Sigilon Therapeutics Reports Third Quarter 2022 Financial Results and Business Highlights

November 10, 2022

Identified important optimization features for its platform to mitigate PFO risks in current and future programs

Advanced iPS cell differentiation protocol for the diabetes program in preparation for anticipated IND-enabling studies in 2023

Continued optimization of the MPS-1 program, with plans to initiate IND-enabling studies in the second half of 2023

CAMBRIDGE, Mass., Nov. 10, 2022 (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 third quarter ended September 30, 2022 as well as certain other business highlights.

"This year, we have made significant progress advancing our SLTx platform, including key improvements to our cross-linking chemistry designed to strengthen the stability of our spheres. In addition, we have developed preclinical models designed to predict pericapsular fibrotic overgrowth, including macrophage attachment assays and humanized mouse models, which we believe will be key to mitigating risk of an allogeneic immune response and accelerate product development," said Rogerio Vivaldi, M.D., President and CEO of Sigilon. "I am grateful for the extraordinary effort put forth by our team to identify these important optimization features for the platform and to incorporate them into our diabetes and MPS-1 programs. We look forward to providing additional preclinical data for both programs showcasing the potential of the SLTx platform in the coming months."

Recent Program Highlights and Anticipated Milestones

- After the development of inhibitors and the discovery of pericapsular fibrotic overgrowth (PFO) in a hemophilia A patient last year, Sigilon evaluated ways to optimize its SLTx platform. This resulted in improvements to the Company's proprietary cross-linking chemistry, which has the potential to strengthen the spheres. Sigilon also developed allogeneic PFO prediction methods designed to rapidly evaluate the potential PFO response to encapsulated cell products. The Company has used these models to evaluate the allogeneic immune response to its current product candidates for diabetes and MPS-1. In addition, the Company expects to use these models to develop product candidates designed to avoid an allogeneic immune response and mitigate the risk of PFO, which the Company refers to as ImmunoQuiet™ cell therapies.

- At the Cell and Gene Therapy Meeting on the Mesa in October 2022, the Company presented data showing its proprietary iPS cell differentiation protocol for SIG-002, its product candidate for type 1 diabetes, which generates stem cell-derived 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 demonstrated that SIG-002 was efficacious in an STZ-induced diabetes mouse model after 10 weeks. The treated mice cleared an oral glucose challenge similar to clearance levels shown in non-diabetic control mice and maintained blood glucose levels at time zero after an overnight fast. The Company expects to initiate Investigational New Drug (IND)-enabling studies for SIG-002 in the second half of 2023 and expects to file an IND application for SIG-002 in 2024.

- Sigilon is optimizing its MPS-1 program to penetrate the blood brain barrier to address neurological manifestations, as well as to extend plasma half-life for the non-neurological manifestations. The Company expects to withdraw its Clinical Trial Applications (CTA) for its first MPS-1 product candidate, SIG-005, before year-end and plans to initiate IND-enabling studies for its optimized MPS-1 program in the second half of 2023. Sigilon also plans to file an IND application for a product candidate in its MPS-1 program in 2024.

- The Company submitted a Clinical Hold Response to the FDA for its hemophilia A program and withdrew its IND application for SIG-001. Sigilon also received approval to withdraw its CTA for SIG-001 for hemophilia A in the United Kingdom and plans to finalize activities pertaining to these regulatory filings before year-end.

Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $78.3 million as of September 30, 2022 compared to $123.4 million as of December 31, 2021. The decrease was primarily driven by cash used for operating activities. The Company expects that its cash, cash equivalents and marketable securities as of September 30, 2022 will support its currently anticipated operating expenses and capital expenditure requirements into 2024.

- **R&D Expenses**: Research and development expenses were $8.3 million for the third quarter of 2022 compared to $16.6 million for the third 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 its facility.

- **G&A Expenses:** General and administrative expenses were $4.4 million for the third quarter of 2022 compared to $5.0 million for the third quarter of 2021. The decrease in general and administrative expenses was primarily related to decreased personnel expenses primarily as a result of the Company's reprioritization and restructuring activities that occurred in December 2021 and the sublease of a portion of its facility.

- **Net Loss:** Net loss was $8.7 million for the third quarter of 2022 compared to $20.2 million for the third quarter of 2021. The decline in net loss as compared to the prior year was primarily due to savings realized from the Company's reprioritization and corporate restructuring in December 2021.

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 lysosomal diseases and 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 our expectations related to mitigation strategies for PFO, the initiation and timing of IND-enabling studies and an IND submission for SIG-002, the timing of an IND submission for a product candidate for our MPS-1 program 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 fail to achieve the expected financial and operational benefits of our corporate restructuring, our business and financial results may be harmed; 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 June 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. 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)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 32,925	$ 107,143
Marketable securities	45,344	16,213
Accounts receivable	23	59
Prepaid expenses and other current assets	2,084	2,729
Restricted cash—current	250	250
Total current assets	80,626	126,394
Property and equipment, net	3,053	3,994
Right-of-use assets	9,908	12,863
Restricted cash	1,031	1,118
Total assets	$ 94,618	$ 144,369
Liabilities and stockholders' equity (deficit)		
Current liabilities:		

Accounts payable	$ 1,408	$ 2,344
Accrued expenses and other current liabilities	5,947	8,998
Lease liabilities, current portion	4,462	4,845
Current portion of long-term debt	6,667	1,667
Deferred revenue from related party, current portion	12,071	17,034
Total current liabilities	30,555	34,888
Deferred revenue from related party, net of current portion	—	5,333
Lease liability, net of current portion	5,856	8,577
Long-term debt, net of discount and current portion	13,621	18,411
Other liabilities	176	—
Total liabilities	50,208	67,209
Stockholders' equity		
Common stock, par value $0.001 per share; 175,000,000 shares authorized at September 30, 2022 and December 31, 2021; 32,454,237 and 32,359,895 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	32	32
Preferred stock, par value $0.001 per share; 25,000,000 shares authorized at September 30, 2022 and December 31, 2021; no shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Additional paid-in capital	295,129	290,377
Accumulated other comprehensive loss	(636)	(10)
Accumulated deficit	(250,115)	(213,239)
Total stockholders' equity	44,410	77,160
Total liabilities and stockholders' equity	$ 94,618	$ 144,369

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenue				
Collaboration revenue	$ 4,252	$ 1,947	$ 10,300	$ 7,609
Operating expenses:				
Research and development	8,280	16,645	31,775	50,381
General and administrative	4,395	5,041	14,461	15,572
Total operating expenses	12,675	21,686	46,236	65,953
Loss from operations	(8,423)	(19,739)	(35,936)	(58,344)
Other income (expense), net:				
Interest income	300	56	542	212
Interest expense	(606)	(499)	(1,640)	(1,481)
Other income, net	58	26	158	47
Total other expense, net	(248)	(417)	(940)	(1,222)
Net loss attributable to ordinary shareholders	$ (8,671)	$ (20,156)	$ (36,876)	$ (59,566)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.27)	$ (0.63)	$ (1.14)	$ (1.88)
Weighted average common stock outstanding—basic and diluted	32,399,855	32,055,551	32,389,771	31,707,068

SOURCE: Sigilon Therapeutics, Inc.

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