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 2, 2023

IGM Biosciences, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39045**	**77-0349194**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

325 E. Middlefield Road **Mountain View, California** **(Address of Principal Executive Offices)**	**94043** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (650) 965-7873

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, par value $0.01 per share	IGMS	The Nasdaq Global Select 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 8.01 Other Events.

On June 2, 2023, IGM Biosciences, Inc. (the "Company") issued a press release announcing an update on its clinical development program for IGM-8444, a novel multivalent death receptor 5 agonist, in patients with metastatic colorectal cancer. The full text of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of IGM Biosciences, Inc., dated June 2, 2023
104	Cover Page Interactive Data file (embedded within the Inline XBRL document)

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 thereunto duly authorized.

IGM BIOSCIENCES, INC.

Date: June 21, 2023

By: /s/ Misbah Tahir
Misbah Tahir
Chief Financial Officer

IGM Biosciences Announces Update on IGM-8444 Phase 1 Trial and Future Clinical Development

June 2, 2023

– Additional data from Phase 1 combination with FOLFIRI continues to show encouraging activity in median third-line metastatic colorectal cancer patients –

– Progression-free survival of 5.6 months in median third-line colorectal cancer patients without bevacizumab –

– Promising safety profile in combination with FOLFIRI and bevacizumab –

– Randomized combination trial in second-line colorectal cancer patients initiated in Q1 2023 –

MOUNTAIN VIEW, Calif., June 02, 2023 (GLOBE NEWSWIRE) — IGM Biosciences, Inc. (Nasdaq: IGMS), a clinical-stage biotechnology company focused on creating and developing IgM antibodies, today announced an update on its clinical development program for IGM-8444, a novel multivalent death receptor 5 (DR5) agonist, in patients with metastatic colorectal cancer.

“We continue to be very pleased with the indications of clinical activity that we are observing with IGM-8444,” said Chris Takimoto, M.D., Ph.D., F.A.C.P., Chief Medical Officer of IGM Biosciences. “We are also very pleased with the excellent safety profile that we have seen to date. The absence of clinically significant hepatotoxicity is particularly important, as this has been a challenge for other multivalent DR5 agonists. The long progression-free survival that we have seen in some patients, especially those who have progressed on prior chemotherapy, is quite encouraging as we proceed to further clinical development with FOLFIRI and other combination agents. Our ongoing randomized trial with FOLFIRI plus bevacizumab is designed to confirm and quantify the activity of IGM-8444 in patients with second-line colorectal cancer.”

Phase 1 data reported from a cohort of patients treated with IGM-8444 in combination with FOLFIRI, with and without bevacizumab, showed a very encouraging safety profile which was broadly comparable to that expected from chemotherapy alone in this setting. Specifically, in the 51 CRC patients treated with IGM-8444 plus FOLFIRI, with and without bevacizumab, no drug related clinically significant hepatotoxicity was observed and only grade 1 and grade 2 transient liver enzyme elevations were noted, through the data cut-off date of April 12, 2023.

The majority of colorectal patients in this study were on their third-line of treatment or beyond and over 70 percent of the patients treated with the combination regimens had previously been treated with irinotecan-based chemotherapy.

In these predominantly third-line metastatic colorectal cancer patients, the combination of IGM-8444 dosed at 3 mg/kg and FOLFIRI without bevacizumab showed promising activity. This is the group of patients which had the longest treatment follow up. In this 24 patient group, the median progression-free survival (PFS) in the 24 patients was 5.6 months as of the data cut-off date of April 12, 2023, which is higher than the historical median progression-free survival of approximately 2 months with standard of care third-line colorectal cancer treatment without bevacizumab. The longest observed progression-free survival in this group has extended beyond 16 months and 11 of these 24 patients remained on treatment as of the data cut-off. Importantly, multiple patients showed longer durations of treatment with IGM-8444 and FOLFIRI than they had with their previous FOLFIRI regimens.

More recently, the Company began treating patients with the addition of bevacizumab to 3 mg/kg of IGM-8444 and FOLFIRI. For the 17 evaluable patients in this group, the median progression-free survival was not reached and 13 of the 17 patients remained on study, as of the data cut-off.

At the time of the data cut-off, multiple confirmed partial responses were observed among the patients treated with 3 mg/kg of IGM-8444 and FOLFIRI, with and without bevacizumab, including some patients who had previously progressed on FOLFIRI treatment.

Encouraged by these results, IGM has initiated a randomized trial in second-line patients with metastatic colorectal cancer to assess the benefit of 3 mg/kg of IGM-8444 combined with the current standard of care regimen of FOLFIRI and bevacizumab. This open-label trial began in the first quarter of 2023, and the Company hopes to have enrolled approximately 110 patients in the trial by the first quarter of 2024 and to have median progression-free survival data from these patients by the end of 2024.

Conference Call and Webcast

The Company will host a conference call and live webcast to provide an update on its clinical development program for IGM-8444 at 7:00 p.m. ET today, June 2, 2023. The webcast can be accessed by clicking the link: https://edge.media-server.com/mmc/p/vd3xogzs, and will be available on the “Events and Presentations” page in the “Investors” section of the Company’s website. A replay of the webcast will be archived on the Company’s website for 90 days following the presentation. A more detailed presentation of the results will be made available on the Company’s website at www.igmbio.com.

About IGM-8444

IGM-8444 is an IgM antibody targeting death receptor 5 (DR5) that is being developed for the treatment of patients with solid and hematologic malignancies. DR5 is a member of the tumor necrosis factor receptor superfamily (TNFrSF) and is often expressed on the surface of cancer cells. Strong activation of the DR5 pathway requires multiple receptors to be cross-linked simultaneously by an antibody or other binding agent to create an apoptotic death signal to the cell. Unlike traditional IgG antibodies, IGM-8444 has 10 binding units, enabling it to cross-link multiple DR5 receptors at the same time, sending a stronger signal to cause cancer cell death. The Company is currently conducting a multicenter, open-label clinical trial to determine the safety, tolerability, and pharmacokinetics of IGM-8444 as a single agent and in combination in subjects with relapsed and/or refractory solid or hematologic cancers.

About IGM Biosciences, Inc.

IGM Biosciences is a clinical-stage biotechnology company committed to developing and delivering a new class of medicines to treat patients with cancer, autoimmune and inflammatory diseases and infectious diseases. The Company's pipeline of clinical and preclinical assets is based on the IgM antibody, which has 10 binding sites compared to conventional IgG antibodies with only 2 binding sites. The Company also has an exclusive worldwide collaboration agreement with Sanofi to create, develop, manufacture, and commercialize IgM antibody agonists against oncology and Immunology and inflammation targets. For more information, please visit www.igmbio.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements, including statements relating to IGM's plans, expectations and forecasts and to future events. Such forward-looking statements include, but are not limited to: the potential of, and expectations regarding, IGM's technology platform and its IgM antibodies and product candidates, including IGM-8444; IGM's plans and expectations regarding its clinical development efforts and activities; statements regarding the clinical development of IGM-8444, including the timing of patient enrollment and availability of clinical data; and statements by IGM's Chief Medical Officer. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially, including but not limited to: IGM's early stages of clinical drug development; risks related to the use of engineered IgM antibodies, which is a novel and unproven therapeutic approach; IGM's ability to demonstrate the safety and efficacy of its product candidates; IGM's ability to successfully and timely advance its product candidates through clinical trials; IGM's ability to enroll patients in its clinical trials; the potential for the results of clinical trials to differ from preclinical, preliminary, initial or expected results; the risk of significant adverse events, toxicities or other undesirable side effects; IGM's ability to successfully manufacture and supply its product candidates for clinical trials; the potential impact of continuing or worsening supply chain constraints; the risk that all necessary regulatory approvals cannot be obtained; the potential market for IGM's product candidates, and the progress and success of alternative therapeutics currently available or in development; IGM's ability to obtain additional capital to finance its operations, if needed; uncertainties related to the projections of the size of patient populations suffering from the diseases IGM is targeting; IGM's ability to obtain, maintain and protect its intellectual property rights; developments relating to IGM's competitors and its industry, including competing product candidates and therapies; any potential delays or disruptions resulting from catastrophic events, including epidemics or other outbreaks of infectious disease; general economic and market conditions, including inflation; and other risks and uncertainties, including those more fully described in IGM's filings with the Securities and Exchange Commission (SEC), including IGM's Quarterly Report on Form 10-Q filed with the SEC on May 12, 2023 and in IGM's future reports to be filed with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and IGM specifically disclaims any obligation to update any forward-looking statement, except as required by law.

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Source: IGM Biosciences, Inc.