UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 28, 2018

Arsanis, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-38295 (Commission File Number) 27-3181608 (IRS Employer Identification No.)

890 Winter Street, Suite 230 Waltham, Massachusetts (Address of principal executive offices)

02451 (Zip Code)

Registrant's telephone number, including area code: (781) 819-5704

Not applicable (Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the
following provisions (see General Instruction A.2. below):

 $\ \square$ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company 🗷

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. \blacksquare

Item 8.01. Other Events.

On June 28, 2018, Arsanis, Inc. issued a press release announcing the completion of a planned interim analysis of its Phase 2 clinical trial of ASN100 for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients by an independent data review committee. A copy of this press release is filed as Exhibit 99.1 to this Form 8-K and incorporated herein by reference. The information contained on websites referenced in this press release is not incorporated herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit

No. Description

99.1 Press release dated June 28, 2018

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ARSANIS, INC.

Date: June 28, 2018 By: /s/ Michael P. Gray

Michael P. Gray Chief Operating Officer and Chief Financial Officer



Arsanis Provides Update Following Completion of Planned Interim Analysis of Phase 2 Clinical Trial of ASN100

Trial Unlikely to Meet Primary Efficacy Endpoint; Arsanis to Cease Trial Enrollment and Evaluate Complete Clinical Trial Dataset Arsanis to Continue Focus on Development of ASN500 for Prevention of RSV Infection

WALTHAM, Mass. and VIENNA, Austria – June 28, 2018 – Arsanis, Inc. (NASDAQ: ASNS), a clinical-stage biopharmaceutical company focused on applying monoclonal antibody immunotherapies to address serious infectious diseases, today announced the discontinuation of its Phase 2 clinical trial of ASN100 for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients following the completion of a planned interim analysis of unblinded trial data by an independent data review committee (DRC). Based on the results of this analysis, the DRC determined that the trial was futile, meaning that it was not likely to meet its primary end-point upon completion and recommended that trial enrollment be discontinued. Arsanis intends to conduct follow-up visits on all patients dosed with ASN100 per the study protocol.

"We are disappointed that this clinical study was futile despite the survival benefit of ASN100 as compared to placebo observed in preclinical models of pneumonia, however Arsanis remains confident in the potential of monoclonal antibodies to prevent and treat serious infections, while also reducing the threat of antibiotic resistance," said René Russo, President and Chief Executive Officer of Arsanis. "We intend to evaluate the complete dataset from the patients that were enrolled in the ASN100 study to better understand the basis for this result and expect to provide an update on the program following this review. We thank the patients and their caregivers who participated in the ASN100 Phase 2 study."

Dr. Russo continued, "We will continue to focus our efforts and resources on our other programs, including the development of ASN500 for the prevention of respiratory syncytial virus (RSV) infection, which contributes to 240,000 hospitalizations per year in the U.S. Pre-clinical data for ASN500 has demonstrated high potency with potential to offer benefits over existing preventive therapies in terms of dosing strategy, manufacturing and route of administration, to better serve both new and existing target patient populations. We expect to advance ASN500 into Phase 1 clinical trials in 2019."

About the ASN100 Phase 2 Clinical Trial

The ASN100 Phase 2 clinical trial was a double-blind, placebo-controlled superiority trial evaluating the efficacy and safety of ASN100 for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients, an indication for which there are no approved therapies. The primary efficacy endpoint of the trial was the proportion of patients who develop *S. aureus* pneumonia through 21 days after dosing. The trial was designed to detect a 50% reduction in the occurrence of *S. aureus* pneumonia in the ASN100 arm when compared to placebo.

About ASN100

ASN100 is a combination of two co-administered fully human monoclonal antibodies (mAbs), ASN-1 and ASN-2, that together neutralize the six cytotoxins critical to *S. aureus* pneumonia pathogenesis. ASN-1 neutralizes alpha-hemolysin (Hla), a cytotoxin that damages lung epithelial cells, and four leukocidins, cytotoxins that destroy human immune cells: gamma-hemolysin AB (HlgAB), gamma-hemolysin CB (HlgCB), Panton-Valentine leukocidin (PVL), and leukocidin ED (LukED). ASN-2 neutralizes the fifth leukocidin, LukGH, a particularly potent human cytotoxin also responsible for the destruction of human immune cells.

About Arsanis

Arsanis, Inc. is a clinical-stage biopharmaceutical company focused on applying monoclonal antibody (mAb) immunotherapies to address serious infectious diseases. A deep understanding of the pathogenesis of infection, paired with access to some of the most advanced mAb discovery techniques and platforms available today, has positioned Arsanis to further its goal of building and advancing a pipeline of novel mAbs with multiple mechanisms of action and high potency against their intended targets. The Company's pipeline is comprised of mAbs targeting multiple serious bacterial and viral pathogens, including respiratory syncytial virus.



Arsanis is a U.S. company headquartered in Waltham, Massachusetts, with a wholly owned subsidiary that is primarily focused on discovery research in Vienna, Austria (Arsanis Biosciences GmbH).

For more information, please visit the Arsanis website at www.arsanis.com.

Cautionary note regarding forward-looking statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties, including statements regarding: the planned analysis of data from the ASN100 trial; the potential benefits of monoclonal antibodies to prevent and treat serious infections, while reducing the threat of antibiotic resistance generally; plans and prospects for ASN500; and statements regarding Arsanis' strategy, prospects, plans and objectives of management. The words "anticipate," "advance," "believe," "continue," "could," "estimate," "expect," "intend," "look forward," "may," "might," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements Arsanis' makes as a result of important factors, including, but not limited to: uncertainties inherent in the availability and timing of data from the stopped Phase 2 trial of ASN100; Arsanis' ability to advance the development of its programs under the timelines it projects, demonstrate the requisite safety, efficacy and combinability of its drug candidates and/or replicate scientific and non-clinical data in clinical trials; the content and timing of decisions made by the U.S. Food and Drug Administration and other regulatory authorities and investigational review boards at clinical trial sites; Arsanis' ability to obtain and maintain requisite regulatory approvals; competitive factors; Arsanis' ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates it is developing; the availability of cash resources, Arsanis' ability to manage expenses, and its need for additional financing; Arsanis' ability to successfully execute on its business strategies; and other important risk factors as set forth in filings that Arsanis periodically makes with the U.S. Securities Exchange Commission, or SEC, including the risk factors described under the caption "Risk Factors" in its Annual Report on Form 10-K for the year ended December 31, 2017, as updated in its Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, each of which is on file with the SEC. The forward-looking statements contained in this press release reflect the current views of Arsanis with respect to future events, and Arsanis assumes no obligation to update any forward-looking statements except as required by applicable law.

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