SECURITIES AND EXCHANGE COMMISSION Washington, D.C.

SECURITIES EXCHANGE ACT OF 1934 Release No. 81253 / July 28, 2017

Admin. Proc. File No. 3-17293

In the Matter of

ADVANCED LIFE SCIENCES HOLDINGS, INC.

OPINION OF THE COMMISSION

SECTION 12(j) PROCEEDING

Grounds for Remedial Action

Failure to Comply with Periodic Filing Requirements

Company failed to file periodic reports in violation of Section 13(a) of the Securities Exchange Act of 1934 and Exchange Act Rules 13a-1 and 13a-13. *Held*, it is in the public interest to revoke the registration of the company's securities.

APPEARANCES:

Michael T. Flavin, Ph.D., Chairman and CEO, for Advanced Life Sciences Holdings, Inc.

David S. Frye and Kevin P. O'Rourke, for the Division of Enforcement.

Appeal filed:

November 15, 2016

Last brief received:

January 19, 2017

Advanced Life Sciences Holdings, Inc. ("ADLS") appeals an administrative law judge's initial decision revoking the registration of its securities pursuant to Section 12(j) of the Securities Exchange Act of 1934. The law judge revoked ADLS's registration after finding that it violated Exchange Act Section 13(a) and Rules 13a-1 and 13a-13² by failing to file quarterly

¹ 15 U.S.C. § 78*l*(j).

² 15 U.S.C. § 78m(a); 17 C.F.R. §§ 240.13a-1, 240.13a-13.

and annual reports since it filed a Form 10-K for the year ended December 31, 2010.³ ADLS admits that it violated these provisions, but asks the Commission to allow it to maintain its registration for another year so that it can achieve compliance and continue its antibiotics research. Based on an independent review of the record, we have determined that revoking the registration of ADLS's securities serves the public interest and is necessary for the protection of investors.

I. Background

ADLS is a Delaware corporation located in Woodbridge, Illinois. Since 2005, it has had a class of securities registered with the Commission pursuant to Exchange Act Section 12(g). ADLS filed all required quarterly and annual reports from 2005 through 2010. These filings were signed by Michael Flavin, in his capacity as ADLS's Chairman and CEO.⁴

In its annual report filed March 24, 2011 for the year ended December 31, 2010, ADLS reported that it had "incurred an accumulated deficit of \$140.9 million as of December 31, 2010 and [it] expect[ed] to incur significant operating losses for the foreseeable future." On May 5, 2011, ADLS issued a press release announcing that it had suspended operations and terminated its staff due to severe lack of liquidity, and that a filing under the federal bankruptcy laws was a distinct possibility. At this point, ADLS stopped making quarterly and annual filings.

On March 3, 2014, the Division of Corporation Finance sent ADLS a delinquency letter stating that ADLS was not in compliance with its reporting requirements under Section 13(a) of the Exchange Act. The letter stated that ADLS's registration could be subject to revocation if it did not file all required reports within fifteen days.

Flavin spoke with staff in the Division of Corporation Finance on March 21, 2014, asking for an accommodation to file a comprehensive Form 10-K to bring ADLS's filings up-to-date. Flavin was told that the Chief Accountant of Corporation Finance generally did not grant such accommodations after a delinquency letter had been sent, and that if ADLS wished to become current by making all of its delinquent filings, it should send a letter of intention with a specific date by which it would do so. Flavin responded by letter dated March 24, 2014, in which he stated: "I believe that Advanced Life Sciences will be completely up-to-date with the required filings by September 30, 2014." Flavin also stated that he had written to the Chief Accountant "to request that Advanced Life Sciences be allowed to file one comprehensive 10K for the period beginning in January, 2011 through December, 2012." ADLS concedes that it failed to meet its

Advanced Life Scis. Holdings, Inc., Initial Decision Release No. 1065, 2016 WL 5930408, at *8 (Oct. 12, 2016).

We take official notice of EDGAR filings pursuant to Rule of Practice 323, 17 C.F.R. § 201.323.

Advanced Life Scis. Holdings, Inc., Annual Report (Form 10-K), 41 (Mar. 24, 2011).

self-imposed deadline. The record does not show, and ADLS does not claim, that any accommodation allowing ADLS to file a comprehensive Form 10-K was granted.

The Commission initiated this proceeding on June 15, 2016. As of that date, ADLS had failed to file twenty-one consecutive periodic reports. On July 27, 2016, ADLS submitted a consolidated Form 10-K for 2011 to 2015 to the Division of Corporation Finance and requested that it be allowed to file this comprehensive document. The record contains no response to this request. The Commission's EDGAR database shows that ADLS did not file this consolidated Form 10-K and continues to be delinquent in its quarterly and annual reports. It has not filed a periodic report in over six years, and has now failed to file twenty-five consecutive periodic reports.

The Division of Enforcement filed a motion for summary disposition on August 10, 2016. The law judge granted Enforcement's motion in an initial decision on October 12, 2016.⁶ The law judge found that ADLS violated Exchange Act Section 13(a) and Rules 13a-1 and 13a-13, and determined that revoking the registration of ADLS's securities was in the public interest. ADLS petitioned for review.

II. Analysis

Exchange Act Section 12(j) authorizes us, as we deem "necessary or appropriate for the protection of investors," to revoke the registration of a security, or suspend that registration for no longer than twelve months, if we find that an issuer has failed to comply with any provision of the Exchange Act or its rules and regulations. Exchange Act Section 13(a) requires issuers of securities registered under Exchange Act Section 12 to file annual and quarterly reports with the Commission "for the proper protection of investors and to insure fair dealing" in the company's securities. Exchange Act Rules 13a-1 and 13a-13 set forth the requirements for those reports. A violation of these provisions does not require scienter. Exchange Act Rules 13a-1 and 13a-13 set forth the requirements for those reports.

ADLS admits to not having filed its annual reports on Form 10-K and its quarterly reports on Form 10-Q since March 2011. We therefore find that ADLS violated Exchange Act

Advanced Life Scis. Holdings, Inc., 2016 WL 5930408, at *8. We have held that "summary disposition is appropriate in proceedings like this one brought pursuant to Exchange Act Section 12(j), where the issuer has not disputed the facts that constitute the violation." Citizens Capital Corp., Exchange Act Release No. 67313, 2012 WL 2499350, at *8 (June 29, 2012).

⁷ 15 U.S.C. § 78*l*(j).

⁸ 15 U.S.C. § 78m(a).

^{9 17} C.F.R. §§ 240.13a-1, 13a-13.

Citizens Capital Corp., 2012 WL 2499350, at *5 (citing Ponce v. SEC, 345 F.3d 722, 737 n.10 (9th Cir. 2003); accord SEC v. McNulty, 137 F.3d 732, 740-41 (2d Cir. 1998)).

Section 13(a) and Rules 13a-1 and 13a-13 thereunder, and that its registration is subject to suspension or revocation under Exchange Act Section 12(j).

A. Revocation under Exchange Act Section 12(j) is warranted.

In Gateway International Holdings, Inc., we established a multi-factor test to use in determining an appropriate sanction when an issuer has failed to make required filings:

[W]e will consider, among other things, the seriousness of the issuer's violations, the isolated or recurrent nature of the violations, the degree of culpability involved, the extent of the issuer's efforts to remedy its past violations and ensure future compliance, and the credibility of its assurances, if any, against further violations.¹¹

These factors are non-exclusive, and no single factor is dispositive.¹² Based on these factors, it is necessary and appropriate for the protection of investors to revoke the registration of ADLS's securities.

1. ADLS's violations are serious, recurrent, and show a high degree of culpability.

"[R]eporting requirements are the primary tools which Congress has fashioned for the protection of investors from negligent, careless, and deliberate misrepresentations in the sale of stock and securities." An issuer's failure to file periodic reports violates "a central provision of the Exchange Act, . . . depriv[ing] both existing and prospective holders of its registered stock of the ability to make informed investment decisions based on current and reliable information."

Gateway Int'l Holdings, Inc., Exchange Act Release No 53907, 2006 WL 1506286, at *4 (May 31, 2006) (citing Steadman v. SEC, 603 F.2d 1126, 1139-40 (5th Cir. 1979)).

See China-Biotics, Exchange Act Release No. 70800, 2013 WL 5883342, at *12 (Nov. 4, 2013).

Am. 's Sports Voice, Inc., Exchange Act Release No. 55511, 2007 WL 858747, at *4 n.17 (Mar. 22, 2007) (internal quotation marks omitted) (citing SEC v. Beisinger Indus. Corp., 552 F.2d 15, 18 (1st Cir. 1977)).

Accredited Bus. Consolidators Corp., Exchange Act Release No. 75840, 2015 WL 5172970, at *2 (Sep. 4, 2015); see also United States v. Arthur Young & Co., 465 U.S. 805, 810 (1984) (observing that "[c]orporate financial statements are one of the primary sources of information available to guide the decisions of the investing public").

ADLS's failure to file twenty-five periodic reports is serious and recurrent.¹⁵ Indeed, we have considered far fewer delinquent periodic reports to be a serious and recurrent violation.¹⁶

Further, it has been over six years since ADLS made a quarterly or annual filing. "[A] long history of ignoring . . . reporting obligations under the Exchange Act evidences a high degree of culpability." And while Exchange Act Section 13(a) and Rules 13a-1 and 13a-13 do not have a scienter requirement, a violation committed in knowing disregard of regulatory responsibilities may play a role in the Commission's determination of an appropriate sanction. ADLS's filings from 2005 to 2010 were signed by Michael Flavin, who is still the company's CEO. Thus, ADLS's management knew of its reporting obligations, yet repeatedly disregarded them.

ADLS argues that it was unable to make the required filings because it was confronted with many problems. These problems included a lack of staff, difficulties finding part-time legal and accounting professionals to help with the filings, and a need to focus on the restructuring of a bank note. But ADLS's business difficulties do not excuse its failure to file; indeed, information about these difficulties would have been significant to both current and potential investors in evaluating whether they wanted to buy, sell or hold ADLS securities.¹⁹

When a company's violations are "so serious," we look to see whether there is a "strongly compelling showing" on the remaining factors—remedial efforts and assurances

Review of the EDGAR database reveals that ADLS has not filed any notifications of late filing on Form 12b-25 as to any of these reports, disclosing its inability to file the reports timely and the reasons for its inability to file. See 17 C.F.R. § 240.12b-25(a) (setting forth filing requirement). This failure is also considered in assessing whether revocation is appropriate. See Accredited, 2015 WL 5172970, at *3 n.17; see also Gateway, 2006 WL 1506286, at *5 n.30 (observing that "[a]lthough we are not finding violations based on those failures, we may consider them, and other matters that fall outside the OIP, in assessing appropriate sanctions").

See, e.g., Am. Stellar Energy, Inc., Exchange Act Release No. 64897, 2011 WL 2783483, at *4 (July 18, 2011) (ten delinquent periodic filings); Impax Labs., Inc., Exchange Act Release No. 57864, 2008 WL 2167956, at *7 (May 23, 2008) (eight delinquent periodic filings).

Calais Res. Inc., Exchange Act Release No. 67312, 2012 WL 2499349, at *4 (June 29, 2012) (internal quotation marks omitted) (citing Am. 's Sports Voice, 2007 WL 858747, at *3).

¹⁸ Gateway, 2006 WL 1506286, at *5 n.28.

¹⁹ Cf. Tara Gold Res. Corp. v. SEC, 678 F.3d 558, 558 (7th Cir. 2012) (observing that firm's inability to pay an auditor to certify financial statements is "something investors surely would want to know").

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against future violations.²⁰ Absent such a showing, we apply "a strong presumption in favor of revocation."²¹ No such showing is made in this case.

2. ADLS has not overcome the presumption in favor of revocation.

The sole concrete evidence of an attempt at remediation is ADLS's submission of a consolidated Form 10-K to the Division of Corporation Finance. But the consolidated Form 10-K is not a substantial remedial effort for three reasons. First, Commission rules do not provide for such a consolidated report. Companies such as ADLS that have a class of securities registered under the Exchange Act must file annual reports every year. And Corporation Finance warned Flavin that it was unlikely that a consolidated report would be accepted as a substitute for all of the delinquent filings after a delinquency letter had been sent. Second, the consolidated Form 10-K was never filed and has not been made available to the public via the EDGAR database. Third, the consolidated Form 10-K would not bring ADLS's filings up to date. As a result, current and prospective investors remain deprived of the ability "to make informed investment decisions based on current and reliable information."

ADLS's assurances that it will become completely compliant are not credible for two reasons: (1) ADLS has failed to meet self-imposed deadlines; and (2) ADLS's statements indicate a lack of resources and will to prepare filings.

Absolute Potential, Inc., Exchange Act Release No. 71866, 2014 WL 1338256, at *6 (Apr. 4, 2014) (citing Impax Labs., 2008 WL 2167956, at *8).

²¹ *Id*.

²² Calais Res., 2012 WL 2499349, at *6 & n.33 (citing additional authority).

Form 10-K specifies that annual reports be filed within between 60 to 90 days after the conclusion of each fiscal year. Form 10-K, http://www.sec.gov/files/form10-k.pdf. "Annual reports shall be filed within the period specified in the appropriate form." 17 C.F.R. § 240.13a-1.

In the transmittal letter for the comprehensive Form 10-K, as well as in ADLS's brief in support of its petition for review, Flavin stated that ADLS was "advised to prepare" a consolidated document. There is nothing in the record to support this claim. In any event, registrants are responsible for understanding and complying with their filing obligations. *Cf. Richard A. Neaton*, Exchange Act Release No. 65598, 2011 WL 5001956, at *7 (Oct. 20, 2011) (stating that "securities industry registrants 'must take responsibility for compliance and cannot be excused for lack of knowledge, understanding or appreciation of these requirements"). Furthermore, ADLS does not assert that the staff told it that preparing a comprehensive report would cure its delinquent filings. For guidance to delinquent filers, see Securities and Exchange Commission, Division of Corporation Finance, Financial Reporting Manual, § 1320.4 (2016), https://www.sec.gov/divisions/corpfin/cffinancialreportingmanual.pdf.

²⁵ Accredited, 2015 WL 5172970, at *2.

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First, ADLS has twice failed to meet self-imposed deadlines. After receiving a delinquency letter, Flavin told Commission staff that he expected the company to be "completely up-to-date with the required filings by September 30, 2014." ADLS admits that it did not meet this deadline; indeed, it had not filed a single one of the missing quarterly or annual reports by that date. Two years later, in a pre-trial conference on July 20, 2016, Flavin stated that he anticipated the company would remedy its filing deficiencies "within the next two weeks." ADLS failed to meet this self-imposed deadline as well. ADLS's inability to meet its own proposed schedules makes its assurance against future violations less credible. 27

Second, ADLS seems to lack the resources and the will to prepare filings. In its brief, ADLS states that a nearly two-year delay in preparing the consolidated Form 10-K it submitted was due in part to reliance on "external, part-time accounting professionals." We have held that such a shortage of resources "suggest[s] the strong likelihood of continuing or future violations." Moreover, even the pendency of this proceeding has not led ADLS to make any filings, manifesting an indifference to its obligations that we find extremely troubling.

B. ADLS should not be given more time before revoking the registration of its securities.

ADLS already has had several years in which to do so before we instituted this proceeding. And we instituted this proceeding to determine whether ADLS violated the securities laws and whether its registration should be suspended or revoked as a result. Having found ADLS liable for violating the Exchange Act, we construe its request as an argument for a suspension of its registration for one year rather than revocation. In light of the seriousness and recurrence of ADLS's failures to file and its culpability, inadequate remedial efforts, and unconvincing assurances against future violations, we find that revocation rather than suspension of its registration is necessary to protect investors and the public interest. This is true for two reasons: (1) it is unlikely that ADLS will become current in its filings within a year; and (2) a lesser sanction would discourage consistent, timely filings.

First, ADLS is unlikely to become current in one year. ADLS has needed substantially more time than anticipated to remedy past filings failures, making us unconvinced that it is

ADLS did submit the consolidated Form 10-K within two weeks of the pre-hearing conference. However, as discussed above, that submission was never filed and did not remedy the filing failures.

Am. Stellar, 2011 WL 2783483, at *5 (citing Nature's Sunshine Prods., Inc., Exchange Act Release No. 59268, 2009 WL 137145 (Jan. 21, 2009)) (observing that "[i]n determining whether an issuer's assurances against future violations are credible, one factor we consider is whether the issuer is able to adhere to reasonable schedules that the issuer has proposed for the fulfillment of delinquent filing obligations").

²⁸ Am. 's Sports Voice, 2007 WL 858747, at *4.

realistic to expect that the company can become current in the foreseeable future.²⁹ ADLS has insisted that it intends to return to full compliance, yet its efforts repeatedly fall short.³⁰ Under these circumstances, we have stated that a suspension "would almost certainly result only in the necessity for another proceeding under Section 12(j) at the end of that period."³¹ This runs contrary to the need for finality in administrative proceedings.³² It risks indefinitely prolonging the period during which public investors would be without accurate, complete, and timely reports.³³

Second, a suspension would discourage consistent, timely filings. It would reward those issuers who fail to file required periodic reports when due and make last-minute filings only after becoming the subject of Exchange Act Section 12(j) proceedings.³⁴ A suspension would encourage the opportunistic practice of complying with regulatory requirements only when the issuer has concluded that its continued failure to do so will result in significant adverse consequences.³⁵ Revocation is necessary to deter issuers from disregarding their obligations to present accurate and timely information to the investing public until spurred by the institution of proceedings.³⁶ Deterrence is effective only if a lengthy delinquency, in the absence of strongly compelling circumstances regarding the other *Gateway* factors, results in revocation.³⁷

We find no merit in ADLS's argument that we should suspend rather than revoke ADLS's registration because the company could make a major difference in bringing new medicines to patients in need. Many companies with registered securities serve worthy social purposes; they are not exempt from completing timely quarterly and annual filings. Current and potential investors need the information contained in those filings to help decide whether to invest or to stay invested. Regardless of the value of ADLS's research goals, we find that it is not in the public interest to give ADLS another year to become current with its filings.

²⁹ See Impax Labs., 2008 WL 2167956, at *9.

³⁰ See Gateway, 2006 WL 1506286, at *6 n.34.

Eagletech Commc'ns, Exchange Act Release No. 54095, 2006 WL 1835958, at *4 (July 5, 2006).

³² See Am. Stellar, 2011 WL 2783483, at *7.

³³ See id. (quoting Nature's Sunshine, 2009 WL 137145, at *8).

³⁴ See id.

³⁵ See China-Biotics, 2013 WL 5883342, at *13 (citing Calais Res., 2012 WL 2499349).

³⁶ See Absolute Potential, 2014 WL 1338256, at *6.

³⁷ See id.

ADLS also argues that allowing it more time to remedy its filing deficiencies would be consistent with the GAIN (Generating Antibiotic Incentives Now) Act³⁸ because it would let ADLS raise money to fund clinical trials in antibiotics. But we would be deficient in fulfilling the Commission's investor protection mandate if we allowed issuers to raise money from investors without giving them the information that issuers are required to provide.

* * *

For these reasons, we find that the registration of all classes of the registered securities of ADLS should be revoked.

An appropriate order will issue.³⁹

By the Commission (Chairman CLAYTON and Commissioners STEIN and PIWOWAR).

Brent J. Fields Secretary

Food and Drug Administration Safety and Innovation Act, 21 U.S.C. §§ 355, 355f, 360a-1, 360n-1 (2012).

We have considered all of the parties' contentions. We have rejected or sustained them to the extent that they are inconsistent or in accord with the views expressed in this opinion.

UNITED STATES OF AMERICA before the SECURITIES AND EXCHANGE COMMISSION

SECURITIES EXCHANGE ACT OF 1934 Release No. 81253 / July 28, 2017

Admin. Proc. File No. 3-17293

In the Matter of

ADVANCED LIFE SCIENCES HOLDINGS, INC.

ORDER IMPOSING REMEDIAL SANCTIONS

On the basis of the Commission's opinion issued this day, it is

ORDERED that the registration of all classes of the registered securities of Advanced Life Sciences Holdings, Inc. under Section 12(g) of the Securities Exchange Act of 1934 is hereby revoked pursuant to Exchange Act Section 12(j).

By the Commission.

Brent J. Fields Secretary