Sigilon Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Business Highlights

March 14, 2023

Advancing IND-enabling activities for lead program in diabetes, SIG-002, with plans to conduct non-human primate studies in second half of 2023

SIG-002 demonstrated efficacy and durability in in vivo mouse models for up to 17 weeks

Extended anticipated cash runway into 2025

CAMBRIDGE, Mass., March 14, 2023 (GLOBE NEWSWIRE) -- 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 fourth quarter and year ended December 31, 2022 as well as certain other business highlights.

“Reflecting on 2022, we made many important strategic decisions that will help shape the future of our Company, including conducting research that informed the optimization of our SLTx platform, as well as refocusing our pipeline to prioritize our diabetes candidate, SIG-002, in a fiscally disciplined manner,” said Rogerio Vivaldi, M.D., President and CEO of Sigilon. “I am pleased to say that our team has made great progress in advancing our diabetes program, namely developing a differentiation protocol for producing functional human islets from induced pluripotent stem cells (iPSC). In combination with improvements to our encapsulation platform, this groundbreaking work has laid an important foundation for the transition of this program into the IND-enabling stage. We look forward to the initiation of what we believe will be an innovative non-human primate study with the goal of further de-risking our approach. Having lived with diabetes for most of my life as well as being a treating physician, I am truly excited about the direction of our program, including our early preclinical efficacy and durability data – which we believe is unparalleled in comparison to the published data for other programs. We believe our focused development strategy will help conserve resources and extend our cash runway into 2025, enabling us to successfully perform the activities needed to advance SIG-002 into the clinic, with an expected IND submission in 2024, and build upon the early successes of this program.”

Recent Program Highlights and Anticipated Milestones

- Sigilon has prioritized its product candidates based on their potential to provide meaningful clinical benefits to patients, rapid time to proof of concept, clear regulatory path, and validated biology and clinical endpoints. Based on these criteria, the Company is focusing its efforts on its product candidate for type 1 diabetes, SIG-002, which is being developed in collaboration with Eli Lilly and Company. Sigilon expects to initiate Investigational New Drug (IND)-enabling activities for SIG-002 in 2023.

- At the Cell and Gene Therapy Meeting on the Mesa in October 2022, the Company presented encouraging data showing its proprietary iPS cell differentiation protocol for SIG-002. The Company’s protocol has generated stem cell-derived human islets that are similar to human cadaveric islets with a high percentage of beta cells, high levels of insulin content and glucose-regulated insulin secretion. In addition, the Company has demonstrated that SIG-002 is efficacious in an STZ-induced diabetes mouse model for up to 17 weeks.

- The Company has incorporated several changes into its SLTx platform intended to avoid immune responses to its product candidates, including changes to the cross-linking chemistry designed to strengthen the integrity and stability of the spheres. The Company’s current programs, including SIG-002, have incorporated a number of these platform optimizations. Furthermore, Sigilon continues to utilize its innovative predictive preclinical models of pericapsular fibrotic overgrowth, including *in vitro* macrophage attachment assays and *in vivo* humanized mouse models, to support the continued development of its 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 is continuing to advance engineering techniques and other cell line strategies designed to minimize 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.

Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $69.6 million as of December 31, 2022 compared to $123.4 million as of December 31, 2021. The decrease was primarily driven by $51.5 million used in operating activities and $1.7 million of debt principal repayments. The Company expects that its cash, cash equivalents and marketable

securities as of December 31, 2022 will be sufficient to support its currently anticipated operating expenses and capital expenditure requirements into 2025.

- **R&D Expenses**: Research and development expenses were $5.9 million for the fourth quarter of 2022 compared to $14.7 million for the fourth quarter of 2021. The decrease in research and development expenses was primarily related to decreased activity in ongoing platform and other early-stage program development, personnel expenses, facility-related expenses, which were offset by increased expenses related to the Company's diabetes program. The decrease in platform and other early-stage program activity and personnel expenses was primarily due to the Company's reprioritization of the development of the MPS-1 program, diabetes program and platform optimization following the Company's restructuring activities in December 2021. The decrease in facility-related expenses was primarily due to the sublease of a portion of the Company's facility.

- **G&A Expenses:** General and administrative expenses were $4.5 million for the fourth quarter of 2022 compared to $4.6 million for the fourth quarter of 2021.

- **Net Loss:** Net loss was $6.7 million for the fourth quarter of 2022 compared to $17.7 million for the fourth quarter of 2021, primarily due to the decrease in R&D expenses discussed above.

About Sigilon Therapeutics

Sigilon Therapeutics seeks to develop functional cures for patients with a broad range of 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 the crucial proteins, enzymes or other therapeutic molecules needed by patients living with chronic diseases, such as diabetes and lysosomal diseases. 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 ability to complete process development and scale up activities for SIG-002 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 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

SIGILON THERAPEUTICS, INC.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(Unaudited)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 42,066	$ 107,143
Marketable securities	27,560	16,213
Accounts receivable	2,171	59
Unbilled accounts receivable	1,287	—
Prepaid expenses and other current assets	1,077	2,729
Restricted cash—current	250	250
Total current assets	74,411	126,394
Property and equipment, net	2,854	3,994
Right-of-use assets	8,979	12,863
Restricted cash	1,034	1,118

Total assets	$ 87,278	$ 144,369
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 936	$ 2,344
Accrued expenses and other current liabilities	6,021	8,998
Lease liabilities, current portion	4,485	4,845
Current portion of long-term debt	6,667	1,667
Deferred revenue from related party, current portion	12,885	17,034
Total current liabilities	30,994	34,888
Deferred revenue from related party, net of current portion	—	5,333
Lease liability, net of current portion	4,888	8,577
Long-term debt, net of discount and current portion	12,021	18,411
Other liabilities	233	—
Total liabilities	48,136	67,209
Stockholders' equity		
Common stock, par value $0.001 per share; 175,000,000 shares authorized at December 31, 2022 and December 31, 2021; 32,466,737 and 32,359,895 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	32	32
Preferred stock, par value $0.001 per share; 25,000,000 shares authorized at December 31, 2022 and December 31, 2021; no shares issued and outstanding at December 31, 2022 and December 31, 2021	—	—
Additional paid-in capital	296,339	290,377
Accumulated other comprehensive loss	(429)	(10)
Accumulated deficit	(256,800)	(213,239)
Total stockholders' equity	39,142	77,160
Total liabilities and stockholders' equity	$ 87,278	$ 144,369

SIGILON THERAPEUTICS, INC.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share data)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
Revenue				
Collaboration revenue	$ 2,644	$ 1,990	$ 12,944	$ 9,599
Operating expenses:				
Research and development	5,856	14,689	37,631	65,069
General and administrative	4,518	4,594	18,979	20,166
Total operating expenses	10,375	19,283	56,610	85,235
Loss from operations	(7,730)	(17,293)	(43,666)	(75,636)
Other income (expense), net:				
Interest income	404	46	946	258
Interest expense	(650)	(507)	(2,290)	(1,988)
Other income, net	1,291	8	1,449	55
Total other expense, net	1,045	(453)	105	(1,675)
Net loss attributable to ordinary shareholders	$ (6,685)	$ (17,746)	$ (43,561)	$ (77,311)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.21)	$ (0.55)	$ (1.34)	$ (2.43)
Weighted average common stock outstanding —basic and diluted	32,462,199	32,314,854	32,405,786	31,860,264

SOURCE: Sigilon Therapeutics, Inc.

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