# Sigilon Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results and Recent Business Highlights

March 14, 2022

*Announced strategic reprioritization, with plans to advance mucopolysaccharidosis type I (MPS-1) and diabetes as lead indications as well as continued platform optimization*

*Strengthened leadership team with appointment of new Chief Technical Operations Officer and other key leadership changes*

*Current cash position expected to fund operating plans into 2024*

CAMBRIDGE, Mass., March 14, 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 fourth quarter and full year ended December 31, 2021 as well as certain other business highlights.

“In 2021, we made important adjustments to our overall corporate and clinical strategy as well as our leadership team to best position us for sustained future growth and success,” said Rogerio Vivaldi, M.D., President and CEO of Sigilon. “Based on key learnings from our first-in-human trial in hemophilia A, we have shifted our clinical focus and plan to prioritize MPS-1, in addition to our diabetes program in partnership with Eli Lilly, as we continue to optimize our novel platform. Looking ahead, we remain dedicated to taking the necessary steps to advance our differentiated, non-viral engineered cell-based therapies with the goal of delivering functional cures to patients with a broad range of chronic diseases.”

**Recent Program Highlights**

- In December 2021, Sigilon announced a strategic reprioritization to enable the Company to focus on MPS-1 and diabetes as well as platform optimization. Sigilon expects the significant reduction in expenses associated with the strategic reprioritization to extend the Company’s cash runway into 2024.
- The Brazilian Health Surveillance Agency, ANVISA, has cleared the Company’s Clinical Trial Application (CTA) for SIG-005 in MPS-1. In addition, Sigilon plans to submit an Investigational New Drug (IND) Application to the U.S. Food and Drug Administration for SIG-005.
- In October 2021, the European Commission granted orphan drug designation to SIG-005 for the treatment of MPS-1.
- Last month, Sigilon presented preclinical data on the rare lysosomal diseases MPS-1 and MPS-6 at the 18th Annual WORLDSymposium™, held February 7-11th in San Diego.

**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.
- Josias Pontes, M.B.A., was promoted from VP, Head of Finance to SVP, acting Chief Financial Officer. Mr. Pontes brings over 30 years of finance and accounting experience.
- Olivia G. Kelly, Ph.D., was promoted from VP, Head of Diabetes Research to SVP, Head of Diabetes Research. Dr. Kelly has over 16 years of experience developing cell therapies for a range of disorders – including type 1 diabetes – in the biotechnology industry.

**Strategic Priorities and Anticipated Milestones**

The Company is focusing its development efforts in three strategic areas:

**MPS-1**: SIG-005 is the Company’s product candidate that contains a cell line genetically modified with a non-viral vector to express human α L iduronidase, or IDUA, encapsulated within Sigilon’s spheres. SIG-005 is being developed to treat the non-neurological manifestations of mucopolysaccharidosis type 1, or MPS-1, in patients with the disease. The Company believes its product candidates for lysosomal diseases can leverage the well understood mechanism of enzyme replacement therapies, or ERTs, by using engineered cells to express functional

human enzyme or other protein that more closely resemble normal physiology in a continuous manner. Sigilon is also working to develop next-generation product candidates to address the neurological manifestations of lysosomal diseases, starting with MPS-1, using transporter molecules designed to penetrate the blood brain barrier and molecules designed to extend plasma half-life.

**Diabetes:** SIG-002 is the Company's product candidate designed to replace islet cells for the treatment of type 1 diabetes, or T1D. In T1D, the immune system attacks and destroys the insulin-producing beta cells within the endocrine islets of the pancreas. Insulin deficiency results in dysregulation of glucose metabolism. In April 2018, the Company partnered with Eli Lilly and Company, a global leader in diabetes, to develop cell therapies for the treatment of T1D, including SIG-002. Under the terms of the partnership, Sigilon is leading execution of the program through an IND and Lilly will develop and commercialize the program worldwide.

**Platform optimization:** Sigilon is continuing to optimize its Shielded Living Therapeutics, or SLTx, platform, which combines advanced cell engineering with cutting-edge innovations in biocompatible materials to pioneer a new class of therapeutics. In November 2021, the Company reported that spheres covered with pericapsular fibrotic overgrowth, or PFO, were observed during a retrieval procedure in its Phase 1/2 study of SIG-001 in severe or moderately severe hemophilia A. With the modularity of the SLTx platform, the Company is evaluating changes designed to further modulate or otherwise reduce the potential for a patient's immune response to its product candidates.

In these prioritized areas, Sigilon expects to achieve the following milestones:

- In the second half of 2022, the Company expects to:
  - Present results of preclinical studies designed to evaluate PFO and mitigation strategies in humanized mice and non-human primates; and
  - Submit amendments to the Company's CTAs for SIG-005 for MPS-1 in the United Kingdom and Brazil.

- In 2023, the Company expects to:
  - Initiate a Phase 1/2 trial of SIG-005 for MPS-1 in the United Kingdom and/or Brazil;
  - Submit an IND application for MPS-1 in the United States; and
  - Conduct IND-enabling studies for SIG-002 in diabetes.

**Financial Results**

- **Cash Position:** Cash, cash equivalents and marketable securities were $123.4 million as of December 31, 2021 compared to $202.2 million as of December 31, 2020.

- **R&D Expenses**: Research and development expenses were $14.7 million for the fourth quarter of 2021 compared to $14.3 million for the fourth quarter of 2020. Research and development expenses were $65.1 million for the year ended December 31, 2021 compared to $53.5 million for the year ended December 31, 2020. The increase in research development for the fourth quarter of 2021 of $0.4 million was primarily the result of an increase in personnel expenses associated with the Company's restructuring activities in December 2021, which were partially offset by a decrease in expenses for Sigilon's SIG-002 program and a reduction in activities associated with its core research and platform development activities. The increase in research and development expenses for the year end December 31, 2021 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. The expenses increased for SIG-005 as the Company submitted a CTA to the MHRA in the United Kingdom and the ANVISA in Brazil. Personnel expenses for the year ended December 31, 2021 increased by $3.6 million primarily as a result of the increase in headcount in Sigilon's research and development function, severance associated with the Company's previously announced December 2021 restructuring and increases in stock-based compensation. These increases were partially offset by a reduction of $3.7 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 $4.6 million for the fourth quarter of 2021 compared to $3.5 million for the fourth quarter of 2020. General and administrative expenses were $20.2 million for the year ended December 31, 2021 compared to $12.5 million for the year ended 2020. The increase in general and administrative expenses for the fourth quarter of 2021 was primarily attributed to a $0.7 million increase in the expansion of internal infrastructure to support the Company's operations as a public company and a $0.3 million increase in employee related expenses associated with the Company's restructuring activities in December 2021. The increase in general and administrative expenses for the year ended December 31, 2021 was driven by a $3.7 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 $3.9 million from $1.8 million for the year ended December 31, 2020. In addition, the increase in general and administrative expenses for the year ended December 31, 2021 was driven by a $3.3 million increase in the expansion of internal infrastructure to support the Company's operations as a public company.

- **Net Loss:** Net loss was $17.7 million for the fourth quarter of 2021 compared to $14.1 million for the fourth quarter of 2020. Net loss was $77.3 million for the year ended December 31, 2021 compared to $54.6 million for the year ended December 31, 2020.

**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 clinical development of our current product candidates and next generation product candidates, our ability to evaluate PFO and mitigation strategies related thereto, the timing of our IND submission and CTA amendments for SIG-005, the timing for the initiation of our Phase 1/2 clinical trial of SIG-005 in MPS-1, 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 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, 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)

| | December 31, | |
|---|---|---|
| | **2021** | **2020** |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 107,143 | $ 202,229 |
| Marketable securities | 16,213 | — |
| Accounts receivable | 59 | 177 |
| Prepaid expenses and other current assets | 2,729 | 1,729 |
| Restricted cash—current | 250 | 75 |
| Total current assets | 126,394 | 204,210 |
| Property and equipment, net | 3,994 | 2,991 |
| Right-of-use assets | 12,863 | 16,731 |
| Restricted cash | 1,118 | 1,118 |
| **Total assets** | $ 144,369 | $ 225,050 |
| **Liabilities and stockholders' equity (deficit)** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,344 | $ 1,988 |
| Accrued expenses and other current liabilities | 8,998 | 7,892 |
| Lease liabilities, current portion | 4,845 | 5,361 |
| Current portion of long-term debt | 1,667 | — |
| Deferred revenue from related party, current portion | 17,034 | 31,777 |
| Total current liabilities | 34,888 | 47,018 |
| Deferred revenue from related party, net of current portion | 5,333 | — |
| Lease liability, net of current portion | 8,577 | 11,893 |
| Long-term debt, net of discount | 18,411 | 19,807 |
| Other liabilities | — | 176 |
| **Total liabilities** | $ 67,209 | $ 78,894 |

| | | |
|---|---|---|
| **Stockholders' equity** | | |
| Common stock, par value $0.001 per share; 175,000,000 shares authorized at December 31, 2021 and 2020; 32,359,895 and 31,464,989 shares issued and outstanding at December 31, 2021 and 2020, respectively | 32 | 31 |
| Preferred stock, par value $0.001 per share; 25,000,000 shares authorized at December 31, 2021 and 2020; no shares issued and outstanding at December 31, 2021 and 2020 | — | — |
| Additional paid-in capital | 290,377 | 282,053 |
| Accumulated other comprehensive income | (10) | — |
| Accumulated deficit | (213,239) | (135,928) |
| Total stockholders' equity | 77,160 | 146,156 |
| **Total liabilities and stockholders' equity** | $ 144,369 | $ 225,050 |

**SIGILON THERAPEUTICS, INC.**
**Condensed Consolidated Statements of Operations and Comprehensive Loss**
(In thousands, except per share data)
(Unaudited)

| | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| Revenue | | | | |
| Collaboration revenue | $ 1,990 | $ 3,756 | $ 9,599 | $ 13,374 |
| Operating expenses: | | | | |
| Research and development | 14,689 | 14,337 | 65,069 | 53,488 |
| General and administrative | 4,594 | 3,505 | 20,166 | 12,528 |
| Total operating expenses | 19,283 | 17,842 | 85,235 | 66,016 |
| Loss from operations | (17,293) | (14,086) | (75,636) | (52,642) |
| Other income (expense), net: | | | | |
| Interest income | 46 | 44 | 258 | 312 |
| Interest expense | (507) | (505) | (1,988) | (1,202) |
| Other income (expense) | 8 | (42) | 55 | (89) |
| Change in fair value of preferred stock warrant liability | — | (600) | — | (644) |
| Loss on extinguishment of debt | — | — | — | (343) |
| Total other expense, net | (453) | (1,103) | (1,675) | (1,966) |
| Net loss attributable to ordinary shareholders | $ (17,746) | $ (15,189) | $ (77,311) | $ (54,608) |
| Net loss per share attributable to common stockholders—basic and diluted | $ (0.55) | $ (1.15) | $ (2.43) | $ (7.55) |
| Weighted average common stock outstanding—basic and diluted | 32,314,854 | 13,230,224 | 31,860,264 | 7,229,626 |

**SOURCE: Sigilon Therapeutics, Inc.**

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