Sigilon Therapeutics Reports First Quarter 2021 Financial Results and Business Highlights

May 10, 2021

CAMBRIDGE, Mass., May 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 first quarter ended March 31, 2021 as well as certain other business highlights.

"We are continuing to execute on our business plan in 2021, as we advance the clinical development of our lead product candidate for hemophilia A, while at the same time working to strengthen our team, expanding our pipeline and further validating the potential of our Shielded Living Therapeutics™, or SLTx, platform," commented Rogerio Vivaldi, M.D., Chief Executive Officer of Sigilon. "As we increased dose levels in our Phase 1/2 safety and dose ranging study of SIG-001, we completed planned manufacturing changes designed to, among other things, increase cell potency and enhance cell function. These changes have been cleared by the MHRA and FDA and we look forward to reporting initial data from this study in the third quarter of this year."

Continued Dr. Vivaldi: "In addition to our clinical initiatives with SIG-001, we continue to focus on advancing our growing pipeline, which currently consists of product candidates targeting rare blood, lysosomal and endocrine diseases. Leveraging the modularity of our platform, we believe our novel approach may provide treatment solutions for other diseases and, as we are presenting at ASGCT this week, we are actively exploring SLTx's potential in additional therapeutic areas with large unmet needs, such as immune-mediated diseases."

Recent Program Highlights

- The Phase 1/2 safety and dose-ranging study of SIG-001 in severe to moderate-severe hemophilia A remains ongoing, with sites initiated in the United Kingdom and United States. Recently, Sigilon cleared amendments to its CTA and IND for SIG-001 with the MHRA and FDA, respectively, to incorporate planned manufacturing changes.

- Four abstracts were selected for poster presentations at the upcoming American Society of Gene and Cell Therapy (ASGCT) 24th Annual Meeting, which will take place May 11 – 14, 2021. The presentations will include initial results from the Company's preclinical studies in immune-mediated hepatitis and hypoparathyroidism, which reflect the modularity and expansion of the Company's pipeline programs.

- Several scientific abstracts outlining ongoing preclinical studies in a range of lysosomal diseases, including an oral presentation on mucopolysaccharidosis type II (MPS-2), were presented at the 17th Annual WORLD*Symposium* ™ .

- In March 2021, the FDA granted Orphan Drug designation for SIG-007 for the treatment of Fabry disease.

Corporate Updates

- In April 2021, Martha Rook, Ph.D., was promoted from SVP, Head of CMC and Analytics to Sigilon's Chief Technical Operations Officer. Dr. Rook has more than 20 years of experience in analytics and bioprocessing including more than 10 years in the development of cell and gene therapy manufacturing processes. In her new role, she will oversee all technical operations for the Company, including manufacturing, supply chain, quality, bioanalytical and CMC analytical development teams at Sigilon.

- In the first week of May 2021, Robert Windsor, Jr., J.D., joined Sigilon as Vice President, Head of Investor Relations. Mr. Windsor has more than 15 years of experience working in equity capital markets, including institutional equity sales at several large investment banks.

Anticipated Milestones

- The Company is on track to file a CTA and/or IND for MPS-1 in the second quarter of 2021 and anticipates additional regulatory filings before the end of 2022.

- The Company is continuing its Phase 1/2 safety and dose-ranging study of SIG-001 in severe to moderate-severe hemophilia:

    - Sigilon expects to disclose up to 9 months of follow up data for 3-4 patients in the third quarter of 2021; and

- Sigilon expects to complete enrollment of the study in the second half of 2021.

Financial Results

- **Cash Position:** Cash was $178.8 million as of March 31, 2021.

- **R&D Expenses:** Research and development expenses were $16.0 million for the first quarter of 2021 compared to $13.3 million for the first quarter of 2020. The increase in research and development expenses was primarily related to ongoing pipeline development activities and advances in our SIG-005 and SIG-007 programs both of which received orphan drug designation in December 2020 and March 2021, respectively. Stock-based compensation expense increased to $0.8 million from $0.2 million for the three months ended March 31, 2021 and 2020, respectively. These increases were partially offset by a reduction of $0.7 million associated with our SIG-001 due to the timing of manufacturing activities in the first quarter of 2020.

- **G&A Expenses:** General and administrative expenses were $5.5 million for the first quarter of 2021 compared to $2.9 million for the first quarter of 2020. The increase in general and administrative expenses was primarily driven by $1.0 million in increased costs from operating as a public company in the first quarter of 2021. In addition, personnel expenses increased by $1.1 million primarily as a result of the increase in headcount in our general and administrative function and increases in stock-based compensation. Stock-based compensation expense increased to $0.9 million from $0.4 million for the three months ended March 31, 2021 and 2020, respectively.

- **Net Loss:** Net loss was $19.0 million for the first quarter ended March 31, 2021 compared to $12.7 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 disorders 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 effect of manufacturing changes on cell potency and cell function, the modularity of our pipeline programs and the potential benefits of our platform, the timing for the submission of INDs and/or CTAs and additional regulatory filings for MPS-1 and other product candidates, and the timing and scope of disclosure of initial data relating to, and the completion of enrollment for, 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, those related to our clinical and preclinical research, product candidates, the enrollment and timeline for our clinical trials and the regulatory filings related thereto, and the risks identified under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020, and filed with the Securities and Exchange Commission, 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)

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash	$ 178,789	$ 202,229
Accounts receivable (inclusive of $83 and $63 from a related party at March 31, 2021 and December 31, 2020, respectively)	140	177
Prepaid expenses and other current assets	4,058	1,729
Restricted cash—current	75	75
Total current assets	183,062	204,210
Property and equipment, net	3,107	2,991
Right-of-use assets	16,098	16,731

Restricted cash	1,118	1,118
Total assets	$ 203,385	$ 225,050
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 2,006	$ 1,988
Accrued expenses and other current liabilities	6,912	7,892
Lease liabilities, current portion	5,427	5,361
Deferred revenue from related party, current portion	20,134	31,777
Total current liabilities	34,479	47,018
Deferred revenue from related party, net of current portion	8,725	—
Lease liability, net of current portion	11,099	11,893
Long-term debt, net of discount	19,874	19,807
Other liabilities	176	176
Total liabilities	$ 74,353	$ 78,894
Commitments and contingencies (Note 9)		
Stockholders' equity		
Common stock, par value $0.001 per share; 175,000,000 shares authorized at March 31, 2021 and December 31, 2020; 31,501,952 and 31,464,989 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	32	31
Preferred stock, par value $0.001 per share; 25,000,000 shares authorized at March 31, 2021 and December 31, 2020; no shares issued and outstanding at March 31, 2021 and December 31, 2020	—	—
Additional paid-in capital	283,901	282,053
Accumulated deficit	(154,901)	(135,928)
Total stockholders' equity	129,032	146,156
Total liabilities, convertible preferred stock and stockholders' equity	$ 203,385	$ 225,050

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,	
	2021	**2020**
Revenue		
Collaboration revenue (inclusive of $2,932 and $3,466 from a related party for the three months ended March 31, 2021 and 2020, respectively)	$ 2,958	$ 3,466
Operating expenses:		
Research and development (inclusive of related party payments to MIT of $66 and $220 for the three months ended March 31, 2021 and 2020, respectively)	15,985	13,274
General and administrative	5,540	2,871
Total operating expenses	21,525	16,145
Loss from operations	(18,567)	(12,679)
Other income (expense), net:		
Interest income	86	203
Interest expense	(488)	(208)
Other expense	(4)	(16)
Change in fair value of preferred stock warrant liability	—	(35)
Total other expense, net	(406)	(56)
Net loss and comprehensive loss	$ (18,973)	$ (12,735)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.60)	$ (2.55)
Weighted average common stock outstanding—basic and diluted	31,487,710	4,984,527

Sigilon Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (18,973)	$ (12,735)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Stock-based compensation expense	1,704	667
Deferred revenue	(2,918)	(3,298)
Other non-cash expenses, net	1,511	987
Other changes in assets and liabilities	(3,997)	(823)
Net cash used in operating activities	(22,673)	(15,202)
Cash flows from investing activities:		
Purchase of property and equipment	(290)	(190)
Net cash used in investing activities	(290)	(190)
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock, including deemed dividend, net of issuance costs	—	26,946
Other financing activities, net	(477)	120
Net cash provided by financing activities	(477)	27,066
Net increase in cash and restricted cash	(23,440)	11,674
Cash and restricted cash at beginning of period	203,422	76,645
Cash and restricted cash at end of period	$ 179,982	$ 88,319
Cash	$ 178,789	$ 87,743
Restricted cash-current	75	—
Restricted cash-non-current	1,118	576
Total cash and restricted cash	$ 179,982	$ 88,319

SOURCE: Sigilon Therapeutics, Inc.

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