# 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): December 11, 2019**

# EXICURE, INC.

**(Exact name of Registrant as specified in its charter)**

| Delaware | 001-39011 | 81-5333008 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

**8045 Lamon Avenue**

**Suite 410**

**Skokie, IL 60077**

**(Address of principal executive offices)**

**Registrant's telephone number, including area code: (847) 673-1700**

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:

☐ 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))

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

| Title of each class | Trading symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, par value $0.0001 per share | XCUR | The Nasdaq Capital Market |

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. ☒

**Item 8.01 Other Events.**

On December 11, 2019, Exicure, Inc. (the "Company") announced an update from its Phase 1b/2 trial with AST-008 in patients with solid tumors. AST-008 is an investigational spherical nucleic acid ("SNA") consisting of toll-like receptor 9 agonists designed for immuno-oncology application, and is being evaluated in combination with pembrolizumab in patients with solid tumors.

The primary objective of the dose escalation portion of the study is to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of AST-008 alone and in combination with pembrolizumab, and to produce a recommended Phase 2 dose. Fourteen patients have been enrolled and dosed with AST-008. No treatment-related serious adverse events or dose-limiting toxicities have been observed. The fifth and final dose escalation cohort is now open and enrolling.

The study has enrolled five melanoma patients, four Merkel cell carcinoma ("MCC") patients, two cutaneous squamous cell carcinoma patients, two head and neck squamous cell carcinoma patients, and one mucosal melanoma patient. Most patients had progressive disease on anti-PD-(L)1 antibodies prior to enrolling.

Available data from the study show:

- AST-008 administration, alone or in combination with pembrolizumab, produced cytokine and chemokine expression and immune cell activation in patient blood indicative of desired immune activation.
- Of the 4 MCC patients, one patient, which had previously progressed on anti-PD-1 antibody therapy, has confirmed stable disease with decreased target lesion diameters for a period in excess of 12 weeks, while a second MCC patient experienced a target lesion complete response and a confirmed overall partial response longer than 24 weeks.
- Nine patients had progressive disease, two patients have not yet been evaluated and one is not evaluable.

Detailed results are expected to be presented at major upcoming oncology meetings. Based on these early results, showing positive biomarker data and initial tumor responses, the Company anticipates enrolling MCC patients, which have previously failed anti PD-1/PD-L1 therapy, in its Phase 2 study during the first quarter of 2020.

**Forward-Looking Statements**

This report contains forward-looking statements (including within the meaning of Section 21E of the United States Securities Exchange Act of 1934, as amended, and Section 27A of the United States Securities Act of 1933, as amended) concerning the Company, the Company's technology, potential therapies (including AST-008 and its potential clinical results), potential studies, and other matters. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "plan," "believe," "intend," "look forward," and other similar expressions among others. Statements that are not historical facts are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: unexpected costs, charges or expenses that reduce cash runway; that the Company's pre-clinical or clinical programs do not advance or result in approved products on a timely or cost effective basis or at all; the cost, timing and results of clinical trials; that many drug candidates that have completed Phase 1 trials do not become approved drugs on a timely or cost effective basis or at all; the ability to enroll patients in clinical trials; possible safety and efficacy concerns; regulatory developments; and the ability of the Company to protect its intellectual property rights. Risks facing the Company and its programs are set forth in the Company's filings with the SEC. Except as required by applicable law, the Company undertakes no obligation to revise or update any forward-looking statement or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

## 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.

Date: December 11, 2019

**EXICURE, INC.**

By: /s/ David A. Giljohann

David A. Giljohann, Ph.D.

Chief Executive Officer