Sigilon Therapeutics Reports Third Quarter 2021 Financial Results and Business Highlights

November 10, 2021

Company expects to complete its investigation of the clinical hold on its Phase 1/2 trial of SIG-001

in hemophilia A by year-end

On track to initiate a Phase 1/2 trial of SIG-005 for MPS-1 in the fourth quarter of 2021

Company appoints May Orfali, M.D., M.B.A, as Chief Medical Officer

CAMBRIDGE, Mass., Nov. 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 third quarter ended September 30, 2021 as well as certain other business highlights.

“In the third quarter, we made meaningful progress advancing the development of our lysosomal disease program, while strengthening our leadership team to bolster our clinical and R&D capabilities,” said Rogerio Vivaldi, M.D., President and CEO of Sigilon. “Most recently, we welcomed Dr. May Orfali as Chief Medical Officer. We believe May’s insights will have an immediate impact on our Company’s operations and overall development strategy.”

Continued Dr. Vivaldi: “We remain committed to working with regulators to resolve the clinical hold on our Phase 1/2 trial of SIG-001 in hemophilia A and we anticipate completing our thorough investigation by year-end. In parallel, we have made meaningful progress advancing the development of our lysosomal disease program. Of note, our CTA for SIG-005 in MPS-1 was accepted in the UK and we received our second orphan drug designation for this product candidate, underscoring the global need for new treatment options to manage patients with this rare lysosomal disease. Each of these milestones represents an important step in advancing the development of SIG-005.”

Recent Program Highlights

- In July 2021, the Phase 1/2 study of SIG-001 in hemophilia A was placed on clinical hold by the U.S. Food and Drug Administration (FDA). To date, three patients have been dosed with SIG-001 and are continuing to be monitored by study protocol. 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 relating to the development of inhibitors to FVIII in the third patient. The Company expects to complete its investigation of this event before year-end.

- In September 2021, the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom accepted the Company’s Clinical Trial Application (CTA) for SIG-005 in mucopolysaccharidosis type I (MPS-1). In addition, the Company filed a CTA in Brazil for SIG-005 in July 2021 and plans to submit an Investigational New Drug Application to the FDA.

- In October 2021, the European Commission granted orphan drug designation to SIG-005 for the treatment of MPS-1.

- Sigilon presented results from several ongoing preclinical studies in the rare lysosomal diseases MPS-1, MPS-2 and MPS-6 at the 16th International Symposium on MPS and Related Diseases (MPS 2021), which took place July 23 – 25, 2021.

Corporate Updates

- May Orfali, M.D., M.B.A., will join the Company as an EVP and Chief Medical Officer (CMO), effective as of November 29, 2021, to lead the Company’s clinical development and medical affairs functions. Dr. Orfali has over 25 years of drug development experience across all phases of clinical development. Prior to joining Sigilon, Dr. Orfali held a number of executive leadership roles, most recently as president of Rare Disease & Oncology Consulting, LLC where she served as interim CMO for multiple small biotech companies in the rare disease and oncology space. Prior to that, she was the CMO of CANbridge Life Sciences, where she led the clinical development and medical affairs group, and Executive Director, Global Product Development at Pfizer, where she was responsible for patient-focused drug development across multiple rare disease assets including hemophilia.

- Susan Drapeau, Ph.D., was promoted from SVP, Head of Pre-clinical Development to EVP, Chief Pre-clinical Operations Officer. Dr. Drapeau has over 20 years of industry experience in cell therapy, biologics, biomaterials, protein therapies and

medical device development.

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

- Sigilon has initiated a search for a full-time Chief Financial Officer (CFO). In the meantime, the Company has entered into a consulting agreement with Michael Wyzga, M.B.A. Previously, Mr. Wyzga served in various senior management positions, including CFO at Genzyme Corporation for over a decade.

Anticipated Milestones

- Sigilon expects to initiate a Phase 1/2 trial of SIG-005 for MPS-1 in the fourth quarter of 2021.

- The Company expects to provide up to 12 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 A in the fourth quarter of 2021.

Financial Results

- **Cash Position:** Cash was $140.4 million as of September 30, 2021 compared to $202.2 as of December 31, 2020.

- **R&D Expenses**: Research and development expenses were $16.6 million for the third quarter of 2021 compared to $13.4 million for the third 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. During the third quarter of 2021, expenses increased for SIG-005 as the Company's CTA was accepted by MHRA in the United Kingdom and the Company filed a CTA in Brazil. The Company expects to initiate a Phase 1/2 trial of SIG-005 for MPS-1 in the fourth quarter of 2021. 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. These increases were partially offset by a reduction of $2.9 million associated with Sigilon's SIG-002 program. The decrease in SIG-002 related expenses was due to timing of preclinical activities.

- **G&A Expenses:** General and administrative expenses were $5.0 million for the third quarter of 2021 compared to $3.3 million for the third quarter of 2020. The increase in general and administrative expenses was driven by a $1.2 million increase in personnel expenses, which was primarily the result of an increase in headcount and an increase in stock-based compensation. Stock-based compensation expense increased to $1.2 million from $0.4 million for the three months ended September 30, 2020. In addition, the increase in general and administrative expenses was driven by a $0.8 million in the expansion of personnel and internal infrastructure to support our operations as a public company.

- **Net Loss:** Net loss was $20.2 million for the third quarter ended September 30, 2021 compared to $13.2 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 timing for the initiation of our Phase 1/2 clinical trial of SIG-005 in MPS-1, the impact and timing of our CMO hiring, the timing of our investigation of the clinical hold of our Phase 1/2 clinical study of SIG-001 in Hemophilia A including the timing of our meeting with the FDA and other regulatory agencies and anticipated follow-up data for three patients from our Phase 1/2 clinical study of SIG-001. 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 September 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)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash	$ 140,393	$ 202,229
Accounts receivable (inclusive of $27 and $63 from a related party at September 30, 2021 and December 31, 2020, respectively)	27	177
Prepaid expenses and other current assets	3,531	1,729
Restricted cash—current	75	75
Total current assets	144,026	204,210
Property and equipment, net	3,910	2,991
Right-of-use assets	14,568	16,731
Restricted cash	1,293	1,118
Total assets	$ 163,797	$ 225,050
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,226	$ 1,988
Accrued expenses and other current liabilities	7,657	7,892
Lease liabilities, current portion	5,673	5,361
Deferred revenue from related party, current portion	24,310	31,777
Total current liabilities	40,866	47,018
Lease liability, net of current portion	9,442	11,893
Long-term debt, net of discount	20,009	19,807
Other liabilities	176	176
Total liabilities	$ 70,493	$ 78,894
Stockholders' equity		
Common stock, par value $0.001 per share; 175,000,000 shares authorized at September 30, 2021 and December 31, 2020; 32,201,338 and 31,464,989 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	32	31
Preferred stock, par value $0.001 per share; 25,000,000 shares authorized at September 30, 2021 and December 31, 2020; no shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Additional paid-in capital	288,766	282,053
Accumulated deficit	(195,494)	(135,928)
Total stockholders' equity	93,304	146,156
Total liabilities, convertible preferred stock and stockholders' equity	$ 163,797	$ 225,050

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue				
Collaboration revenue	$ 1,947	$ 4,201	$ 7,609	$ 9,618
Operating expenses:				
Research and development	16,645	13,425	50,381	39,151
General and administrative	5,041	3,334	15,572	9,023
Total operating expenses	21,686	16,759	65,953	48,174
Loss from operations	(19,739)	(12,558)	(58,344)	(38,556)
Other income (expense), net:				
Interest income	56	30	212	268
Interest expense	(499)	(293)	(1,481)	(697)
Other income (expense)	26	(20)	47	(47)
Change in fair value of preferred stock warrant liability	—	(10)	—	(44)
Loss on extinguishment of debt	—	(343)	—	(343)
Total other expense, net	(417)	(636)	(1,222)	(863)
Net loss and comprehensive loss	$ (20,156)	$ (13,194)	$ (59,566)	$ (39,419)

Net loss per share attributable to common stockholders —basic and diluted	$ (0.63)	$ (2.47)	$ (1.88)	$ (7.56)
Weighted average common stock outstanding—basic and diluted	32,055,551	5,338,177	31,707,068	5,214,818

SOURCE: Sigilon Therapeutics, Inc.

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