# 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)**
**November 4, 2021**

# 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, CA 94043**
**(Address of principal executive offices, including zip code)**

**(650) 965-7873**
**(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 (see General Instruction A.2. below):

☐ 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 2.02 Results of Operations and Financial Condition.**

On November 4, 2021, IGM Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2021. The full text of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

All of the information furnished in this Item 2.02 and Item 9.01 (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release of IGM Biosciences, Inc., dated November 4, 2021. |
| 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 hereunto duly authorized.

**IGM BIOSCIENCES, INC.**

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

Date: November 4, 2021

**IGM Biosciences Announces Third Quarter 2021 Financial Results and Provides Corporate Update**

*– Plans to Initiate Phase 2 Studies of IGM-2323 in Diffuse Large B-cell Lymphoma and Follicular Lymphoma –*

*– Data from IGM-2323 Selected for Oral Presentation at 2021 ASH Annual Meeting –*

*– IGM-8444 Successfully Completes Phase 1 Monotherapy Dose Escalation –*

*– IGM-8444 Showed No Clinically Significant Liver Toxicity or Dose Limiting Toxicities Observed to Date –*

*– IGM-2644 (CD38 x CD3) Expected to Enter Clinical Testing for Multiple Myeloma in 2022 –*

*– IGM Establishes Infectious Diseases and Autoimmunity and Inflammation Business Units –*

**MOUNTAIN VIEW, Calif., Nov. 4, 2021** (GLOBE NEWSWIRE) — IGM Biosciences, Inc. (Nasdaq: IGMS), a clinical-stage biotechnology company focused on creating and developing engineered IgM antibodies, today announced its financial results for the third quarter ended September 30, 2021 and provided an update on recent developments.

“IGM continues to validate and expand the IgM platform through the clinical development of IGM-2323, our CD20 x CD3 T cell engager IgM antibody for the treatment of B cell proliferative diseases, IGM-8444, our Death Receptor 5 (DR5) agonist IgM antibody for the treatment of solid and hematologic cancers, and the establishment of our infectious diseases and autoimmunity and inflammation business units,” said Fred Schwarzer, Chief Executive Officer of IGM Biosciences. “We plan to continue to expand our clinical development efforts, and by the end of 2022 we expect to be actively pursuing the clinical development of four oncology product candidates, led by two Phase 2 clinical studies of IGM-2323.”

“We are encouraged by the emerging data from the clinical testing of IGM-2323 in our most fully explored titration dose cohort, 100 mg, where we have seen multiple complete responses in both diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL), and we look forward to sharing the initial data from this 100 mg dose cohort at our American Society of Hematology (ASH) presentation in December,” said Chris Takimoto, M.D., Ph.D., F.A.C.P., Chief Medical Officer of IGM Biosciences. “While the number of patients we have treated at 100 mg is relatively small, we believe that the planned Phase 2 expansion studies could potentially provide the basis for accelerated review and approval. As a first step, consistent with the spirit of the U.S. Food and Drug Administration’s (FDA) Project Optimus, we plan to test doses of 100 mg and 300 mg in two separate randomized ‘pick the winner’ Phase 2 studies of 30 patients at each dose level, one in DLBCL and one in FL. We plan to then expand the Phase 2 studies at the optimal dose, while including the prior data from that dose for purposes of potential registration. While our safety profile at 600 mg and 1000 mg is consistent with lower doses and very encouraging, we do not plan to continue to explore doses higher than 300 mg for purposes of greater efficacy in either DLBCL or FL.”

**Pipeline Updates**

**IGM-2323 (CD20 x CD3)**

- **Plans to initiate potentially registrational Phase 2 study.** IGM today announced plans to commence two potentially registrational Phase 2 studies to assess the safety and efficacy of two doses of IGM-2323, 100 mg and 300 mg, in patients with DLBCL and FL, one Phase 2 study in DLBCL and one Phase 2 study in FL. Each Phase 2 multicenter, open-label study will take place in two stages. In the first stage, cohorts of 30 patients at each dose level (100 mg and 300 mg) will be randomized in a 'pick the winner' design in both DLBCL and FL, respectively. The optimal dose arm in each Phase 2 clinical trial will then be expanded to additional patients in the second stage, potentially providing the basis for accelerated review and approval of IGM-2323, assuming the clinical data support that expansion.
- **Data from Phase 1 trial evaluating IGM-2323 selected for oral presentation at 2021 ASH Annual Meeting and Exposition**, being held virtually and in-person in Atlanta, Georgia, December 11-14, 2021. The results will be presented on Saturday, December 11, 2021, at 1:15 p.m. ET, in an oral presentation titled "A Phase 1 Dose Escalation Study of IGM-2323, a Novel Anti-CD20 x Anti-CD3 IgM T Cell Engager (TCE) in Patients with Advanced B-Cell Malignancies." In the ASH oral presentation, IGM plans to present additional safety and efficacy data collected subsequent to the April 30, 2021 data cut-off for the ASH abstract, which was released online today in *Blood*, ASH's official journal.

  As described in the abstract released today, as of April 30, 2021, 29 patients had been enrolled in the Phase 1 study of IGM-2323: 12 at 5 fixed dose levels (0.5, 2.5, 10, 20, 100 mg) and 17 at 5 dose titration levels (100, 200, 300, 600, and 1000 mg). All 29 patients received at least one dose and were evaluable for safety. There were no dose limiting toxicities (DLTs) and no neurotoxicity adverse events (AEs). No patients discontinued due to an AE. Of the 29 patients evaluable for safety, 6 patients had cytokine release syndrome (CRS), primarily Grade 1. As previously described, there were only two higher grade CRS events as of April 30, 2021, one Grade 2 and one Grade 3. As previously described, the Grade 3 patient had been treated with an experimental CAR-T and had high baseline circulating B-cells. Of the 11 evaluable patients treated in the titration dose cohorts, as of the April 30, 2021 data cut-off, there were 5 responses, 3 complete responses and 2 partial responses.

**IGM-8444 (DR5)**

- **Clinical development of IGM-8444 advances.** IGM continues to advance the clinical development of IGM-8444, the Company's IgM DR5 agonist, in an open-label, multicenter, Phase I study of IGM-8444 as a single agent and in combination in subjects with relapsed and/or refractory solid and hematologic cancers.
- **Every two-week monotherapy dose escalation cohort successfully completed.** IGM announced that it has successfully cleared its highest single-agent dose escalation cohort (10 mg/kg Q2W) with no DLTs and no clinically significant liver toxicity observed to date.
- **Second FOLFIRI dose cohort successfully completed.** IGM also announced that it has cleared the second of four planned FOLFIRI combination dose escalation cohorts (1.0 mg/kg Q2W) with no DLTs and no clinically significant liver toxicity observed to date. IGM is currently enrolling patients in the third of four planned FOLFIRI combination dose escalation cohorts (3.0 mg/kg Q2W).
- **No acute or chronic clinically significant liver toxicity or clinically significant anti-drug antibodies observed to date.** IGM also announced today that there have been no DLTs and no clinically significant liver toxicities observed to date in the 32 patients treated with IGM-8444, of whom 11 remain on treatment. Importantly, 7 patients have been on treatment for 5 or more months without showing signs of any chronic toxicities to date. No patient has discontinued treatment for drug related safety reasons, and no clinically significant anti-drug antibodies have been observed to date.
- **First patient dosed in combination with birinapant.** IGM announced that it has treated its first patient in a combination clinical study of IGM-8444 with birinapant, a SMAC mimetic which binds to and degrades inhibitors of apoptosis proteins (IAPs) leading to apoptotic cell death in tumors. The combination of these two apoptotic agents, IGM-8444 and birinapant, has shown strong synergy in preclinical testing, and IGM has acquired exclusive worldwide rights to manufacture, develop and commercialize birinapant. The first patient in this combination cohort was successfully treated with no clinically significant adverse events observed to date. IGM is currently enrolling additional patients in this first birinapant dose cohort. IGM is also preparing to enroll patients with chronic lymphocytic leukemia/small lymphocytic lymphoma in a venetoclax-IGM-8444 combination cohort.
- **Markers of on-target biological activity observed.** Signs of biological activity consistent with the activation of DR5 by a DR5 agonist have been observed in some patients, both in circulating biomarkers and histological tumor samples.

“IGM-8444’s toxicity profile to date, which has not shown any clinically significant liver toxicity, differentiates it from some of the second generation DR5 agonists that have struggled to progress in the clinic due to liver toxicity,” said Dr. Takimoto. “Importantly, we believe this safety profile will be critical to successful combinations with other drugs, which we believe represent by far the most exciting and promising uses of DR5 agonists for the treatment of multiple solid and hematologic cancers. For this reason, our clinical development focus continues to be on combinations of IGM-8444 with standard of care and novel agents, such as FOLFIRI, venetoclax and birinapant.”

**IGM-6268 (COVID-19)**

- **IGM-6268 for the treatment and prevention of COVID-19 expected to advance into the clinic in the fourth quarter.** IGM-6268 is an IgM version of an anti-SARS-CoV-2 IgG monoclonal antibody and is being developed as an intranasally administered agent for the treatment and prevention of COVID-19. It is expected to start clinical development by the end of 2021, initially in healthy volunteers.

**IGM-7354 (IL-15 x PD-L1)**

- **Phase 1 clinical testing expected to initiate in 2022.** IGM plans to initiate a Phase 1 study of IGM-7354, the Company’s IL-15 x PD-L1 bispecific IgM antibody, in solid tumors in 2022.

**IGM-2644 (CD38 x CD3)**

- **Phase 1 clinical testing expected to initiate in 2022.** IGM announced today that it plans to initiate a Phase 1 study of IGM-2644, the Company’s CD38 x CD3 bispecific IgM antibody, in multiple myeloma in 2022.

“We believe the safety and efficacy profile that we have observed to date in the clinical development of IGM-2323, our T cell engaging IgM antibody targeting CD20 on lymphoma cells, is very encouraging with respect to the future clinical development of IGM-2644, our T cell engaging IgM antibody targeting CD38 on multiple myeloma cells, as it has shown similar preclinical safety and efficacy features to those we observed with IGM-2323,” said Bruce Keyt, Ph.D., Chief Scientific Officer of IGM Biosciences. “We hope to file an investigational new drug (IND) application with the FDA and begin the Phase 1 clinical development of IGM-2644 next year.”

**Corporate Updates**

- **Announced leadership appointments and formation of IGM Infectious Diseases and IGM Autoimmunity and Inflammation business units.** The new business units will utilize and build upon IGM’s platform technology to create and develop novel IgM and IgA antibodies to address infectious diseases, autoimmunity and inflammation. To lead the IGM Autoimmunity and Inflammation business unit, IGM announced the appointment of Mary Beth Harler, M.D., as President. To lead the IGM Infectious Diseases business unit, IGM announced the appointments of John Shiver, Ph.D. and Tong-Ming Fu, M.D., Ph.D., as Chief Strategy Officer and Chief Scientific Officer, respectively.

**Third Quarter 2021 Financial Results**

- **Cash and Investments:** Cash and investments as of September 30, 2021 were $265.6 million, compared to $366.3 million as of December 31, 2020.
- **Research and Development (R&D) Expenses:** For the third quarter of 2021, R&D expenses were $34.2 million, compared to $15.8 million for the same period in 2020.
- **General and Administrative (G&A) Expenses:** For the third quarter of 2021, G&A expenses were $10.0 million, compared to $4.7 million for the same period in 2020.
- **Net Loss:** For the third quarter of 2021, net loss was $44.2 million, or a loss of $1.32 per share, compared to a net loss of $20.3 million, or a loss of $0.66 per share, for the same period in 2020.

**2021 Financial Guidance**

IGM reiterates its previously issued financial guidance expecting full year GAAP operating expenses to be between $175 million and $185 million including estimated non-cash stock-based compensation expense of approximately $25 million. IGM expects to end 2021 with a balance of over $200 million in cash and investments.

**About IGM Biosciences, Inc.**

Headquartered in Mountain View, California, IGM Biosciences is a clinical-stage biotechnology company focused on creating and developing engineered IgM antibodies. Since 2010, IGM Biosciences has worked to overcome the manufacturing and protein engineering hurdles that have limited the therapeutic use of IgM antibodies. Through its efforts, IGM Biosciences has created a proprietary IgM technology platform for the development of IgM antibodies for those clinical indications where their inherent properties may provide advantages as compared to IgG antibodies.

**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 and IgA antibodies and product candidates, including IGM-2323, IGM-8444, IGM-6268, IGM-7354 and IGM-2644; IGM's plans and expectations regarding its clinical development efforts and activities; statements regarding the clinical development of IGM-2323, including IGM's plans to initiate two Phase 2 studies of IGM-2323, the design of such studies, expectations regarding dosing and the potential for accelerated approvals and such Phase 2 studies serving as potentially registrational studies; statements regarding the clinical development of IGM-8444, including IGM's plans to enroll patients with chronic lymphocytic

leukemia/small lymphocytic lymphoma in a venetoclax-IGM-8444 combination cohort, the safety profile of IGM-8444 and its potential for use in combination with other drugs for the treatment of multiple solid and hematologic cancers; plans to initiate Phase 1 studies of IGM-6268, IGM-7354 and IGM-2644, and the expected timing of the initiation of such studies and the filing of an IND with the FDA for IGM-2644; IGM's expansion into infectious diseases and autoimmunity and inflammation, and its newly created infectious diseases and autoimmunity and inflammation business units; the Company's research and development strategy; IGM's expectations regarding its financial position, including operating expenses, cash and investments and non-cash stock-based compensation; and statements by IGM's Chief Executive Officer, Chief Medical Officer and Chief Scientific 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: potential delays and disruption resulting from the COVID-19 pandemic and governmental responses to the pandemic, including any future impacts to IGM's operations, the manufacturing of its product candidates, the progression of its clinical trials, enrollment in its current and future clinical trials and progression of its collaborations and related efforts; 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 preclinical studies and 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, the potential diminishing need for therapeutics to address COVID-19, particularly in the United States and other major markets, 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; risks related to collaborations with third parties, including the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of any such collaboration; general economic and market conditions; and other risks and uncertainties, including those more fully described in IGM's filings with the Securities and Exchange Commission (SEC), including IGM's Annual Report on Form 10-K filed with the SEC on March 30, 2021, IGM's Quarterly Report on Form 10-Q filed with the SEC on November 4, 2021 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.

**Contact**

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**IGM Biosciences, Inc.**
**Selected Statement of Operations Data**
**(unaudited)**
**(in thousands, except share and per share data)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Operating expenses: | | | | |
| Research and development (1) | $ 34,196 | $ 15,829 | $ 87,857 | $ 45,431 |
| General and administrative (1) | 10,003 | 4,732 | 26,786 | 13,110 |
| Total operating expenses | 44,199 | 20,561 | 114,643 | 58,541 |
| Loss from operations | (44,199) | (20,561) | (114,643) | (58,541) |
| Other income, net | 35 | 291 | 121 | 1,808 |
| Net loss | $ (44,164) | $ (20,270) | $ (114,522) | $ (56,733) |
| Net loss per share, basic and diluted | $ (1.32) | $ (0.66) | $ (3.43) | $ (1.86) |
| Weighted-average common shares outstanding, basic and diluted | 33,438,477 | 30,646,729 | 33,380,143 | 30,563,614 |
| (1) Amounts include stock-based compensation expense as follows: | | | | |
| Research and development | $ 3,095 | $ 1,244 | $ 7,605 | $ 2,957 |
| General and administrative | 3,117 | 1,350 | 9,720 | 2,915 |
| Total stock-based compensation expense | $ 6,212 | $ 2,594 | $ 17,325 | $ 5,872 |

**IGM Biosciences, Inc.**
**Selected Balance Sheet Data**
**(unaudited)**
**(in thousands)**

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| Cash and investments | $ 265,626 | $ 366,269 |
| Total assets | 332,229 | 408,632 |
| Accounts payable | 3,345 | 7,924 |
| Accrued liabilities | 13,929 | 6,649 |
| Total liabilities | 46,653 | 26,817 |
| Accumulated deficit | (303,082) | (188,560) |
| Total stockholders' equity | 285,576 | 381,815 |