

**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): June 10, 2022

IMAGO BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40604
(Commission
File Number)

45-4915810
(IRS Employer
Identification Number)

**329 Oyster Point Blvd., 3rd Floor
South San Francisco, California 94080**
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (415) 529-5055

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, par value \$0.0001 per share	IMGO	The Nasdaq Stock Market LLC

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 7.01 Regulation FD Disclosure.

On June 10, 2022, Imago BioSciences, Inc. (“Imago”) announced the presentation of positive data from ongoing Phase 2 study of Bomedemstat in Essential Thrombocythemia (ET) and in advanced myelofibrosis (MF), respectively, at the 30th European Hematology Association Annual Meeting and Congress (EHA). Copies of the press releases Imago issued announcing the positive data are furnished herewith as Exhibit 99.1 and Exhibit 99.2, respectively, and are incorporated by reference into this Item 7.01.

The information in Item 7.01, including Exhibit 99.1 and Exhibit 99.2, is being furnished and shall not be deemed to be “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 and shall not be deemed incorporated by reference into any registration statement or other document filed pursuant to the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

ITEM 9.01 Financial Statements and Exhibits.**(d) Exhibits.**

Exhibit	Description
99.1	Press Release dated June 10, 2022 (ET)
99.2	Press Release dated June 10, 2022 (MF)
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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.

IMAGO BIOSCIENCES, INC.

Date: June 10, 2022

By: /s/ Hugh Y. Rienhoff, Jr., M.D.
Hugh Y. Rienhoff, Jr., M.D.
Chief Executive Officer



Imago BioSciences Presents Positive Data from Ongoing Phase 2 Study of Bomedemstat in Essential Thrombocythemia at EHA 2022

The study completed enrollment with 73 patients in April 2022 -

- As of the data cutoff of 29 April 2022, bomedemstat demonstrated durability of response with 81% of patients achieving normalized platelet counts for at least 12 weeks -

- 58% of patients treated with bomedemstat experienced symptomatic improvement, defined as a decrease in Total Symptom Score, at 24 weeks -

- Both JAK2 and CALR mutation burdens were decreased during treatment with bomedemstat

- The EHA data cut represents the last presentation before an End of Phase 2 meeting with FDA expected in 2H22 -

- Company to host virtual investor event on Saturday, 11 June 2022 at 10:30 AM ET-

SOUTH SAN FRANCISCO, Calif. – 10 June 2022 – Imago BioSciences, Inc. (“Imago” or the “company”) (Nasdaq: IMGO), a clinical stage biopharmaceutical company discovering and developing new medicines for the treatment of myeloproliferative neoplasms (MPNs) and other bone marrow diseases, today presented updated positive data from its ongoing global Phase 2 clinical study evaluating bomedemstat in patients with essential thrombocythemia (ET).

The data were presented in a poster session during the 30th European Hematology Association Annual Meeting and Congress (EHA) taking place 9-12 June 2022. A Phase 2 data set with a cut-off of 1 November 2021 was previously presented at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition in December 2021.

Updated Highlights (available data as of 29 April 2022):

- Enrollment completed with 73 patients in April 2022
- Of the 32 patients treated with bomedemstat for more than 24 weeks:
 - 97% (31/32) achieved platelet count reduction to $\leq 400 \times 10^9/L$.

- 94% (30/32) achieved platelet count reduction to $\leq 400 \times 10^9/L$ with no thromboembolic events, the primary efficacy endpoint of this study.
- 81% (26/32) of patients achieved a durable response, defined as platelet count of $\leq 400 \times 10^9/L$ for at least 12 weeks.
- Of the 31 patients with Total Symptom Score (TSS) data available at 24 weeks:
 - 58% (18/31) showed a decrease in TSS.
 - 32% (10/31) showed improvements ≥ 10 points, one component of the ELN criteria for response.
- Importantly, platelet response rates were similar across all genotypes identified in the study (*CALR*, *JAK2^{V617F}*, *MPL* and *triple negative*). Additionally, 67% (16/24) patients demonstrated a net decrease in mutation allele frequencies including both *CALR* and *JAK2*.

“I am genuinely thrilled with the results of our ongoing Phase 2 clinical study of bomedemstat in essential thrombocythemia (ET) that continues to support the tremendous potential of our drug candidate. Based on the most recent data cutoff for this Phase 2 trial, as monotherapy in patients with ET who have failed a standard-of-care treatment, bomedemstat demonstrated both favorable platelet and white count reduction and sustained durability of treatment effects,” said Hugh Young Rienhoff, Jr. MD, CEO of Imago. “Having now completed, indeed exceeded, our target enrollment in the study, we remain on track for an End-of-Phase 2 meeting with the FDA later this year. Based on our clinical results to date and our productive interactions with regulatory authorities, we are excited about the upcoming Phase 3 registrational trial.”

Safety & Tolerability

- Bomedemstat was generally well-tolerated with no safety signals identified per the Safety Advisory Board.
- The most common adverse events (AEs) (>20%) regardless of causality were dysgeusia (altered taste), fatigue, constipation, and arthralgia.
- There were 19 reported serious adverse events (SAEs), 6 of which were deemed drug-related by the Investigator in 5% (3/67) of patients.
- 14 patients have discontinued treatment, with 10 due to AEs (1 death from aspiration pneumonia unrelated to bomedemstat), 2 due to withdrawal of consent, and 2 due to investigator decision.

Details on the Imago EHA Presentation

Oral Presentation Title: A Phase 2 Study of the LSD1 Inhibitor IMG-7289 (Bomedemstat) for the Treatment of Essential Thrombocythemia (ET)

Session: 16. Myeloproliferative neoplasms – Clinical

Presenter: Francesca Palandri, M.D., Ph.D., Institute of Hematology “L. & A. Seràgnoli” Sant’Orsola-Malpighi University Hospital, Bologna, Italy

Date & Time: Friday, June 10, 2022, at 10:30 AM ET

For further details, please see the EHA 2022 abstract and presentation on the Imago website [here](#).

Virtual Investor Event Details

Individuals interested in listening to the event at 10:30 a.m. ET on Saturday, 11 June 2022 may do so by dialing (844) 348-6880 for domestic callers, or +1 (914) 800-3944 for international callers, and reference conference ID: 3493998; or from the webcast link in the investor relations section of the company’s website at: www.imagobio.com. The webcast will be available in the investor relations section on the company’s website for 90 days following the completion of the call.

About Imago’s Phase 2 Essential Thrombocythemia Program

Essential thrombocythemia (ET) is a rare blood cancer resulting in the overproduction of platelets which increases the risk of blood clots and bleeding. It is one of the myeloproliferative neoplasms (MPN) family of rare bone marrow diseases and affects approximately 80,000 – 100,000 patients in the U.S. Imago BioSciences is developing bomedemstat (IMG-7289), an orally administered LSD1 inhibitor, as a potential therapy for patients with ET.

This Phase 2 multi-center, open-label study was designed to assess the safety, efficacy, and pharmacodynamics of bomedemstat, an oral inhibitor of lysine-specific demethylase 1 (LSD1) (www.clinicaltrials.gov Identifier NCT04254978). Eligible patients aged 18 or older with ET who had failed at least one standard therapy and required treatment in order to lower their platelet count were considered for participation in this study. Exploratory assessments include the serial measurement of mutant allele frequencies and changing plasma cytokine profiles. The trial is being conducted in the United States, the United Kingdom, Europe, Hong Kong, New Zealand, and Australia. Imago announced first patient dosed on October 1, 2020. As of April 29, 2022, the trial completed enrollment with 73 participants.

About Imago BioSciences

Imago BioSciences is a clinical-stage biopharmaceutical company discovering and developing novel small molecule product candidates that target lysine-specific demethylase 1 (LSD1), an enzyme that plays a central role in the production of blood cells in the bone marrow. Imago is focused on improving the quality and length of life for patients with cancer and bone marrow diseases. Bomedemstat, an orally available, small molecule inhibitor of LSD1, is the lead product candidate discovered by Imago for the treatment of certain myeloproliferative neoplasms (MPNs), a family of related, chronic cancers of the bone marrow. Imago is evaluating Bomedemstat as a potentially disease-modifying therapy in two Phase 2 clinical trials for the treatment of essential thrombocythemia ([NCT04254978](#)) and myelofibrosis ([NCT03136185](#)). Bomedemstat has U.S. FDA Orphan Drug and Fast Track Designation for the treatment of ET and MF, European Medicines Agency (EMA) Orphan Designation for the treatment of ET and MF, and PRiority MEdicines (PRIME) Designation by the EMA for the treatment of MF. The company is based in South San Francisco, California. To learn more, [visit www.imagobio.com](#), [www.myelofibrosisclinicalstudy.com](#), [www.etclinicalstudy.com](#) and follow us on Twitter [@ImagoBioRx](#), [Facebook](#) and [LinkedIn](#).

Forward Looking Statements

This press release contains forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “anticipates,” “may,” “will,” “should,” “expect,” “believe” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

These statements may relate to, but are not limited to, the results, conduct, progress and timing of Imago clinical trials, the regulatory approval path for bomedemstat, plans for future operations, and the impact of the ongoing COVID-19 pandemic and the development of new variants of COVID-19, such as the omicron and delta variants, on enrollment of our clinical trials, as well as assumptions relating to the foregoing. Forward looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Important factors that could affect future results and cause those results to differ materially from those expressed in the forward-looking statements include: our limited operating history and lack of products for commercial sale; our significant losses since inception and for the foreseeable future; our need for substantial additional financing; our unpredictable operating results; our business’s dependence on development, regulatory approval and commercialization of our product candidates; difficulties in enrolling patients and risks of substantial delays in our clinical trials; our minimal control over product candidates in investigator-initiated clinical trials; uncertainties in the outcomes of our clinical studies; uncertainties in the regulatory review and approval of our product candidates if our pivotal studies are positive; potentially material changes to the interim, top-line and preliminary data from our clinical trials; potential undesirable effects of our product candidates and safety or supply issues with combination-use products; our potential inability to obtain and maintain orphan drug designation and delays in approvals despite Fast Track designation; risks related to clinical trials outside of the United

States; our need to manufacture multiple batches of bomedemstat using a commercial current Good Manufacturing Process; risks related to COVID-19 or other pandemics, natural disasters and wars; risks related to competition; difficulties in expanding our organization and managing growth, attracting and retaining senior management and key scientific personnel and establishing sales and other commercialization functions; risks related to information technology system and cybersecurity; risks related to misconduct of our employees and independent contractors; risks related to hazardous materials and our compliance with environmental laws and regulations; risks related to litigation and other claims; risks related to reliance on third parties to conduct and support preclinical studies and clinical trials, and to manufacture our product candidates; risks related to third-party intellectual property infringement claims and our ability to protect our own intellectual property; risks related to governmental policies and regulations including with respect to drug prices and reimbursement, and changes thereof; risks related to our common stock; risks related to our public company, “emerging growth company” and “smaller reporting company” status; risks related to internal control over financial reporting; and other risks and uncertainties, including those listed in the section titled “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021 and our subsequent quarterly reports. You should not put undue reliance on any forward-looking statements. Forward looking statements should not be read as a guarantee of future performance or results and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved, if at all.

Except as required by law, Imago does not undertake any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

INVESTORS

Laurence Watts

Gilmartin Group, LLC.

laurence@gilmartinir.com

MEDIA

Ian Stone

Evoke Canale

ian.stone@evokegroup.com

Source: Imago BioSciences



01/22

Imago BioSciences Presents Positive Data from Ongoing Phase 2 Study of Bomedemstat in Advanced Myelofibrosis at EHA 2022

- As of the data cutoff date of 29 April 2022, in addition to improvements in the standard metrics of spleen volume reduction and symptom scores, long term treatment with bomedemstat showed:
 - 52% had reductions in mutant allele frequencies, including ASXL1
 - 85% of evaluable patients demonstrated improved or stable fibrosis scores
 - 90% of transfusion independent patients had stable or improved hemoglobin
- MF patients initially treated in this Phase 2 study have rolled into an extension study to evaluate longer term safety and impact of bomedemstat on natural history of MF-
- Evaluation of bomedemstat in combination with ruxolitinib in patients with MF who have a sub-optimal response to JAK inhibition or are JAK naive to commence-
- Company to host virtual investor event on Saturday, 11 June 2022 at 10:30 AM ET-

SOUTH SAN FRANCISCO, Calif. – 10 June 2022 – [Imago BioSciences, Inc.](#) (“Imago” or the “company”) (Nasdaq: IMGO), a clinical stage biopharmaceutical company discovering and developing new medicines for the treatment of myeloproliferative neoplasms (MPNs) and other bone marrow diseases, today presented updated positive data from its ongoing global Phase 2 clinical study evaluating bomedemstat in patients with advanced myelofibrosis (MF).

The data were presented in a poster session during the 30th European Hematology Association Annual Meeting and Congress (EHA), taking place 9-12 June 2022. Previously, a Phase 2 data set with a cut-off of 31 October 2021 was presented at the 63rd American Society of Hematology (ASH) Annual Meeting and Exposition in December 2021.

Updated Highlights (as of 29 April 2022 data cutoff):

- Of the evaluable patients at 24 weeks,
 - 55% (28/51) showed a decrease in Total Symptom Score (TSS).
 - 22% (11/51) showed a $\geq 50\%$ decrease in TSS.
 - 64% (32/50) showed spleen volume reductions.

- 52% (36/69) of patients had a decrease in mutant allele frequencies (MAFs) including driver mutations (e.g., *JAK2*) with the greatest reduction in *ASXL1*, a high molecular risk (HMR) mutation.
- 90% (37/41) of transfusion-independent patients had stable or improved hemoglobin at Week 12.
- 85% (50/59) of patients had an improved (19/59) or stable (31/59) bone marrow fibrosis score post-baseline.
- No new mutations or transformation to acute myeloid lymphoma (AML) in patients with high risk of progression.

“The potential of bomedemstat to be a unique and differentiated monotherapy for patients living with advanced myelofibrosis is underscored by the data presented at EHA today,” said Hugh Young Rienhoff, Jr., M.D., CEO of Imago. “The data continue to show improvements across multiple hallmarks of disease, such as symptom scores, spleen volume, fibrosis, and anemia, while at the same time demonstrating a favorable safety and tolerability profile relative to the current available therapies. Of particular interest is the effect on patients with *ASXL1* mutations, a mutation that confers an increased risk of leukemia. Importantly, these data also point to the potential utility of bomedemstat in other myeloproliferative diseases, such as polycythemia vera and essential thrombocythemia, with similar mutation profiles. Patients in this study will continue to be treated in an extension study while we further explore these patient responses and evaluate the added value of bomedemstat combined with ruxolitinib.”

Safety & Tolerability

- Bomedemstat was generally safe and well-tolerated in patients with myelofibrosis.
- The most common non-hematologic adverse event (AE) related to bomedemstat was dysgeusia (altered taste), which occurred in 36% of patients and dysgeusia led to discontinuation in 1 patient
- There were 14 serious adverse events (SAEs) deemed related to bomedemstat *per* the Investigator

Details on the Imago EHA Presentation

Poster Presentation Title: A Phase 2 Study of IMG-7289 (Bomedemstat) in Patients With Advanced Myelofibrosis

Session: 16. Myeloproliferative neoplasms – Clinical

Presenter: Harinder Gill, M.D., study investigator and presenter of the data, Department of Medicine, University of Hong Kong, Queen Mary Hospital, Pok Fu Lam, Hong Kong

Date & Time: Friday, June 10, 2022, at 10:30 AM ET

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About the Imago Phase 2 Advanced Myelofibrosis Program

Myelofibrosis (MF) is a progressive cancer in which the bone marrow is gradually replaced by fibrous, scar-like tissue. There is a significant unmet need for a disease-modifying therapy. The need is greatest in patients with MF whose disease is not adequately managed with current JAK inhibitors, the current standard of care.

This Phase 2 multi-center, open-label study is designed to assess the safety, efficacy, pharmacodynamics, and spleen volume reduction of bomedemstat, an oral inhibitor of lysine-specific demethylase 1 (LSD1). Eligible patients aged 18 or older with MF who were refractory or resistant to, intolerant of, were inadequately controlled by or ineligible for approved therapies were considered for the study. Exploratory assessments include symptom reduction, changes in cytokine profiles, changes in the frequency of mutant alleles and bone marrow fibrosis. The trial was conducted in the United States, the United Kingdom, European Union, Australia, and Hong Kong. This 24-week study completed enrollment in May 2021 with a total of 89 patients.

About Imago BioSciences

Imago BioSciences is a clinical-stage biopharmaceutical company discovering and developing novel small molecule product candidates that target lysine-specific demethylase 1 (LSD1), an enzyme that plays a central role in the production of blood cells in the bone marrow. Imago is focused on improving the quality and length of life for patients with cancer and bone marrow diseases. Bomedemstat, an orally available, small molecule inhibitor of LSD1, is the lead product

candidate discovered by Imago for the treatment of certain myeloproliferative neoplasms (MPNs), a family of related, chronic cancers of the bone marrow. Imago is evaluating Bomedemstat as a potentially disease-modifying therapy in two Phase 2 clinical trials for the treatment of essential thrombocythemia (NCT04254978) and myelofibrosis (NCT03136185). Bomedemstat has U.S. FDA Orphan Drug and Fast Track Designation for the treatment of ET and MF, European Medicines Agency (EMA) Orphan Designation for the treatment of ET and MF, and PRiority MEdicines (PRIME) Designation by the EMA for the treatment of MF. The company is based in South San Francisco, California. To learn more, visit www.imagobio.com, www.myelofibrosisclinicalstudy.com, www.etclinicalstudy.com and follow us on Twitter @ImagoBioRx, Facebook and LinkedIn.

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Except as required by law, Imago does not undertake any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

INVESTORS

Laurence Watts
Gilmartin Group, LLC.
laurence@gilmartinir.com

MEDIA

Ian Stone
Evoke Canale
ian.stone@evokegroup.com

Source: Imago BioSciences