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): November 29, 2021

SIGILON THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39746**	**47-4005543**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

100 Binney Street, Suite 600, Cambridge, MA	**02142**
(Address of principal executive offices)	**(Zip Code)**

(Registrant's telephone number, including area code): (617) 336-7540

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):

☐ 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, $0.001 par value per share	**SGTX**	**The Nasdaq Global Select 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 November 29, 2021, Sigilon Therapeutics, Inc. (the "Company") provided an update on the Company's Phase 1/2 clinical trial of SIG-001 in hemophilia A, which is on clinical hold. The Company issued a press release reporting that fibrosed spheres were observed during a retrieval procedure in a patient dosed in the study, which is filed as Exhibit 99.1 to this Current Report on Form 8-K, and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Issued by Sigilon Therapeutics, Inc. on November 29, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

SIGILON THERAPEUTICS, INC.

By: /s/ Rogerio Vivaldi Coelho, M.D.
Rogerio Vivaldi Coelho, M.D.
President and Chief Executive Officer

Date: November 29, 2021

Sigilon Therapeutics Announces Update on SIG-001 Phase 1/2 Study in Hemophilia A

Cambridge, MA— November 29, 2021—Sigilon Therapeutics, Inc. (NASDAQ:SGTX), a biotechnology company that seeks to develop functional cures for chronic diseases through its Shielded Living Therapeutics™ platform, today reported that fibrosed spheres were observed during a retrieval procedure in a patient in its Phase 1/2 study of SIG-001 in severe or moderately severe hemophilia A.

The SIG-001 trial had been placed on clinical hold by the FDA in July 2021 following Sigilon's submission of a serious adverse event report relating to the development of inhibitors to Factor VIII in one of three patients treated. This patient underwent a laparoscopic procedure prescribed by the investigator to retrieve implanted spheres. Upon inspection, it was determined that the spheres placed in the patient had fibrosed and that cells within the spheres were no longer viable.

While the Company investigates the fibrosed spheres in this patient, all three patients enrolled in the SIG-001 trial will continue to be followed per study protocol. These findings may have an impact on the timing of initiating dosing of patients in its planned Phase 1/2 clinical trial of SIG-005 for mucopolysaccharidosis type I (MPS-1).

"Patients' safety and welfare are our highest priority. We are gathering information in order to understand these observations," said Rogerio Vivaldi, M.D., President and CEO of Sigilon. "We will be working closely with the FDA, other regulators, and advisors to determine the impact of these observations on our programs."

The status of Sigilon's clinical hold investigation, including these findings, will be reviewed by the Safety Review Committee for SIG-001 at its next meeting in December.

About Sigilon Therapeutics
Sigilon Therapeutics seeks to develop functional cures for chronic diseases through its Shielded Living Therapeutics™ platform. Sigilon's product candidates are non-viral engineered cell-based therapies designed to produce the crucial proteins, enzymes or factors needed by patients living with chronic diseases such as hemophilia, lysosomal diseases and diabetes. The engineered cells are encapsulated by Sigilon's Afibromer™ biomaterials matrix, which is designed to shield them from immune rejection and fibrosis. Sigilon was founded by Flagship Pioneering in conjunction with Daniel Anderson, Ph.D., and Robert Langer, Sc.D., of the Massachusetts Institute of Technology.

Forward-Looking Statements
This press release includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as "anticipate," "expect," "plan," "could," "may," "will," "believe," "estimate," "forecast," "goal," "project," and other words of similar meaning. These forward-looking statements address various matters, including the potential impact of this observation on our programs, including our ability to resolve the clinical hold of the Phase 1/2 clinical trial of SIG-001 and our timeline for the Phase 1/2 clinical trial of SIG-005. Each forward-looking statement contained in this press release is subject to risks and uncertainties that could cause actual results to differ materially from

those expressed or implied by such statement. Applicable risks and uncertainties include, among others, that favorable preclinical results are not predictive of clinical trial results, our ability to resolve the clinical hold on SIG-001, the FDA or other regulators may request additional preclinical studies or clinical trials beyond those that we currently anticipate, manufacturing changes may not have the desired effect, the SLTx platform consists of novel technologies that are not yet clinically validated for human therapeutic use, and the risks identified under the heading “Risk Factors” in our Quarterly Report on Form 10-Q for the period ended September 30, 2021 and in any subsequent filings with the Securities and Exchange Commission. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at www.sec.gov, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this document, and we undertake no obligation to update or revise any of these statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

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