences Holdings, Inc. dated October 12, 2016.

The purpose of this document is to file a brief in support of a petition for review of this initial decision which was granted on November 22, 2016.

Advanced Life Sciences Holdings, Inc. ("ADLS") is a Delaware corporation located in Woodridge, IL and is a biopharmaceutical company focused on the discovery, development and commercialization of novel drugs in the area of infectious disease.

We have been developing our antibiotic cethromycin through clinical trials for the treatment of a variety of dangerous infections such as pneumonia, especially those caused by pathogenic bacteria that are resistant to other antibiotics. There is a great need for new antibiotics given the increasingly rapid emergence of drug-resistant pathogens here in the United States and around the globe.

In late 2008, we completed our Phase 3 clinical trials of cethromycin against pneumonia and, in 2009, we submitted our New Drug Application (NDA) to the FDA for their review. Later that year, the FDA convened an advisory committee meeting of expert infectious disease physicians to review our NDA and provide recommendations regarding the safety and efficacy of cethromycin to the agency. The advisory committee voted overwhelming in favor of the safety of the drug. However, with regard to drug efficacy,

the advisory committee asked us to go back and redo clinical trials according to guidelines the FDA had put in place even after our clinical trials had been completed.

Thus, even though we met the efficacy goals of the Phase 3 clinical trials we had designed and agreed to with the FDA in 2005, we were asked to design and carry out new trials under the new FDA guidelines.

Because of this setback, our stock price plummeted into penny stock range in 2009. Although we worked diligently to design a new clinical trial that would meet the new FDA guidelines, it took us almost a year to reach agreement with the FDA on what the specifications would be for the new clinical trial. As we reached the end of 2010, it became extremely difficult to raise additional capital to continue to fund our clinical program.

In late April, 2011, because of our lack of liquidity, we were forced to put the Company into suspension and terminate every employee on our staff. Our last filing with the SEC was our 10-K document for 2010. We were just about ready to file our 10-Q document for the first quarter of 2011 during the late April, 2011 timeframe when we put the Company in suspension. That filing was not made.

We spent the next two years, without any cash compensation from ADLS, attempting to restructure a bank note which, on top of the clinical program uncertainty, was inhibiting

our ability to move the Company forward. In May of 2013, we successfully reached an agreement with the bank which finally made it possible to begin to rebuild ADLS.

From that point in time until present, again without any cash compensation from ADLS, we have been working to assemble a filing to the SEC to move ADLS closer to compliance. During the course of that time, we have had several discussions with staff professionals at the SEC regarding the nature of the document we should file at this point.

We were advised to prepare a comprehensive 10-K document covering the years 2011 through the present. Over the past couple of years, we have worked to prepare that document. The progress to complete this filing has been slow due to the part-time involvement of the legal and accounting professionals that we have worked with on this project, along with the complex and time-consuming nature of the task.

In his brief, Mr. David S. Frye of the SEC makes the point several times that ADLS has failed to file twenty-one consecutive periodic reports, and has not made a compliant filing since it filed its Form 10-K for the period ending December 31, 2010 on March 24, 2011. We agree that we have not made those filings. However, there are several reasons why those filings were not made:

(1) We were forced to terminate every employee on our staff on April 29, 2011. Thus, we did not have any manpower with which to make SEC filings.

(2) It was very difficult and time-consuming to rebuild and assemble the financial statements for 2011 because our financial staff was no longer employed with the Company.

(3) We had to spend two years negotiating with our bank to restructure a note that was preventing us from taking the Company forward.

(4) It proved to be very difficult to access the necessary legal and accounting professionals on a part-time basis to assist in assembling the comprehensive 10-K document along with the necessary financial statements from 2011 through 2015. The ADLS management team invested their own personal funds when accessing these professionals, which limited their involvement in assisting with the filing activities.

We continued to press on, however, because of our firm belief that our antibiotic cethromycin would be of great benefit to patients with its ability to overcome the drug resistance that has been building globally to "superbugs".

Mr. Frye, in his brief, states that ADLS's CEO Michael Flavin responded to an SEC delinquency letter from Ms. Marva Simpson requesting an accommodation to file a comprehensive 10-K, which resulted in a letter in which Michael Flavin said he believed that ADLS would be completely up to date with the required filings by September 30, 2014. Mr. Frye also states that ADLS failed to meet its own self-defined target date and has not made any filing of any type since it filed an 8-K on May 12, 2011.

It is true that we made numerous inquires of SEC staff in order to request the accommodation to file a comprehensive 10-K, and we attempted to follow any protocol we were asked to carry out so as to secure that accommodation. ADLS CEO Michael Flavin accepts responsibility for failing to meet the self-defined target date for 10-K submission. The reason for this is that he misjudged the amount of time that would be required to build the multi-year financial statements using external, part-time accounting professionals and the locating of key financial documents necessary for completion of those statements, most of which he needed to locate himself.

In response to Mr. Frye's statement that ADLS has failed to make any filings of any type since it filed an 8-K on May 12, 2011, we did submit to Suzanne Hayes of the Division of Corporate Finance at the SEC our comprehensive 10-K document covering the years 2011 through 2015 on July 27, 2016. Although we admit that it took a long time to prepare that document, we did reach our corporate goal of completing that submission after several years of effort.

In his brief, Mr. Frye also states that ADLS's long history of delinquencies leads to a reasonable inference that the Court cannot rely on any assurance it may offer against future violations and that ADLS's promises are simply not credible. It would have been easy to give up on our efforts to move ADLS forward in 2011 and just file for bankruptcy protection. Instead, our team pushed ahead, investing our own time and personal funds over several years to keep the Company alive and work to assemble the comprehensive 10-K filing. In going through this process, we have put in place legal

and accounting processes that we can continue to enlist to maintain our ability to make required SEC filings. The foundation is in place for the Company to continue to be rebuilt.

Although our management team is not being compensated, we meet regularly and discuss strategies for moving our program forward. We are in regular contact with our board of directors and have designed a plan for moving ADLS forward. In addition, we have been in communication with the FDA and have met with agency representatives to learn what ADLS will need to do to receive approval for cethromycin. We believe that, once we bring ADLS back into compliance with SEC regulations, Company shareholders will realize value in their investment, while we deliver an important new drug to patients who are in need of cethromycin.

We respectfully request, then, that the SEC work with us in the filing of our comprehensive 10-K document which we submitted to Suzanne Hayes of the Division of Corporate Finance at the SEC on July 27, 2016 (See Exhibit 1). It is a document that brings investors up to date on the current status of the Company. Maintaining our registration status would allow us to position ADLS to raise the additional capital required to carry out the clinical trials that the FDA has asked us to conduct in order to achieve regulatory approval and commercialization of what can be a life-saving antibiotic. We would greatly appreciate the opportunity to help make that happen.

We have petitioned the initial decision of Administrative Law Judge James E. Grimes because we feel that some of the assertions in his decision are too strongly negative given the circumstances associated with the ADLS events described above, most of which were beyond our control.

What we are requesting is an opportunity to rebuild the Company and achieve compliance with SEC regulations. Is it possible to be given one year to become completely compliant, knowing exactly what is needed to reach compliance? We understand that we should have filed 22 10Qs and 10Ks over the past 5 years. But is there not a more practical approach, given where things stand today, than submitting all of these documents, most of which would convey almost exactly the same information? That is why we assembled and submitted, on July 27, 2016, the comprehensive 10K for the years 2011 through 2015. This document covers anything and everything an investor would need or want to know about ADLS. If we can work with the SEC on that filing, we can proceed to bring subsequent filings up to date. These filings are all very similar given the fact that very little has changed in the way of Company status. Our comprehensive 10K would serve investors well, despite the long delay, and would be the foundation for moving forward with further filings.

If given the opportunity to rebuild ADLS and regain compliance with the SEC, we believe our Company could make a major difference in bringing new medicines to patients in need. Given the fact that there are so very few companies here in the US working on the discovery and development of new antibiotics, would it be a good idea to

encourage and work with those companies, such as ADLS, that have an interest in bringing new antibiotics to patients in need of them? The US government put in place the GAIN (Generating Antibiotic Incentives Now) Act in July of 2012 to incentivize and assist companies in discovering and developing new antibiotics because of rapidly emerging antibiotic resistance around the world and the intense need for new antibiotics to combat these emerging "superbugs". Over the last two decades, most large pharmaceutical companies have abandoned antibiotic R&D because of the low return on investment and the difficult regulatory landscape for approval of new antibiotics. Is it possible for the SEC, as a US government agency, to provide assistance in the spirit of the GAIN Act to companies like ADLS who enter the public market in order to raise the sums of money necessary to fund advanced clinical trials, but who are subject to significant uncertainties regarding the success of their drug development programs given changes in the regulatory and commercial areas that can cause major setbacks in company progress? This assistance would be much appreciated during the ADLS rebuilding process and can allow the Company the opportunity to assemble the resources necessary to achieve compliance with the SEC and continue its mission to bring new antibiotics to patients.

That is why we have filed this petition for review. We hope that the SEC can visualize the big picture and help companies that are uniquely qualified to pursue programs of National interest (such as the GAIN Act) regain compliance and enable their discovery and development programs to get back on track. We greatly appreciate the consideration of the SEC in these matters and in our particular case.