Sigilon Therapeutics Reports Second Quarter 2021 Financial Results and Business Highlights

August 10, 2021

CAMBRIDGE, Ma., Aug. 10, 2021 (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 second quarter ended June 30, 2021 as well as certain other business highlights.

"While we remain focused on patient safety and resolving the clinical hold on our Phase 1/2 trial in hemophilia A, we are also taking important steps to advance our broad pipeline of product candidates," said Rogerio Vivaldi, M.D., M.B.A., Chief Executive Officer of Sigilon. "Last month, we had the opportunity to present preclinical data on our candidate, SIG-005, for MPS-1 – a rare genetic disorder – and are encouraged by these results. With our CTA recently filed in the UK and Brazil and an additional filing in the U.S. anticipated, we look forward to starting our clinical journey in lysosomal diseases. If these filings are approved, we plan to initiate our second trial before year-end. In addition, we are working to streamline the manufacturing process of SIG-005 by incorporating cryopreservation of the cell component, potentially reducing the manufacturing lead times by approximately 80 percent. We remain committed to realizing the promise of our platform technology and advancing our current pipeline of product candidates, which includes programs in diabetes and immune-mediated disease. We are also continuing to look for additional opportunities, including strategic partnerships, to grow our existing portfolio."

Recent Program Highlights

- In July 2021, the Phase 1/2 study of SIG-001 was placed on clinical hold by the U.S. Food and Drug Administration (FDA). The clinical hold was initiated following Sigilon's submission of a serious adverse event (SAE) and temporary enrollment halt to the FDA and other regulatory agencies. To date, three patients have been dosed with SIG-001 and are continuing to be monitored by study protocol. The third patient, who received the highest dose of study drug, developed inhibitors to FVIII, which is a well-known complication of FVIII therapy. The patient responded well to medical treatment. Among other things, the FDA has requested additional information and data on factors potentially contributing to the development of inhibitors in this patient as well as follow-up data relating to FVIII inhibitor and activity levels.

- Three scientific abstracts were selected for presentation—including an oral presentation on mucopolysaccharidosis type I (MPS-1)—at the 16th International Symposium on MPS and Related Diseases (MPS 2021), which took place July 23 – 25, 2021. The Company also presented initial results from preclinical studies of expanded pipeline programs in immune-mediated and metabolic disorders at the American Society of Gene and Cell Therapy (ASGCT) 24th Annual Meeting in May.

- In June 2021, the Company filed a Clinical Trial Application (CTA) in the UK for SIG-005 for the treatment of MPS-1. In addition, the Company filed a CTA in Brazil for SIG-005 in July 2021.

- The Company plans to cryopreserve the cell component for the manufacture of SIG-005 in the Phase 1/2 clinical trial of MPS-1, allowing these cells to be produced in advance of the manufacture of drug product. This planned manufacturing change is expected to reduce the manufacturing lead times for patient doses of SIG-005 by approximately 80 percent.

Corporate Updates

- Deya Corzo, M.D., is stepping down as Chief Medical Officer. The Company entered into an agreement with Dr. Corzo providing for transition services until her separation on August 13, 2021. As Sigilon initiates a search for a CMO, the Board of Directors and management will work closely together on key clinical priorities.

- Philip Ashton-Rickardt, Ph.D., joined Sigilon as Chief Scientific Officer. Dr. Ashton-Rickardt is a highly regarded scientific leader in the field of immunology with a successful track record of developing cell therapies and platform technologies.

- Ajay Rai, M.B.A., joined the Company as Senior Vice President, Head of Business Development. Mr. Rai brings over two decades of business development, finance and partnering experience in the life sciences to Sigilon.

- Sigilon has initiated a search for a full-time Chief Financial Officer and, in the meantime, has engaged Michael Wyzga, M.B.A., former Chief Financial Officer of Genzyme, to provide finance-related services on an interim basis.

- Brooke Story, M.B.A., was appointed to the Company's Board of Directors. Ms. Story has more than 20 years of extensive commercial and operating experience in the healthcare industry.

Anticipated Milestones

- Sigilon expects to initiate a Phase 1/2 trial of SIG-005 in patients with MPS-1 in the second half of 2021.
- The Company expects to disclose up to 9 months of follow-up data for three patients from the Phase 1/2 safety and dose-ranging study of SIG-001 in severe to moderate-severe hemophilia in the third quarter of 2021.

Financial Results

- **Cash Position:** Cash was $162.4 million as of June 30, 2021 compared to $202.2 million as of December 31, 2020.
- **R&D Expenses**: Research and development expenses were $17.8 million for the second quarter of 2021 compared to $12.5 million for the second quarter of 2020. The increase in research and development expenses was primarily related to ongoing platform, pipeline, and development activities related to Sigilon's SIG-005 and SIG-007 programs, which received orphan drug designation in December 2020 and March 2021, respectively. Personnel expenses increased primarily as a result of the increase in headcount in Sigilon's research and development function and increases in stock-based compensation. Stock-based compensation expense increased to $0.9 million from $0.3 million for the three months ended June 30, 2021 and 2020, respectively. These increases were partially offset by a reduction of $0.5 million and $0.6 million associated with Sigilon's SIG-001 and SIG-002 programs, respectively. The decrease in SIG-001-related expenses was due to the timing of manufacturing activities in the second quarter of 2020 and the decrease in SIG-002-related expenses was due to changes in the timeline for preclinical activities.
- **G&A Expenses:** General and administrative expenses were $5.0 million for the second quarter of 2021 compared to $2.8 million for the second quarter of 2020. The increase in general and administrative expenses was primarily driven by a $0.8 million in increased costs from operating as a public company in the second quarter of 2021. In addition, personnel expenses increased by $1.0 million primarily as a result of the increase in headcount in Sigilon's general and administrative function and increases in stock-based compensation. Stock-based compensation expense increased to $1.1 million from $0.4 million for the three months ended June 30, 2021 and 2020, respectively.
- **Net Loss:** Net loss was $20.4 million for the second quarter ended June 30, 2021 compared to $13.5 million for the same period of 2020.

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 protected by Sigilon's Afibromer™ biomaterials matrix, which shields 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 modularity of our pipeline programs and the potential benefits of our platform, the timing for the initiation of our Phase 1/2 clinical trial of SIG-005 in MPS-1 as well as the filings related thereto, our ability to cryopreserve cell components of SIG-005 and other product candidates and the associated impact on manufacturing lead times, the timing for the submission of regulatory filings for MPS-1 and other product candidates, and the timing and scope of disclosure of initial data relating to our Phase 1/2 clinical study of SIG-001 in Hemophilia A. 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, and the risks identified under the heading "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 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. 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)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash	$ 162,406	$ 202,229
Accounts receivable (inclusive of $63 and $63 from a related party at June 30, 2021 and December 31, 2020, respectively)	178	177
Prepaid expenses and other current assets	3,611	1,729
Restricted cash—current	75	75
Total current assets	166,270	204,210
Property and equipment, net	3,630	2,991
Right-of-use assets	14,928	16,731
Restricted cash	1,293	1,118
Total assets	$ 186,121	$ 225,050
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 4,661	$ 1,988
Accrued expenses and other current liabilities	8,693	7,892
Lease liabilities, current portion	5,075	5,361
Deferred revenue from related party, current portion	25,957	31,777
Total current liabilities	44,386	47,018
Deferred revenue from related party, net of current portion	272	—
Lease liability, net of current portion	10,279	11,893
Long-term debt, net of discount	19,941	19,807
Other liabilities	176	176
Total liabilities	$ 75,054	$ 78,894
Stockholders' equity		
Common stock, par value $0.001 per share; 175,000,000 shares authorized at June 30, 2021 and December 31, 2020; 31,864,020 and 31,464,989 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	32	31
Preferred stock, par value $0.001 per share; 25,000,000 shares authorized at June 30, 2021 and December 31, 2020; no shares issued and outstanding at June 30, 2021 and December 31, 2020	—	—
Additional paid-in capital	286,373	282,053
Accumulated deficit	(175,338)	(135,928)
Total stockholders' equity	111,067	146,156
Total liabilities, convertible preferred stock and stockholders' equity	$ 186,121	$ 225,050

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue				
Collaboration revenue (inclusive of $2,662, $5,606, $1,951 and $5,417 from a related party for the three and six months ended June 30, 2021 and 2020, respectively)	$ 2,704	$ 1,951	$ 5,662	$ 5,417
Operating expenses:				
Research and development	17,751	12,452	33,736	25,726
General and administrative	4,992	2,818	10,532	5,689
Total operating expenses	22,743	15,270	44,268	31,415
Loss from operations	(20,039)	(13,319)	(38,606)	(25,998)
Other income (expense), net:				
Interest income	71	35	157	238
Interest expense	(494)	(196)	(982)	(404)
Other expense	25	(11)	21	(27)
Change in fair value of preferred stock warrant liability	—	1	—	(34)
Total other expense, net	(398)	(171)	(804)	(227)

Net loss and comprehensive loss	$ (20,437)	$ (13,490)	$ (39,410)	$ (26,225)
Net loss per share attributable to common stockholders —basic and diluted	$ (0.65)	$ (2.54)	$ (1.25)	$ (5.09)
Weighted average common stock outstanding—basic and diluted	31,571,704	5,320,427	31,529,939	5,152,477

SOURCE: Sigilon Therapeutics, Inc.

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