Sigilon Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results and Business Highlights

March 18, 2021

CAMBRIDGE, Mass., March 18, 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 fourth quarter and full year ended December 31, 2020 as well as certain other business highlights.

“2020 was a transformational period for Sigilon marked by the achievement of numerous key regulatory, clinical, and financial milestones, which we believe have positioned us to deliver on our commitments over the next several years,” commented Rogerio Vivaldi, M.D., Chief Executive Officer of Sigilon. “The modularity of our Shielded Living Therapeutics™ platform has enabled us to build a robust pipeline spanning a diverse range of chronic disorders, including rare blood, lysosomal and endocrine diseases. Notably, in 2020, our lead product candidate SIG-001 received IND and CTA clearance and we dosed the first patients in our Phase 1/2 safety and dose-ranging study in severe to moderate-severe hemophilia A—a significant milestone for both our platform technology and the hemophilia community.”

Continued Dr. Vivaldi: “While our immediate priority is developing SIG-001, looking ahead, we are also leveraging our platform to advance several additional candidates—including SIG-005 for MPS-1, SIG-007 for Fabry disease and SIG-002 for Type 1 Diabetes—into the clinic over the next two years. Having successfully completed an upsized Initial Public Offering in December, which attracted a breadth of healthcare specialists and long-term focused shareholders, we are well-positioned to execute across each of these initiatives as we work to provide functional cures for patients.”

Recent Program Highlights

- In the fourth quarter, the Company dosed the first two patients in its Phase 1/2 safety and dose-ranging study with SIG-001 in severe to moderate-severe hemophilia A. No serious adverse events have been reported. At the initial dose levels for this study, tested in the first two patients, the Company has observed FVIII activity levels in the low- to mid-single digits.

- As dose levels increase, Sigilon initiated planned manufacturing changes in the first quarter of 2021 designed to, among other things, increase cell potency and enhance cell function. The Company has filed amendments to its CTA and IND for SIG-001 with the MHRA and FDA, respectively, to incorporate these changes.

- In December 2020, the FDA granted Orphan Drug designation to SIG-005 for the treatment of mucopolysaccharidosis type I (MPS-1), a chronic, progressive lysosomal disease.

- Four scientific abstracts outlining several ongoing preclinical studies in a range of lysosomal diseases were selected for presentation – including an oral presentation on mucopolysaccharidosis type II (MPS-2) – at the 17th Annual WORLD*Symposium* ™ . In all these preclinical studies, platform cells produced high levels of biochemically active enzyme having characteristics nearly identical to the enzyme replacement therapies. Significant reduction in substrates across tissues were observed.

- In March 2021, the FDA granted Orphan Drug designation for SIG-007 for the treatment of Fabry disease, which is also a progressive, life-threatening lysosomal disease.

Corporate Updates

- In December 2020, the Company raised $144.9 million in gross proceeds from an initial public offering of 8,050,000 shares of common stock at a public offering price of $18.00 per share.

- Devyn Smith, Ph.D., will step down as Chief Operating Officer of Sigilon, effective on April 26, 2021, to assume a CEO role within the biotech industry.

Anticipated Milestones

- The Company is planning 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.

- 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 $202.2 million as of December 31, 2020.

- **R&D Expenses:** Research and development expenses were $14.3 million for the fourth quarter of 2020 compared to $15.0 million for the fourth quarter of 2019. For the full year of 2020, research and development expenses were $53.5 million compared to $48.1 million for the same period in 2019. The increase in research and development expenses as compared to the prior year period was related to increased costs associated with Sigilon's lead programs, increased costs associated with platform and pipeline development, an increase in personnel expenses costs due to headcount additions and an increase in stock-based compensation associated with stock option grants.

- **G&A Expenses:** General and administrative expenses were $3.5 million for the fourth quarter of 2020 compared to $2.9 million for the fourth quarter of 2019. For the full year of 2020, general and administrative expenses were $12.5 million compared to $10.2 million for the same period in 2019. The increase in general and administrative expenses as compared to the prior year period was primarily driven by an increase in professional fees and insurance costs that are primarily due to the costs of operating as a public company, an increase in personnel related costs due to increased headcount and an increase in stock-based compensation associated with stock option grants.

- **Net Loss:** Net loss was $15.2 million for the quarter ended December 31, 2020 compared to $14.7 million for the same period of 2019. For the full year 2020, Sigilon reported a net loss of $54.6 million, compared to a net loss of $43.9 million for the full year 2019.

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 timing for the submission of INDs or CTAs for MPS-1 and other product candidates and the timing for patient enrollment and dosing, disclosure of data and the completion of 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 Prospectus filed with the Securities and Exchange Commission on December 7, 2020, 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)

	December 31,	
	2020	**2019**
Assets		
Current assets:		
Cash	$ 202,229	$ 76,069
Accounts receivable	177	136
Prepaid expenses and other current assets	1,729	732
Restricted cash—current	75	—
Total current assets	204,210	76,937
Deferred offering costs	—	65
Property and equipment, net	2,991	2,949
Right-of-use assets	16,731	9,851
Restricted cash	1,118	576
Total assets	$ 225,050	$ 90,378
Liabilities, convertible preferred stock and stockholders' equity (deficit)		

Current liabilities:		
Accounts payable	$ 1,988	$ 2,005
Accrued expenses and other current liabilities	7,892	5,852
Lease liabilities, current portion	5,361	3,378
Deferred revenue from related party, current portion	31,777	29,140
Total current liabilities	47,018	40,375
Deferred revenue from related party, net of current portion	—	15,550
Lease liability, net of current portion	11,893	6,808
Long-term debt, net of discount	19,807	14,868
Preferred stock warrant liability	—	333
Other liabilities	176	—
Total liabilities	$ 78,894	$ 77,934
Commitments and contingencies		
Preferred stock, par value $0.001 per share; 25,000,000 and no shares authorized at December 31, 2020 and 2019, respectively; no shares issued and outstanding at December 31, 2020 and 2019	—	—
Convertible preferred stock (Series A, A-1, A-3 and B), par value $0.001 per share; no and 35,536,001 shares authorized at December 31, 2020 and 2019, respectively; no and 31,836,001 issued and outstanding at December 31, 2020 and 2019, respectively; liquidation preference of $0 and $90,461 at December 31, 2020 and 2019, respectively	—	90,206
Stockholders' equity (deficit)		
Common stock, par value $0.001 per share; 175,000,000 and 60,000,000 shares authorized at December 31, 2020 and December 31, 2019, respectively; 31,464,989 and 5,221,628 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	31	5
Additional paid-in capital	282,053	3,553
Accumulated deficit	(135,928)	(81,320)
Total stockholders' equity (deficit)	146,156	(77,762)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 225,050	$ 90,378

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

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Revenue				
Collaboration revenue	$ 3,756	$ 3,098	$ 13,374	$ 14,155
Operating expenses:				
Research and development	14,337	15,014	53,488	48,108
General and administrative	3,505	2,900	12,528	10,170
Total operating expenses	17,842	17,914	66,016	58,278
Loss from operations	(14,086)	(14,816)	(52,642)	(44,123)
Other income (expense), net:				
Interest income	44	277	312	1,058
Interest expense	(505)	(188)	(1,202)	(650)
Other expense	(42)	—	(89)	(6)
Change in fair value of preferred stock warrant liability	(600)	(2)	(644)	(204)
Loss on extinguishment of debt	—	—	(343)	—
Total other income (expense), net	(1,103)	87	(1,966)	198
Net loss and comprehensive loss	$ (15,189)	$ (14,729)	$ (54,608)	$ (43,925)
Net loss per share attributable to common stockholders—basic and diluted	$ (1.15)	$ (3.17)	$ (7.55)	$ (10.74)
Weighted average common stock outstanding—basic and diluted	13,230,224	4,642,290	7,229,626	4,090,691

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

	Year Ended December 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (54,608)	$ (43,925)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Stock-based compensation expense	3,127	2,073
Deferred revenue	(12,913)	(13,172)
Other non-cash expenses, net	5,293	2,668
Other changes in assets and liabilities	(2,547)	2,282
Net cash used in operating activities	(61,648)	(50,074)
Cash flows from investing activities:		
Purchase of property and equipment	(972)	(1,209)
Net cash used in investing activities	(972)	(1,209)
Cash flows from financing activities:		
Proceeds from issuance of common stock in connection with the initial public offering, net of underwriting discounts and commissions	132,527	(65)
Proceeds from issuance of convertible preferred stock, including deemed dividend, net of issuance costs	51,723	53,136
Repayment of debt	(15,000)	(1,000)
Proceeds from long term debt	19,788	11,000
Other financing activities, net	359	171
Net cash provided by financing activities	189,397	63,242
Net increase in cash and restricted cash	126,777	11,959
Cash and restricted cash at beginning of period	76,645	64,686
Cash and restricted cash at end of period	$ 203,422	$ 76,645
Cash	$ 202,229	$ 76,069
Restricted cash-current	75	—
Restricted cash-non-current	1,118	576
Total cash and restricted cash	$ 203,422	$ 76,645

SOURCE: Sigilon Therapeutics, Inc.

Investor Contacts
Glenn Reicin
Sigilon Therapeutics, Chief Financial Officer
glenn.reicin@sigilon.com
646-696-4344

Jennifer Porcelli
Solebury Trout
jporcelli@soleburytrout.com
646-378-2962

Media Contact
Amy Bonanno
Solebury Trout
abonanno@soleburytrout.com
914-450-0349