Sigilon Therapeutics Reports First Quarter 2022 Financial Results And Business Highlights

May 12, 2022

On track to announce results from preclinical studies of SIG-005 in second half of 2022

Current cash position expected to fund operating plans into 2024

CAMBRIDGE, Mass., May 12, 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 first quarter ended March 31, 2022 as well as certain other business highlights.

"This quarter, we continued to make headway with our strategic reprioritization plans. Due to our strengthened leadership team, we have advanced our clinical and corporate strategy, with a focus on the three strategic areas we previously outlined: MPS-1, diabetes and platform optimization," said Rogerio Vivaldi, M.D., President and CEO of Sigilon. "To that end, the Sigilon team has been hard at work completing preclinical studies necessary to advance the clinical development of the SIG-005 program in patients with MPS-1, a lysosomal disease. We believe we remain on track to announce the results from our preclinical work in the second half of this year."

Recent Program Highlights and Anticipated Milestones

- The Company plans to report results from the SIG-005 preclinical studies designed to evaluate pericapsular fibrotic overgrowth (PFO) and strategies to mitigate PFO in humanized mice and non-human primates in the second half of 2022.
- Sigilon expects to submit amendments to the Company's Clinical Trial Applications (CTA) for SIG-005 for MPS-1 in the United Kingdom and Brazil in the second half of 2022.
- In February, the Company presented preclinical data on the rare lysosomal diseases MPS-1 and MPS-6 at the 18th Annual WORLDSymposium™, held in San Diego.
- In 2023, Sigilon expects to:
    - Initiate its planned Phase 1/2 trial of SIG-005 for MPS-1 in the UK and Brazil;
    - Submit an Investigational New Drug (IND) application for MPS-1 in the United States; and
    - Conduct IND-enabling studies for SIG-002 in type 1 diabetes.

Corporate Updates

- In March 2022, Sarah Yuan, Ph.D., joined the Company as Chief Technical Operations Officer (CTOO). Dr. Yuan brings more than 20 years of experience in process development, manufacturing sciences and CMC strategies from a broad range of leading biopharmaceutical companies. Prior to joining Sigilon, she held a number of leadership roles, most recently as Vice President of Process and Analytical Development at 2seventy bio, the oncology spinoff of bluebird bio.

Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $103.1 million as of March 31, 2022 compared to $123.4 million as of December 31, 2021. The decrease was primarily driven by cash used for operating activities and capital expenditures. The Company expects that its cash, cash equivalents and marketable securities as of March 31, 2022 will support its currently anticipated operating expenses and capital expenditure requirements into 2024.
- **R&D Expenses**: Research and development expenses were $11.6 million for the first quarter of 2022 compared to $16.0 million for the first quarter of 2021. The decrease in research and development expenses was primarily related to decreases in ongoing platform and pipeline development activities, personnel expenses and the SIG-007 program, which were partially offset by increases in the SIG-005 program. The decrease in platform and pipeline development, personnel expenses and SIG-007 and the increase in SIG-005 were primarily due to the Company's reprioritization on the development of MPS-1, diabetes and platform optimization following the restructuring activities in December 2021.
- **G&A Expenses:** General and administrative expenses were $5.0 million for the first quarter of 2022 compared to $5.5

million for the first quarter of 2021. The decrease in general and administrative expenses was driven by a reduction in personnel expenses that resulted from the restructuring that occurred in December 2021.

- **Net Loss:** Net loss was $13.9 million for the first quarter of 2022 compared to $19.0 million for the first quarter of 2021. The decline in net loss as compared to the prior year was primarily due to savings realized in the Company's operating expenses as a result of the Company's updated strategy and corporate restructuring.

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 the timing and results of our preclinical studies and our evaluation of PFO and mitigation strategies related thereto, the timing of our IND submission or CTA amendments for SIG-005, and the timing for the initiation of our Phase 1/2 clinical trial of SIG-005 in MPS-1, and the initiation and timing of IND-enabling studies for SIG-002, 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; the results of our investigation of the preliminary results of our Phase 1/2 clinical trial of SIG-001 in Hemophilia A or failure of SIG-005 in clinical development 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, 2021, 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
(in thousands, except share and per share amounts)
(Unaudited)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 64,487	$ 107,143
Marketable securities	38,618	16,213
Accounts receivable	62	59
Prepaid expenses and other current assets	6,234	2,729
Restricted cash—current	250	250
Total current assets	109,651	126,394
Property and equipment, net	3,689	3,994
Right-of-use assets	11,708	12,863
Restricted cash	1,118	1,118
Total assets	$ 126,166	$ 144,369
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 2,040	$ 2,344
Accrued expenses and other current liabilities	8,060	8,998
Lease liabilities, current portion	4,407	4,845
Current portion of long-term debt	3,333	1,667
Deferred revenue from related party, current portion	19,206	17,034
Total current liabilities	37,046	34,888

Deferred revenue from related party, net of current portion	—	5,333
Lease liability, net of current portion	7,721	8,577
Long-term debt, net of discount	16,811	18,411
Total liabilities	$ 61,578	$ 67,209
Stockholders' equity		
Common stock, par value $0.001 per share; 175,000,000 shares authorized at March 31, 2022 and December 31, 2021; 32,399,257 and 32,359,895 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	32	32
Preferred stock, par value $0.001 per share; 25,000,000 shares authorized at March 31, 2022 and December 31, 2021; no shares issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Additional paid-in capital	292,043	290,377
Accumulated other comprehensive income	(389)	(10)
Accumulated deficit	(227,098)	(213,239)
Total stockholders' equity	64,588	77,160
Total liabilities and stockholders' equity	$ 126,166	$ 144,369

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

	Three Months Ended March 31,	
	2022	**2021**
Revenue		
Collaboration revenue	$ 3,165	$ 2,958
Operating expenses:		
Research and development	11,618	15,985
General and administrative	5,024	5,540
Total operating expenses	16,642	21,525
Loss from operations	(13,477)	(18,567)
Other income (expense), net:		
Interest income	64	86
Interest expense	(491)	(488)
Other income (expense)	45	(4)
Total other expense, net	(382)	(406)
Net loss	$ (13,859)	$ (18,973)
Net loss per share—basic and diluted	$ (0.43)	$ (0.60)
Weighted average common stock outstanding—basic and diluted	32,360,786	31,487,710

SOURCE: Sigilon Therapeutics, Inc.

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