UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

ADMINISTRATIVE PROCEEDING
File No. 3-17293

In the Matter of

Advanced Life Sciences Holdings, Inc.,

Respondent.

DECLARATION OF DAVID S. FRYE IN SUPPORT OF DIVISION OF ENFORCEMENT'S MOTION FOR SUMMARY DISPOSITION

DAVID S. FRYE, pursuant to 28 U.S.C. § 1746, declares:

1. I am a Senior Counsel with the Division of Enforcement ("Division") of the Securities and Exchange Commission ("Commission"), and co-counsel for the Division in the captioned administrative proceeding. I submit this Declaration in support of the Division's Brief in Opposition to Advanced Life Sciences Holdings, Inc.'s ("ADLS's") Petition for Review of the Initial Decision in this matter ("Brief").

2. Attached hereto as Exhibit 1 is a true copy of the cover page from a Form 8-A12G for ADLS filed with the Commission on July 15, 2005.[1]

3. Attached hereto as Exhibit 2 is a true copy of a printout from the CLEAR online, subscription based, data retrieval service showing ADLS's corporate status and history with the Delaware Secretary of State as of the morning of January 19, 2017. The

[1] In order to reduce the volume of paper submitted with these pleadings, the Division has provided excerpts of certain of ADLS's EDGAR filings. The full version of each of these documents may be downloaded without charge from the Commission's public EDGAR website at http://www.sec.gov/edgar/searchedgar/companysearch.html. The Division will provide full copies of any of these filings to the Commission or the respondent on request.

CLEAR system provides real-time access to the Delaware Secretary of State corporate records.

4. Based on information obtained from Michael T. Corrao, the Chief Compliance Officer of OTC Link, L.L.C., a subsidiary of OTC Markets Group, Inc. as of June 14, 2016, the common stock of ADLS was quoted on OTC Link and was eligible for the "piggyback" exception of Exchange Act Rule 15c2-11(f)(3). Attached hereto as Exhibit 3 is a true copy of a printout from showing the identity of the market makers for ADLS's common stock as of June 8, 2016.

5. Attached hereto as Exhibit 4 is a true copy of a list of all filings made by ADLS (CIK No. 1018336) in the Commission's EDGAR database through the morning of January 19, 2017. The list has been reformatted for ease of reference. Periodic filings and periodic filing amendments are presented in bold italics for easy identification. The list is in reverse chronological order by filing date. The first column indicates the form type. The second column indicates the Commission file number. The third column indicates the filing date. The fourth column indicates the period end to which the filing relates (if any). The fifth column provides the unique document control number for the filing.

6. Attached hereto as Exhibit 5 is a table prepared by the Division of Enforcement setting forth certain information concerning the required periodic reports ADLS failed to file. The first column shows the type of periodic report in question. The second column gives the period end to which the report relates. The third column gives the due date of the report. The filings are sorted in reverse chronological order. The fourth column gives the date on which the report was actually made or indicates it was

not filed. The fifth column shows the number of months and days by which a filing was made late or, if not filed, is still delinquent, or indicates that the report was timely filed. Note that the fifth column is calculated as of January 18, 2017. The sixth column states whether or not a Form 12b-25 was filed for the report in in question.

7. Attached hereto as Exhibit 6 are true copies of a letter dated July 27, 2016 from ADLS and a "comprehensive" Form 10-K for ADLS, both of which were sent to the Division of Corporation Finance.

8. Attached hereto as Exhibit 7 is a true copy of an email, dated June 28, 2016, from Michael Flavin to David Frye transmitting a copy of ADLS's answer in this proceeding.

9. Attached hereto as Exhibit 8 is a true copy of the transcript of the telephonic prehearing conference in this proceeding, held on July 20, 2016.

10. Attached hereto as Exhibit 9 is a true copy of an email, dated August 31, 2016, from Michael Flavin to David Frye transmitting a copy of ADLS's opposition brief before the Administrative Law Judge.

11. Attached hereto as Exhibit 10 is a true copy of an email, dated November 23, 2016, from the Office of the Secretary to David S. Frye transmitting a copy of the Commission's Order Granting Petition for Review in this proceeding. Before receiving this email, the Division was not aware that ADLS had filed a Petition for Review in this proceeding.

12. Attached hereto as Exhibit 11 is a true copy of an email dated November 23, 2016, from Kathy Shields, an employee of the Office of Administrative Law Judges, transmitting a copy of ADLS's Petition for Review. Before receiving this email, the

Division had never seen, nor, to our knowledge, was ever served with, a copy of the Petition for Review.

13. ADLS's brief in support of its petition for review was due on December 22, 2016. Having failed to receive a copy of this document, on December 23, 2016, the Division called the Office of the Secretary to determine whether or not ADLS had filed such a brief and was advised that it had done so. Attached hereto as Exhibit 12 is a true copy of an email, dated December 23, 2016, from Melissa Kimps, an employee of the Office of the Secretary, attaching a copy of ADLS's Brief in Support of its Petition for Review. The Division was never served with a copy of this document.

I declare under penalty of perjury that the foregoing is true and correct.

Executed: January 19, 2017.

David S. Frye

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-A

FOR REGISTRATION OF CERTAIN CLASSES OF SECURITIES PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

ADVANCED LIFE SCIENCES HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware (State of incorporation or organization)	[redacted] (I.R.S. Employer Identification No.)
1440 Davey Road **Woodridge, Illinois** (Address of principal executive offices)	**60517** (Zip Code)

Securities to be registered pursuant to Section 12(b) of the Act:

Title of each class to be so registered	Name of each exchange on which each class is to be registered
None	N/A

If this form relates to the registration of a class of securities pursuant to Section 12(b) of the Exchange Act and is effective pursuant to General Instruction A.(c), check the following box. ☐

If this form relates to the registration of a class of securities pursuant to Section 12(g) of the Exchange Act and is effective pursuant to General Instruction A.(d), check the following box. ☒

Securities Act registration statement file number to which this form relates: **333-124396**

Securities to be registered pursuant to Section 12(g) of the Act:

Common Stock, par value $0.01 per share
(Title of Class)

Report Section Summary

General Information

Name:	ADVANCED LIFE SCIENCES HOLDINGS, INC.
Date:	01-19-2017
Time:	09:04:44 AM
Address:	
County:	
Country:	
File Number:	3894627
Company Stock:	true
Kind of Corporation:	Corporation
Type of Corporation:	General
Status:	Void, ARâs or Tax Delinquent
Status Date & Time:	03-01-2015
Residency:	
Incorporation State:	DE
Incorporation Date & Time:	12-10-2004
Renewal Date & Time:	
Merged to Number:	
Foreign Incorporation Name:	
Type of Foreign Corporation:	
Expiration Date:	
Foreign Date of Incorporation:	
Original State:	
Quarterly Filing:	
Date of Last Annual Report:	

Tax Information

Tax Type:	A/R Filing Required
Tax Balance:	258727.22

Tax Year:	2014
Filing Fee:	50
Total Taxes:	180000
Total Penalty:	125
Total Interest:	5033.07
Total Other:	0
Total Paid:	0
Total Unpaid Balance:	185208.07

Tax Year:	2013
Filing Fee:	50
Total Taxes:	62136.99
Total Penalty:	125
Total Interest:	11207.16
Total Other:	0
Total Paid:	0
Total Unpaid Balance:	73519.15

Tax Year:	2012
Filing Fee:	50
Total Taxes:	350
Total Penalty:	125
Total Interest:	0
Total Other:	0
Total Paid:	525
Total Unpaid Balance:	0

File History Information

Filing Year:	2013
Document Code Description:	Renewal for Void
Number of pages in Document:	1
Number of Domestication Pages:	0
Document Filing Date & Time:	08-28-2013 07:33:00 PM
Document Effective Date & Time:	08-28-2013
Document Filing Status:	Completed
Name Prior to Merger:	
Merger Type:	

Filing Year:	2011
Document Code Description:	Amendment Stock
Number of pages in Document:	3
Number of Domestication Pages:	0
Document Filing Date & Time:	03-23-2011 05:03:00 PM
Document Effective Date & Time:	03-28-2011
Document Filing Status:	Completed
Name Prior to Merger:	
Merger Type:	

Filing Year:	2010
Document Code Description:	Restated; Stock
Number of pages in Document:	5
Number of Domestication Pages:	0
Document Filing Date & Time:	05-07-2010 06:50:00 PM

Document Effective Date & Time:	05-07-2010
Document Filing Status:	Completed
Name Prior to Merger:	
Merger Type:	

Filing Year:	2009
Document Code Description:	Restated; Stock
Number of pages in Document:	5
Number of Domestication Pages:	0
Document Filing Date & Time:	04-07-2009 06:14:00 PM
Document Effective Date & Time:	04-07-2009
Document Filing Status:	Completed
Name Prior to Merger:	
Merger Type:	

Filing Year:	2005
Document Code Description:	Restated; Stock
Number of pages in Document:	6
Number of Domestication Pages:	0
Document Filing Date & Time:	06-29-2005 09:54:00 PM
Document Effective Date & Time:	06-29-2005
Document Filing Status:	Completed
Name Prior to Merger:	
Merger Type:	

Stock Information

Stock Amendment Number:	4
Effective Date & Time:	03-28-2011
Total Authorized Shares:	25666666
No Par Shares:	0

Description:	COMMON
Class:	
Series:	
Number of Authorized Shares:	20666666
Designated Shares:	0
Par Value:	0.01

Description:	PFD
Class:	
Series:	
Number of Authorized Shares:	5000000
Designated Shares:	0
Par Value:	0.01

Registered Agent Information

Agent's Name:	THE CORPORATION TRUST COMPANY
Agent's Number:	9000010
Agent's County:	New Castle
Agent's Country:	US
Address:	CORPORATION TRUST CENTER 1209 ORANGE ST WILMINGTON, DE 19801
Phone:	
Fax:	

Report section(s) with no matches

Merger Information, Possible Bankruptcies

OTC Dealer

MMID: 1SEC UserID: DFRYE Name: David Frye
Phone1: 202 551 5455 Phone2: Fax: Email: fryed@sec.gov

Security Search

Issue or symbol *

advanced search >>

- Today's Notices
- Pending Corporate Actions
- MMID Directory
- Quote History
- Quote & Inside History
- Market Maker Security List
- Market Maker Security Activity
- Trader Open/Close History
- OTC Link/BB Quote Divergence
- Trade History
- OTC Link History
- Security Information
- Security Changes
- Security Search
-
- Help

OTC Markets Group Inc.® Quote & Inside History

Security Quote History from 06/08/2016 to 06/08/2016

Export to excel Back to search page

ADLS -- Advanced Life Sciences Holdings, Inc.

CUSIP: 00765H305 OTC ID:131889 Security Type:CS

Exclude: None

Action Date	Last Updated Date	Action	Price	Update: MMID	Update: User	Reason for Inside
06/08/2016	**ADLS**					
06/08/2016	06/07/2016 07:50:00.816	Start	U / U(0 x 0)	cETRF		
06/08/2016	06/07/2016 08:26:44.073	Start	0.00010 / 8.00000 (10000 x 100)	cMAXM		
06/08/2016	06/07/2016 08:30:10.125	Start	0.00010 / 0.06000 (10000 x 10000)	cCANT		

06/08/2016	06/07/2016 16:00:01.200	Start	U / U(0 x 0)	cCDEL	
06/08/2016	06/07/2016 16:00:01.296	Start	0.00450 / 0.00690 (10000 x 10000)	cNITE	
06/08/2016	06/07/2016 16:30:04.096	Start	0.00010 / 0.25700 (10000 x 2500)	cCSTI	
	06/08/2016 06:46:01.343	Update	U / U(0 x 0)	cCDEL	
	06/08/2016 07:11:44.857	Inside	0.00010 / 8.00000 (10000 x 100)		Open
	06/08/2016 07:11:44.857	Open		MAXM	
	06/08/2016 07:34:32.299	Inside	0.00010 / 0.25700 (20000 x 2500)		Open
	06/08/2016 07:34:32.299	Open		CSTI	
	06/08/2016 07:50:00.878	Update	U / U(0 x 0)	cETRF	
	06/08/2016 07:59:58.665	Inside	0.00450 / 0.00690 (10000 x 10000)		Open
	06/08/2016 07:59:58.665	Open		NITE	
	06/08/2016 08:30:06.847	Update	0.00010 / 0.25700 (10000 x 2500)	CSTI	
	06/08/2016 08:30:11.362	Update	0.00010 / 0.06000 (10000 x 10000)	CANT	
	06/08/2016 09:30:01.206	Update	0.00160 / 0.00880 (134200 x 22600)	CDEL	
	06/08/2016 09:30:14.524	Update	0.00250 / 0.25700 (15000 x 2500)	CSTI	
	06/08/2016 09:31:21.490	Update	0.00600 / 0.00690 (100000 x 10000)	NITE	
	06/08/2016 09:31:21.490	Inside	0.00600 / 0.00690 (100000 x 10000)		Update

No of Records: 20

For Security Quote History, please enter a symbol, Security ID or CUSIP. You may filter quote information by date range or quote type.

Security: adls

Date:(mm/dd/yyyy) ◉ From 06/08/2016 To 06/08/2016

quote: ☑ inside ☑

GO

EXCEL

☐ Start of day ○ First Day of Activity

☐ Updates ○ Last Day of Activity
☐ Inserts
☐ Deletes

* Data for quote activity is provided only from start of electronics OTC Link service 15th Sept 1999

Advanced Life Sciences Holdings, Inc.
CIK No. 1322734
EDGAR filings (through January 18, 2017)

Form Type	File No	Filing Date	Period End	DCN
8-K	0-51436	5/12/2011	5/5/2011	11836494
8-K	0-51436	5/3/2011	4/29/2011	11806229
8-K	0-51436	4/22/2011	4/18/2011	11775860
424B1	33-171748	4/22/2011		11774585
EFFECT	33-171748	4/20/2011		11771853
DEF 14A	0-51436	4/13/2011	5/24/2011	11757602
8-K	0-51436	4/8/2011	4/4/2011	11750175
POS AM	33-171748	4/8/2011		11747572
PRER14A	0-51436	4/7/2011		11746151
PRE 14A	0-51436	4/4/2011	5/24/2011	11736652
10-K*	***0-51436***	***3/24/2011***	***12/31/2010***	***11709042***
8-K	0-51436	3/24/2011	3/24/2011	11707854
8-K	0-51436	3/17/2011	3/11/2011	11695598
424B3	33-171748	3/2/2011		11657135
8-K	0-51436	3/2/2011	2/21/2011	11657120
8-K	0-51436	2/23/2011	2/17/2011	11632739
424B1	33-171748	1/31/2011		11557722
EFFECT	33-171748	1/28/2011		11557444
8-K	0-51436	1/21/2011	1/18/2011	11541937
S-1	33-171748	1/18/2011		11533677
8-K	0-51436	1/14/2011	1/10/2011	11530642
8-K	0-51436	1/4/2011	1/4/2011	11507431
8-K	0-51436	12/29/2010	12/22/2010	101279076
8-K	0-51436	12/8/2010	12/3/2010	101240389
8-K	0-51436	11/30/2010	11/23/2010	101222419
424B3	33-169622	11/16/2010		101196614
10-Q	***0-51436***	***11/12/2010***	***9/30/2010***	***101187977***
8-K	0-51436	11/12/2010	11/12/2010	101183039
8-K	0-51436	11/3/2010	10/28/2010	101160019
EFFECT	33-169622	10/18/2010		101129074
8-K	0-51436	9/29/2010	9/28/2010	101094945
S-1	33-169622	9/29/2010		101094917
8-K	0-51436	9/15/2010	9/9/2010	101074317

* Periodic reports and amendments are in bold and italics for ease of reference.
Note that this does not include the purported consolidated
Form 10-K sent to the staff of Corporation Finance, but not filed in EDGAR.

Advanced Life Sciences Holdings, Inc.
CIK No. 1322734
EDGAR filings (through January 18, 2017)

Form Type	File No	Filing Date	Period End	DCN
424B3	33-165388	8/12/2010		101010598
10-Q	***0-51436***	***8/11/2010***	***6/30/2010***	***101006608***
SC 13D	5-81504	7/30/2010		10981910
424B3	33-165388	7/27/2010		10972324
8-K	0-51436	7/22/2010	7/22/2010	10965127
8-K	0-51436	7/8/2010	7/7/2010	10942843
424B4	33-165388	7/1/2010		10928673
EFFECT	33-165388	6/30/2010		10928690
8-K	0-51436	6/18/2010	6/15/2010	10904314
S-1/A	33-165388	6/16/2010		10901337
S-1/A	33-165388	6/2/2010		10871385
S-1/A	33-165388	5/28/2010		10867341
S-1/A	33-165388	5/10/2010		10816518
10-Q	***0-51436***	***5/10/2010***	***3/31/2010***	***10816382***
8-K	0-51436	5/10/2010	5/6/2010	10814331
8-K	0-51436	4/13/2010	4/8/2010	10747671
DEFA14A	0-51436	4/1/2010		10724433
8-K	0-51436	3/11/2010	3/10/2010	10672448
EFFECT	33-158494	3/10/2010		10672233
S-1	33-165388	3/10/2010		10671449
POS AM	33-158494	3/10/2010		10671271
10-K	***0-51436***	***3/10/2010***	***12/31/2009***	***10671187***
DEF 14A	0-51436	3/10/2010	4/8/2010	10671115
SC 13G	5-81504	3/9/2010		10666518
424B2	33-158494	3/5/2010		10660841
424B2	33-158494	2/26/2010		10639927
424B2	33-158494	2/19/2010		10619984
SC 13G/A	5-81504	2/16/2010		10605703
424B2	33-158494	2/10/2010		10588080
8-K	0-51436	2/10/2010	2/9/2010	10586166
DEFA14A	0-51436	2/10/2010		10586163
PRE 14A	0-51436	2/9/2010	4/8/2010	10584929
424B2	33-158494	2/3/2010		10571165
424B2	33-158494	1/21/2010		10539081
8-K	0-51436	1/4/2010	1/4/2010	10502990
424B2	33-158494	12/24/2009		091259187
424B2	33-158494	12/9/2009		091231216
424B2	33-158494	11/25/2009		091208779
424B2	33-158494	11/12/2009		091177442
10-Q	***0-51436***	***11/10/2009***	***9/30/2009***	***091172150***

Advanced Life Sciences Holdings, Inc.
CIK No. 1322734
EDGAR filings (through January 18, 2017)

Form Type	File No	Filing Date	Period End	DCN
8-K	0-51436	11/10/2009	11/10/2009	091170505
8-K	0-51436	11/2/2009	10/29/2009	091149536
424B2	33-158494	10/29/2009		091144934
424B2	33-158494	10/14/2009		091119424
8-K	0-51436	10/6/2009	9/30/2009	091108267
424B2	33-158494	9/24/2009		091085188
424B2	33-158494	9/16/2009		091072311
424B2	33-158494	9/3/2009		091053956
8-K	0-51436	8/28/2009	8/24/2009	091043950
25-NSE	0-51436	8/20/2009		
424B2	33-158494	8/19/2009		091024255
424B2	33-158494	8/12/2009		091006929
10-Q	***0-51436***	***8/11/2009***	***6/30/2009***	***091003924***
8-K	0-51436	8/11/2009	8/11/2009	091002268
424B2	33-158494	8/3/2009		09980742
8-K	0-51436	7/31/2009	7/31/2009	09977849
424B2	33-158494	7/24/2009		09962633
424B2	33-158494	7/17/2009		09951080
424B2	33-158494	7/9/2009		09937379
424B2	33-158494	7/1/2009		09921666
EFFECT	33-154579	6/22/2009		09904455
8-K	0-51436	6/19/2009	6/19/2009	09902054
424B2	33-158494	6/19/2009		09902044
POS AM	33-154579	6/19/2009		09902030
RW	33-159549	6/19/2009		09902019
8-K	0-51436	6/8/2009	6/2/2009	09880297
S-1	33-159549	5/28/2009		09857869
424B3	33-154579	5/12/2009		09819730
10-Q	***0-51436***	***5/12/2009***	***3/31/2009***	***09819312***
8-K	0-51436	5/12/2009	5/12/2009	09819203
8-K	0-51436	5/4/2009	4/28/2009	09794505
EFFECT	33-158494	4/15/2009		09752567
8-K	0-51436	4/10/2009	4/6/2009	09745299
S-3	33-158494	4/8/2009		09740265
8-K	0-51436	3/30/2009	3/27/2009	09714786
SC 13D/A	5-81504	3/16/2009		09685498
424B2	33-154579	3/3/2009		09649113
EFFECT	33-154579	3/2/2009		09649604
POS AM	33-154579	2/27/2009		09643351
8-K	0-51436	2/27/2009	2/23/2009	09639921

Advanced Life Sciences Holdings, Inc.
CIK No. 1322734
EDGAR filings (through January 18, 2017)

Form Type	File No	Filing Date	Period End	DCN
DEF 14A	0-51436	2/25/2009	4/1/2009	09634243
PRER14A	0-51436	2/24/2009		09629457
DFAN14A	0-51436	2/23/2009		09626151
SC 13D	5-81504	2/20/2009		09626148
SC 13G/A	5-81504	2/17/2009		09607115
POS AM	33-154579	2/13/2009		09603287
8-K/A	0-51436	2/12/2009	2/11/2009	09596211
10-K	***0-51436***	***2/12/2009***	***12/31/2008***	***09594252***
8-K	0-51436	2/11/2009	2/5/2009	09587824
PRE 14A	0-51436	2/6/2009	4/1/2009	09578228
8-K	0-51436	1/9/2009	1/5/2009	09517025
EFFECT	33-154579	12/3/2008		081231001
8-K	0-51436	12/3/2008	12/3/2008	081227017
AW	33-154579	12/3/2008		081226185
S-1/A	33-154579	12/3/2008		081226190
CT ORDER	0-51436	12/2/2008		081224081
S-3/A	33-154579	11/26/2008		081218917
S-3/A	33-154579	11/19/2008		081201540
10-Q	***0-51436***	***11/6/2008***	***9/30/2008***	***081167474***
8-K	0-51436	11/6/2008	11/6/2008	081165564
8-K	0-51436	10/29/2008	10/23/2008	081148246
S-3	33-154579	10/21/2008		081133726
8-K	0-51436	10/3/2008	9/29/2008	081107457
8-K	0-51436	9/24/2008	9/24/2008	081086669
10-Q	***0-51436***	***8/14/2008***	***6/30/2008***	***081017497***
8-K	0-51436	8/14/2008	8/14/2008	081015619
10-Q	***0-51436***	***5/7/2008***	***3/31/2008***	***08808853***
8-K	0-51436	5/7/2008	5/7/2008	08808313
8-K	0-51436	4/18/2008	4/14/2008	08765304
10-K/A	***0-51436***	***4/3/2008***	***12/31/2007***	***08737445***
DEF 14A	0-51436	3/28/2008	5/1/2008	08719825
8-K	0-51436	3/7/2008	3/4/2008	08674588
10-K	***0-51436***	***2/19/2008***	***12/31/2007***	***08625761***
8-K	0-51436	2/19/2008	2/19/2008	08624783
SC 13G/A	5-81504	2/14/2008		08608971
8-K	0-51436	2/5/2008	1/31/2008	08577631
424B3	33-148483	1/18/2008		08538822
EFFECT	33-148483	1/17/2008		08537411
S-3	33-148483	1/4/2008		08512810
8-K	0-51436	12/26/2007	12/21/2007	071326683

Advanced Life Sciences Holdings, Inc.
CIK No. 1322734
EDGAR filings (through January 18, 2017)

Form Type	File No	Filing Date	Period End	DCN
REGDEX	021-87632	12/18/2007		07086433
8-K	0-51436	12/14/2007	12/13/2007	071307837
8-K	0-51436	12/12/2007	12/10/2007	071302215
8-K	0-51436	11/15/2007	11/15/2007	071247703
10-Q	***0-51436***	***11/14/2007***	***9/30/2007***	***071246007***
8-K	0-51436	11/6/2007	11/6/2007	071216788
8-K	0-51436	9/26/2007	9/26/2007	071136128
8-K	0-51436	9/14/2007	9/12/2007	071118539
8-K	0-51436	8/17/2007	8/13/2007	071065577
10-Q	***0-51436***	***8/9/2007***	***6/30/2007***	***071038835***
8-K	0-51436	8/9/2007	8/8/2007	071037846
8-K	0-51436	7/3/2007	7/2/2007	07957784
8-K	0-51436	6/25/2007	6/21/2007	07939381
10-K/A	***0-51436***	***5/9/2007***	***12/31/2006***	***07832814***
10-Q	***0-51436***	***5/9/2007***	***3/31/2007***	***07832803***
8-K	0-51436	5/9/2007	5/8/2007	07830241
DEF 14A	0-51436	3/30/2007	5/3/2007	07732778
10-K	***0-51436***	***3/22/2007***	***12/31/2006***	***07712079***
8-K	0-51436	3/22/2007	3/20/2007	07710564
SC 13G/A	5-81504	2/13/2007		07605981
SC 13G/A	5-81504	2/12/2007		07602700
SC 13G/A	5-81504	2/2/2007		07575996
8-K	0-51436	12/21/2006	12/20/2006	061293643
8-K	0-51436	12/11/2006	12/8/2006	061267343
8-K	0-51436	11/28/2006	11/28/2006	061240749
10-Q	***0-51436***	***11/8/2006***	***9/30/2006***	***061198098***
8-K	0-51436	11/8/2006	11/7/2006	061195159
8-K	0-51436	11/2/2006	10/27/2006	061183765
SC 13G/A	5-81504	10/24/2006		061160736
SC 13G	5-81504	10/24/2006		061160697
424B3	33-132900	8/23/2006		061050363
EFFECT	33-132900	8/22/2006		061049781
POS AM	33-132900	8/15/2006		061035399
10-Q	***0-51436***	***8/14/2006***	***6/30/2006***	***061030842***
8-K	0-51436	8/9/2006	8/9/2006	061015314
424B3	33-132900	5/23/2006		06861811
10-Q	***0-51436***	***5/11/2006***	***3/31/2006***	***06829166***
8-K	0-51436	5/10/2006	5/9/2006	06823430
424B3	33-132900	4/20/2006		06770238
S-1/A	33-132900	4/20/2006		06769605

Advanced Life Sciences Holdings, Inc.
CIK No. 1322734
EDGAR filings (through January 18, 2017)

Form Type	File No	Filing Date	Period End	DCN
8-K	0-51436	4/20/2006	4/18/2006	06769554
SC 13G/A	5-81504	4/10/2006		06750310
S-1	33-132900	3/31/2006		06729438
DEF 14A	0-51436	3/30/2006	5/2/2006	06721169
REGDEX	021-87632	3/20/2006		06028992
8-K	0-51436	3/16/2006	3/14/2006	06692096
10-K	***0-51436***	***3/15/2006***	***12/31/2005***	***06688717***
SC 13G	5-81504	3/13/2006		06680607
8-K	0-51436	3/9/2006	3/3/2006	06676029
8-K	0-51436	3/2/2006	2/24/2006	06661043
SC 13G	5-81504	2/14/2006		06612696
SC 13G	5-81504	2/14/2006		06611002
SC 13G	5-81504	2/13/2006		06604357
8-K	0-51436	1/6/2006	1/6/2006	06517317
8-K	0-51436	11/23/2005	11/18/2005	051225206
8-K/A	0-51436	11/14/2005	11/7/2005	051195599
10-Q	***0-51436***	***11/10/2005***	***9/30/2005***	***051195219***
8-K	0-51436	11/10/2005	11/7/2005	051194628
S-8	33-128094	9/2/2005		051068540
8-K	0-51436	9/1/2005	8/29/2005	051063872
8-K	0-51436	8/12/2005	8/10/2005	051022117
424B4	33-124396	8/5/2005		051003207
POS AM	33-124396	8/4/2005		05997394
POS AM	33-124396	8/2/2005		05990776
S-1/A	33-124396	7/28/2005		05982105
S-1/A	33-124396	7/28/2005		05978942
S-1/A	33-124396	7/22/2005		05968402
8-A12G	0-51436	7/15/2005		05956086
S-1/A	33-124396	7/1/2005		05930170
S-1/A	33-124396	6/28/2005		05919468
S-1/A	33-124396	6/3/2005		05878477
S-1	33-124396	4/28/2005		05778207

Advanced Life Sciences Holdings, Inc.
Schedule of Required Periodic Reports for the periods from
March 31, 2011 through September 30, 2016
and filing history, as of January 18, 2017

Form Type	Period End	Due date	Filed?*	Months/Days late**	12b-25?
10-Q	3/31/2011	5/16/2011	Not filed	68 months, 2 days	Not filed
10-Q	6/30/2011	8/15/2011	Not filed	65 months, 3 days	Not filed
10-Q	9/30/2011	11/14/2011	Not filed	62 months, 4 days	Not filed
10-K	12/31/2011	3/30/2012	Not filed	57 months, 19 days	Not filed
10-Q	3/31/2012	5/15/2012	Not filed	56 months, 3 days	Not filed
10-Q	6/30/2012	8/14/2012	Not filed	53 months, 4 days	Not filed
10-Q	9/30/2012	11/14/2012	Not filed	50 months, 4 days	Not filed
10-K	12/31/2012	4/1/2013	Not filed	45 months, 17 days	Not filed
10-Q	3/31/2013	5/15/2013	Not filed	44 months, 3 days	Not filed
10-Q	6/30/2013	8/14/2013	Not filed	41 months, 4 days	Not filed
10-Q	9/30/2013	11/14/2013	Not filed	38 months, 4 days	Not filed
10-K	12/31/2013	3/31/2014	Not filed	33 months, 18 days	Not filed
10-Q	3/31/2014	5/15/2014	Not filed	31 months, 3 days	Not filed
10-Q	6/30/2014	8/14/2014	Not filed	29 months, 4 days	Not filed
10-Q	9/30/2014	11/14/2014	Not filed	26 months, 4 days	Not filed
10-K	12/31/2014	3/31/2015	Not filed	21 months, 18 days	Not filed
10-Q	3/31/2015	5/15/2015	Not filed	20 months, 3 days	Not filed
10-Q	6/30/2015	8/14/2015	Not filed	17 months, 4 days	Not filed
10-Q	9/30/2015	11/14/2015	Not filed	14 months, 4 days	Not filed
10-K	12/31/2015	3/30/2016	Not filed	9 months, 19 days	Not filed
10-Q	3/31/2016	5/14/2016	Not filed	8 months, 4 days	Not filed
10-Q***	6/30/2016	8/14/2016	Not filed	5 months, 4 days	Not filed
10-Q***	9/30/2016	11/14/2016	Not filed	2 months, 4 days	Not filed

* This does not include a document sent to Corporation Finance by ADLS purporting to be a comprehensive Form 10-K. This form was not actually filed in EDGAR and does not comply with the Commission's rules for such a filing.

**The degree of delinquency is calculated as of January 18, 2017

*** The last two filings became due since this proceeding was instituted.

ADVANCED LIFE SCIENCES

Advancing Discoveries For Health

July 27, 2016

Suzanne Hayes
Assistant Director
Division of Corporate Finance
United States Securities and Exchange Commission
100 F Street NE
Washington, D.C. 20549

Dear Ms. Hayes:

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, especially those caused by pathogenic bacteria that are resistant to other antibiotics.

In late 2008, we completed our Phase 3 clinical trials of cethromycin against pneumonia and, in 2009, we submitted our New Drug Application to the FDA for their review. Later that year, the FDA convened an advisory committee meeting 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 10K document for 2010. We were just about ready to file our 10Q 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

1440 Davey Road Woodridge, Illinois 60517 Tel (630) 739-3215 Fax: (630) 739-1753

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 10K 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.

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

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 allow us to file the comprehensive 10K document we have prepared and submitted in this package. It is a document that would bring 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.

Sincerely,

Michael T. Flavin, Ph.D.
Chief Executive Officer
(630) 991-3013
mflavin@flavinventures.com

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal years 2011 through 2015

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File No.: 000-51436

ADVANCED LIFE SCIENCES HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	30-0296543
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1440 Davey Road
Woodridge, IL 60517
(Address of principal executive offices) (Zip code)

Registrant's telephone number, including area code: (630) 739-8215

Securities registered pursuant to Section 12(b) of the Act: None.

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value $0.01 per share

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. ☐ Yes ☒ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☐ Yes ☒ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ☐ Yes ☒ No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of

the Exchange Act. (Check one):

Large accelerated filer ☐	Accelerated filer ☐	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). ☐ Yes ☒ No

The aggregate market value of common stock held by non-affiliates of the registrant as of December 31, 2015 was approximately $350,000, based upon the closing price of the registrant's common stock of $0.02 per common share as quoted on the OTC Bulletin Board on such date, the last trading day of the registrant's recently completed second fiscal quarter. For purposes of this calculation only, all directors and executive officers of the registrant and owners of more than 10% of the registrant's common stock are assumed to be affiliates of the registrant. This determination of affiliate status is not necessarily conclusive for any other purpose.

Total common stock outstanding as of December 31, 2015 was 17,586,830 shares.

Documents Incorporated By Reference: None.

ADVANCED LIFE SCIENCES HOLDINGS, INC.

FORM 10-K

Table of Contents

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Statements in this Annual Report on Form 10-K and in documents incorporated by reference herein (or otherwise made by us or on our behalf) may contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. In addition, we may make other written and oral communications from time to time that contain such statements. Forward-looking statements include statements as to industry trends, our future expectations and other matters that do not relate strictly to historical facts and are based on certain assumptions of our management. These statements, which express management's current views concerning future events or results, use words like "anticipate," "assume," "believe," "continue," "estimate," "expect," "future," "intend," "plan," "project," "strive," and future or conditional tense verbs like "could," "may," "might," "should," "will," "would" and similar expressions. Forward-looking statements are subject to risks, uncertainties and other factors which may cause actual results to differ materially from future results expressed or implied by such forward looking statements. Important factors that could cause actual results to differ materially from the forward looking statements include, without limitation, those described in Item 1A. "Risk Factors" of this report. Moreover, such forward-looking statements speak only as of the date of this report. We undertake no obligation to update any forward looking statements to reflect events or circumstances after the date of such statements.

In this report, the "Company," "we", "our" and "us" refer to Advanced Life Sciences Holdings, Inc. and its subsidiary, Advanced Life Sciences, Inc., included in the consolidated financial statements, except as otherwise indicated or as the context otherwise requires.

PART I

Item 1. Business

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of novel drugs in the area of infectious disease. Using our internal discovery capabilities and our network of pharmaceutical and academic partners, we are assembling a pipeline of clinical and preclinical product candidates. The following is a summary of our current programs:

- *Infectious Disease – Respiratory Tract Infections and Gonorrhea.* We have an exclusive worldwide license (excluding Japan) from Abbvie ("Abbvie") to develop and commercialize cethromycin (Restanza™), a once-a-day antibiotic for the treatment of respiratory tract infections and gonorrhea. In December 2005, we initiated our pivotal Phase III clinical trials for the treatment of mild-to-moderate community acquired bacterial pneumonia ("CABP"), an indication for which we have been seeking Food and Drug Administration ("FDA") approval. In 2007, we successfully completed these two pivotal Phase III clinical trials. Cethromycin has been tested in approximately 5,600 human subjects in clinical trials to date. In September 2008, we submitted a New Drug Application ("NDA") with the FDA for the use of cethromycin in CABP. In July 2009, we received a complete response letter from the FDA regarding cethromycin NDA for the outpatient treatment of adults with CABP. In its letter, the FDA indicated that they could not approve the application for cethromycin in its current form and that, to gain approval, additional clinical data is required to demonstrate efficacy with defined statistical methodology. In August 2010, we reached an agreement with the FDA under the Special Protocol Assessment ("SPA") process, on the design of a Phase III study of cethromycin to treat CABP. Further discussion with the FDA has led us to focus initially on the indication of gonorrhea. Progress in this development program is subject to funds becoming available to support our activities.
- *Infectious Disease – Biodefense.* Along with our clinical work in the treatment of CABP, we collaborated with several groups within the U.S. Government to evaluate cethromycin's potential in preventing inhalation anthrax and other high-priority bioterror agents. In March 2007, the FDA designated cethromycin as an Orphan Drug for the prophylactic treatment of patients exposed to inhalation anthrax, and in May 2007, cethromycin was shown to be 100% protective against a lethal dose of inhaled anthrax in non-human primates. In August 2008, we announced that the Defense Threat Reduction Agency ("DTRA") of the U.S. Department of Defense awarded us a two-year contract worth up to $3.8 million to fund NDA-enabling studies evaluating cethromycin's efficacy in combating Category A and B bioterror agents such as *Fransicella tularensis* (tularemia), *Yersinia pestis* (plague) and *Burkholderia pseudomallei* (melioidosis). In June 2009, we announced that a second non-human primate study involving cethromycin showed that a 14-day course of cethromycin achieved a 100% survival rate against an inhaled lethal dose of anthrax. In August 2009, we announced positive results from an animal study that was conducted to measure cethromycin's therapeutic efficacy in treating inhalation anthrax after symptoms of infection had developed. In September 2009, the FDA granted Orphan Drug Designation to cethromycin for the prophylactic treatment of plague and tularemia. Also in September 2009, we announced positive top-line results from a pivotal, non-human primate study involving cethromycin demonstrating statistical significance at a 90% survival rate against an inhaled lethal dose of plague. In December 2009, we announced positive top-line results from a pivotal, non-human primate study involving cethromycin against an inhaled lethal dose of tularemia. A 14-day course of cethromycin achieved a 100% survival rate at the doses tested. We will continue to pursue the biodefense track with cethromycin to the extent to which we can secure grant and/or contract funding from U.S. Government agencies to financially support this program.

- *Oncology.* ALS-357 is a compound that has shown evidence of anti-tumor activity against malignant melanoma in preclinical studies. Currently available therapies have not had significant success at prolonging survival for patients with melanoma that has spread beyond the primary growth site. In June of 2013, we discontinued the development of ALS-357 due to its limited potential for systemic administration along with its shortened patent life.

In addition to the compounds summarized above, we are attempting to in-license additional product candidates in preclinical and clinical development utilizing our network of academic and industrial contacts. We are particularly interested in in-licensing antibiotics and anti-viral agents. We have not received FDA approval for any of our product candidates. Our revenues to date have consisted solely of management fees, one-time or limited payments associated with our collaborations and government grant and contract awards. We do not anticipate generating any revenue from the sale of cethromycin or any other product candidates in the near term.

At present, our liabilities are significantly greater than our assets. As a result of our current financial situation and the uncertainty in our ability to obtain needed financing through equity offerings, commercial partnerships, grant awards, service offerings or other means, there is substantial doubt about our ability to continue as a going concern.

Company History and Recent Developments

In June 1999, MediChem Life Sciences ("MediChem"), our former parent, exchanged its investment in 100% of the outstanding common stock of Advanced Life Sciences, Inc. ("ALS Inc.") for nonvoting preferred stock issued by ALS Inc. affecting a spin-off of ALS Inc. Prior to the spin-off, Dr. Michael Flavin, the sole stockholder, owned 100% of MediChem and ALS Inc., then a wholly-owned subsidiary of MediChem. As a result of the spin-off, Dr. Flavin became the sole common stockholder of ALS Inc. MediChem holds 100% of the preferred stock of our subsidiary, ALS Inc., which was issued in exchange for common stock held at the June 1999 spin-off. In 2004, Advanced Life Sciences Holdings, Inc. ("ADLS") was created as part of a recapitalization, and ALS, Inc. became a subsidiary of ADLS. ADLS was incorporated in the State of Delaware on December 10, 2004.

On February 25, 2011, we announced that our Chief Executive Officer informed the Company's employees that, as a measure to help address its liquidity issues, it had implemented a company-wide compensation reduction plan that would reduce salaries of impacted employees by 30%-50%. Included in this reduction were all of our officers with whom we had entered into employment agreements. In connection with this cost-savings plan, we also announced the departure of Dr. David Eizmhamer, Executive Vice President of Clinical Affairs.

On May 5, 2011, the Company suspended all operations and terminated its entire staff due to its severe lack of liquidity.

Over the ensuing three years, there were no company operations and only a few minor transactions. There were, however, numerous discussions with Leaders Bank regarding their outstanding loan with the Company. The Bank took two actions, one of which was to take possession of the building which housed the Company under a lease agreement and which was owned by Flavin Ventures and that had been used as collateral in the loan transaction. The other action taken by Leaders Bank was to file a lawsuit in May, 2012 against Michael Flavin in connection with the personal guarantee that had been established during a renegotiation of the loan terms. After a nine month negotiation period, a settlement agreement was reached on May 23, 2013 under the following terms:

(1) Michael Flavin paid Leaders Bank $300,000 in full settlement and release of the personal guarantee dated September 9, 2010 in connection with the loan between the Company and Leaders Bank and the lawsuit was dismissed.

(2) The loan from Leaders Bank would be repaid up to a maximum of $4,000,000 as a result of a monetizing event, such as the sale of the Company or the sale of assets within the Company. If a monetizing event nets less than $4,000,000, then a tiered payment system would be operative and the proceeds would be divided between Leaders Bank and the Company according to this system. A monetizing event does not include any capital raise designed to advance an R&D program or product within the Company.

Since the May 23, 2013 settlement agreement with Leaders Bank, there have been no material transactions through the present day for the Company.

Our Strategy

Our strategy is to discover and develop therapeutics to treat life-threatening diseases with particular focus in the area of infectious disease.m We plan to sustain our drug development pipeline through our internal drug discovery capabilities and by opportunistically in-licensing promising compounds and technologies that fit into our areas of focus. Specific key aspects of our strategy include the following:

Maximize the Commercial Potential of Cethromycin in Gonorrhea

We currently intend to focus a portion of our business efforts on the regulatory approval and commercialization of cethromycin in gonorrhea. Upon FDA approval, we believe that, along with a strategic partner, we will be able to successfully commercialize cethromycin for the treatment of infectious disease. We are concentrating our efforts on the development of cethromycin for the treatment of gonorrhea. This sexually transmitted disease has become a major global public health challenge given the emergence of drug resistant strains of *Neisseria gonorrhoeae* worldwide. We will continue this initiative as funds become available to support this development program.

Advance our Biodefense Program

We have collaborated with several groups within the U.S. Government to evaluate cethromycin's potential in preventing inhalation anthrax and other high-priority bioterror agents. Although we do not have any additional grant or contract applications currently being evaluated by government agencies, we will continue to pursue these opportunities as they arise.

Leverage our Drug Discovery and Development Capabilities

We intend to expand our product portfolio by exploiting and enhancing our internal drug discovery and development capabilities using our integrated chemistry and biology drug discovery platform to design, optimize and evaluate high-potential product candidates.

Continue to Develop Strategic Collaborations

We plan to continue developing relationships with key pharmaceutical and biotechnology companies, governmental institutions and academic laboratories in order to in-license promising compounds that are not core to their strategy but fit closely with our corporate strengths. We also intend to identify co-development partners for the out-licensing of certain product candidates. Further, we may choose to establish collaborative partnerships through which certain of our clinical candidates can be marketed and commercialized.

Cethromycin for the Treatment of Bacterial Infections

In December 2004, Abbott Laboratories granted us an exclusive worldwide license, except in Japan, to commercialize cethromycin, our most advanced product candidate. Cethromycin is a next generation once-a-day oral antibiotic from the ketolide class used in the treatment of bacterial infections. Over the last decade, the rapid rise in severe and fatal infections caused by antibiotic-resistant bacteria has posed a serious threat to public health. There is a need to discover new antibiotics that are effective against resistant bacteria. As a new class of antibiotics, ketolides have shown activity against penicillin- and macrolide-resistant Gram-positive pathogens. Cethromycin has demonstrated activity toward a variety of drug-resistant pathogens commonly found in bacterial infections, when compared to the published data on antibiotics currently on the market. Cethromycin has also shown *in vitro* evidence of an extended post-antibiotic effect, meaning that the suppression of bacterial growth persists in the absence of measurable antibiotic concentration.

In December 2005, we initiated our pivotal Phase III clinical program for the treatment of mild-to-moderate CABP using a 300 mg once-daily dosing regimen, which enrolled a total of 1,106 patients and were successfully completed in 2007. Cethromycin reported per protocol clinical cure rates of 94.0% in trial CL05-001 (comparator, Biaxin, was 93.8%) and 91.5% in trial CL06-001 (comparator, Biaxin, was 95.9%). In February 2008, we announced that both the therapeutic and supratherapeutic doses of cethromycin showed no signal of any electrocardiographic effects and hence supported its favorable cardiac safety profile, the results from a thorough QT study of cethromycin (trial CL07-001). In September 2008, we submitted an NDA for the use of cethromycin in mild-to-moderate CABP. In June 2009, the FDA AIDAC reviewed the cethromycin NDA. The AIDAC voted that cethromycin demonstrated safety for the outpatient treatment of adults with mild-to-moderate CABP, but voted that cethromycin did not demonstrate efficacy in the treatment of CABP. The committee's negative vote on the drug candidate's efficacy followed a discussion that the cethromycin NDA included data on patients with mild-to-moderate disease and that the new draft guidance for developing treatments for CABP, released in March 2009, requires the enrollment of more severe CABP patients for approval in the outpatient CABP indication. Our pivotal Phase III program included in the NDA was designed and conducted under prior FDA guidance and before the new draft guidance was released. In July 2009, we received a complete response letter from the FDA regarding cethromycin NDA for the outpatient treatment of adults with CABP. In its letter, the FDA indicated that they could not approve the application for cethromycin in its current form and that, to gain approval, additional clinical data is required to demonstrate efficacy with defined statistical methodology.

In March 2010, we met with officials from the FDA's Anti-Infectives Division to gain clarity on the registration pathway for cethromycin and in the meeting, the FDA guided that, to assess the approvability for cethromycin to treat CABP, we should establish an SPA using a superiority clinical trial design comparing cethromycin to a marketed macrolide antibiotic in two clinical trials. In light of this guidance, we worked with the FDA to finalize an SPA using a superiority design for the outpatient CABP indication, and in August 2010, we reached an agreement with the FDA, under the SPA process, on the design of our planned Phase III study of cethromycin to treat CABP.

In July 2010 we announced positive results from preclinical toxicology and pharmacokinetic studies of an IV formulation for cethromycin that support its use in a hospital setting. Cethromycin IV was administered as a single dose up to 60 mg/kg/day, the highest dose tested. Results demonstrated cethromycin IV was well tolerated and generated 10-fold greater plasma exposure compared to oral administration. The studies were conducted in rats in accordance with good laboratory practices. The increased bioavailability of cethromycin IV may allow for the treatment of serious hospital infections as well as the treatment of bioterror pathogens, such as anthrax, plague and tularemia after signs and symptoms are present.

Further discussion with the FDA has led us to focus initially on the indication of gonorrhea, which has become a major global public health challenge given the emergence of drug resistant strains of *Neisseria gonorrhoeae* worldwide. Cethromycin has demonstrated potent *in vitro* and *in vivo* activity against *Neisseria gonorrhoeae,* including macrolide-resistant strains. Cethromycin also exhibits potent *in vitro* activity against *Chlamydia trachomatis*, and has the potential to treat both gonorrhea and chlamydia, which would constitute a significant clinical advantage. We will continue this initiative as funds become available to support this development program.

Market Overview

Bacterial infections occur when bacteria that naturally exist in the body, or that are acquired through inhalation, ingestion or direct penetration, are not controlled by the normal immune defense system. These uncontrolled bacteria can multiply and either excrete toxins or provoke the immune system to mount a response, in either case damaging tissue. Antibiotics work by binding to specific targets in a bacterial pathogen, thereby inhibiting a function that is essential to the pathogen's survival. Many antibiotics were developed and introduced into the market during the 1970s and 1980s and have proven to be effective in treating most bacterial infections. We believe this historic efficacy prompted pharmaceutical companies to shift their resources to other areas of drug discovery and develop-

ment. As a result, very few antibiotics from new chemical classes have been introduced in the last several years.

Antibiotic resistance is widely considered a significant threat to public health, and the problem continues to worsen. The Centers for Disease Control continues to report on new strains of bacteria that are resistant to one or more antibiotics currently on the market. The increasing prevalence of drug-resistant bacteria has led to prolonged illnesses and hospitalizations, increased healthcare costs and significantly higher mortality rates. As a result, there is a strong demand for new treatments that are more effective against resistant strains and do not show potential for inducing the rapid development of additional resistant strains. We do not believe that this demand for new antibiotic therapies is being met by large pharmaceutical companies because of a shift in research and development focus in these companies toward chronic conditions that require sustained medication over long periods of time.

Gonorrhea is the second most commonly reported infectious disease in the U.S., after chlamydia. The Centers for Disease Control estimates that nearly 900,000 new cases of gonorrhea occur in the U.S. each year with 100,000,000 annual cases being estimated to occur worldwide. *Neisseria gonorrhoeae*, the bacteria responsible for causing gonorrhea, is becoming increasingly resistant to all known antibiotics and is causing a major global public health challenge.

Current Treatment Options and Limitations

The global burden of infection with *Neisseria gonorrhoeae is* increasing. While *N. gonorrhoeae* has been successfully treated and contained for the past 70-80 years, new strains have been found worldwide that exhibit resistance to most antibiotic agents and classes available (e.g. sulfonamides, penicillins, earlier generation cephalosporins, tetracyclines, macrolides and fluoroquinolones). Recent evidence of resistance against extended spectrum cephalosporins has brought about great concern in both the scientific and lay literature.

In most global clinical settings, ceftriaxone is the last remaining option for empirical first-line therapy. Because almost half of all gonorrhea patients are also infected with *chlamydia trachomatis*, ceftriaxone, which does not cover this pathogen, must be combined with azithromycin or doxycycline. Additionally, as ceftriaxone is required to be administered intramuscularly, concerns have increased that non-compliance and reluctance could lead to more patients going untreated. Clearly, the development of new anti-gonorrheal agents is necessary in order to stem the development of resistance and offer treatment options for individuals infected with resistant forms of *N. gonorrhoeae*.

Increased bacterial resistance to many of the currently available antibiotics has been caused by certain common medical practices and sociological factors. By necessity, a wide variety of antibiotics are often administered before the specific disease-causing pathogen has been identified. Bacterial resistance is fostered through the erroneous prescription of antibiotics for non-bacterial infections. The lack of full patient compliance with prescribed courses of therapies has further contributed to bacterial resistance against currently marketed antibiotics. Patients will frequently discontinue a prescribed dosing regimen after symptoms subside, but bacteria that are not entirely eradicated may re-emerge in resistant forms.

ADLS Solution

We intend to continue to develop cethromycin, a next-generation once-a-day oral antibiotic from the ketolide class, in response to the emerging antibiotic resistance observed in the treatment of bacterial infections. Prior to the initiation of our clinical trials, cethromycin had been tested by Abbvie in approximately 4,400 human subjects during clinical trials. As of November 2007, we successfully completed two pivotal Phase III clinical trials of cethromycin for the treatment of mild-to-moderate CABP. We are now focused on evaluating opportunities for cethromycin in the treatment of gonorrhea and certain biodefense applications.

Based on publicly available data regarding current antibiotic compounds, we believe that there is a potential opportunity for further development of cethromycin in the treatment of bacterial infections for a number of reasons:

- cethromycin has shown higher *in vitro* potency and a broader range of activity than macrolides against Gram-positive bacteria;
- cethromycin appears to be effective against penicillin-, macrolide- and fluoroquinolone-resistant bacteria;
- cethromycin has a mechanism of action, unique to ketolides, that may slow the onset of future resistance;
- cethromycin has shown specific activity against Gram-positive pathogens, unlike fluoroquinolones, while leaving normally-present Gram-negative bacteria undisturbed;
- cethromycin has shown *in vitro* evidence of extended post-antibiotic effects against a variety of pathogens;
- cethromycin, unlike Ketek®, has not demonstrated visual disturbance side effects in clinical trials;
- cethromycin exhibits promising activity against the USA300 strain of community-associated methicillin-resistant *Staphylococcus aureus* (CA-MRSA), which has been implicated in recent outbreaks in the USA and is resistant to many currently marketed antimicrobial agents;
- cethromycin has demonstrated potent activity against serotype 19A of *S. pneumoniae* strains, which has recently emerged, due to widespread use of the 7-valent protein-conjugated pneumococcal vaccine (PCV-7), to cause invasive pneumococcal

disease and are resistant to many antibiotics;

- cethromycin has shown in vitro activities against multiple CDC Category A and B bioterror agents such as *Bacillus anthracis, Fransicella tularensis, Yersinia pestis* and *Burkholderia pseudomallei* and has demonstrated 100% protection of anthrax assault in the post-exposure prophylactic monkey model; and
- cethromycin has demonstrated potent *in vitro* and *in vivo* activity against *Neisseria gonorrhoeae,* including macrolide- resistant strains.
- cethromycin exhibits potent *in vitro* activity against *Chlamydia trachomatis*, and has the potential to treat both gonorrhea and chlamydia, which would constitute a significant clinical advantage.

We believe that cethromycin, if approved, would address a growing need in the marketplace to overcome bacterial resistance.

Abbott Laboratories Collaboration

In December 2004, we entered into an agreement with Abbott Laboratories under which we acquired a license to certain patent applications, patents and proprietary technology relating to cethromycin. The term of the agreement commenced in December 2004 and continues until the expiration of the last patent licensed under the agreement, unless the agreement is otherwise terminated. The primary patent licensed under the agreement, used by us in connection with cethromycin, expires in the U.S. in September 2016, and in most foreign countries or jurisdictions in September 2017, all subject to any term restoration that may be granted for the time necessary for regulatory approval in each respective jurisdiction. Upon the expiration of the license agreement, we maintain a non-exclusive, perpetual and irrevocable license to use Abbott's proprietary technology and other types of information directly related or used in connection with cethromycin and its manufacture into pharmaceutical products without any further payment obligations to Abbott, except for those payment obligations accruing prior to such expiration. The agreement may be terminated by either party on 30 days' notice if the other party ceases its business operations or if the other party passes a resolution or a court of competent jurisdiction makes an order for winding up its business. Either party may also terminate the agreement for material breach if not cured within 90 days of notice or if not cured within 30 days of notice if the breach relates to a payment provision. Finally, we have the right to sublicense our rights under the agreement at our discretion.

In March 2009, we alleged in a notice of dispute delivered to Abbott Laboratories that Abbott had breached its obligations under the license agreement for cethromycin entered into between Abbott and us in December 2004. Subsequent to delivering the notice of dispute, we initiated arbitration proceedings against Abbott under the alternative dispute resolution provisions of the license agreement. In September 2009, prior to the completion of arbitration proceedings, we and Abbott entered into a binding term sheet in settlement of the dispute. The binding term sheet provides for certain amendments to the license agreement. The license agreement was amended to restructure the $30.0 million lump sum milestone payment due from us to Abbott upon U.S. regulatory approval of cethromycin, such that $20.0 million is payable within twenty days of U.S. regulatory approval, $5.0 million is payable within 6 months of U.S. regulatory approval and $5.0 million is payable within 12 months of U.S. regulatory approval. In addition, the license agreement was amended to reduce the royalty due from us to Abbott by two percentage points per tier such that we will owe Abbott royalty payments of 17% on the first $100.0 million of aggregate net sales of cethromycin, 16% on net sales once aggregate net sales exceed $100.0 million but are less than $200.0 million, and 15% on all net sales once aggregate net sales exceed $200.0 million. Finally, the terms to pay to Abbott $2.5 million upon cethromycin reaching $200.0 million in aggregate net sales and $5.0 million upon the drug reaching $400.0 million in aggregate net sales was unchanged.

Intellectual Property

Patents and Trade Secrets

We continue to hold an exclusive worldwide license (excluding Japan) from Abbvie to develop and commercialize cethromycin (Restanza™). The Abbvie patent is U.S. patent number 5866549 which expires on September 4, 2016. In order to lengthen the period of exclusivity, we applied for and received Qualified Infectious Disease Product (QDIP) designation from the FDA under the Generating Antibiotic Incentives Now (GAIN) Act. The GAIN Act provides new incentives for the development of QDIPs including:

- Extending the Hatch-Waxman provisions related to data exclusivity by 5 years while maintaining the current paradigm for an abbreviated NDA paragraph IV certification;
- Providing six months of additional exclusivity for products with companion diagnostics;
- Providing priority review by the FDA;
- Making products eligible for fast-track designation by the FDA;
- Requiring a review and possible revising of FDA guidelines regarding clinical trials and other requirements for approval of antibiotic drugs.

Cethromycin was designated as a QDIP on December 18, 2014 by the FDA for the indication of gonorrhea.

In addition, under the Hatch-Waxman Act, a newly approved antibiotic is eligible for a U.S. Patent extension of up to 5 years to compensate for market time lost during the drug approval process undertaken by the FDA.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that we may issue in the future, or those licensed to us, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. In addition, there can be no assurance that this patent coverage will be broad enough to prevent third parties from developing or commercializing similar or identical technologies and thus the rights granted under any issued patents may not provide us with any meaningful competitive advantages against our competitors. Furthermore, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent. There can also be no assurance that our technologies will not be deemed to infringe the IP rights of third parties or that we will be able to acquire licenses to the IP rights of third parties under satisfactory terms or at all.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. We believe that our most significant competitors are Pfizer, GlaxoSmithKline, Johnson & Johnson and Cempra.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

We rely upon our collaborators for support in advancing certain of our product candidates and intend to rely on our collaborators for the commercialization of these products. Our collaborators may be conducting multiple product development efforts within the same disease areas that are the subjects of their agreements with us. Generally, our agreements with our collaborators do not preclude them from pursuing development efforts using a different approach from that which is the subject of our agreement with them. Therefore, any of our product candidates may be subject to competition with a product candidate under development by a collaborator.

There are also a number of companies working to develop new drugs and other therapies for these diseases that are undergoing clinical trials. The key competitive factors affecting the success of all of our product candidates are likely to be their efficacy, safety, price and convenience. See "Risk Factors—We will face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively."

Government Regulation

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, marketing and export and import of pharmaceutical products such as those we are developing. The process of obtaining regulatory approvals and the subsequent substantial compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Government Regulation

In the United States, the FDA regulates and approves drugs under the Federal Food, Drug, and Cosmetic Act. If we fail to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency enforcement action could have a material adverse effect on us.

The steps required before a drug may be marketed in the United States include:

- preclinical laboratory tests, animal studies and formulation studies under the FDA's good laboratory practices regula-

tions;

- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;
- adequate and well-controlled clinical trials in accordance with FDA good clinical practice regulations, to establish the safety and efficacy of the product for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practices, ("cGMP"); and
- FDA review and approval of the NDA.

Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. The IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. If these issues are unresolved, the FDA may not allow the clinical trials to commence.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Each trial must be reviewed and approved by an independent Institutional Review Board before it can begin. Phase I clinical trials usually involve the initial introduction of the investigational drug into humans to evaluate the product's safety, dosage tolerance and pharmacodynamics and, if possible, to gain an early indication of its effectiveness.

Phase II clinical trials usually involve controlled trials in a limited patient population to:

- evaluate dosage tolerance and appropriate dosage;
- identify possible adverse effects and safety risks; and
- evaluate preliminarily the efficacy of the drug for specific indications.

Phase III clinical trials usually further evaluate clinical efficacy and test further for safety in an expanded patient population. Phase I, Phase II and Phase III clinical trials may not be completed successfully within any specified period, if at all. Furthermore, the FDA or we may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical studies, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and has a favorable risk/benefit profile. In addition, FDA inspects selected clinical trial sites for good clinical practice (GCP) compliance to ensure the clinical trial data quality and integrity.

Under the Pediatric Research Equity Act of 2003 NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. In most cases, the NDA must be accompanied by a substantial user fee.

Before approving an application, the FDA will inspect the facility or the facilities where the product is manufactured. The FDA will not approve the product unless cGMP compliance is considered satisfactory. The FDA will issue an approval letter if it determines that the application, manufacturing process and manufacturing facilities are acceptable. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable; it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. The FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the products. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval.

After regulatory approval of a product is obtained, we are required to comply with a number of post-approval requirements. For

example, as a condition of approval of an application, the FDA may require post-marketing testing and surveillance to monitor the product's safety or efficacy. In addition, holders of an approved NDA are required to report certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes numerous procedural and documentation requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other regulations.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Future FDA inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product, or the failure to comply with requirements, may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary or FDA-initiated action that could delay further marketing. Newly discovered or developed safety or efficacy data may require changes to a product's approved labeling, including the addition of new warnings and contraindications. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

FDA's "Animal Efficacy Rule"

The FDA's "Animal Efficacy Rule" allows for approval of new drug products based on animal data when adequate and well-controlled efficacy studies in humans cannot be ethically conducted because the studies would involve administering a potentially lethal or permanently disabling toxic substance or organism to healthy human volunteers. Approval of a drug under the "Animal Efficacy Rule" is subject to certain post-approval commitments, including the submission of a plan for conducting post-marketing studies, post-marketing restrictions to ensure safe use (if deemed necessary), and product labeling information intended for patient advising that, among other things, indicates the product's approval was based on efficacy studies conducted in animals alone.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sale and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, we may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by biotechnology and optional for those which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

Pharmaceutical Pricing and Reimbursement

In both domestic and foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third party payors. Third party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. These third party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare product candidates. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Our product candidates may not be considered cost-effective. Adequate third party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes. There have been, and we expect there will continue to be, a number of legislative and regulatory proposals and enactments to change the healthcare system in ways that could significantly affect our business, such as the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 signed into law in March 2010. We anticipate that Congress, state legislatures and the private sector will continue to consider and may adopt healthcare policies intended to curb rising healthcare costs. These cost containment measures include:

- controls on government funded reimbursement for medical products and services;

- controls on healthcare providers;

- challenges to the pricing of medical products and services or limits or prohibitions on reimbursement for specific products and therapies through other means;

- reform of drug importation laws; and

- expansion of use of managed care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person.

We are unable to predict what additional legislation, regulations or policies, if any, relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business. Any cost containment measures, including those listed above, or other healthcare system reforms that are adopted could have a material adverse effect on our ability to operate profitably.

Research and Development

During 2011, $342,292 was spent on research and development activities. No additional funds were spent on research and development activities during 2012, 2013, 2014 or 2015.

Employees

We currently do not employ any individuals with the Company, with the exception of Michael Flavin, our Chief Executive Officer, who has not received any cash compensation since April, 2011.

Item 1A. Risk Factors.

Our business involves a high degree of risk. If any of the following risks actually occurs, our business, financial condition or results of operations could suffer. The risks described below are not the only ones facing us. Additional risks not presently known to us or that we currently consider immaterial also may adversely affect our company.

Risks Related to Our Industry and Business

We have limited operating history since suspending our operations in 2011.

Since suspending our operations in May 2011, we have not generated any revenues from operations and we have limited resources. Any operating losses, together with risks associated with our ability to be competitive in the pharmaceutical industry may have a material adverse effect on our liquidity. In addition, we may not have the resources to resume operations to the historical levels prior to suspending our operations, which would have a material adverse effect on our ability to continue as a company. An investor in our common stock must evaluate the risks, uncertainties, and difficulties encountered by a company with limited operations. There can be no assurance that we will generate sufficient revenues to maintain our business operations.

We may not be able to continue as a going concern or fund our existing capital needs.

Our independent registered public accounting firm included an explanatory paragraph in the report on our 2010 financial statements related to the uncertainty in our ability to continue as a going concern. The paragraph states that we do not have sufficient cash on-hand or other funding available to meet our obligations and sustain our operations, which raises substantial doubt about our ability to continue as a going concern. We will not be generating any product-based revenues or realizing cash flows from operations in the near term, if at all. We may not have sufficient cash or other funding available to complete our anticipated business activities. In order to address our working capital shortfall, we must raise additional capital. There is no assurance that we will be able to obtain adequate capital funding in the future to continue operations and implement our strategy. As a result of these uncertainties, there is significant doubt about our ability to continue as a going concern.

We are a development stage company and may never attain product sales.

We have not received approval for any of our product candidates from the FDA. Any compounds that we discover or in-license will require extensive and costly development, preclinical testing and/or clinical trials prior to seeking regulatory approval for commercial sales. Our most advanced product candidate, cethromycin, and any other compounds we discover, develop or in-license, may never be approved for commercial sale. The time required to attain product sales and profitability is lengthy and highly uncertain, and we cannot assure you that we will be able to achieve or maintain product sales. We expect our net operating losses to continue for at least several years, and we are unable to predict the extent of future losses or when we will become profitable, if ever.

We have incurred significant net losses since our formation in 1999. Our net losses are due in large part to the significant research and development costs required to identify, validate and license potential product candidates, conduct preclinical studies and conduct clinical trials of our more advanced product candidates. To date, we have generated only limited revenues, consisting of management fees, one-time or limited payments associated with our collaborations and government grant awards, and we do not anticipate generating any significant revenues in the near term, if ever. Our operating expenses may increase over the next several years if we:

- conduct additional Phase III clinical trials and prepare for the commercial launch of cethromycin;
- continue the preclinical development and commence the clinical development of other product candidates;
- expand our research and development activities;
- acquire or in-license new technologies and product candidates; and
- increase our required corporate infrastructure and overhead.

As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with our research and product development efforts, we are unable to predict the extent of any future losses or when we will become profitable, if ever. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

We will require additional funding to satisfy our future capital needs, and future financing strategies may further dilute or otherwise adversely affect holders of our common stock.

Our operations will require significant additional funding due to the absence of any meaningful revenues in the near future. We do not know whether additional financing will be available to us on favorable terms or at all. To the extent we are successful in raising additional capital by issuing equity securities, our stockholders are likely to experience substantial further dilution. Any additional equity securities we issue may have rights, preferences or privileges senior to those of existing holders of stock. To the extent that we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. There can be no assurance that we will be able to obtain adequate capital funding in the future to continue operations and implement our strategy. As a result of these uncertainties, there is substantial doubt about our ability to continue as a going concern.

We will not be able to commercialize our drug candidates if our clinical trials do not demonstrate safety and efficacy.

Before obtaining regulatory approval for the sale of our drug candidates, we must conduct extensive development and clinical trials to demonstrate the safety and efficacy of our drug candidates and clinical or animal trials to demonstrate the efficacy of our drug candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome.

A failure of one or more of our clinical trials or animal efficacy studies can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of clinical trials or animal efficacy studies that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates, including:

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may decide, or regulators may require us, to conduct additional clinical trials, or we may abandon projects that we expect to be promising, if our clinical trials or animal efficacy studies produce negative or inconclusive results;
- we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements;

- the cost of our clinical trials could escalate and become cost prohibitive;
- any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable;
- we may not be successful in recruiting a sufficient number of qualifying subjects for our clinical trials; and
- the effects of our drug candidates may not be the desired effects or may include undesirable side effects or the drug candidates may have other unexpected characteristics.

Our business would be materially harmed if we fail to obtain FDA approval of a new drug application for cethromycin.

Our ability to generate any significant product revenues in the near future will depend solely on the successful development and commercialization of cethromycin, our most advanced product candidate. The FDA may not approve in a timely manner, or at all, any NDA that we submit. If any NDA we submit is not approved by the FDA, we will be unable to commercialize that product in the United States and our business will be materially harmed. In June 2010, as part of the testimony for a hearing of the U.S. Congress Committee on Energy and Commerce, Subcommittee on Health, our Chief Executive Officer commented on the challenges that we and other innovator companies have faced in the clinical development and regulatory approval of new antibiotics to improve public health. The FDA can and does reject NDAs, and often requires additional clinical trials, even when product candidates performed well or achieved favorable results in large-scale Phase III clinical trials. The FDA imposes substantial requirements on the introduction of pharmaceutical products through lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years and may vary substantially based upon the type and complexity of the pharmaceutical product. A number of our product candidates are novel compounds, which may further increase the period of time required for satisfactory testing procedures.

As discussed in further detail in Item 1. "Business", in July 2009, we received a complete response letter from the FDA regarding the NDA for cethromycin for the outpatient treatment of adults with CABP. In its letter, the FDA indicated that they could not approve the application for cethromycin in its current form and that, to gain approval, additional clinical data is required to demonstrate efficacy. In August 2010, we reached an agreement with the FDA, under the SPA process, on the design of our planned Phase III study of cethromycin to treat CABP. Further discussion with the FDA has led us to focus initially on the indication of gonorrhea, which has become a major global public health challenge given the emergence of drug resistant strains of *Neisseria gonorrhoeae* worldwide. We will continue this initiative as funds become available to support this development program.

Because we are heavily dependent on our license agreement with Abbott Laboratories and our collaborations with other third parties, our product development programs may be delayed or terminated by factors beyond our control.

In December 2004, we entered into a license agreement with Abbott Laboratories for certain patent applications, patents and proprietary technology relating to cethromycin. We may also enter into a number of license agreements for intellectual property and other rights needed to develop product candidates that are in earlier stages of development. Our collaborations generally present additional risks to our business, such as the risk that our collaborators encounter conflicts of interest to their arrangements with us, inadequately defend our intellectual property rights or develop other products that compete with us. Our ability to generate any significant product revenues in the near future will depend on the successful commercialization of cethromycin. If for any reason we are unable to realize the expected benefits of our license agreement with Abbott Laboratories, or under any of our other collaborations, then our business and financial condition may be materially harmed.

Our collaborators and third party manufacturers may not be able to manufacture our product candidates, which would prevent us from commercializing our product candidates.

To date, our product candidates have been manufactured by our collaborators and third party manufacturers for preclinical and clinical trials. If any of our product candidates is approved by the FDA or other regulatory agencies for commercial sale, we will need third parties to manufacture the product in larger quantities. Due to factors beyond our control, our collaborators and third party manufacturers may not be able to increase their manufacturing capacity for any of our product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to increase the manufacturing capacity for a product candidate successfully, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in the supply of the product candidate. Our product candidates require precise, high-quality manufacturing. The failure of our collaborators and third party manufacturers to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business.

If we are unable to enter into agreements with third parties to sell and market any products we may develop, we may be unable to

generate revenues.

We do not currently have product sales and marketing capabilities. If we receive approval to commercialize cethromycin, we intend to engage additional pharmaceutical or health care companies with existing distribution systems and direct sales organizations to assist us in North America and abroad. We may not be able to negotiate favorable distribution partnering arrangements, if at all, and to the extent we enter co-promotion or other licensing arrangements, any revenues we receive will depend on the efforts of third parties and will not be under our control. If we are unable to establish adequate sales, marketing and distribution capabilities with third parties, our ability to generate product revenues, and become profitable, would be severely limited.

Our most advanced product candidate, cethromycin, will face significant competition in the marketplace if it receives marketing approval from the FDA.

Our pivotal Phase III clinical trials for cethromycin were limited to the treatment of mild-to-moderate CABP. We also intend to pursue opportunities for cethromycin in the treatment of other types of bacterial infections such as gonorrhea. There are several classes of antibiotics that are primary competitors for the treatment of one or more of these indications, including:

- macrolides such as Biaxin® (clarithromycin), a product of Abbott Laboratories; and Zithromax® (azithromycin), a product of Pfizer Inc.;
- one other ketolide antibiotic, Ketek® (telithromycin), a product of Aventis Pharmaceuticals;
- semi-synthetic penicillins such as Augmentin® (amoxicillin and clavulanate potassium), a product of GlaxoSmithKline;
- fluoroquinolones such as Levaquin® (levofloxacin), a product of Ortho-McNeil Pharmaceutical, Inc.; Tequin® (gatifloxacin), a product of Bristol-Myers Squibb Company; FACTIVE® (gemifloxacin mesylate) tablets, a product of Oscient Pharmaceuticals; and Cipro® (ciprofloxacin) and Avelox® (moxifloxacin), both products of Bayer Corporation;
- tetracyclines such as Tygacil® (tigecycline), a product of Pfizer to treat in-patient CABP; and
- an oxazolidinone, Zyvox® (linezolid), a product of Pfizer to treat nosocomial pneumonia.

Cethromycin may show evidence of side effects that could diminish its prospects for commercialization and wide market acceptance. If cethromycin is approved by the FDA, it will not be the first ketolide antibiotic introduced to the marketplace. Ketek® has been available for sale in Europe since 2002 and in the United States since August 2004. There are additional ketolide product candidates in preclinical development or in clinical development. If ultimately approved by the FDA, these product candidates may have improved efficacy, ease of administration or more favorable side effect profiles when compared to cethromycin. The availability of additional ketolide antibiotics may have an adverse effect on our ability to generate product revenues and achieve profitability.

The availability of generic equivalents may adversely affect our ability to generate product revenues from cethromycin.

Many generic antibiotics are currently prescribed to treat respiratory tract infections. As competitive products lose patent protection, makers of generic drugs will likely begin to market additional competing products. Companies that produce generic equivalents are generally able to offer their products at lower prices. Ketek® may lose patent protection as early as 2015, which would enable generic drug manufacturers to sell generic ketolide antibiotics at a lower cost than cethromycin. Generic equivalents of Biaxin® and Zithromax®, two macrolide antibiotic products, are currently available. Cethromycin, if approved for commercial sale, may be at a competitive disadvantage because of its higher cost relative to generic products. This may have an adverse effect on our ability to generate product revenues from cethromycin.

Even if we successfully develop and obtain approval for cethromycin or any of our other product candidates, our business will not be profitable if those products do not achieve and maintain market acceptance.

Even if any of our product candidates are approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product candidate by physicians, healthcare professionals, patients and third-party payors, and our resulting profitability and growth, will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- the availability of alternative treatments;
- the details of FDA labeling requirements, including the scope of approved indications and any safety warnings;

- pricing and cost effectiveness;
- the effectiveness of our or our collaborators' sales and marketing strategy;
- our ability to obtain sufficient third-party insurance coverage or reimbursement; and
- our ability to have the product listed on insurance company formularies.

If any of our product candidates achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are received more favorably or are more cost effective. Complications may also arise, such as antibiotic or viral resistance, that render our products obsolete. We rely on the favorable resistance profile of cethromycin observed to be a potential competitive distinction from currently marketed compounds. Even if we receive FDA approval to market cethromycin, resistance may emerge that will substantially harm our ability to generate revenues from its sale.

Because the results of preclinical studies for our preclinical product candidates are not necessarily predictive of future results, our product candidates may not have favorable results in later clinical trials or ultimately receive regulatory approval.

Only one product candidate in our development pipeline, cethromycin, has been tested in clinical trials. Our other product candidates have only been through preclinical studies. In addition, other product candidates we may in-license may also be in preclinical studies. Positive results from preclinical studies, particularly *in vitro* studies, are no assurance that later clinical trials will succeed. Preclinical trials are not designed to establish the clinical efficacy of our preclinical product candidates. We will be required to demonstrate through clinical trials that these product candidates are safe and effective for use before we can seek regulatory approvals for their commercial sale. There is typically an extremely high rate of failure as product candidates proceed through clinical trials. If our product candidates fail to demonstrate sufficient safety and efficacy in any clinical trial, we would experience potentially significant delays in, or be required to abandon, development of that product candidate. This would adversely affect our ability to generate revenues and may damage our reputation in the industry and in the investment community.

The future clinical testing of our product candidates could be delayed, resulting in increased costs to us and a delay in our ability to generate revenues.

Our product candidates will require preclinical testing and extensive clinical trials prior to submitting a regulatory application for commercial sales. We do not know whether clinical trials will begin on time, if at all. Delays in the commencement of clinical testing could significantly increase our product development costs and delay product commercialization. In addition, many of the factors that may cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to denial of regulatory approval of a product candidate. Each of these results would adversely affect our ability to generate revenues.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations and trial sites;
- manufacturing sufficient quantities of a product candidate; and
- obtaining institutional review board approvals to conduct clinical trials at prospective sites.

In addition, the commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease, and the eligibility criteria for the clinical trial. If we are unable to enroll a sufficient number of microbiologically evaluable patients, the clinical trials for our product candidates could be delayed until sufficient numbers are achieved.

If we fail to obtain regulatory approvals in other countries for our product candidates under development, we will not be able to generate revenues in such countries.

In order to market our products outside of the United States, we must comply with numerous and varying regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval in the United States. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. The risks involved in the non-U.S. regulatory approval process, as well as the consequences for failing to comply with applicable regulatory requirements, generally include the same considerations as in the United States. A description of U.S. regulatory considerations can be found under the section entitled "—Our business would be materially harmed if we fail to obtain FDA approval of a new drug application for cethromycin."

We will face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer

If we fail to compete effectively.

We are a development stage company. Most of our competitors, such as Pfizer, GlaxoSmithKline and Bayer, are large pharmaceutical companies with substantially greater financial, technical and human resources than we have. The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Many of the drugs that we are attempting to discover or develop will compete with existing therapies if we receive marketing approval. Because of their significant resources, our competitors may be able to use discovery technologies and techniques, or partnerships with collaborators, in order to develop competing products that are more effective or less costly than the product candidates we develop. This may render our technology or product candidates obsolete and noncompetitive. Academic institutions, government agencies, and other public and private research organizations may seek patent protection with respect to potentially competitive products or technologies and may establish exclusive collaborative or licensing relationships with our competitors.

As a company, our only experience in conducting Phase III clinical trials is for our cethromycin development program. Our competitors may succeed in obtaining FDA or other regulatory approvals for product candidates more rapidly than us. Companies that complete clinical trials, obtain required regulatory agency approvals and commence commercial sale of their drugs before we do may achieve a significant competitive advantage, including certain FDA marketing exclusivity rights that would delay or prevent our ability to market certain products. Any approved drugs resulting from our research and development efforts, or from our joint efforts with our existing or future collaborative partners, might not be able to compete successfully with our competitors' existing or future products.

Off-label promotion of our products could result in substantial penalties.

If any of our product candidates receive marketing approval, we will only be permitted to promote the product for the uses indicated on the label cleared by the FDA. Our pivotal Phase III clinical trials of cethromycin are for the treatment of CABP, although we believe that cethromycin may have other applications in gonorrhea, bronchitis, pharyngitis, sinusitis, inhalation anthrax, plague and tularemia and skin and skin structure infections. If we request additional label indications for cethromycin or our other product candidates, the FDA may deny those requests outright, require extensive clinical data to support any additional indications or impose limitations on the intended use of any approved products as a condition of approval. U.S. Attorneys' offices and other regulators, in addition to the FDA, have recently focused substantial attention on off-label promotional activities and have initiated civil and criminal investigations related to such practices. If it is determined by these or other regulators that we have promoted our products for off-label use, we could be subject to fines, legal proceedings, injunctions or other penalties.

If our efforts to obtain rights to new products or product candidates from third parties are not successful, we may not generate product revenues or achieve profitability.

Our long-term ability to earn product revenues depends on our ability to identify, through internal research programs, potential product candidates that may be developed into new pharmaceutical products and/or obtain new products or product candidates through licenses from third parties. If our internal research programs do not generate sufficient product candidates, we will need to obtain rights to new products or product candidates from third parties. We may be unable to obtain suitable products or product candidates from third parties for a number of reasons, including:

- we may be unable to purchase or license products or product candidates on terms that would allow us to make an appropriate return from resulting products;
- competitors may be unwilling to assign or license product or product candidate rights to us;
- we may not have access to the capital necessary to purchase or license products or product candidates; or
- we may be unable to locate suitable products or product candidates within, or complementary to, our areas of interest.

If we are unable to obtain rights to new products or product candidates from third parties, our ability to generate product revenues and achieve profitability may suffer.

Because our product candidates and development and collaboration efforts depend on our intellectual property rights, adverse events affecting our intellectual property rights will harm our ability to commercialize products.

Our success will depend to a large degree on our own, our licensees' and our licensors' ability to obtain and defend patents for each party's respective technologies and the compounds and other products, if any, resulting from the application of such technologies. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Accordingly, we cannot predict the breadth of claims that will be allowed or maintained, after challenge, in our or other companies' patents.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- we were the first to make the inventions covered by each of our pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our pending patent applications will result in issued patents;

- any patents issued to us or our collaborators will provide a basis for commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies that are patentable; or
- the patents of others will not have a negative effect on our ability to do business.

We are a party to certain in-license agreements that are important to our business, and we generally do not control the prosecution of in-licensed technology. Accordingly, we are unable to exercise the same degree of control over this intellectual property as we exercise over our internally developed technology. Moreover, some of our academic institution licensors, research collaborators and scientific advisors have rights to publish data and information in which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information will be impaired. In addition, some of the technology we have licensed relies on patented inventions developed using U.S. government resources. Under applicable law, the U.S. government has the right to require us to grant a nonexclusive, partially exclusive or exclusive license for such technology to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, if the government determines that such action is necessary.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property.

We rely on trade secrets to protect our technology, particularly when we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. In order to protect our proprietary technology and processes, we rely in part on confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case we could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Market acceptance and sales of our product candidates will be severely limited if we cannot arrange for favorable reimbursement policies.

Our ability to commercialize any product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish reimbursement levels for the cost of our products and related treatments. Third-party payors are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed healthcare in the United States, as well as legislative proposals to reform healthcare, control pharmaceutical prices or reduce government insurance programs, may also result in exclusion of our product candidates from reimbursement programs. Because many generic antibiotics are available for the treatment of bacterial infections, our ability to list cethromycin on insurance company formularies will depend on its effectiveness compared to lower-cost products. The cost containment measures that health care payors and providers are instituting, and the effect of any health care reform, could materially and adversely affect our ability to earn revenues from the sales of cethromycin and our other product candidates.

Healthcare law and policy changes, based on recently enacted legislation, may have an adverse effect on us.

Healthcare costs have risen significantly over the past decade. In March 2010, President Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or, collectively, the Healthcare Reform Act. This law substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that are expected to impact our business and operations, including provisions governing enrollment in federal healthcare programs, reimbursement and discount programs and fraud and abuse prevention and control, which will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. We anticipate that if we obtain approval for our product candidates, some of our revenue and the revenue from our collaborators may be derived from U.S. government healthcare programs, including Medicare. Additionally, in 2009, the Department of Defense implemented a program pursuant to the National Defense Authorization Act for Fiscal Year 2008 that requires rebates, based on Federal statutory pricing, from manufacturers of innovator drugs and biologics. Furthermore, beginning in 2011, the Healthcare Reform Act imposes a non-deductible fee treated as an excise tax on pharmaceutical manufacturers or importers who sell "branded prescription drugs," which includes innovator drugs and biologics (excluding certain orphan drugs, generics and over-the-counter drugs) to U.S. government programs. We expect that the Healthcare Reform Act and other healthcare reform measures that may be adopted in the future could have an adverse effect on our industry generally and our ability to successfully commercialize our product candidates or could limit or eliminate our spending on development projects. In addition to this legislation, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to keep these costs down while expanding individual healthcare benefits. Certain of these changes could impose limitations on the prices we will be able

to charge for any product candidates that are approved or the amounts of reimbursement available for these products from governmental agencies or third-party payors, or may increase the tax obligations on life sciences companies such as ours. While it is too early to predict specifically what effect the Health Reform Act and its implementation or any future legislation or policies will have on our business, we believe that healthcare reform may have an adverse effect on our business and financial condition.

We will need to increase the size of our organization, and we may encounter difficulties managing our growth, which could adversely affect our results of operations.

We are currently a development stage company with no current employees, other than our Chief Executive Officer. We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our research, development and commercialization effort. To manage any growth, we will be required to continue to improve our operational, financial and management controls, reporting systems and procedures and to attract and retain sufficient numbers of talented employees. We may be unable to successfully manage the expansion of our operations or operate on a larger scale and, accordingly, may not achieve our research, development and commercialization goals.

If we are unable to attract and retain qualified scientific, technical and key management personnel, or if Michael T. Flavin, Ph.D., discontinues his employment with us, it may delay our research and development efforts.

We are highly dependent upon and our business would be significantly harmed if we lost the services of Michael T. Flavin, Ph.D., our founder and Chairman and Chief Executive Officer. We do not currently have a key man life insurance policy. Our research and drug discovery programs also depend on our ability to attract and retain highly skilled chemists, biologists and preclinical and clinical personnel. We may not be able to attract or retain qualified scientific personnel in the future due to intense competition among biotechnology and pharmaceutical businesses, particularly in the Chicago area. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our research and development objectives and our ability to meet the demands of our collaborators in a timely fashion.

Our business will expose us to potential product liability risks and there can be no assurance that we will be able to acquire and maintain sufficient insurance to provide adequate coverage against potential liabilities.

Our business will expose us to potential product liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products. The use of our product candidates in clinical trials also exposes us to the possibility of product liability claims and possible adverse publicity. These risks will increase to the extent our product candidates receive regulatory approval and are commercialized. We do not currently have any product liability insurance, although we plan to obtain product liability insurance in connection with future clinical trials of our product candidates. There can be no assurance that we will be able to obtain or maintain any such insurance on acceptable terms. Moreover, our product liability insurance may not provide adequate coverage against potential liabilities. On occasion, juries have awarded large judgments in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us would decrease our cash reserves and could cause our stock price to fall significantly.

We face regulation and risks related to hazardous materials and environmental laws, violations of which may subject us to claims for damages or fines that could materially affect our business, cash flows, financial condition and results of operations.

Our research and development activities involve the controlled use of hazardous materials and chemicals. The risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages or fines that result, and the liability could have a material adverse effect on our business, financial condition and results of operations. We are also subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. If we fail to comply with these laws and regulations or with the conditions attached to our operating licenses, the licenses could be revoked, and we could be subjected to criminal sanctions and substantial liability or be required to suspend or modify our operations. In addition, we may have to incur significant costs to comply with future environmental laws and regulations. We do not currently have a pollution and remediation insurance policy.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, telecommunication and electrical failures. Our drug discovery and preclinical testing systems are highly technical and proprietary. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug discovery programs. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability as a result, our drug discovery programs may be adversely affected and the further development of our product candidates may be delayed. In addition, we may incur additional costs to remedy the damages caused by these disruptions or security breaches.

Risks Related to Our Common Stock

We are not current in our reporting obligations with the SEC and our status as a public company could be revoked at any time.

We are not current in our filing obligations with the SEC. While we are working to become current with our filing obligations with the SEC, if we are unable to complete those filings before the SEC seeks to bring an administrative action against us, it is likely that we would cease being a public company. In that event, the liquidity of our common stock would be severely diminished and our ability to continue our operations could be materially affected.

Our common stock price has been highly volatile, and your investment could suffer a decline in value.

The market price of our common stock has been highly volatile since we completed our initial public offering in August 2005. There is also limited trading volume of our common stock on the OTCBB. The market price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors and events, including but not limited to:

- the progress of our cethromycin development program and the timing and results from any of our other programs.programs;
- the in-licensing or acquisition of additional product candidates;
- the loss of licenses or proprietary rights to technologies and products;
- FDA or international regulatory actions and approvals;
- changes or developments in laws or regulations applicable to our product candidates;
- failure of any of our product candidates, if approved, to achieve commercial success;
- introduction of competitive products or technologies;
- general economic and market conditions, including market conditions in the pharmaceutical and biotechnology sectors, and overall fluctuations in U.S. equity markets;
- litigation or public concern about the safety of our potential products;
- comments by securities analysts;
- actual and anticipated fluctuations in our quarterly operating results;
- deviations in our operating results from the estimates of securities analysts;
- rumors relating to us or our competitors;
- public concern as to the efficacy or safety of new technologies;
- third party reimbursement policies;
- developments concerning current or future collaborations, including disputes or termination events and the achievement, timing and accounting treatment of milestone payments;
- the addition or termination of research programs or funding support; and
- the other factors described in this "Risk Factors" section.

These and other factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit and the time and attention of our management may be diverted.

Because our common stock is not listed on a national securities exchange, you may have difficulty trading our securities and our securities may trade at a lower market price than they otherwise would.

Our common stock is listed on the OTC Bulletin Board and in the over-the-counter market in the so-called "pink sheets." Because of this, you may not be able to sell as many securities as you desire, you may experience delays in the execution of your transactions and our securities may trade at a lower market price than they otherwise would. In addition, our securities could become subject to the SEC's "penny stock rules." These rules would impose additional requirements on broker-dealers who effect trades in our securities, other than trades with their established customers and accredited investors. Consequently, the delisting of our securities and the applicability of the penny stock rules may adversely affect the ability of broker-dealers to sell our securities, which may adversely affect your ability to resell our securities. The delisting of our securities from Nasdaq could also have other negative results, including the potential loss of confidence by employees and others, the loss of institutional investor interest and fewer business development and commercial partnership opportunities.

Our Chairman and Chief Executive Officer has significant voting control over our company which may delay, prevent or deter corporate actions that may be in the best interest of our stockholders.

The Company entered into a business loan agreement with the Leaders Bank, for which Michael Flavin served as the personal guarantor as required by the Leaders Bank to consummate the loan. The Company defaulted on the loan and the Leaders Bank sued Michael Flavin to recover the approximately $8,000,000 in principal and interest due under the loan. Michael Flavin and the Leaders Bank settled the suit and Michael Flavin paid $300,000 to achieve the Settlement Agreement with the Bank (see **Company History**

and Recent Developments). In recognition of this payment for the benefit of the Company and its shareholders, the Board of Directors determined that Michael Flavin should be repaid his payment of $300,000. Effective on July 1, 2015, the Board approved the issuance of 5,000,000 shares of the Company's common stock, in connection with Michael Flavin's payment of $300,000. As a result of this issuance, Michael Flavin beneficially owned approximately 40.4% of our outstanding common stock as of December 31, 2015 and will be able to exert significant influence for all matters requiring approval of our stockholders, including the election of directors and approval of significant corporate transactions. This concentration of ownership may delay, prevent or deter a change in control of our company even when such a change may be in the best interest of all the stockholders, could deprive stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or assets and might affect the prevailing market price of our common stock.

Provisions of Delaware law or our charter documents could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our stockholders, and could make it more difficult for you to change management.

Provisions of our amended and restated certificate of incorporation and bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. This is because these provisions may prevent or frustrate attempts by stockholders to replace or remove our current management or members of our Board of Directors.

These provisions include:

- a classified Board of Directors under which approximately one third of the directors will be elected each year;
- a requirement that the authorized number of directors to be changed only by a resolution of the Board of Directors;
- authorized and unissued additional shares of our common stock and preferred stock;
- advance notice requirements for proposals that can be acted upon at stockholder meetings; and
- a requirement that only our Chairman or our Board of Directors, acting by resolution, may call stockholder meetings.

As a result, these provisions and others available under Delaware law could limit the price that investors are willing to pay in the future for shares of our common stock.

We have never paid cash dividends on our capital stock and we do not anticipate paying dividends in the foreseeable future.

We have paid no cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any future debt or credit facility may preclude us from paying any dividends. Capital appreciation of our common stock, if any, will be your sole source of potential gain for the foreseeable future. Consequently, in the foreseeable future, you will only experience a gain from your investment in our common stock if the price of our common stock increases.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate office is located in Woodridge, Illinois and consists of approximately 1,500 square feet of office space. We believe that our current facilities are adequate to meet our needs for the foreseeable future. Our facilities are leased and our current lease expires in August, 2016. We believe that suitable additional or alternative space will be available in the future on commercially reasonable terms as needed.

Item 3. Legal Proceedings.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock is currently traded on the OTC Bulletin Board ("OTCBB") under the symbol "ADLS". The following table sets forth the range of high and low bid quotations for our common stock for each quarter of the last five fiscal years, as reported on the OTCBB. The quotations represent inter-dealer prices without retail markup, markdown or commission, and may not necessarily represent actual transactions. On March 28, 2011, the Company effected a 1-for-30 reverse stock split.

2015	High	Low
First Quarter	$0.03	$0.02
Second Quarter	0.03	0.02
Third Quarter	0.03	0.01
Fourth Quarter	0.02	0.01
2014	**High**	**Low**
First Quarter	$0.05	$0.01
Second Quarter	0.10	0.03
Third Quarter	0.06	0.03
Fourth Quarter	0.05	0.01
2013	**High**	**Low**
First Quarter	$0.09	$0.02
Second Quarter	0.07	0.02
Third Quarter	0.10	0.01
Fourth Quarter	0.29	0.01
2012	**High**	**Low**
First Quarter	$0.06	$0.03
Second Quarter	0.06	0.03
Third Quarter	0.07	0.01
Fourth Quarter	0.10	0.02
2011	**High**	**Low**
First Quarter	$0.69	$0.01
Second Quarter	0.30	0.03

Third Quarter	0.18	0.04
Fourth Quarter	0.08	0.03

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2013. Based on that evaluation, our CEO and CFO concluded that the Company's disclosure controls and procedures were not effective as of December 31, 2013 [due to our inability to file periodic reports on a timely basis with the SEC as a result of our lack of capital resources and internal financial and accounting personnel].

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2013, using the criteria set forth in the *Internal Control—Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Our management concluded that we did not maintain effective internal control over financial reporting because of lack of capital resources and internal financial and accounting personnel.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting due to the permanent exemption from such requirement for smaller reporting companies.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers and Directors

The following table sets forth certain information regarding our executive officers and directors as of December 31, 2015.

Name	Age	Positions
Michael T. Flavin, Ph.D.	60	Chief Executive Officer and Chairman of the Board of Directors
Scott F. Meadow	62	Director
Terry W. Osborn, Ph.D.	72	Director
Richard A. Reck	66	Director

Thomas V. Thornton	50	Director
Rosalie Sagraves, Pharm. D.	70	Director
Israel Rubinstein, M.D.	64	Director
John L. Flavin	47	Director

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than ten percent of our common stock, to file with the SEC and any exchange or other system on which such securities are traded or quoted, initial reports of ownership and reports of changes in ownership of our common stock.

To our knowledge, based solely on a review of the copies of such reports furnished to us, we believe that all required reports of our officers, directors and greater than ten percent stockholders under Section 16(a) were timely filed during the years ended December 31, 2011, 2012, 2013, 2014 and 2015.

Code of Business Conduct and Ethics

We have established a Code of Business Conduct and Ethics that applies to our officers, directors, employees, representatives, agents and consultants. We intend to satisfy the requirements under Item 5.05 of Form 8-K regarding disclosure of amendments to, or waivers from, provisions of our Code of Business Conduct and Ethics that apply to our directors and principal executive, financial and accounting officers by posting such information on our website.

Audit Committee

The Company has a separately designated Audit Committee. The Audit Committee reviews and monitors our corporate financial reporting, our external audits, the results and scope of the annual audit, other services provided by our independent auditors and our compliance with legal matters that have a significant impact on our financial reports. The Audit Committee also consults with management and our independent auditors before the presentation of financial statements to stockholders and, as appropriate, initiates inquiries into aspects of our financial affairs. In addition, the Audit Committee has the responsibility to consider and recommend the appointment of, and to review fee arrangements with, our independent auditors. The current members of the Audit Committee are Richard Reck, Scott Meadow and Terry Osborn, each of whom is an independent director. Richard Reck is an audit committee financial expert as defined in Item 407(d)(5) of Regulation S-K.

Item 11. Executive Compensation.

Summary Compensation Table

The following table shows information concerning the annual compensation for services to the Company of the Chief Executive Officer and the two (2) other most highly compensated executive officers of the Company (collectively the "Named Executive Officers" or "NEOs") during fiscal years 2011, 2012, 2013, 2014 and 2015.

Name & Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	Total ($)
Michael T. Flavin, Ph.D., Chief Executive Officer, Chairman of the Board	2015	0	0	0	4,000		4,000
	2014	0	0	0			
	2013	0	0	0			
	2012	0	0	0			
	2011	50,000	0	0			50,000

John L. Flavin, President, Chief Financial Officer, Secretary and Director	2015	0	0	0	2,000	2,000
	2014	0	0	0		
	2013	0	0	0		
	2012	0	0	0		
	2011	45,000	0	0		45,000
Ze-Qi Xu, Ph.D., Executive Vice President and Chief Scientific Officer	2015	0	0	0	1,700	1,700
	2014	0	0	0		
	2013	0	0	0		
	2012	0	0	0		
	2011	40,000	0	0		40,000

(1) Under the new 2015 Equity Incentive Plan, the NEOs listed above were awarded non-qualified stock options with an exercise price of $0.02 which vested on July 1, 2015. The amounts in this column represent the aggregate grant date fair value of option awards computed in accordance with FASB ASC Topic 718.

Compensation Program Components

The Compensation Committee is responsible for reviewing and determining compensation for our NEOs and senior management. The Compensation Committee believes that the total compensation opportunity available to members of management should consist of base salary, annual bonuses and equity-based compensation. The Compensation Committee considers all elements of the program when setting compensation levels. The Compensation Committee periodically meets individually with members of management in order to assess progress toward meeting objectives set by the Board of Directors for both annual and long-term compensation.

Base Salaries

Base salaries are determined in accordance with the responsibilities of each officer, median market data for the position and the officer's performance achieving corporate goals. The Compensation Committee considers each of these factors but does not assign a specific value to each factor. Furthermore, a subjective element is acknowledged in evaluating the officer's overall span of responsibility and control. Total compensation for the Company's officers is believed to be generally in line with similarly situated companies.

Annual Bonuses

The Compensation Committee reviews annual bonuses with senior management. Awards are based on an evaluation of the performance, level of responsibility and leadership of the individual in relation to overall corporate results.

Equity-Based Compensation

The Compensation Committee believes strongly that equity-based awards are an integral part of total compensation for officers and certain key managers with significant responsibility for the Company's long-term results. The Compensation Committee believes that stock option grants, which are tied to the increase in value of the Company's common stock, provide an effective means of delivering incentive compensation and foster stock ownership on the part of management.

On June 25, 2015, the Board of Directors adopted a new equity incentive plan for purposes of new equity awards going forward and terminated the Company's 2005 Stock Incentive Plan. The 2005 Plan was terminated in its entirety and no further grants will be made thereunder, but any grants outstanding thereunder will remain outstanding in accordance with their terms and conditions.

The new plan, the 2015 Equity Incentive Plan, enables certain employees, officers, directors, consultants, agents, advisors and independent contractors of the Company to acquire shares of the Company's common stock. The 2015 Plan sets aside and reserves up to 2,000,000 shares of the Company's common stock for issuance pursuant to equity awards under the 2015 Plan. The importance of the new 2015 Equity Incentive Plan is that it can provide a way for the Company to compensate the individuals who have worked and will continue to work on behalf of the Company to help rebuild the value of ADLS.

In 2015, the Board of Directors awarded 99,868 stock options under the 2005 Stock Incentive Plan to the NEO's. In 2010, Drs. Michael Flavin and Ze-Qi Xu received 200,000 and 85,000 stock options respectively and John Flavin received a total of 100,000 stock options, each of which vested on July 1, 2015.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth aggregate holdings of stock options by our NEOs as of December 31, 2010.

	Option Awards				
Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable(#)(1)	Number of Securities Underlying Unexercised Options Unexercisable(#)	Option Exercise Price($)(2)	Option Expiration Date
Michael T. Flavin, Ph.D.	July 1, 2015	200,000		0.02	2025
John L. Flavin	July 1, 2015	100,000		0.02	2025
Ze-Qi Xu, Ph.D.	July 1, 2015	85,000		0.02	2025

(1) Options vested on July 1, 2015.

Director Compensation

There has been no cash compensation paid to directors during 2011, 2012, 2013, 2014 or 2015.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Scott F. Meadow	0	—	500	—	—	—	500
Terry W. Osborn	0	—	500	—	—	—	500
Richard A. Reck	0	—	500	—	—	—	500
Israel Rubinstein	0	—	500	—	—	—	500
Rosalie Sagraves	0	—	500	—	—	—	500
Thomas V. Thornton	0	—	500	—	—	—	500

(1) Under the new 2015 Equity Incentive Plan, each director was granted 25,000 non-qualified stock options with an exercise price of $0.02 which vested on July 1, 2015. The amounts in this column represent the aggregate grant date for fair value of option awards computed in accordance with FASB ASC Topic 718.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Ownership by Our Directors, Executive Officers and Greater than 5% Stockholders

The following table sets forth information with respect to the beneficial ownership of our common stock as of December 31, 2015 by:

- each person (or group of affiliated persons) who is known by us to own beneficially more than 5% of our outstanding common stock or convertible preferred stock;
- each current director;
- each of the named executive officers listed in the Summary Compensation Table above; and
- all directors and executive officers as a group.

Beneficial ownership is determined in accordance with SEC rules. In computing a person's percentage ownership of common stock, shares of common stock subject to options or restricted stock units held by that person that are currently exercisable, or exercisable (or, in the case of restricted stock units, scheduled to vest and settle) within 60 days after December 31, 2015. None of these shares, however, are deemed outstanding for the purpose of computing the percentage ownership of any other person.

Except as indicated and pursuant to applicable community property laws, each stockholder named in the table has sole voting and

investment power with respect to the shares set forth opposite such stockholder's name. Percentage ownership is based on 17,586,830 shares of our common stock outstanding on December 31, 2015. Unless otherwise indicated below, the address for each director and named executive officer listed below is in care of Advanced Life Sciences Holdings, Inc., 1440 Davey Road, Woodridge, IL 60517.

Name and Address(1)	Number of Shares Beneficially Owned	Approximate Percent of Class
DIRECTORS AND EXECUTIVE OFFICERS:		
Michael T. Flavin(2)	7,107,529	40.4%
John L. Flavin(3)	420,101	2.4%
Ze-Qi Xu, Ph.D.(4)	85,033	*
Richard Reck(5)	86,366	*
Terry W. Osborn(6)	3,940	*
Rosalie Sagraves(7)	3,840	*
Israel Rubinstein	3,607	*
Thomas V. Thornton	3,607	*
Scott Meadow	3,720	*
All directors and executive officers as a group (11 persons)	7,717,743	43.9%

* = less than 1%

(1) Unless otherwise indicated, the address for each five percent stockholder, director, director nominee and executive officer is c/o Advanced Life Sciences Holdings, Inc., 1440 Davey Road, Woodridge, Illinois 60517.

(2) Dr. Michael Flavin is a member and a manager of Flavin Ventures, LLC, which is the sole voting member of ALS Ventures, LLC. In such capacity he may be deemed to have shared voting and investment power with respect to 314,677 shares held by ALS Ventures, LLC and 5,051 shares held by Flavin Ventures, LLC. Dr. Michael Flavin disclaims beneficial ownership of the shares held by ALS Ventures, LLC and Flavin Ventures, LLC, except to the extent of his proportionate pecuniary interest therein. Includes 1,587,801 shares of common stock held directly and 200,000 shares issuable upon the exercise of stock options that are currently exercisable or exercisable within 60 days.

(3) Mr. John Flavin is a member and a manager of Flavin Ventures, LLC, which is the sole voting member of ALS Ventures, LLC. In such capacity he may be deemed to have shared voting and investment power with respect to 314,677 shares held by ALS Ventures, LLC and 5,051 shares held by Flavin Ventures, LLC. Mr. John Flavin disclaims beneficial ownership of the shares held by ALS Ventures, LLC and Flavin Ventures, LLC, except to the extent of his proportionate pecuniary interest therein. Includes 373 shares of common stock held directly and 100,000 shares issuable upon the exercise of stock options that are currently exercisable or exercisable within 60 days.

(4) Includes 33 shares of common stock held directly by Dr. Xu and 85,000 shares issuable upon the exercise of stock options that are currently exercisable or exercisable within 60 days.

(5) Includes 82,000 shares held indirectly by Mr. Reck as Trustee for the Richard A. Reck Trust and 666 shares held indirectly by Mr. Reck as Trustee for the Daniel M. Reck Trust and 3,220 shares issuable upon the exercise of stock options that are currently exercisable or exercisable within 60 days.

(6) Includes 333 shares of common stock held directly by Dr. Osborn and 3,107 shares issuable upon the exercise of stock options that are currently exercisable or exercisable within 60 days.

(7) Includes 266 shares of common stock held directly by Dr. Sagraves and 3,073 shares issuable upon the exercise of stock options that are currently exercisable or exercisable within 60 days.

Equity Compensation Plan Information

On June 25, 2015, the Board of Directors adopted a new equity incentive plan for purposes of new equity awards going forward and terminated the Company's 2005 Stock Incentive Plan. The 2005 Plan was terminated in its entirety and no further grants will be made thereunder, but any grants outstanding thereunder will remain outstanding in accordance with their terms and conditions.

The new plan, the 2015 Equity Incentive Plan, enables certain employees, officers, directors, consultants, agents, advisors and independent contractors of the Company to acquire shares of the Company's common stock. The 2015 Plan sets aside and reserves up to 2,000,000 shares of the Company's common stock for issuance pursuant to equity awards under the 2015 Plan. The importance of the new 2015 Equity Incentive Plan is that it can provide a way for the Company to compensate the individuals who have worked and will continue to work on behalf of the Company to help rebuild the value of ADLS. Of the 2,000,000 shares that have been reserved for the 2015 Equity Incentive Plan, 995,000 non-qualified stock options have been awarded and are exercisable, leaving 1,005,000 shares available for future stock option awards.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Related Person Transactions

Michael Flavin was the only officer or director to have transactions with the Company since April 2011. These transactions included: (1) ADLS entered into a Business Loan Agreement with Leaders Bank for which Michael Flavin served as a personal guarantor as required by the Leaders Bank to consummate the loan. The Company defaulted on the loan and the Leaders Bank filed a lawsuit against Michael Flavin to recover the approximately $8,000,000 in principal and interest due under the loan. (2) In connection with the settlement agreement with Leaders Bank, Michael Flavin paid the bank $300,000 to fully satisfy the debt and remove the outstanding liability on the Company. (3) Michael Flavin incurred approximately $75,000 in legal fees during discussions leading to the settlement agreement with Leaders Bank. (4) In recognition of this payment for the benefit of the Company and its shareholders, the Board of Directors determined that Michael Flavin should be repaid for his payment of $300,000. (5) Therefore, the Board approved the issuance of 5,000,000 shares of the Company's common stock in connection with Michael Flavin's payment of $300,000. (6) Michael Flavin and John Flavin have worked on several projects associated with Advanced Life Sciences during 2011, 2012, 2013, 2014 and 2015 without any cash compensation. For these efforts, the Board of Directors granted Michael Flavin 200,000 non-qualified stock options and John Flavin 100,000 non-qualified stock options at an exercise price of $0.02, all of which vested on July 1, 2015, as described in the table above.

Director Independence

Michael Flavin and John Flavin are not an independent directors as defined in rules of the NASDAQ Stock Market. However, the other six directors are independent directors as defined in rules of the NASDAQ Stock Market.

Item 14. Principal Accounting Fees and Services.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) Financial Statements.

The financial statements filed as part of this report are listed under Item 8. "Financial Statements and Supplementary Data."

(2) Financial Statement Schedules

All financial statement schedules have been omitted because they are not required, are not applicable or the information is included in financial statements and notes thereto.

(3) Exhibits

There a no exhibits attached as part of this report.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ADVANCED LIFE SCIENCES HOLDINGS, INC.

By: /s/ Michael T. Flavin, Ph.D.
Name: Michael T. Flavin, Ph.D.
Title: Chairman and Chief Executive Officer

Date: July 19, 2016

Advanced Life Sciences, Inc.

SUMMARY

For the Twelve Months Ending December 31, 2011

	ALS, Holding Dec 31, 2011	ALS, Inc. Dec 31, 2011	Eliminations DR	Eliminations CR	Consolidated Dec 31, 2011
Income					
Research and Development Expense					
Manufacturing - Clinical Tablets		1,890.75			[illegible]
Clinical trials - Cervix		2,827.88			[illegible]
Antimicrobial Peptide Study		4,946.10			4,946.10
Clinical trial insurance		3,862.50			3,862.50
Salaries		157,193.74			157,193.74
Benefits		36,849.50			36,849.50
Payroll taxes		16,465.45			16,465.45
Incentive compensation	19,602.47				19,602.47
Outsourced analytical services		1,583.14			1,583.14
Lab supplies		767.24			767.24
Product storage		2,059.17			2,059.17
Hazardous waste disposal		789.54			789.54
Conference & seminars		1,750.00			1,750.00
Allocations from G&A		3,000.00			3,000.00
Severance costs		86,734.06			86,734.06
Total Research and Development	19,602.47	322,669.14	0	0	342,291.61
General and Administrative Expense					
Payroll					
Salaries		260,863.76			260,863.76
G&A incentive compensation	31,268.84				31,268.84
Payroll taxes		29,487.01			29,487.01
Benefits		44,714.72			44,714.72
Vacation expense		19,112.16			19,112.16
Worker's compensation insurance		1,793.42			1,793.42
Benefit plan fees		108.00			108.00
Payroll processing fees		2,156.85			2,156.85
Total Payroll Expenses	31,268.84	386,215.76	0	0	418,484.61
Professional Services					
Accounting services expense	29,254.25	306.60			29,560.85
Legal fees - corporate	1,043.00	81,077.06			82,120.06
Legal fees - patents		7,800.00			7,800.00
Printing fees	3,583.00				3,583.00
Transfer agent fees	22,163.40	[illegible]			22,163.40
Directors fees	68,751.00				68,751.00
Directors/officers insurance	75,228.26				75,228.26
Total Professional Services	200,994.51	89,002.66	0	0	289,997.20
Investor Relations					
IR website/conference call	3,182.00				3,182.00
Investor relations program	12,344.50				12,344.50
Total Investor Relations	15,526.50	0	0	0	15,526.50

Advanced Life Sciences, Inc.

SUMMARY

For the Twelve Months Ending December 31, 2011

	ALS, Holding Dec 31, 2011	ALS, Inc. Dec 31, 2011	Eliminations DR	Eliminations CR	Consolidated Dec 31, 2011
Administrative Expenses					
Employment practices insurance		2,509.26			2,509.26
Bank charges	748.25	1,353.89			2,102.14
Conference & seminars		600.00			600.00
Copies/printing		503.86			503.86
Dues & subscriptions		150.00			150.00
Franchise taxes	1,583.70	1,491.20			3,074.90
Freight & postage		501.39			501.39
Office supplies		3,572.30			3,572.30
Software support		2,041.23			2,041.23
Total Administrative Expenses	2,331.95	12,723.13	0	0	15,055.08
Facilities Expense					
Rent		35,341.49			35,341.49
Common area maintenance		(4,167.00)			(4,167.00)
Depreciation		23,463.79			23,463.79
Property and casualty insurance		3,564.24			3,564.24
Equipment leases		2,370.00			2,370.00
Repairs & maintenance		2,681.50			2,681.50
Telephone/internet		7,467.46			7,467.46
Utilities		16,030.31			16,030.31
Facilities expense allocated to R&D		(3,000.00)			(3,000.00)
Total Facilities Expense	0	83,771.79	0	0	83,771.79
Travel Expense					
Meals & entertainment		313.61			313.61
Travel		5,832.78			5,832.78
Travel - Mileage/parking	806.30				806.30
Total Travel Expense	806.30	6,146.39	0	0	6,952.69
Total General and Administrative Expenses	250,938.10	559,859.79	0	0	810,797.89
Sales and Marketing Expense					
Salaries		61,341.86			61,341.86
Payroll taxes		5,350.38			5,350.38
Benefits		14,703.52			14,703.52
Incentive compensation	7,191.43				7,191.43
Total Sales and Marketing	7,191.43	81,395.74	0	0	88,587.17
Total Expenses	277,722.00	964,944.67	0	0	1,242,666.67
Net Ordinary Income	(277,722.00)	(964,944.67)	0	0	(1,242,666.67)
Other Income Expenses					
Interest income	(15.03)				(15.03)
Interest expense	1,332.58	234,204.20			235,536.78
(Gain)Loss on Disposal of Assets	0.00	21,058.91			21,058.91
Total Other Expense (Net)	1,317.55	255,263.11	0.00	0.00	256,580.66
Net Income (Loss)	(279,039.55)	(1,220,207.78)	0	0	(1,499,247.33)

1

Advanced Life Sciences, Inc.
SUMMARY
For the Twelve Months Ending December 31, 2011

	ALS, Holding Dec 31, 2011	ALS, Inc. Dec 31, 2011	Eliminations DR	Eliminations CR	Consolidated Dec 31, 2011
ASSETS					
Current Assets					
Checking/Savings					
Cash - Leaders	0.00	0.00			0.00
Cash - JPM Chase Operating	0.00	54.07			54.07
Cash - RSVP	0.00				0.00
Total Checking/Savings	0.00	54.07	0.00	0.00	54.07
Accounts Receivable	0.00	0.00			
Grant Receivable	0.00	0.00			
Total Account Receivable	0.00	0.00	0.00	0.00	0.00
Other Current Assets					
Prepaid expenses	0.00	(0.00)		[redacted]	(30,141.49)
Prepaid insurance	57,351.45	17,983.46			75,334.91
Restricted cash - interest reserve		0.00			0.00
Total Other Current Assets	57,351.45	17,983.46	0.00	(30,141.49)	45,193.42
Total Current Assets	57,351.45	18,037.53	0.00	(30,141.49)	45,247.49
Fixed Assets					
Furniture and fixtures		0.00			0.00
Computer equipment		0.00			0.00
Leasehold improvements		0.00			0.00
Accumulated Depreciation		0.00			0.00
Total Fixed Assets	0.00	0.00	0.00	0.00	0.00
Other Assets					
Restricted cash - Chase CC	0.00				0.00
Deposits		555.09			555.09
Deferred financing	62,040.77	87,131.46			149,172.23
Due from ALS Holdings, Inc	124,488,532.89			(124,488,532.89)	0.00
Other long term assets		250,000.00			250,000.00
Total Other Assets	124,550,573.66	347,686.55	0.00	(124,488,532.89)	399,727.32
TOTAL ASSETS	124,597,925.11	365,724.08	0.00	(124,518,674.38)	444,974.81

Advanced Life Sciences, Inc.
SUMMARY
For the Twelve Months Ending December 31, 2011

	ALS, Holding Dec 31, 2011	ALS, Inc. Dec 31, 2011	Eliminations DR	Eliminations CR	Consolidated Dec 31, 2011
LIABILITIES & EQUITY					
Liabilities					
Current Liabilities					
Accounts Payable					
Accounts payable	112,601.85	1,241,468.85	(30,141.49)		1,323,928.31
Total Accounts Payable	112,601.85	1,241,468.85	(30,141.49)	0.00	1,323,928.31
Other Current Liabilities					
Accrued expenses	373,555.47	206,348.96			579,904.43
Accrued expenses - credit card		2,886.71			2,886.71
Accrued purchases		12.10			12.10
Deferred rent		2,762.94			2,762.94
Accrued severance payable		54,608.78			54,608.78
ST lease payable		4,982.25			4,982.25
Payroll clearing		(2,882.16)			(2,882.16)
Accrued vacation payable		19,112.16			19,112.16
401(k) payable		0.00			0.00
Health insurance payable		396.47			396.47
Medical flex and dependant care payable		(0.60)			(0.60)
Accrued interest payable		47,604.40			47,604.40
Notes payable - Leader's Bank				8,080,000.00	8,080,000.00
Notes payable - Michael T Flavin		63,000.00			63,000.00
Total Other Current Liabilities	373,555.47	398,832.01	0.00	8,080,000.00	8,852,387.48
Total Current Liabilities	486,157.42	1,640,300.86	(30,141.49)	8,080,000.00	10,176,315.79
Long Term Liabilities					
Notes payable - Leaders back		8,080,000.00	(8,080,000.00)		0.00
Grants Payable LT		500,000.00			500,000.00
LT lease payable		14,706.46			14,706.46
Due to ALS Holdings, Inc		124,488,532.85	(124,488,532.85)		0.00
Total Long Term Liabilities	0.00	133,083,239.32	(132,568,532.85)	0.00	514,706.46
Total Liabilities	486,157.42	134,723,540.18	(132,598,674.35)	8,080,000.00	10,691,023.25
Equity					
Common stock	3,261,143.97		(3,104,472.00)		156,671.97
Additional paid-in capital	129,864,736.20			3,104,472.00	131,969,210.20
Retained Earnings (Deficit)	(7,735,074.63)	(133,137,606.32)			(140,872,683.25)
Net Profit (Loss) for the Period	(279,039.05)	(1,220,207.78)			(1,499,247.33)
Total Equity	124,111,767.69	(134,357,816.10)	(3,104,472.00)	3,104,472.00	(10,248,048.41)
TOTAL LIABILITIES & EQUITY	124,597,925.11	365,724.08	(135,703,146.35)	11,184,472.00	444,974.84
	0.00	(0.00)	135,703,146.35	(135,703,146.38)	(0.03)

Advanced Life Sciences, Inc.
SUMMARY
For the Twelve Months Ending December 31, 2013

	ALS Holding Dec 31, 2013	ALS, Inc. Dec 31, 2013	Eliminations DR	Eliminations CR	Consolidated Dec 31, 2013
ASSETS					
Current Assets					
Checking/Savings					
Cash - Leaders	0.00	0.00			0.00
Cash - JPM Chase Operating	0.00	0.00			0.00
Cash - Bank of America	3,110.08	0.00			3,110.08
Cash - RSVP	0.00				0.00
Total Checking/Savings	3,110.08	0.00	0.00	0.00	3,110.08
Accounts Receivable	0.00	0.00			
Grant Receivable	0.00	0.00			
Total Account Receivable	0.00	0.00	0.00	0.00	0.00
Other Current Assets					
Prepaid expense	0.00	(0.00)		[redacted]	(30,141.49)
Prepaid insurance	57,351.45	17,983.46			75,334.91
Restricted cash - interest reserve		0.00			0.00
Total Other Current Assets	57,351.45	17,983.46	0.00	(30,141.49)	45,193.42
Total Current Assets	60,461.53	17,983.46	0.00	(30,141.49)	48,303.50
Fixed Assets					
Furniture and fixtures		0.00			0.00
Computer equipment		0.00			0.00
Leasehold improvements		0.00			0.00
Accumulated Depreciation		0.00			0.00
Total Fixed Assets	0.00	0.00	0.00	0.00	0.00
Other Assets					
Restricted cash - Chase CC	0.00				0.00
Deposits		555.09			555.09
Deferred financing	52,040.77	97,131.46			149,172.23
Due from ALS Holdings, Inc.	124,488,532.89			(124,488,532.89)	0.00
Other long term assets		250,000.00			250,000.00
Total Other Assets	124,540,573.66	347,686.55	0.00	(124,488,532.89)	399,727.32
TOTAL ASSETS	124,601,035.19	365,670.01	0.00	(124,518,674.38)	448,030.82

Advanced Life Sciences, Inc.
SUMMARY
For the Twelve Months Ending December 31, 2013

	ALS, Holding Dec 31, 2013	ALS, Inc. Dec 31, 2013	Eliminations DR	Eliminations CR	Consolidated Dec 31, 2013
LIABILITIES & EQUITY					
Liabilities					
Current Liabilities					
Accounts Payable					
Accounts payable	112,601.95	1,241,468.85	[redacted]		1,323,929.31
Total Accounts Payable	112,601.95	1,241,468.85	(30,141.49)	0.00	1,323,929.31
Other Current Liabilities					
Accrued expenses	376,055.43	206,224.91			582,280.35
Accrued expenses - credit card		2,886.71			2,886.71
Accrued purchases		12.10			12.10
Deferred rent		2,762.94			2,762.94
Accrued severance payable		54,608.78			54,608.78
ST lease payable		4,982.25			4,982.25
Payroll clearing		(2,882.16)			(2,882.16)
Accrued vacation payable		19,112.16			19,112.16
401(k) payable		0.00			0.00
Health insurance payable		396.47			396.47
Medical fire and dependant care payable		(0.60)			(0.60)
Accrued interest payable		0.00			0.00
Notes payable - Leader's Bank				4,000,000.00	4,000,000.00
Notes payable - Michael T Flavin		63,000.00			63,000.00
Total Other Current Liabilities	376,055.43	351,103.36	0.00	4,000,000.00	4,727,159.03
Total Current Liabilities	488,657.42	1,592,572.41	(30,141.49)	4,000,000.00	6,051,088.34
Long Term Liabilities					
Notes payable - Leaders bank		4,000,000.00	(4,000,000.00)		0.00
Grants Payable L-T		500,000.00			500,000.00
LT lease payable		14,706.48			14,706.48
Due to ALS Holdings, Inc.		124,488,532.89	(124,488,532.89)		0.00
Total Long Term Liabilities	0.00	129,003,239.37	(128,488,532.89)	0.00	514,706.48
Total Liabilities	488,657.42	[redacted]	(128,518,674.38)	4,000,000.00	6,565,794.80
Equity					
Common stock	3,261,143.97		[redacted]		136,671.97
Additional paid-in capital	125,894,735.20			[redacted]	131,969,210.20
Retained Earnings (Deficit)	(5,014,114.48)	(133,357,746.12)			(142,371,860.60)
Net Profit (Loss) for the Period	610.08	4,129,894.40			4,129,214.48
Total Equity	124,112,377.77	(129,227,851.72)	(3,104,472.00)	3,104,472.00	(9,117,763.95)
TOTAL LIABILITIES & EQUITY	124,601,035.19	365,670.01	(131,623,146.38)	7,104,472.00	448,030.85
	0.00	(0.00)	131,623,146.38	(131,623,146.38)	(0.03)

Advanced Life Sciences, Inc.
SUMMARY
For the Twelve Months Ending December 31, 2014

	ALS, Holding Dec 31, 2014	ALS, Inc. Dec 31, 2014	Eliminations DR	Eliminations CR	Consolidated Dec 31, 2014
Income					
Research and Development Expense					
Manufacturing - Clinical Tablets		-			0.00
Clinical trials - Cellvtx		-			0.00
Antimicrobial Peptide Study		0.00			0.00
Clinical trial insurance		0.00			0.00
Salaries		0.00			0.00
Benefits		0.00			0.00
Payroll taxes		0.00			0.00
Incentive compensation	0.00	-			0.00
Outsourced preclinical services		0.00			0.00
Lab supplies		0.00			0.00
Product storage		0.00			0.00
Hazardous waste disposal		-			0.00
Conference & seminars		-			0.00
Allocations from G&A		0.00			0.00
Severance costs		-			0.00
Total Research and Development	0.00	0.00	0	0	0.00
General and Administrative Expense					
Payroll					
Salaries		0.00			0.00
G&A incentive compensation	0.00	-			0.00
Payroll taxes		0.00			0.00
Benefits		0.00			0.00
Vacation expense		0.00			0.00
Worker's compensation insurance		0.00			0.00
Benefit plan fees		-			0.00
Payroll processing fees		0.00			0.00
Total Payroll Expenses	0.00	0.00	0	0	0.00
Professional Services					
Accounting services expense	0.00	-			0.00
Legal fees - corporate	0.00	0.00			0.00
Legal fees - patents		0.00			0.00
Printing fees	0.00				0.00
Transfer agent fees	0.00	0.00			0.00
Directors fees	0.00				0.00
Directors/officers insurance	0.00				0.00
Total Professional Services	0.00	0.00	0	0	0.00
Investor Relations					
IR website/conference call	0.00				0.00
Investor relations program	(3,063.11)				(3,063.11)
Total Investor Relations	(3,063.11)	0	0	0	(3,063.11)

Advanced Life Sciences, Inc.
SUMMARY
For the Twelve Months Ending December 31, 2014

	ALS, Holding Dec 31, 2014	ALS, Inc. Dec 31, 2014	Eliminations DR	Eliminations CR	Consolidated Dec 31, 2014
Administrative Expenses					
Employment practices insurance		0.00			0.00
Bank charges	0.00	0.00			0.00
Conference & seminars		-			0.00
Copier/printing		-			0.00
Dues & subscriptions		-			0.00
Franchise taxes	0.00	0.00			0.00
Freight & postage		0.00			0.00
Office supplies		0.00			0.00
Software support		0.00			0.00
Total Administrative Expenses	0.00	0.00	0	0	0.00
Facilities Expense					
Rent		0.00			0.00
Common area maintenance		0.00			0.00
Depreciation		0.00			0.00
Property and casualty insurance		0.00			0.00
Equipment leases		0.00			0.00
Repairs & maintenance		0.00			0.00
Telephone/internet		0.00			0.00
Utilities		0.00			0.00
Facilities expense allocated to R&D		0.00			0.00
Total Facilities Expense	0	0.00	0	0	0.00
Travel Expense					
Meals & entertainment		0.00			0.00
Travel		-			0.00
Travel - Mileage/parking		-			0.00
Total Travel Expense	-	0.00	0	0	0.00
Total General and Administrative Expenses	(3,063.11)	0.00	0	0	(3,063.11)
Sales and Marketing Expense					
Salaries		0.00			0.00
Payroll taxes		0.00			0.00
Benefits		0.00			0.00
Incentive compensation	0.00	-			0.00
Total Sales and Marketing	0.00	0.00	0	0	0.00
Total Expenses	(3,063.11)	0.00	0	0	(3,063.11)
Net Ordinary Income	3,063.11	0.00	0	0	3,063.11
Other Income/Expenses					
Interest income	0.00				0.00
Interest expense	0.00	0.00			0.00
Miscellaneous income		0.00			0.00
Total Other Expense (Net)	0.00	0.00	0	0	0.00
Net Income (Loss)	3,063.11	0.00	0	0	3,063.11

Advanced Life Sciences, Inc.
SUMMARY
For the Twelve Months Ending December 31, 2014

	ALS Holding Dec 31, 2014	ALS, Inc. Dec 31, 2014	Eliminations DR	Eliminations CR	Consolidated Dec 31, 2014
ASSETS					
Current Assets					
Checking/Savings					
Cash - Leaders	0.00	0.00			0.00
Cash - JPM Chase Operating	0.00	0.00			0.00
Cash - Bank of America	6,173.16	0.00			6,173.16
Cash - ESVF	0.00				0.00
Total Checking/Savings	6,173.16	0.00	0.00	0.00	6,173.16
Accounts Receivable	0.00	0.00			
Grant Receivable	0.00	0.00			
Total Account Receivable	0.00	0.00	0.00	0.00	0.00
Other Current Assets					
Prepaid expenses	2,828.87	(0.00)		(30,141.48)	27,312.62
Prepaid insurance	37,351.45	17,983.46			75,334.91
Restricted cash - interest reserve		0.00			0.00
Total Other Current Assets	62,180.32	17,983.46	0.00	(30,141.48)	49,022.26
Total Current Assets	68,353.51	17,983.46	0.00	(30,141.48)	54,195.48
Fixed Assets					
Furniture and fixtures		0.00			0.00
Computer equipment		0.00			0.00
Leasehold improvements		0.00			0.00
Accumulated Depreciation		0.00			0.00
Total Fixed Assets	0.00	0.00	0.00	0.00	0.00
Other Assets					
Restricted cash - Chase CC	0.00				0.00
Deposits		555.09			555.09
Deferred financing	52,040.77	97,131.46			149,172.23
Due from ALS Holdings, Inc.	124,488,532.89			(124,488,532.89)	0.00
Other long term assets		250,000.00			250,000.00
Total Other Assets	124,540,573.66	347,686.55	0.00	(124,488,532.89)	399,727.32
TOTAL ASSETS	124,608,927.17	365,670.01	0.00	(124,518,674.36)	453,922.80

Advanced Life Sciences, Inc.
SUMMARY
For the Twelve Months Ending December 31, 2014

	ALS Holding Dec 31, 2014	ALS, Inc. Dec 31, 2014	Eliminations DR	Eliminations CR	Consolidated Dec 31, 2014
LIABILITIES & EQUITY					
Liabilities					
Current Liabilities					
Accounts Payable					
Accounts payable	112,601.95	1,241,468.85	(30,141.49)		1,323,929.31
Total Accounts Payable	112,601.95	1,241,468.85	(30,141.49)	0.00	1,323,929.31
Other Current Liabilities					
Accrued expenses	378,285.77	206,224.91			584,510.68
Accrued expenses - credit card		2,656.71			2,656.71
Accrued purchases		12.10			12.10
Deferred rent		2,762.94			2,762.94
Accrued severance payable		54,608.78			54,608.78
ST lease payable		4,982.25			4,982.25
Payroll clearing		(2,882.18)			(2,882.18)
Accrued vacation payable		19,112.18			19,112.18
401(k) payable		0.00			0.00
Health insurance payable		396.47			396.47
Medical flex and dependant care payable		(0.60)			(0.60)
Accrued interest payable		0.00			0.00
Notes payable - Leader's Bank				4,000,000.00	4,000,000.00
Notes payable - Michael T Flavin		63,000.00			63,000.00
Total Other Current Liabilities	378,285.77	351,103.56	0.00	4,000,000.00	4,729,389.33
Total Current Liabilities	490,887.72	1,592,572.41	(30,141.49)	4,000,000.00	6,053,318.64
Long Term Liabilities					
Notes payable - Leaders bank		4,000,000.00	(4,000,000.00)		0.00
Grants Payable L-T		500,000.00			500,000.00
LT lease payable		14,706.46			14,706.46
Due to ALS Holdings, Inc		124,488,532.89	(124,488,532.89)		0.00
Total Long Term Liabilities	0.00	129,003,239.35	(128,488,532.89)	0.00	514,706.46
Total Liabilities	490,887.72	130,595,811.76	(128,518,674.38)	4,000,000.00	6,568,025.10
Equity					
Common stock	3,261,143.97		(3,104,472.00)		156,671.97
Additional paid in capital	126,964,728.20			3,104,472.00	131,969,210.20
Retained Earnings - (Ltd Sell)	(8,012,935.83)	(130,230,141.72)			(138,243,047.55)
Net Profit (Loss) For the Period	3,083.11	0.00			3,083.11
Total Equity	124,116,039.45	(130,230,141.72)	(3,104,472.00)	3,104,472.00	(6,114,162.27)
TOTAL LIABILITIES & EQUITY	124,606,927.17	365,670.01	(131,623,146.38)	(131,623,146.38)	453,922.83
	0.00	(0.00)	131,623,146.38	(131,623,146.38)	(0.00)

Advanced Life Sciences, Inc.
SUMMARY
For the Twelve Months Ending December 31, 2015

	ALS Holding Dec 31, 2015	ALS, Inc. Dec 31, 2015	Eliminations DR	Eliminations CR	Consolidated Dec 31, 2015
Income					
Research and Development Expense					
Manufacturing - Clinical Tablets		-			0.00
Clinical trials - Cellvia		-			0.00
Antimicrobial Peptide Study		0.00			0.00
Clinical trial insurance		0.00			0.00
Salaries		0.00			0.00
Benefits		0.00			0.00
Payroll taxes		0.00			0.00
Incentive compensation	0.00				0.00
Outsourced analytical services		0.00			0.00
Lab supplies		0.00			0.00
Product storage		0.00			0.00
Hazardous waste disposal		-			0.00
Conference & seminars		-			0.00
Allocations from G&A		0.00			0.00
Severance costs					0.00
Total Research and Development	0.00	0.00	0	0	0.00
General and Administrative Expense					
Payroll					
Salaries		0.00			0.00
G&A incentive compensation	0.00				0.00
Payroll taxes		0.00			0.00
Benefits		0.00			0.00
Vacation expense		0.00			0.00
Worker's compensation insurance		0.00			0.00
Benefit plan fees		-			0.00
Payroll processing fees		0.00			0.00
Total Payroll Expenses	0.00	0.00	0	0	0.00
Professional Services					
Accounting services expense	0.00	-			0.00
Legal fees - corporate	3,000.00	0.00			3,000.00
Legal fees - patents		0.00			0.00
Printing fees	0.00				0.00
Transfer agent fees	0.00	0.00			0.00
Directors' fees	0.00				0.00
Director/officers insurance	0.00				0.00
Total Professional Services	3,000.00	0.00	0	0	3,000.00
Investor Relations					
IR website/conference call	0.00				0.00
Investor relations program	0.00				0.00
Total Investor Relations	0.00	0	0	0	0.00

Advanced Life Sciences, Inc.
SUMMARY
For the Twelve Months Ending December 31, 2015

	ALS Holding Dec 31, 2015	ALS, Inc. Dec 31, 2015	Eliminations DR	Eliminations CR	Consolidated Dec 31, 2015
Administrative Expenses					
Employment practices insurance		0.00			0.00
Bank charges	0.00	0.00			0.00
Conference & seminars		-			0.00
Copier/printing		-			0.00
Dues & subscriptions		-			0.00
Franchise taxes	0.00	0.00			0.00
Freight & postage		0.00			0.00
Office supplies		0.00			0.00
Software support		0.00			0.00
Total Administrative Expenses	0.00	0.00	0	0	0.00
Facilities Expense					
Rent		0.00			0.00
Common area maintenance		0.00			0.00
Depreciation		0.00			0.00
Property and casualty insurance		0.00			0.00
Equipment leases		0.00			0.00
Repairs & maintenance		0.00			0.00
Telephone/internet		0.00			0.00
Utilities		0.00			0.00
Facilities expense allocated to R&D		0.00			0.00
Total Facilities Expense	0	0.00	0	0	0.00
Travel Expense					
Meals & entertainment		0.00			0.00
Travel		-			0.00
Travel - Mileage/parking					0.00
Total Travel Expense		0.00	0	0	0.00
Total General and Administrative Expenses	3,000.00	0.00	0	0	3,000.00
Sales and Marketing Expense					
Salaries		0.00			0.00
Payroll taxes		0.00			0.00
Benefits		0.00			0.00
Incentive compensation	0.00				0.00
Total Sales and Marketing	0.00	0.00	0	0	0.00
Total Expenses	3,000.00	0.00	0	0	3,000.00
Net Ordinary Income	(3,000.00)	0.00	0	0	(3,000.00)
Other Income/Expenses					
Interest income	0.00				0.00
Interest expense	0.00	0.00			0.00
Miscellaneous income		0.00			0.00
Total Other Expense (Net)	0.00	0.00	0	0	0.00
Net Income (Loss)	(3,000.00)	0.00	0	0	(3,000.00)

Advanced Life Sciences, Inc.
SUMMARY
For the Twelve Months Ending December 31, 2015

	ALS, Holding Dec 31, 2015	ALS, Inc. Dec 31, 2015	Eliminations DR	Eliminations CR	Consolidated Dec 31, 2015
ASSETS					
Current Assets					
Checking/Savings					
Cash - Leaders	0.00	0.00			0.00
Cash - JPM Chase Operating	0.00	0.00			0.00
Cash - Bank of America	3,173.19	0.00			3,173.19
Cash - RSVP	0.00				0.00
Total Checking/Savings	3,173.19	0.00	0.00	0.00	3,173.19
Accounts Receivable	0.00	0.00			
Grant Receivable	0.00	0.00			
Total Account Receivable	0.00	0.00	0.00	0.00	0.00
Other Current Assets					
Prepaid expenses	2,828.87	(0.00)			2,82
Prepaid insurance	57,351.45	17,983.46			75,334.91
Restricted cash - interest reserve		0.00			0.00
Total Other Current Assets	60,180.32	17,983.46	0.00	(30,141.49)	48,022.29
Total Current Assets	63,353.51	17,983.46	0.00	(30,141.49)	51,195.48
Fixed Assets					
Furniture and fixtures		0.00			0.00
Computer equipment		0.00			0.00
Leasehold improvements		0.00			0.00
Accumulated Depreciation		0.00			0.00
Total Fixed Assets	0.00	0.00	0.00	0.00	0.00
Other Assets					
Restricted cash - Chase CC	0.00				0.00
Deposits		555.09			555.09
Deferred financing	52,040.77	97,131.46			149,172.23
Due from ALS Holdings, Inc.	124,488,532.89			(124,488,532.89)	0.00
Other long term assets		250,000.00			250,000.00
Total Other Assets	124,540,573.66	347,686.55	0.00	(124,488,532.89)	399,727.32
TOTAL ASSETS	124,603,927.17	365,670.01	0.00	(124,518,674.38)	450,922.80

Advanced Life Sciences, Inc.
SUMMARY
For the Twelve Months Ending December 31, 2015

	ALS, Holding Dec 31, 2015	ALS, Inc Dec 31, 2015	Eliminations DR	Eliminations CR	Consolidated Dec 31, 2015
LIABILITIES & EQUITY					
Liabilities					
Current Liabilities					
Accounts Payable					
Accounts payable	112,801.95	1,241,468.85	(30,141.49)		1,323,929.31
Total Accounts Payable	112,801.95	1,241,468.85	(30,141.49)	0.00	1,323,929.31
Other Current Liabilities					
Accrued expenses	378,285.77	206,224.91			584,510.68
Accrued expenses - credit card		2,886.71			2,886.71
Accrued purchases		12.10			12.10
Deferred rent		2,762.94			2,762.94
Accrued serverance payable		54,608.78			54,608.78
ST lease payable		4,982.25			4,982.25
Payroll clearing		(2,882.16)			(2,882.16)
Accrued vacation payable		19,112.16			19,112.16
401(k) payable		0.00			0.00
Health insurance payable		398.47			398.47
Medical flex and dependant care payable		(0.60)			(0.60)
Accrued interest payable		0.00			0.00
Notes payable - Leaders Bank				4,000,000.00	4,000,000.00
Notes payable - Michael T Flavin		63,000.00			63,000.00
Total Other Current Liabilities	378,285.77	351,103.56	0.00	4,000,000.00	4,729,389.33
Total Current Liabilities	490,887.72	1,592,572.41	(30,141.49)	4,000,000.00	6,053,318.64
Long Term Liabilities					
Notes payable - Leaders bank		4,000,000.00	(4,000,000.00)		0.00
Grants Payable L-1		500,000.00			500,000.00
LT lease payable		14,700.48			14,700.48
Due to ALS Holdings, Inc.		124,488,532.89	(124,488,532.89)		0.00
Total Long Term Liabilities	0.00	129,003,233.37	(128,488,532.89)	0.00	514,700.48
Total Liabilities	490,887.72	130,595,805.78	(128,518,674.38)	4,000,000.00	6,568,019.12
Equity					
Common stock	3,261,143.27		(3,104,472.00)		156,671.27
Additional paid-in capital	128,864,738.20			3,104,472.00	131,969,210.20
Retained Earnings (Deficit)	(8,009,842.72)	(130,230,141.72)			(138,239,984.44)
Net Profit (Loss) for the Period	(3,000.00)	0.00			(3,000.00)
Total Equity	124,113,039.45	(130,230,141.72)	(3,104,472.00)	3,104,472.00	(6,117,102.27)
TOTAL LIABILITIES & EQUITY	124,603,927.17	365,670.01	(131,623,146.38)	7,104,472.00	450,922.85
	0.00	(0.00)	131,623,146.38	(131,623,146.38)	(0.03)

Frye, David

From:	Mike Flavin <mflavin@flavinventures.com>
Sent:	Tuesday, June 28, 2016 12:58 PM
To:	Frye, David; Welch, Neil (Chip)
Subject:	Answer to the Order Initiating Administrative Proceedings in the Matter of Advanced Life Sciences Holdings, Inc.
Attachments:	1430_001.pdf

Dear Mr. Frye and Mr. Welch,

I have attached our Answer to the Order Initiating Administrative Proceedings in the Matter of Advanced Life Sciences Holdings, Inc. that I faxed and mailed today to Brent J. Fields, Secretary, U.S Securities and Exchange Commission.

Thank you for your assistance in discussing the process of the Order.

Sincerely,

Michael Flavin

Michael T. Flavin, Ph.D.
Chief Executive Officer
Advanced Life Sciences Holdings, Inc.
1440 Davey Road
Woodridge, IL 60517
(630) 991-3013

THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION

In the Matter of:	)	
	)	File No. 3-17293
ADVANCED LIFE SCIENCES	)	
HOLDINGS, INC., ET AL	)	

ADMINISTRATIVE PROCEEDINGS - PRE-HEARING CONFERENCE

PAGES: 1 through 16

PLACE: Securities and Exchange Commission
100 F Street, NE
Washington, D.C. 20549

DATE: Wednesday, July 20, 2016

The above-entitled matter came on for pre-hearing, pursuant to notice, at 10:33 a.m.

Before (Via Telephone):
JAMES GRIMES, ADMINISTRATIVE LAW JUDGE

Diversified Reporting Services, Inc.
(202) 467-9200

APPEARANCES:

On behalf of the Securities and Exchange Commission:

DAVID S. FRYE, ESQ.
Securities and Exchange Commission
Division of Enforcement
100 F Street, NE
Washington, D.C. 20549

On behalf of Advanced Life Sciences Holdings, Inc.:

MICHAEL FLAVIN, Ph.D.

P R O C E E D I N G S

JUDGE GRIMES: Good morning. Today is July 20, 2016, and we are holding a telephonic pre-hearing conference in Securities and Exchange Commission Administrative Proceeding File Number 3-17293. This is in the matter of five Respondents and they are Advanced Life Sciences Holdings, Incorporated; Anoteros, Incorporated; Emperial Americas, Incorporated; Nord Resources Corporation; and UNR Holdings, Incorporated.

My name is James Grimes and I am the administrative law judge assigned to preside in this matter.

Could I have an appearance of counsel for the Division of Enforcement, please?

MR. FRYE: Yes, Your Honor. This is David Frye for the Division of Enforcement.

JUDGE GRIMES: Thank you, Mr. Frye.

And I understand for Advanced Life Sciences Holdings, we have Mr. Flavin; is that right?

DR. FLAVIN: Yes, thank you, Your Honor.

JUDGE GRIMES: So for the record, the Division of Enforcement filed evidence showing that all Respondents were served with the order instituting proceedings by June 20. And except for Advanced Life Sciences, no Respondent answered the order instituting

proceedings.

As a result, I ordered the four respondents that failed to file an answer to show cause by July 18 why the proceeding should not be determined against them and none of them has filed an answer.

Mr. Frye, has the Division heard from any of the other four Respondents?

MR. FRYE: Well, the only -- the only contact that we have received was a former officer of Nord Resources received a copy of the -- a service copy of the order instituting proceedings and contacted us. And he indicated that he would not be contesting the relief sought by the Commission or by the Division and would allow a default to be entered.

Other than that, I haven't heard from anyone except Mr. Flavin.

JUDGE GRIMES: Okay. All right. Thank you, Mr. Frye.

Well, as I mentioned, Advanced Life Sciences has filed an answer, so we will address the proceedings as to Advanced Life Sciences.

Because the other Respondents have not filed an answer or responded to the order instituting proceedings -- excuse me, have not responded to the order to show cause, I will most likely enter a default as to those

Respondents.

So, moving on, does anyone object to serving other parties and my office by e-mail, in addition to the normal service of papers, paper copies on the secretary? Mr. Frye, does that work for you?

MR. FRYE: No objection, Your Honor.

JUDGE GRIMES: Mr. Flavin, does that work for you

DR. FLAVIN: Yes, it does.

MR. FRYE: You know, actually, I'm looking at your letter. You're actually Dr. Flavin, aren't you? I'm sorry.

DR. FLAVIN: No problem at all. I'm a scientist by training, so I'm not an attorney, so I'll do my best with this.

JUDGE GRIMES: Very well. Okay.

So I think everyone knows this, but my office's e-mail address is alj@sec.gov. So we can all -- when filings are made, you can file a courtesy copy to that e-mail address. But you still have to send paper copies to the secretary's office.

DR. FLAVIN: And what was that e-mail address again? I'm sorry, Your Honor.

JUDGE GRIMES: That's fine. It's alj@sec.gov.

DR. FLAVIN: Thank you.

JUDGE GRIMES: Sure. And were it up to me, we would just use electronic filing, but the rules are that we have to also send paper copies -- excuse me. The parties have to also send paper copies to the secretary's office of any filing.

So by my count, my decision in this case is going to be due by October 18, 2016.

Mr. Frye, is there an investigative file that has been made available to Advanced Life Sciences?

MR. FRYE: I offered -- I -- yes, I offered it to them. A letter accompanied the order instituting proceedings, offering them the investigative file. Mr. Flavin -- Dr. Flavin hasn't contacted me to request to follow up on that. But it certainly is available, and I can provide it promptly if he would like to see it.

JUDGE GRIMES: All right. Dr. Flavin, it appears that in your letter that you have admitted all the operative facts in the order instituting proceedings, either affirmatively or by not denying allegations.

DR. FLAVIN: That's correct.

JUDGE GRIMES: Okay.

DR. FLAVIN: Yes, that's correct. I -- I must say, we have not filed in a timely manner, as the allegations put forth. But I've tried to put forth some reasons why that is and what our company has been

attempting to do about it in the intervening years, given the fact that our financial resources have been low and our -- our, you know, work force has been very low, as well. And so I just tried to explain what we're trying to do to address this issue and am asking the Court to allow us a little more time to attempt to make a filing that I believe would bring things very close to up to date and -- and try to serve at least the public good in terms of letting everyone know where the company stands and what it intends to do and what's been happening the last few years.

And basically, we had to put the company in suspension in April of 2011, so there really hasn't been much happening, outside of a number of activities that I've been trying to conduct in order to raise the necessary funds to continue the clinical development of what could be an important antibiotic to overcome the resistance that's out there in the world right now to, you know, try to make a difference that way. You know, it requires quite a lot of funds to continue this clinical development.

We know what we have to do. Our team is still active, to the best of their abilities, although many of them have other positions. Our board of directors is still in place. And we believe we could make a run at it

again, if we had an opportunity to, you know, come back into compliance with SEC guidelines, raise additional funds, which I've been attempting to do these last few years and have some leads toward that, and execute the plan that we have, based on meetings we've had with the FDA face to face over the last couple of years, to determine what we need to do next.

So we have a plan, we know what we want to do. It's just that, you know, it's taken a lot of, you know, part-time resources to try to get to where we are today and we're just asking for a little bit more time to get in compliance with the SEC, because we have a filing that's almost ready.

JUDGE GRIMES: So how long do you anticipate it will take to remedy your filing deficiencies?

DR. FLAVIN: I would say within the next two weeks.

JUDGE GRIMES: All right, well the purpose of this proceeding is to determine whether or not the filing deficiencies are as alleged. And you've admitted that. So then the secondary purpose would be to determine what to do about it. And in order to determine that, what I would propose is that we deal with this case as we deal with most cases of this sort. That is through motions practice.

So the main thing that we need to do today is to set up a schedule for filing those motions. And then Mr. Frye can determine how he wants to proceed. And I can wait, as I said, until October to issue a decision in this case. But, in any event, by decision will be due October 18. And I can't wait until to the last minute, because I actually have to write the decision.

DR. FLAVIN: Understood.

JUDGE GRIMES: So what I suggest is that we set up a schedule in which the Division can move for summary disposition in three weeks. Advanced Life Sciences could respond three weeks after that. And then I could wait until, say, the first week of October to issue a decision.

And if, in fact, Advanced Life Sciences is able to become current in its filing requirements, you could of course let us know that when that happens, and that would factor into the decision that I would issue.

DR. FLAVIN: Yes.

JUDGE GRIMES: So what I propose -- does that make sense, Dr. Flavin?

DR. FLAVIN: Yes, it does.

JUDGE GRIMES: Mr. Frye, do you have any comments about that proposal?

MR. FRYE: I have no problem with setting up a

briefing schedule, you know. In fact, that's what we were going to request, is that we proceed by summary disposition.

However, I must -- you know, the idea, you know, the Commission has repeatedly emphasized that an order instituting proceedings is not an extension of time to file. It's not -- 120 days is not a 120-day extension to bring their filings current.

JUDGE GRIMES: Mr. Frye, I completely understand. That's exactly right. The filing of the order instituting proceedings is not a time out for Respondents to do that and to do that which they were already required to do.

MR. FRYE: Thank you.

JUDGE GRIMES: Nevertheless, I do have 120 days to issue a decision and I am certainly willing to wait a good portion of that time to see if Advanced Life Sciences can become current.

I will say, Dr. Flavin, this is a frequent refrain that I hear from respondents, that they are going to become current. I have only seen it happen once.

DR. FLAVIN: Okay.

JUDGE GRIMES: But I am willing to wait to see if you can do that. Now, the fact that I'm willing to wait doesn't mean that you'll get a ruling in your favor.

It just means that I would certainly take that into account.

DR. FLAVIN: I understand. Yes.

JUDGE GRIMES: All right. So what I propose is that we set up a schedule in which the Division of Enforcement would file its motion for summary disposition in three weeks. That would be on August 10. Does that work for your schedule, Mr. Frye?.

MR. FRYE: Yes, Your Honor, that's fine.

JUDGE GRIMES: Okay. Go ahead.

MR. FRYE: I just wanted to mention, you know, I sent an e-mail to your staff that I have jury duty in federal district court between August 12 and August 26. This is that, you know -- this is where you have to call in every day and find out if you have to show up the next day.

JUDGE GRIMES: Understood. Understood.

Okay, so I think we can work around that.

MR. FRYE: On the other hand, you know, I am not the only person working on this case. So if for some reason, I can certainly get my brief in by the 10th, absolutely no problem with that. However, our reply -- certainly, you know, that time is going for be for Dr. Flavin -- you know, if everything works out, I won't get picked and that will just be Dr. Flavin's period for

preparing and filing his response. You know, but I just wanted to make sure the Court is aware of my scheduling issues.

But other than that, I'm sure it can be dealt with. I just wanted to make the Court aware of that.

JUDGE GRIMES: Okay, thank you. I'm sure it can be dealt with as well.

So I think what we'll do is we'll make your initial motion for summary disposition due in three weeks.

MR. FRYE: August 10.

JUDGE GRIMES: That's August 10. And then any opposition by Advanced Life Sciences would be due on August 31. And any reply would be due on September 12.

MR. FRYE: Excellent. That's perfectly -- that's very good. Thank you.

JUDGE GRIMES: Now, Dr. Flavin, if you want -- you don't have to do this, but you can file your own cross-motion for summary disposition. Most respondents don't, but if you wanted to, you could do that and you would follow the same schedule, whereby your motion would be due August 10, the Division's opposition would be due August 31, and then you can file a reply on September 12.

As I said, most respondents don't do that, because in this case it's the Division's burden to -- to

get the relief that it seeks and to prove the allegations. But I just want to make you aware of that.

DR. FLAVIN: Thank you. I'd probably stay with the program that you outlined, Your Honor.

JUDGE GRIMES: Okay, very good.

All right. So just to be clear then, the Division's motion for summary disposition will be due in three weeks. Any opposition will be due three weeks after that. And if there is an opposition filed, the Division will have the opportunity to file a reply, which will be due September 12.

Mr. Frye, is there anything else that you would like to address at this point?

MR. FRYE: Just -- I think -- forgive me, Your Honor. I believe you covered this in the opening session, but just to make sure, you know, we do ask for a default -- initial decision of default as to the other Respondents.

JUDGE GRIMES: Very good. That's most likely what will happen, because they have not answered and they have not responded to the order to show cause.

Dr. Flavin, is there anything else that you would like to discuss this morning?

DR. FLAVIN: No, not at this time, Your Honor.

JUDGE GRIMES: All right. Well, then I'll

thank everyone for their time, wish everyone a good day. And we're adjourned.

(Whereupon, at 10:47 a.m., the pre-hearing conference was concluded.)

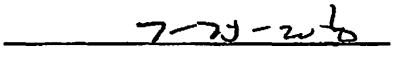
* * * * *

PROOFREADER'S CERTIFICATE

In The Matter of: ADVANCED LIFE SCIENCES, INC., ET AL
ADMINISTRATIVE PROCEEDINGS - PRE-HEARING CONFERENCE
File Number: 3-17293
Date: July 20, 2016
Location: Washington, D.C.

This is to certify that I, Nicholas J. Wagner, (the undersigned), do hereby swear and affirm that the attached proceedings before the U.S. Securities and Exchange Commission were held according to the record and that this is the original, complete, true and accurate transcript that has been compared to the reporting or recording accomplished at the hearing.

(Proofreader's Name)



(Date)

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

REPORTER'S CERTIFICATE

I, Jon Hindley, reporter, hereby certify that the foregoing transcript is a complete, true and accurate transcript of the testimony indicated, held on 7/20/16 at Washington, D.C. in the matter of:

Advanced Data Services Holdings, Inc.

I further certify that this proceeding was recorded by me and that the foregoing transcript has been prepared under my direction.

Date: 7-25-2016

Official Reporter: [signature]

Diversified Reporting Service, Inc.

Diversified Reporting Services, Inc.
(202) 296-9200
Fax: (202) 296-9220

From:	Mike Flavin
To:	ALJ; Frye, David; ORourke, Kevin
Subject:	Courtesy Copy of Filing of Advanced Life Sciences" Opposition to the Division of Enforcement"s Motion for Summary Disposition
Date:	Wednesday, August 31, 2016 3:54:50 PM
Attachments:	Opposition to Motion.pdf Exhibit 1 - Comprehensive 10-K: 2011 through 2015.pdf

In connection with Administrative Proceeding File No. 3-17293 in the Matter of Advanced Life Sciences Holdings, Inc., we have attached our filing made today, August 31, 2016, with the Office of the Secretary via facsimile.

The two attachments are the Opposition to Motion document and Exhibit 1 to that document, which is our comprehensive 10-K submission made on July 27, 2016 to Suzanne Hayes of the Division of Corporate Finance at the SEC covering the years 2011 through 2015.

Thank you for your consideration.

Best regards,

Michael T. Flavin

Michael T. Flavin, Ph.D.
Chief Executive Officer
Advanced Life Sciences Holdings, Inc.
1440 Davey Road
Woodridge, IL 60517
(630) 991-3013

From: RightFax E-mail Gateway
To: Frye, David
Subject: A new fax has arrived from 2027729324 (Part 1 of 1) on Channel 23
Date: Wednesday, November 23, 2016 8:33:00 AM
Attachments: Adefad1c0-1c21-4fb7-b80b-5a7286f6f85d.TIF

11/23/2016 8:30:59 AM Transmission Record
Received from remote ID: 2027729324
Inbound user ID FRYED, routing code 7038139740
Result: (0/352;0/0) Success
Page record: 1 - 3
Elapsed time: 01:38 on channel 23

Fax Images: [double-click on image to view page(s)]

From: Shields, Kathy Moore
To: Frye, David
Subject: Advanced Life Sciences, et al. 3-17293
Date: Wednesday, November 23, 2016 11:33:19 AM
Attachments: Petition for Review.pdf

Hi David,

There was no service list with what the judge received.
Kathy

Kathy Moore Shields
Office of Administrative Law Judges
U.S. Securities & Exchange Commission
100 F Street NE, Mail Stop 2557
Washington, DC 20549
202-551-6030

From:	Kimps, Melissa
To:	Frye, David
Cc:	Kimps, Melissa
Subject:	3-17293 Advanced Life Sciences Brief - as promised per your request
Date:	Friday, December 23, 2016 9:33:05 AM
Attachments:	Scan0573.pdf