

**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 7, 2026

IMAGENEBIO, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40287
(Commission
File Number)

81-1697316
(I.R.S. Employer
Identification No.)

12526 High Bluff Drive, Suite 345
San Diego, California
(Address of principal executive offices)

92130
(Zip Code)

Registrant's telephone number, including area code: (858) 345-6265

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	IMA	The Nasdaq Capital 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 7, 2026, ImagenBio, Inc. (the “Company”) announced its financial results for the quarter ended March 31, 2026. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Item 2.02, including the attached Exhibit 99.1, is being furnished and shall not be deemed “filed” for the 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 made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	<u>Description</u>
99.1	Press Release dated May 7, 2026.
104	Cover Page Interactive Data File (embedded with the Inline XBRL document).

SIGNATURE

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.

IMAGENE BIO, INC.

Date: May 7, 2026

By: /s/ Kristin Yarema
Kristin Yarema, Ph.D.
Chief Executive Officer



ImageBio Reports First Quarter 2026 Financial Results and Provides IMG-007 Program Update

SAN DIEGO, May 7, 2026 (GLOBE NEWSWIRE) — ImageBio, Inc. (Nasdaq: IMA) (“ImageBio” or the “Company”) today reported financial results for the quarter ended March 31, 2026, and provided an update for its lead program, IMG-007, a non-T cell-depleting, ADCC-silenced anti-OX40 receptor antagonist with an extended half-life.

Company Highlights

- In April 2026, the Company completed a private placement for gross proceeds of approximately \$30 million led by new investor, Coastlands Capital, with participation from Trails Edge Capital Partners and existing investors Omega Funds and OrbiMed, among others. The financing extends the Company’s cash runway into the first quarter of 2028 and enables advancement of IMG-007 into a Phase 2 clinical trial in alopecia areata.
- IMG-007 is the leading receptor-targeting, non-T cell-depleting OX40 antagonist in active clinical development. The Phase 2b ADAPTIVE trial is progressing under the previously announced amended protocol in North America, with topline data anticipated in the fourth quarter of 2027.
- The Company will present preclinical data on IMG-007 at the 83rd Annual Society for Investigative Dermatology (SID) Meeting in May 2026 in Chicago, IL. The oral presentation will characterize how IMG-007’s distinctive design, which targets the OX40 receptor for efficacy while not depleting a patient’s T cells for safety, distinguishes it from other agents in the OX40 class.

“The conviction that brought our investors to this round reflects a fundamental belief that we share: OX40 is an important target with the potential to effectively treat heterogeneous and difficult diseases like atopic dermatitis and alopecia areata in a new way that is focused on T cell biology rather than simply blocking downstream cytokines, and that IMG-007 is the right molecule to showcase what the mechanism can deliver,” said Kristin Yarema, PhD, Chief Executive Officer of ImageBio. “With our \$30 million financing in place and cash runway extending into Q1 2028, we have the resources to drive these programs forward. We believe the disease-modifying potential of OX40 blockade is beginning to be shown in this evolving field, and we further believe that IMG-007 will ultimately demonstrate a powerful ability to bring patients into deep and durable disease control with infrequent dosing.”

IMG-007 Program Updates

Atopic Dermatitis

- The previously announced protocol amendment to the ADAPTIVE trial has been implemented, and the study is now progressing under the amended protocol in North America.
- The amendment introduces a robust design intended to fully evaluate the potential of IMG-007 in moderate-to-severe AD, including the time to onset, depth, and durability of response. The updated protocol systematically explores three variables — exposure, loading regimen, and dosing interval — across an approximately 400-patient study with continuous treatment over one year:
 - **Exposure:** The amended protocol expands to four IMG-007 dosing regimens plus placebo, evaluating two different doses at each of two dosing intervals. The expanded exposure range is designed to test the hypothesis that broader exposures can deliver better efficacy than has been demonstrated to date in the OX40 class. ADAPTIVE will also be the first OX40 program to evaluate continuous exposure of up to one year in a Phase 2b setting, enabling a systematic assessment of the deepening of response that has been attributed to OX40 blockade.

- **Loading regimen:** Reflecting the recognized and growing importance of loading in immunologic and inflammatory diseases — and particularly relevant for the OX40 class given its upstream targeting of activated T cells — the amended protocol systematically studies the contribution of a loading dose regimen to the speed, depth, and consistency of clinical effect.
- **Dosing interval:** The four dosing regimens evaluate monthly and quarterly dosing intervals, supported by IMG-007's approximately 5-week half-life. Less frequent dosing is intended to reduce treatment burden for patients managing a chronic disease.
- The primary endpoint under the amended protocol is percent change from baseline in EASI at 24 weeks. Secondary endpoints include patients reaching EASI-75, EASI-90, and IGA 0/1, along with safety, pharmacokinetics, and additional clinical and patient-reported outcomes.
- The amended protocol also incorporates additional study refinements, including stratification of biologic- and/or oral JAK inhibitor-experienced versus naive patients, baseline EASI scores, standardized photography, and a refined approach to rescue therapy.
- The efficacy dataset will be composed of patients initiated under the amended protocol and is designed to enable a registrational Phase 3 program.
- Patients currently enrolled under the original ADAPTIVE protocol will continue as planned, providing safety data to contribute to the safety database and support pharmacokinetic and pharmacodynamic profiling of IMG-007.
- Across all IMG-007 clinical studies to date, IMG-007 has shown an encouraging early safety and tolerability profile. As of the blinded safety review in March 2026, there had been no cases of Kaposi sarcoma, no malignancies, and no severe infections. No treatment-related serious adverse events had been reported, and no treatment-related pyrexia, chills, aphthous ulcers, or gastrointestinal ulcers had been observed. Injection site reactions had been reported in less than 0.10% of subjects. The ADAPTIVE protocol includes clinical monitoring and risk mitigation measures specific to Kaposi sarcoma, including patient and physician education and close longitudinal tracking, in the interest of patient safety.
- Topline data from the study is anticipated in the fourth quarter of 2027.

Upcoming Scientific Presentation

Imagegene will deliver an oral presentation of preclinical data at the 83rd Annual Society for Investigative Dermatology (SID) Meeting in May 2026 in Chicago, IL. The presentation includes preclinical data that demonstrate IMG-007 combines high-affinity OX40 binding with potent inhibition of downstream signaling, supporting a differentiated non-depleting mechanism for modulating pathogenic T cell responses.

- **Title:** Preclinical characterization of IMG-007, a high-affinity, non-depleting anti-OX40 monoclonal antibody for the treatment of inflammatory and autoimmune disease
- **Session:** Translational Studies, Preclinical
- **Date:** Friday, May 15, 2026
- **Time:** 9:35 AM – 9:45 AM (Continental Ballroom C, Lobby Level)



Alopecia Areata (AA)

- The Company plans to initiate a Phase 2 study of IMG-007 in alopecia areata (AA) in 2026, with initial data expected in 2028, leveraging the clinical operations and investigator network the Company has developed through its AD program.
- In a completed open-label proof-of-concept study, IMG-007 demonstrated a mean SALT 30 improvement of 30% out to 36 weeks after just three 600 mg IV doses given within the first month of the study in patients with baseline SALT 50 to < 95.

“We are entering a period of real clinical momentum,” said Dr. Ben Porter-Brown, Chief Medical Officer of Imagene. “ADAPTIVE is advancing under the amended protocol, and we are now moving IMG-007 into a second indication with proof-of-concept data providing a strong foundation. AA is a disease with significant unmet need. JAK inhibitors, the only approved targeted option, are indicated only for severe disease and require at least daily dosing to maintain hair regrowth, and there are no approved biologics for AA. Approximately 1 in 50 people will develop AA over their lifetimes. IMG-007 is the first OX40 antagonist to report clinical data in AA, and that early data and its mechanism support further clinical development, with the potential for durable responses with a low dosing burden. . In both AA and AD, IMG-007 could provide patients with a therapeutic that stands apart from existing options.”

First Quarter 2026 Financial Results

Cash Position: As of March 31, 2026, the Company had cash, cash equivalents, and marketable securities of \$117.2 million. Additionally, in April 2026, the Company completed a private placement for gross proceeds of approximately \$30 million, issuing all pre-funded warrants led by Coastlands Capital with participation from additional new and existing investors.

Research and Development (R&D) Expenses: R&D expenses for the three months ended March 31, 2026 were \$6.0 million as compared to \$4.0 million for the three months ended March 31, 2025. The company continues to invest in clinical trial and personnel related expenses associated with its primary development program.

General and administrative (G&A) Expenses: G&A expenses for the three months ended March 31, 2026 were \$6.1 million as compared to \$2.8 million for the three months ended March 31, 2025.

Net Loss: Net loss for the three months ended March 31, 2026 was \$ 10.6 million as compared to \$ 9.1 million for the same period in 2025.

About IMG-007

IMG-007 is an investigational, non-T cell-depleting monoclonal antibody targeting OX40, a receptor protein primarily found on activated human T cells. When OX40 binds its ligand OX40L in human tissue, the signal generated plays a key role in the activation, expansion, and survival for many subtypes of T cells. Targeted inhibition of OX40 is being studied in the clinic across a range of autoimmune, inflammatory and immunological conditions where aberrant signaling of one or more T cell subtypes is believed to drive disease. IMG-007 has been engineered to include a silenced antibody-dependent cell-mediated cytotoxicity function demonstrated to avoid T cell depletion or killing and intended to minimize safety risk. This technology also resulted in an approximately 5-week half-life, prolonging therapeutic activity with the aim of maximizing time between doses for a patient. In proof-of-concept studies in patients with moderate-to-severe atopic dermatitis and severe alopecia areata, IMG-007 exhibited sustained clinical and pharmacodynamic activity and was well tolerated. IMG-007 was originally discovered by HUTCHMED and Imagene has worldwide commercialization rights. Clinical development is ongoing: additional information about the ongoing Phase 2b trial in moderate-to-severe atopic dermatitis is available at www.clinicaltrials.gov using identifier: NCT07037901.



About IMG-007 ADAPTIVE Trial

The ADAPTIVE trial (NCT07037901) is an ongoing Phase 2b, randomized, placebo-controlled dose ranging study designed to evaluate the efficacy and safety of various dose regimens of IMG-007 in adults with moderate-to-severe AD, recruiting both biologic- and/or JAK inhibitor-experienced and naive patients.

About Atopic Dermatitis

Atopic dermatitis (AD) is a chronic, relapsing inflammatory skin disease characterized by intense itch, recurrent eczematous lesions, and significant impacts on sleep, mental health, and quality of life. AD affects approximately 26 million people in the United States and 237 million people globally, with approximately 6.8 million adults in the United States and 49 million people worldwide living with moderate-to-severe disease. Despite the availability of advanced therapies including biologics and JAK inhibitors, 30–40% of patients on these treatments continue to report inadequate disease control, and only approximately 15% of biologic-eligible patients are receiving treatment. Existing options also impose meaningful treatment burden, requiring daily or bi-weekly dosing over what is often a lifetime of disease management. Substantial unmet need remains for therapies that deliver deeper and more durable disease control with dosing schedules patients can sustain.

About Alopecia Areata

Alopecia areata (AA) is a chronic autoimmune disease in which T cell-mediated attack on the hair follicle, resulting from loss of immune-protection of the follicle, causes hair loss across the scalp, face, and body. The disease can affect people of all ages, ethnicities, and races, and approximately 1 in 50 people will develop AA over their lifetimes. Beyond its visible physical impact, AA carries a significant psychosocial and emotional burden, often persisting for years and recurring unpredictably. JAK inhibitors are the only approved targeted treatment for AA and are indicated only for severe disease. They require at least daily oral dosing with sustained adherence to maintain hair regrowth and carry a boxed warning. There are no approved biologics for AA. Substantial unmet need remains for treatments that are durable, well tolerated, and able to address the full spectrum of disease severity.

About ImageBio, Inc.

ImageBio is a clinical-stage biotechnology company dedicated to developing therapeutics for patients with immunological, autoimmune and inflammatory diseases with differentiated clinical profiles. The Company's program, IMG-007, is a receptor targeting, non-T cell-depleting, ADCC-silenced, anti-OX40 monoclonal antibody with an approximately 5-week half-life. ImageBio has completed proof-of-concept clinical trials of IMG-007 in both atopic dermatitis and alopecia areata and is currently conducting a Phase 2b clinical trial of IMG-007 in patients with moderate-to-severe atopic dermatitis.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements regarding: the ongoing Phase 2b ADAPTIVE study, including the potential benefits from the protocol amendment thereto; belief that the anti-OX40/OX40L class is on a promising path towards adoption in AD and other inflammatory and autoimmune indications; the potential benefits of OX40/OX40L antagonists generally and IMG-007 specifically in AD and AA; IMG-007 is the right molecule to showcase the benefits of the OX40 target; the Company's expected cash runway, including that it is sufficient to achieve inflection points in the development of both AD and AA; the anticipated timing for initiating clinical trials and reporting clinical trial results; whether the efficacy dataset from the ADAPTIVE trial will enable a registrational Phase 3 trial; and other statements regarding management's intentions, plans, beliefs, expectations or forecasts for the future. Words such as "will," "can," "expect," "may," "plan,"



“potential,” “goal,” or other words that convey uncertainty of future events or outcomes are used to identify these forward-looking statements. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: risks associated with the nonclinical and clinical development and regulatory approval of IMG-007, including potential delays in the completion of clinical trials and potential safety and other complications thereof; the timing of the availability of data from the Company’s clinical trials; the clinical utility, potential differentiation and/or benefits and market acceptance of IMG-007; the requirement for additional capital to continue to advance the IMG-007 program, which may not be available on favorable terms or at all; the Company’s ability to attract, hire, and retain skilled executive officers and employees; the Company’s ability to protect its intellectual property and proprietary technologies; the Company’s reliance on third parties, contract manufacturers, and contract research organizations; the possibility that the Company may be adversely affected by other economic, political, business, or competitive factors; and risks associated with changes in applicable laws or regulations or government resources and policies. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties. These and other risks and uncertainties are more fully described in the Company’s filings with the Securities and Exchange Commission (the SEC), including the factors described in the section titled “Risk Factors” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 10, 2026, and in the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, being filed with the SEC later today. You should not place undue reliance on these forward-looking statements, which are made only as of the date hereof. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.



Select Condensed Statement of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended	
	March 31	
	2026	2025
License revenue	\$ —	\$ 800
Operating expenses:		
Research and development	5,961	4,040
General and administrative	6,118	2,755
Total operating expenses	12,079	6,795
Loss from operations	(12,079)	(5,995)
Interest income (expense)	1,129	(77)
Other income (expense), net	341	(5)
Loss before income taxes	(10,609)	(6,077)
Income tax expense	(10)	—
Net loss	\$ (10,619)	\$ (6,077)
Accretion of redeemable convertible preferred shares	—	(3,051)
Net loss attributable to common stockholders	\$ (10,619)	\$ (9,128)
Net loss per share:		
Net loss per share- basic and diluted	\$ (0.95)	\$ (3.80)
Weighted-average common shares outstanding, basic and diluted	<u>11,211,268</u>	<u>2,404,832</u>

Select Balance Sheet Items
(In thousands)

	March 31, 2026	December 31, 2025
Cash, cash equivalents, and marketable securities	\$ 117,208	\$ 135,349
Total assets	\$ 136,682	\$ 152,976
Total liabilities	\$ 13,355	\$ 19,837
Total stockholders' equity	\$ 123,327	\$ 133,139

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