

**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): May 13, 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
(I.R.S. Employer
Identification No.)

iTeos Therapeutics, Inc.
139 Main Street
Cambridge, Massachusetts 02142
(Address of principal executive offices, including zip code)

(339) 217-0161
(Registrant's telephone number, including area code)

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	Trade 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 May 13, 2021, iTeos Therapeutics, Inc. announced its financial results for the quarter ended March 31, 2021. A copy of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this 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 filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 2.02 shall be deemed furnished, and not filed:

99.1 [Press release dated May 13, 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.

Date: May 13, 2021

ITEOS THERAPEUTICS, INC.

By: /s/ Michel Detheux

Michel Detheux

President and Chief Executive Officer



iTeos Reports First Quarter 2021 Financial Results and Provides Business Update

- *Presented differentiated clinical and pharmacodynamic data from Phase 1/2a trial of anti-TIGIT antibody, EOS-448, at AACR 2021; expansion into combination cohorts expected mid-2021 -*
- *Inupadenant updated monotherapy clinical data and evidence of association of A_{2A} receptor expression with anti-tumor activity to be presented at the ASCO 2021 Annual Meeting in June -*
- *Strong cash balance of \$321.4 million to support clinical advancements and continued investment in discovery efforts to expand pipeline -*
- *Company to host conference call today at 4:30 p.m. ET -*

Cambridge, MA and Gosselies, Belgium – May 13, 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 first quarter ended March 31, 2021 and provided recent business highlights.

“Our current clinical strategy includes six studies for our two clinical programs in different indications and combinations that are expected to provide meaningful readouts before the end of 2022. In addition to our recent EOS-448 Phase 1 data presentation at AACR, we also continue to advance our adenosine A_{2A} receptor antagonist, inupadenant, and we look forward to reporting updated data with evidence that expression of the A_{2A} receptor in tumor biopsy samples is associated with anti-tumor benefit at the upcoming ASCO meeting in June,” said Michel Detheux, PhD, president and chief executive officer of iTeos. “In addition to this progress across our two lead programs, we also remain committed to our ongoing discovery efforts to identify and advance new novel product candidates that could expand our pipeline and continue to serve our mission to improve the lives of people with cancer.”

Program Highlights

EOS-448: EOS-448 is an IgG1 antibody with the ability to engage the Fc gamma receptor (FcγR) and to enhance the anti-tumor response through a multifaceted mechanism.

- The company presented initial clinical and safety data from the monotherapy dose escalation part of the Phase 1 trial in adult patients with advanced solid tumors at the American Association for Cancer Research (AACR) Annual Meeting in April 2021. These preliminary data showed the drug was well-tolerated across dose levels, caused depletion of TIGIT-expressing Treg cells in the blood, providing evidence of target and FcγR engagement, and had encouraging signs of anti-cancer activity.
- The company plans to advance EOS-448 into combination trials in both checkpoint-naïve and resistant patients in mid-2021. These Phase 1b trials will assess the safety of EOS-448 in combination with pembrolizumab and with iTeos’ novel agent inupadenant in patients with solid tumors, and as a monotherapy and in combination with an Immunomodulatory Drug (IMiD) in patients with multiple myeloma.

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Inupadenant (EOS-850): Designed as a highly selective small molecule antagonist of the adenosine A_{2A} receptor. Inupadenant is currently in an open-label multi-arm Phase 1/2a clinical trial in adult patients with advanced solid tumors.

- iTeos is currently enrolling patients in three distinct cohorts in its Phase 1/2a clinical trial as both as a single agent and in combination. The initial cohort is evaluating inupadenant as a monotherapy in prostate cancer, and the second cohort is evaluating the safety of inupadenant in combination with pembrolizumab in patients with solid tumors with planned expansions in prostate cancer and melanoma. The final cohort is evaluating inupadenant in combination with chemotherapy in patients with triple-negative breast cancer.
- iTeos plans to report updated single-agent data, including results from tumor biopsy analyses as part of an e-poster at the upcoming 2021 American Society of Clinical Oncology (ASCO) Annual Meeting held virtually June 4-8, 2021. The abstract will be available on Wednesday, May 19th at 5:00 p.m. ET, and the e-poster will be available for on-demand viewing starting on Friday, June 4 at 9:00 a.m. ET.

Abstract Title: Phase 1 trial of the adenosine A_{2A} receptor antagonist inupadenant (EOS-850): Update on tolerability, and antitumor activity potentially associated with the expression of the A_{2A} receptor within the tumor.

Abstract Number: 2562

Preclinical programs: iTeos continues to progress research programs focused on additional targets that address additional pathways of immunosuppression and complement the mechanism of action of A_{2A}R and TIGIT programs. iTeos expects to nominate an additional product candidate for Investigational New Drug-enabling studies before the end of 2021.

Upcoming Events

- Corporate presentation at the Jefferies Healthcare Conference, June 1-4, 2021
- Present on inupadenant in an e-poster at the ASCO Annual Meeting, June 4-8, 2021
- Corporate presentation at the Citi European Healthcare Conference, June 15-16, 2021

First Quarter 2021 Financial Results

- **Cash Position:** The Company had cash and cash equivalents of \$321.4 million as of March 31, 2021, compared to \$147.7 million as of March 31, 2020. This cash balance provides a runway into 2023.
- **Research and Development (R&D) Expenses:** R&D expenses were \$11.6 million for the quarter ended March 31, 2021, compared to \$5.8 million for the same quarter of 2020. This increase was primarily due to an increase in activities related to clinical trials for inupadenant and EOS-448 and increased headcount.
- **General and Administrative (G&A) Expenses:** G&A expenses were \$7.0 million for the quarter ended March 31, 2021, compared to \$2.4 million for the same quarter of 2020. The increase was primarily due to increased headcount and professional fees and other costs associated with becoming a publicly traded company.
- **Net Loss:** Net loss attributable to common shareholders was \$13.5 million, or a net loss of \$0.39 per basic and diluted share, for the quarter ended March 31, 2021, as compared to \$6.5 million, or a net loss of \$25.53 per basic and diluted share, for the same quarter of 2020.

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Conference Call Details:

iTeos Therapeutics will host a conference call and webcast today, Thursday, May 13th, at 4:30 p.m. ET. To access the live event, please dial the numbers and reference the conference ID listed below. A live audio webcast of the event will also be accessible from the Events page of the Company's website at <https://investors.iteostherapeutics.com/news-and-events/events>. The archived webcast will be available approximately two hours after the completion of the event and for 30 days following the call.

Dial-in Numbers:

(833) 607-1661 (US/Canada)

(914) 987-7874 (International)

Conference ID: 6160559

About iTeos Therapeutics, 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 cancer immunology and immunosuppressive pathways to design novel product candidates with the potential to fully restore the immune response against cancer. The Company's innovative pipeline includes two clinical-stage programs targeting novel, validated immuno-oncology pathways designed with optimized pharmacologic properties for improved clinical outcomes. The initial antibody product candidate, EOS-448, is a high affinity, potent, anti-TIGIT antibody with a functional Fc domain, designed to enhance the anti-tumor response through a multifaceted immune modulatory mechanism. An open-label Phase 1/2a clinical trial of EOS-448 is ongoing in adult cancer patients with advanced solid tumors with preliminary data indicating preliminary clinical activity as a monotherapy and a favorable tolerability profile. The Company is also advancing inupadenant, a next-generation adenosine A_{2A} receptor antagonist tailored to overcome cancer immunosuppression. iTeos is conducting an open-label multi-arm Phase 1/2a clinical trial of inupadenant in adult cancer patients with advanced solid tumors. Preliminary results indicate encouraging single-agent activity in the dose escalation portion of the trial. 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, including statements regarding the Company's future expectations and plans for presenting clinical data, the anticipated timing of clinical trials and regulatory filings, and the development of product candidates and advancement of clinical programs, 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; our financial performance; whether our cash resources

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will be sufficient to fund our foreseeable and unforeseeable operating expenses and capital expenditure requirements; risks, uncertainties and assumptions regarding the impact of the 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.

For further information, please contact:

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