# 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 03, 2022**

# 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**<br>**Mountain View, California** | **94043** |
|---|---|
| **(Address of Principal Executive Offices)** | **(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 2.02 Results of Operations and Financial Condition.**

On November 3, 2022, IGM Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2022. 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 3, 2022. |
| 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: November 3, 2022

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

**Exhibit 99.1**

**IGM Biosciences Announces Third Quarter 2022 Financial Results and Provides Corporate Update**

*– Data from T cell Engager Portfolio for Hematologic Malignancies, Including First Preclinical Data for IGM-2644 and IGM-2537, Selected for Poster Presentations at 2022 ASH Annual Meeting –*

*– Data Update from Phase 1 Trial of Imvotamab Demonstrates Durable Benefit for R/R NHL Patients, with 7/8 Complete Response Patients Tumor Free After 1 Year –*

**MOUNTAIN VIEW, Calif., November 03, 2022 –** IGM Biosciences, Inc. (Nasdaq: IGMS), a clinical-stage biotechnology company focused on creating and developing IgM antibodies, today announced its financial results for the third quarter ended September 30, 2022 and provided an update on recent developments.

"We have made substantial progress in advancing our IgM platform in the third quarter, particularly in expanding the body of evidence underlying our T cell engager portfolio for hematologic malignancies and in generating additional clinical data for IGM-8444. We continue to believe that each of our T cell engager product candidates has the potential to change the treatment paradigm in its respective indication. Notably, we are excited to share the first insight into the preclinical profiles of IGM-2644, our CD38 x CD3 bispecific IgM antibody, and IGM-2537, our CD123 x CD3 bispecific IgM antibody, during poster presentations at the upcoming ASH meeting in December," said Fred Schwarzer, Chief Executive Officer of IGM Biosciences. "Additionally, today we are providing an update from the Phase 1 dose escalation trial of imvotamab in relapsed and/or refractory NHL describing its durable benefit for relapsed and/or refractory NHL patients. We look forward to sharing an initial Phase 2 efficacy and safety update for imvotamab and an initial efficacy and safety update on the FOLFIRI combination for IGM-8444 in Q1 2023."

**Pipeline Updates**

**Imvotamab (CD20 x CD3)**

- **Biomarker data from the Phase 1 trial evaluating imvotamab, the Company's novel IgM T cell engaging bispecific antibody, selected for presentation at 2022 American Society of Hematology (ASH) Annual Meeting and Exposition** being held virtually and in-person in New Orleans, Louisiana, December 10-13, 2022. The results will be presented on Sunday, December 11, 2022, at 6:00 p.m. CT, in a poster presentation titled "Pharmacodynamics and Biomarker Correlates of Imvotamab (IGM-2323), the First-in-Class CD20 x CD3 Bispecific IgM Antibody with Dual Mechanisms of Action, in Patients with Advanced B Cell Malignancies."
    - Biomarker data obtained from patients in dose escalation cohorts will be presented illuminating the relationship between T cell levels and response as well as pharmacodynamic data confirming T cell dependent (TDCC) and complement dependent (CDC) mechanisms of action for imvotamab in patients. Biomarker data (minimal residual disease data) to support durability of response will also be presented.
    - The ASH abstract is available through the ASH online meeting program.
- **Clinical development of imvotamab advances.** IGM today provided an update on response duration from the Phase 1 dose escalation study of imvotamab in patients with relapsed and/or refractory (R/R) non-Hodgkin's lymphoma (NHL).
    - In data previously reported at the 2021 American Society of Hematology (ASH) Annual Meeting, imvotamab showed a 50% complete response (CR) rate at the likely optimal 100 mg dose (n=10). Of the 28 patients treated in the titration dosing cohorts at that time, cytokine release syndrome was seen in less than 20% of patients.
    - Seven of eight complete response patients were tumor free after more than 1 year as of the data cut-off of August 31, 2022, and as of the data cut-off, the median overall duration of response in these patients had not yet been reached. All DLBCL patients with a complete response reported as of ASH 2021 remained in complete response. Seven responding patients switched from weekly to Q3W therapy and all remain on study with sustained responses.
- **IGM expects to provide an initial Phase 2 efficacy and safety update for imvotamab in the first quarter of 2023.**

- **Announced clinical trial collaboration and supply agreement with ADC Therapeutics SA.** IGM expects to initiate clinical testing evaluating the combination of imvotamab and ZYNLONTA® (loncastuximab tesirine-lpyl), ADC Therapeutics' CD19-directed antibody drug conjugate (ADC), for the treatment of patients with R/R NHL in the first quarter of 2023.

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

- **Preclinical data for IGM-2644, the Company's CD38 x CD3 bispecific IgM antibody, selected for poster presentation at 2022 ASH Annual Meeting and Exposition**. The results will be presented on Sunday, December 11, 2022, at 6:00 p.m. CT, in a poster presentation titled "IGM-2644, a Novel CD38 x CD3 Bispecific IgM T Cell Engager Demonstrates Potent Efficacy on Myeloma Cells with an Improved Preclinical Safety Profile."
    - Preclinical data will be presented that highlights the potency of IGM-2644 with potential activity in daratumumab resistant tumors and a preclinical safety profile with lower cytokine release and reduced T cell fratricide compared to other CD38 x CD3 bispecific T cell engagers.
    - The ASH abstract is available through the ASH online meeting program.
- **Phase 1 trial expected to initiate in first quarter of 2023.** IGM expects to initiate a Phase 1 trial of IGM-2644 in multiple myeloma in the first quarter of 2023, subject to IND clearance.

**IGM-2537 (CD123 x CD3)**

- **Preclinical data for IGM-2537, the Company's CD123 x CD3 bispecific IgM antibody, selected for poster presentation at 2022 ASH Annual Meeting and Exposition**. The results will be presented on Sunday, December 11, 2022, at 6:00 p.m. CT, in a poster presentation titled "CD123 Directed IgM Antibody-based T-cell Engager, IGM-2537, Demonstrates Potent in vitro and in vivo Activity with Minimal Cytokine Release."
    - Preclinical data will be presented highlighting potent in vitro and in vivo activity with minimal cytokine induction providing initial evidence of a favorable preclinical safety profile for a CD123 directed IgM-based T cell engager.
    - The ASH abstract is available through the ASH online meeting program.
- **IND application expected to be filed next year.** IGM expects to file an IND application for IGM-2537 in acute myeloid leukemia in 2023.

**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 1 clinical trial in multiple combination treatment regimens in subjects with relapsed and/or refractory solid and hematologic cancers.
    - **Expansion dosing ongoing in the FOLFIRI combination.** IGM continues to enroll patients in an expansion of its 3 mg/kg FOLFIRI combination dose cohort in colorectal cancer patients, and it has recently further expanded this 3 mg/kg dose cohort to include treatment with IGM-8444 in combination with both bevacizumab and FOLFIRI in colorectal cancer patients. After completion of these 3mg/kg expansion cohorts, IGM expects to begin expansion of its 10 mg/kg FOLFIRI combination dose cohort. The Company expects to provide an initial efficacy and safety update on colorectal cancer patients treated with 3 mg/kg of IGM-8444 plus FOLFIRI in the first quarter of 2023.
    - **Dosing ongoing in the fourth birinapant dose cohort.** IGM is currently enrolling patients in the fourth planned birinapant combination dose escalation cohort.

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

- **Phase 1 trial to initiate in the first quarter of 2023.** IGM today announced that it expects to dose the first patient in the Phase 1 trial for IGM-7354, IGM's targeted IL-15 IgM antibody for the treatment of patients with solid and hematologic malignancies, in the first quarter of 2023, subject to IND clearance.

- **Preclinical data to be presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting.** The poster, titled "IGM-7354, an anti-PD-L1/IL-15 IgM immunocytokine, activates and expands NK cells and effector memory CD8+ T cells in vivo" will be made available beginning at 9:00 a.m. ET on Thursday, November 10, 2022, through the SITC online meeting program.

**Corporate Updates**

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- **Albert Candia, Ph.D. appointed Senior Vice President of Preclinical Sciences.** Dr. Candia brings over 22 years of biotechnology experience to IGM in both research and development in a variety of therapeutic areas and drug modalities. Prior to joining IGM, he was Vice President of Bioanalytical Development at Nektar Therapeutics, leading cross functional teams supporting clinical development and chemistry, manufacturing and control. Dr. Candia has also held previous positions at Dynavax Technologies and Xencor, where he oversaw IND enabling, translational and biomarker activities. Dr. Candia received his B.A. in Biology and Chemistry from Bucknell University and a Ph.D. in Cell Biology from Vanderbilt University School of Medicine.

**Third Quarter 2022 Financial Results**

- **Cash and Investments:** Cash and investments as of September 30, 2022 were $469.1 million, compared to $229.5 million as of December 31, 2021.
- **Collaboration Revenue:** For the third quarter of 2022, collaboration revenue was $0.3 million, compared to no revenue for the same period in 2021.
- **Research and Development (R&D) Expenses:** For the third quarter of 2022, R&D expenses were $48.2 million, compared to $34.2 million for the same period in 2021.
- **General and Administrative (G&A) Expenses:** For the third quarter of 2022, G&A expenses were $12.7 million, compared to $10.0 million for the same period in 2021.
- **Net Loss:** For the third quarter of 2022, net loss was $58.0 million, or a loss of $1.32 per share, compared to a net loss of $44.2 million, or a loss of $1.32 per share, for the same period in 2021.

**2022 Financial Guidance**

IGM is updating its financial guidance and expects to end 2022 with a balance of more than $410 million in cash and investments and full year GAAP operating expenses of $240 million to $245 million including estimated non-cash stock-based compensation expense of approximately $45 million. IGM estimates full year collaboration revenue of approximately $1 million related to the Sanofi agreement.

**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, infectious diseases and autoimmune and inflammatory 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 imvotamab, IGM-8444, IGM-7354, IGM-2644 and IGM-2537; expectations regarding IGM's collaborations with Sanofi and ADC Therapeutics, including the potential benefits and results of each collaboration and the objectives of each collaboration; IGM’s plans and expectations regarding its clinical development efforts and activities; statements regarding the clinical development of imvotamab, IGM-8444, IGM-7354 and IGM-2644, including the timing of initiation of clinical trials, patient enrollment, data reporting and scientific presentations; the expected timing of filing an IND for IGM-2537; IGM’s expectations regarding its financial position and guidance, including collaboration revenue, operating expenses, stock-based compensation expense, and ending 2022 cash and investments; and statements by IGM’s Chief Executive 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 manufacture 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; the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of collaborations with third parties, including the agreement with Sanofi; 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, 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; 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 Quarterly Report on Form 10-Q filed with the SEC on November 3, 2022 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, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Collaboration revenue | $ 331 | $ — | $ 697 | $ — |
| Operating expenses: | | | | |
| Research and development [1] | 48,179 | 34,196 | 134,272 | 87,857 |
| General and administrative [1] | 12,664 | 10,003 | 38,117 | 26,786 |
| Total operating expenses | 60,843 | 44,199 | 172,389 | 114,643 |
| Loss from operations | (60,512) | (44,199) | (171,692) | (114,643) |
| Other income (expense) | | | | |
| Interest income | 2,475 | 35 | 3,289 | 121 |
| Other expense | — | — | (123) | — |
| Total other income (expense) | 2,475 | 35 | 3,166 | 121 |
| Net Loss | $ (58,037) | $ (44,164) | $ (168,526) | $ (114,522) |
| Net loss per share, basic and diluted | $ (1.32) | $ (1.32) | $ (4.15) | $ (3.43) |
| Weighted-average common shares outstanding, basic and diluted | 44,034,652 | 33,438,477 | 40,634,893 | 33,380,143 |
| [1] Amounts include stock-based compensation expense as follows: | | | | |
| Research and development | $ 6,096 | $ 3,095 | $ 19,038 | $ 7,605 |
| General and administrative | 4,720 | 3,117 | 14,563 | 9,720 |
| Total stock-based compensation expense | $ 10,816 | $ 6,212 | $ 33,601 | $ 17,325 |

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

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Cash and investments | $ 469,139 | $ 229,542 |
| Total assets | 540,936 | 298,127 |
| Accounts payable | 2,731 | 5,584 |
| Accrued liabilities | 32,647 | 18,876 |
| Deferred revenue | 149,303 | — |
| Total liabilities | 212,761 | 53,219 |
| Accumulated deficit | (522,250) | (353,724) |
| Total stockholders' equity | 328,175 | 244,908 |