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): May 9, 2023

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 2.02 Results of Operations and Financial Condition.

On May 9, 2023, Sigilon Therapeutics, Inc. (the "Company") issued a press release announcing the Company's financial results for the quarter ended March 31, 2023. A copy of this press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

The information in this Form 8-K (including Exhibit 99.1 attached hereto) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing by the Company, under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Issued by Sigilon Therapeutics, Inc. on May 9, 2023
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: May 9, 2023

SIGILON THERAPEUTICS REPORTS FIRST QUARTER 2023 FINANCIAL RESULTS AND BUSINESS HIGHLIGHTS

SIG-002, Sigilon's lead program for the treatment of diabetes, transitioning to IND-enabling and NHP studies in the second half of 2023

Pipeline prioritization extends anticipated cash runway into 2025

Cambridge, MA—May 9, 2023—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 financial results for the first quarter ended March 31, 2023 as well as certain other business highlights.

"In the first quarter, we prioritized our diabetes program, SIG-002, which we are advancing with Eli Lilly and Company. With Lilly reimbursing us for the costs of our diabetes research and development activities, we are able to advance IND-enabling activities for SIG-002, including non-human primate studies, that we expect to initiate in the second half of this year," said Rogerio Vivaldi, M.D., President and CEO of Sigilon. "I am truly excited about the progress our team has made over the past five years in collaboration with Lilly; this includes successfully differentiating induced pluripotent stem cells into mixed populations of cell types approximating human islet cells, and importantly, improving the stability and integrity of our spheres to encapsulate these cells. Additionally, with an expected IND submission for SIG-002 in 2024, we have extended our anticipated cash runway into 2025."

Added Sarah Yuan, Ph.D., the Company's Chief Technical Operations Officer: "As we advance our diabetes program toward the clinic, this quarter we welcomed Dr. Ying Jing as our new incoming VP of Process Development. Dr. Jing brings nearly two decades of industry expertise, including experience with the development and scale up of biomanufacturing processes to support clinical trials. We look forward to her contributions as we advance our diabetes program toward the clinic."

Recent Program Highlights and Anticipated Milestones

- Sigilon's near-term focus is on development efforts for SIG-002, its product candidate for type 1 diabetes, which is being developed in collaboration with Eli Lilly and Company. Sigilon initiated IND-enabling activities for SIG-002, including process development activities and *in vivo* studies and anticipates initiating non-human primate (NHP) studies in the second half of this year.

- The Company recently incorporated several important changes into its SLTx platform designed to mitigate immune responses to its product candidates resulting in pericapsular fibrotic overgrowth (PFO). In addition, using an innovative high-throughput *in vitro* macrophage attachment assay developed by the Company to rapidly evaluate the potential PFO response to allogeneic cell products together with preclinical studies in more than 700 humanized mice designed to recapitulate PFO, the Company has continued to improve its SLTx platform and generate *in vitro* and *in vivo* data. All of these platform optimizations have been incorporated into SIG-002 and will be used to support the continued development of the current and future product candidates.

- In the first quarter of 2023, Sigilon decreased its external spend relating to the mucopolysaccharidosis type 1 (MPS-1) program to preserve capital. For MPS-1 and other lysosomal disorders, Sigilon remains focused on engineering techniques and other cell line strategies that could limit or otherwise avoid a patient's immune response to the Company's product candidates, as well as optimize blood-brain barrier penetration and product half-life.

Corporate Updates

- Ying Jing, Ph.D., recently joined the Company as the new VP of Process Development. Dr. Jing has more than 17 years of industry experience in developing innovative, scalable, productive, and robust biomanufacturing processes to support clinical trials and commercial supply of biotherapeutics for patients. Most recently, Dr. Jing worked at 2seventy bio—the oncology spinoff of bluebird bio—as a Sr. Director of Process Science.

Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $56.4 million as of March 31, 2023 compared to $69.6 million as of December 31, 2022. The decrease was primarily driven by cash used in operating activities and scheduled principal payments on the Company's debt. The Company expects that its cash, cash equivalents and marketable securities as of March 31, 2023 will be sufficient to support its currently anticipated operating expenses and capital expenditure requirements into 2025.

- **R&D Expenses**: Research and development expenses were $7.8 million for the first quarter of 2023 compared to $11.6 million for the first quarter of 2022. The decrease in research and development expenses was primarily due to the Company's decrease in external spend relating to the MPS-1 program to preserve capital and the close out of the clinical trial for hemophilia A. This decrease was partially offset by increased activities related to the diabetes program.

- **G&A Expenses:** General and administrative expenses were $4.3 million for the first quarter of 2023 compared to $5.0 million for the first quarter of 2022. The decrease in

general and administrative expenses is due to decreased insurance-related costs related to operating as a publicly traded company.

- **Net Loss:** Net loss was $7.4 million for the first quarter of 2023 compared to $13.9 million for the first quarter of 2022. The decrease was primarily due to savings in Sigilon's operating expenses from its updated strategy and increased collaboration revenue associated with Sigilon's collaboration with Eli Lilly and Company.

About Sigilon Therapeutics
Sigilon Therapeutics seeks to develop functional cures for patients with a broad range of acute and chronic diseases by harnessing the power of the human cell through its Shielded Living Therapeutics™ platform. Sigilon's product candidates are non-viral engineered cell-based therapies designed to produce a wide range of functions or therapeutic molecules that may be missing or deficient in patients living with diseases such as diabetes. The engineered cells are encapsulated by Sigilon's Afibromer™ biomaterials matrix, which is designed to shield them from immune rejection. 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 initiation and timing of IND-enabling activities and non-human primate studies for SIG-002, our plan to submit an IND for SIG-002in 2024 and advance our diabetes program into the clinic, and our expected cash runway. 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 if we cannot comply with Nasdaq's continued listing standards, our common stock could be delisted; if negative results of preclinical or clinical studies of any of our product candidates could adversely affect our business and may require us to discontinue or delay development of other product candidates, which are all based on the same SLTx platform; the SLTx platform consists of novel technologies that are not yet clinically validated for human therapeutic use and the approaches we are taking to discover and develop novel therapeutics are unproven; we may not be successful in our efforts to identify and develop product candidates; if clinical trials of our current and future product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates; if we are unable to obtain and maintain patent and other intellectual property protection our product candidates, our SLTx platform may be adversely affected, and the risks identified under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, and filed with the Securities and Exchange Commission (the "SEC"), as well as the other information we file with the SEC. 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, except as required by law. 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.

Sigilon Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited, in thousands, except share and per share amounts)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 41,255	$ 42,066
Marketable securities	15,114	27,560
Accounts receivable	3,162	2,171
Unbilled accounts receivable	1,798	1,287
Prepaid expenses and other current assets	3,067	1,077
Restricted cash, current portion	251	250
Total current assets	64,647	74,411
Property and equipment, net	2,872	2,854
Right-of-use assets	8,031	8,979
Restricted cash	1,038	1,034
Total assets	$ 76,588	$ 87,278
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,331	$ 936
Accrued expenses and other current liabilities	3,506	6,021
Lease liabilities, current portion	4,498	4,485
Current portion of long-term debt	6,667	6,667
Deferred revenue from related party, current portion	12,987	12,885
Total current liabilities	28,989	30,994
Lease liability, net of current portion	3,892	4,888
Long-term debt, net of discount and current portion	10,413	12,021
Other liabilities	—	233
Total liabilities	43,294	48,136
Stockholders' equity		
Common stock, par value $0.001 per share; 175,000,000 shares authorized at March 31, 2023 and December 31, 2022; 32,524,816 and 32,466,737 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	32	32
Preferred stock, par value $0.001 per share; 25,000,000 shares authorized at March 31, 2023 and December 31, 2022; no shares issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Additional paid-in capital	297,713	296,339
Accumulated other comprehensive loss	(273)	(429)
Accumulated deficit	(264,178)	(256,800)
Total stockholders' equity	33,294	39,142
Total liabilities and stockholders' equity	$ 76,588	$ 87,278

Sigilon Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited, in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2023	2022
Revenue		
Collaboration revenue	$ 4,858	$ 3,165
Operating expenses:		
Research and development	7,782	11,618
General and administrative	4,323	5,024
Total operating expenses	12,105	16,642
Loss from operations	(7,247)	(13,477)
Other income (expense), net:		
Interest income	476	64
Interest expense	(611)	(491)
Other income, net	4	45
Total other income (expense), net	(131)	(382)
Net loss attributable to ordinary shareholders	$ (7,378)	$ (13,859)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.23)	$ (0.43)
Weighted average common stock outstanding—basic and diluted	32,467,382	32,360,786

SOURCE: Sigilon Therapeutics, Inc.

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