

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 24, 2021

ITEOS THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39401

(Commission File Number)

84-3365066
(IRS Employer
Identification No.)

iTeos Therapeutics, Inc.
139 Main Street
Cambridge, MA
(Address of Principal Executive Offices)

02142
(Zip Code)

Registrant's Telephone Number, Including Area Code: (339) 217-0161

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	ITOS	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On March 24, 2021, iTeos Therapeutics, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the fiscal quarter and year ended December 31, 2020 and providing a business update. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated March 24, 2021

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ITEOS THERAPEUTICS, INC.

Date: March 24, 2021

By: /s/ Michel Detheux

Michel Detheux

President and Chief Executive Officer



iTeos Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update

- *Initial data from Phase 1/2a trial of EOS-448 to be presented at American Association for Cancer Research Annual Meeting. Company to hold conference call at 8:00 am on April 12th to discuss results –*
- *Updated, single-agent data of inupadenant (EOS-850) from Phase 1/2a trial and initial pembrolizumab combination data are expected to be reported later in 2021 –*
- *Strong cash balance of \$336.3M allows company to rapidly advance clinical programs and continue to invest in discovery efforts to expand pipeline –*

Cambridge, MA and Gosselies, Belgium – March 24, 2021 -- iTeos Therapeutics, Inc. (Nasdaq: ITOS), a clinical-stage biopharmaceutical company pioneering the discovery and development of a new generation of highly differentiated immuno-oncology therapeutics for patients, today reported financial results for the fourth quarter and full year ended December 31, 2020 and provided recent business highlights.

"In 2020, we laid a strong foundation, growing our leadership team and completing an IPO in July that solidified our cash position to support our clinical trials and operations into the second half of 2023. We are making strong progress advancing the Phase 1/2a trials for our two lead clinical candidates, inupadenant, our adenosine A_{2A} receptor antagonist, and EOS-448, our anti-TIGIT antibody. We look forward to reporting initial data for our TIGIT program at the upcoming AACR Annual Meeting in April, followed by updated data from our expansion cohorts for inupadenant later this year," said Michel Detheux, PhD, president and chief executive officer of iTeos. "As we approach multiple near-term clinical milestones, we also continue to leverage our deep knowledge of the tumor microenvironment to perform rigorous preclinical evaluations to grow our pipeline of highly differentiated immuno-oncology therapeutics and expect to nominate an additional product candidate by year-end."

Program Highlights

Inupadenant (EOS-850): Designed as a highly selective small molecule insurmountable antagonist of the adenosine A_{2A} receptor, or A_{2A}R, to inhibit the adenosine pathway which is a key driver of immunosuppression in the tumor microenvironment across a broad range of tumors. Currently in a multi-arm Phase 1/2a clinical trial in adult patients with advanced solid tumors.

- The company is currently enrolling patients in three distinct cohorts in its Phase 1/2a study as both a monotherapy and in combination. The initial cohort is evaluating inupadenant as a monotherapy in a basket of cancers and the second cohort, is evaluating the safety of inupadenant in combination with pembrolizumab in patients with solid tumors. The final cohort is evaluating inupadenant in combination with chemotherapy in patients with triple-negative breast cancer.
- Updated single-agent data, including results from tumor biopsy analyses, and initial pembrolizumab combination data are expected to be reported later in 2021.

EOS-448: Antagonistic antibody specifically designed to target TIGIT (T-cell immunoreceptor with Ig and ITIM domains), a checkpoint with multiple mechanisms leading to immunosuppression. EOS-448 was also selected to engage the Fc gamma receptor, or FcγR, and so enhance the anti-tumor response through a multifaceted immune modulatory mechanism. These mechanisms include the activation of macrophages and dendritic cells, and promotion of antibody-dependent cellular cytotoxicity, or ADCC, leading to the selective depletion of cells which express high levels of TIGIT including immunosuppressive regulatory T cells and exhausted T cells. Currently in a Phase 1/2a clinical trial in multiple advanced solid tumors.

- Enrollment in the dose escalation portion of the study has now been completed. Following the determination of the recommended Phase 2 dose, the company expects to begin trials in mid-2021 to evaluate EOS-448 in combination with pembrolizumab, an anti-PD-1 antibody, in combination with inupadenant, and in other combinations in specific tumor types.
- The company will present initial clinical and safety data as part of a late-breaking e-poster at the first session of the upcoming American Association for Cancer Research (AACR) Annual Meeting being held virtually April 10-15, 2021. The poster will go live on Saturday, April 10th at 8:30 a.m. ET, and company management will hold a call on Monday, April 12th at 8:00 a.m. ET to discuss the results.
 - **Abstract Title:** CT118 - Preliminary data from Phase I first-in-human study of EOS884448, a novel potent anti-TIGIT antibody, monotherapy shows favorable tolerability profile and early signs of clinical activity in immune-resistant advanced cancers.
 - **Abstract Number:** IO-002-Abst-001

Preclinical programs: The company continues to progress research programs focused on additional targets that complement the mechanism of action of A2AR and TIGIT programs or address additional pathways of immunosuppression. The company is optimizing its screening and selection process to identify potential product candidates and expects to nominate an additional product candidate for Investigational New Drug-enabling studies before the end of 2021.

Upcoming Events

- American Association for Cancer Research (AACR) Annual Meeting, April 10-15, 2021
- Kempen Life Sciences Conference - European Immuno and Targeted Oncology, April 21, 2021
- Jefferies Healthcare Conference, June 1-4, 2021

Fourth Quarter and Full Year 2020 Financial Results

- **Cash Position:** The Company's cash and cash equivalent position was \$336.3 million as of December 31, 2020, as compared to \$19.9 million as of December 31, 2019. Cash balance provides runway into second half of 2023.
- **Research and Development (R&D) Expenses:** R&D expenses were \$9.2 million for the quarter and \$29.9 million for the full year ended December 31, 2020, as compared to \$6.0 million for the fourth quarter and \$19.2 million for the full year of 2019. The increase was primarily due to an increase in activities related to clinical trials for inupadenant and EOS-448.
- **General and Administrative (G&A) Expenses:** G&A expenses were \$5.7 million for the quarter and \$15.3 million for the full year ended December 31, 2020, as compared to \$2.3 million for the fourth quarter and \$8.8 million for the full year of 2019. The increase in both periods was primarily due to increased headcount and professional fees associated with becoming a publicly traded company.

- **Net Loss:** Net loss attributable to common shareholders was \$14.9 million, or a net loss of \$0.43 per basic and diluted share, for the quarter ended December 31, 2020, as compared to \$6.6 million, or a net loss of \$23.30 per basic and diluted share, for the fourth quarter of 2019. Net loss was \$43.4 million, or a net loss of \$2.88 per basic and diluted share, for the year ended December 31, 2020, as compared to \$26.5 million, or a net loss of \$130.85 per basic and diluted share, for the full year of 2019.

About iTeosTherapeutics, Inc.

iTeos Therapeutics is a clinical-stage biopharmaceutical company pioneering the discovery and development of a new generation of highly differentiated immuno-oncology therapeutics for patients. iTeos Therapeutics leverages its deep understanding of the tumor microenvironment and immunosuppressive pathways to design novel product candidates with an aim to improve the clinical benefit of oncology therapies. The innovative pipeline includes two clinical-stage programs targeting novel, validated immuno-oncology pathways designed to build on prior learnings in the field to have differentiated pharmacological and clinical profiles. The most advanced product candidate, inupadenant, is designed as a highly selective small molecule insurmountable antagonist of the adenosine A_{2A} receptor, in the adenosine pathway, a key driver of immunosuppression in the tumor microenvironment across a broad range of tumors. Inupadenant is being investigated in an open-label multi-arm Phase 1/2a clinical trial in adult cancer patients with advanced solid tumors and encouraging preliminary single-agent activity was observed in the dose escalation portion of the trial. The lead antibody product candidate, EOS-448, is an antagonist of TIGIT, a checkpoint that has a role in both inhibitory and stimulatory pathways in the immune system. EOS-448 was also selected to engage the Fc gamma receptor, or FcγR, and so enhance the anti-tumor response through a multifaceted immune modulatory mechanism. These mechanisms include the activation of macrophages and dendritic cells, and promotion of antibody-dependent cellular cytotoxicity, or ADCC, leading to the selective depletion of cells which express high levels of TIGIT including immunosuppressive regulatory T cells and exhausted T cells. An open-label Phase 1/2a clinical trial of EOS-448 was initiated in adult cancer patients with advanced solid tumors. iTeos Therapeutics is headquartered in Cambridge, MA with a research center in Gosselies, Belgium.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995 and other federal securities laws, including express or implied statements regarding iTeos' future expectations, plans and prospects, which are based on currently available information. All statements other than statements of historical facts contained in this press release, including statements regarding our strategy, future financial condition, future operations, prospects, plans, objectives of management and expected growth, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "positioned," "potential," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology and similar expressions that constitute forward-looking statements under the Private Securities Litigation Reform Act of 1995. These forward-looking statements include statements about the initiation, timing, progress and results of our current and future clinical trials and current and future preclinical studies of our product candidates, including our clinical trials of inupadenant, our clinical trials of EOS-448 and of our research and development programs; uncertainties inherent in clinical studies and in the availability and timing of data from ongoing clinical trials; the expected timing of announcing additional product candidates; the enrollment of our ongoing clinical trials; whether interim results from a clinical trial will be predictive of the final results of the trial; whether results from preclinical studies or earlier clinical studies will be predictive of the results of future clinical trials; our ability to successfully establish or maintain collaborations or strategic relationships for our product candidates; the expected timing for submissions for regulatory approval or review by governmental authorities; the composition of our board of directors; our financial performance; whether our cash resources will be sufficient to fund our foreseeable and unforeseeable operating expenses and capital expenditure requirements; risks, uncertainties and assumptions regarding the impact of the

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continuing COVID-19 pandemic on our business, operations, strategies and anticipated timelines, including mitigation efforts and economic effects, including but not limited to our preclinical studies and future clinical trials; and our plans to develop and commercialize our current product candidates and any future product candidates and the implementation of our business model and strategic plans for our business, current product candidates and any future product candidates, and other risks concerning iTeos' programs and operations that are described in additional detail in our Annual Report on Form 10-K and our other filings made with the Securities and Exchange Commission from time to time. Although our forward-looking statements reflect the good faith judgment of management, these statements are based solely on facts and circumstances currently known to iTeos. As a result, you are cautioned not to rely on these forward-looking statements. Any forward-looking statement made in this press release speaks only as of the date on which it is made. iTeos undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, the occurrence of certain events or otherwise.

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