

**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)  
March 29, 2022**

**IGM Biosciences, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-39045**  
(Commission  
File Number)

**77-0349194**  
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
<b>Common Stock, par value \$0.01 per share</b>	<b>IGMS</b>	<b>The Nasdaq Global Select Market</b>

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.

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**Item 2.02 Results of Operations and Financial Condition.**

On March 29, 2022, IGM Biosciences, Inc. (the “Company”) issued a press release announcing its financial results for the quarter and year ended December 31, 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.

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release of IGM Biosciences, Inc., dated March 29, 2022.</a>
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

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Misbah Tahir

Chief Financial Officer

Date: March 29, 2022



### **IGM Biosciences Announces Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update**

*– Announced Global Collaboration Agreement with Sanofi for Oncology, Autoimmune and Inflammation Targets; IGM to Receive \$150 Million Upfront Payment and potentially more than \$6 Billion in Aggregate Development, Regulatory and Commercial Milestones –*

*– Ongoing Progress in Clinical Programs with Two Phase 2 Studies of Two Doses of IGM-2323, 100 mg and 300 mg, in Patients with DLBCL and FL Initiated –*

*– Company to Host Conference Call and Webcast Today at 8:00 a.m. EST –*

**MOUNTAIN VIEW, Calif., March 29, 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 fourth quarter and full year ended December 31, 2021 and provided an update on recent developments.

“IGM continues to make progress in creating a new class of antibody medicines, which strengthens our commitment to use our expertise to develop and improve upon the inherent qualities of IgM antibodies,” said Fred Schwarzer, Chief Executive Officer of IGM Biosciences. “Notably, our exclusive collaboration agreement with Sanofi, announced today, will accelerate the development of our IgM antibody platform across multiple areas of high unmet need beyond our current pipeline efforts. This partnership is a significant step towards exploring and validating our platform in multiple therapeutic areas, and we look forward to working with Sanofi’s impressive team. Simultaneously, our pipeline continues to progress with considerable speed. Namely, the initiation of two Phase 2 studies for our T cell bispecific antibody IGM-2323 and the continued progress in our DR5 agonist IGM-8444 Phase 1 combination treatment regimens. We look forward to sharing information on these efforts later this year.”

#### **Global R&D Collaboration with Sanofi**

- An exclusive worldwide collaboration agreement with Sanofi for multiple oncology, autoimmune and inflammation targets was announced.
  - IGM and Sanofi will leverage IGM’s proprietary IgM antibody technology platform to discover IgM antibody agonists against three oncology targets and three autoimmune/inflammation targets.
  - IGM will receive a \$150 million upfront payment and potentially over \$6 billion in aggregate development, regulatory and commercial milestones. A 50:50 profit share in certain major market countries and tiered royalties in the rest of world is planned for oncology targets, and IGM will receive tiered royalties for autoimmune/inflammation targets. Sanofi has also expressed an interest in purchasing up to \$100 million of IGM non-voting common stock in a public financing.

- Closing of the collaboration is contingent on completion of review under antitrust laws, including the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976 in the U.S., and other customary closing conditions.

## Pipeline Updates

### IGM-2323 (CD20 x CD3)

- **Phase 2 studies initiated.** IGM announced the initiation of two Phase 2 studies to assess the safety and efficacy of two doses of IGM-2323, 100 mg and 300 mg, in patients with diffuse large B cell lymphoma (DLBCL) and follicular lymphoma (FL). If supportive, the data from this Phase 2 multicenter, open-label study could potentially be used as the basis for accelerated review and approval of IGM-2323.
- **Presented Phase 1 clinical results:** In December 2021, IGM presented clinical results from its Phase 1 trial evaluating IGM-2323 at the 63rd American Society of Hematology (ASH) Annual Meeting and Exposition. The data was featured 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”.

### 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. IGM expects to report initial monotherapy and combination data in solid tumors from the dose escalation portion of this Phase 1 trial in 2022.
- **Third FOLFIRI dose cohort successfully completed.** IGM announced that it has cleared the third of four planned FOLFIRI combination dose escalation cohorts (3.0 mg/kg Q2W) with no dose limiting toxicities (DLTs) and no clinically significant liver toxicity observed to date. IGM is currently enrolling patients in the final planned FOLFIRI combination dose escalation cohort (10.0 mg/kg Q2W).
- **First birinapant dose cohort successfully completed.** IGM also announced that it has cleared the first of four planned birinapant combination dose escalation cohorts with no DLTs and no clinically significant liver toxicity observed to date. IGM is currently enrolling patients in the second planned birinapant combination dose escalation cohort.

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

- **IND filing expected in 2022.** IGM expects to file an Investigational New Drug Application (IND) for IGM-7354, the Company’s IL-15 x PD-L1 bispecific IgM antibody, in solid tumors in 2022.

### IGM-2644 (CD38 x CD3)

- **IND filing expected in 2022.** IGM expects to file an IND for IGM-2644, the Company’s CD38 x CD3 bispecific IgM antibody, in multiple myeloma in 2022.

## Corporate Updates

- **Announced grant agreement with the Bill & Melinda Gates Foundation.** The agreement aims to leverage IGM's engineered IgM and IgA antibodies for the potential prevention of malaria, a significant driver of morbidity and mortality in low- and middle-income countries.
- **Carrie Brodmerkel, Ph.D., appointed Chief Scientific Officer of IGM Autoimmunity and Inflammation.** Dr. Brodmerkel brings extensive experience across a broad range of disciplines to this role. Most recently, she served as Vice President and Global Head of Exploratory Biology and Scientific Strategy at Janssen R&D, a division of Johnson & Johnson, where she was responsible for scientific and strategic leadership of the biotherapeutics portfolio, functional planning and execution, computational sciences, and exploratory biology across therapeutic areas including immunology, hematology, and oncology.

## Fourth Quarter and Full Year 2021 Financial Results

- **Cash and Investments:** Cash and investments as of December 31, 2021 were \$229.5 million, compared to \$366.3 million as of December 31, 2020.
- **Research and Development (R&D) Expenses:** For the fourth quarter and year ended 2021, R&D expenses were \$39.2 million and \$127.0 million, respectively, compared to \$19.6 million and \$65.0 million for the fourth quarter and year ended 2020, respectively.
- **General and Administrative (G&A) Expenses:** For the fourth quarter and year ended 2021, G&A expenses were \$11.5 million and \$38.3 million, respectively, compared to \$5.1 million and \$18.3 million for the fourth quarter and year ended 2020, respectively.
- **Net Loss:** For the fourth quarter of 2021, net loss was \$50.6 million, or a loss of \$1.50 per share, compared to a net loss of \$24.6 million, or a loss of \$0.79 per share, for the fourth quarter of 2020. For the year ended 2021, net loss was \$165.2 million, or a loss of \$4.93 per share, compared to a net loss of \$81.4 million, or a loss of \$2.65 per share, for the year ended 2020.

## 2022 Financial Guidance:

IGM expects full year GAAP operating expenses of \$250 million to \$260 million including estimated non-cash stock-based compensation expense of approximately \$50 million. Concurrent with the Company's first quarter 2022 financial results expected in May, IGM anticipates providing full year collaboration and license revenue guidance as well as ending 2022 cash and investments guidance.

## Conference Call and Webcast

IGM will host a conference call and webcast to discuss the Sanofi R&D collaboration announcement today, March 29, at 8:00 a.m. ET. The conference call may be accessed by dialing (866) 649-1996 (domestic) or (409) 217-8769 (international) and referring to conference ID 4983742. A live webcast of the presentation will be available on the "Events and Presentations" page in the "Investors" section of the Company's website at <https://investor.igmbio.com/news-and-events/events-and-presentations>. A replay of the webcast will be archived on the Company's website for 90 days following the presentation.

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## **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-7354 and IGM-2644; expectations regarding the transaction with Sanofi, including all financial aspects of the collaboration and an equity investment; the potential benefits and results of the transaction with Sanofi, including goals of the collaboration and the potential for accelerated development of IGM's platform; IGM's plans and expectations regarding its clinical development efforts and activities; statements regarding the clinical development of IGM-2323, including the potential for the Phase 2 studies to potentially serve as the basis for a regulatory filing and accelerated review and approval of IGM-2323; statements regarding the clinical development of IGM-8444, including timing for data and the safety profile of IGM-8444; the expected timing of filing INDs with for IGM-7354 and IGM-2644; IGM's expectations regarding a grant agreement with the Bill & Melinda Gates Foundation; IGM's expectations regarding its financial position and guidance, including operating expenses and stock-based compensation expense, and the timing of providing guidance for full year collaboration and license revenue 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 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; the risks that the transaction with Sanofi may not be completed in a timely manner or at all; the possibility that certain closing conditions to the transaction with Sanofi will not be satisfied, including the risks related to obtaining the requisite regulatory approvals, such as those required under antitrust laws; 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 (including without limitation the failure to timely obtain requisite regulatory approvals); the possibility that Sanofi may not invest in IGM; risks related to the effect of the announcement of the Sanofi transaction on IGM's business relationships, operating results, stock price and business generally; 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; 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 29, 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 December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
Operating expenses:				
Research and development (1)	\$ 39,169	\$ 19,599	\$ 127,026	\$ 65,030
General and administrative (1)	11,511	5,140	38,297	18,250
Total operating expenses	<u>50,680</u>	<u>24,739</u>	<u>165,323</u>	<u>83,280</u>
Loss from operations	(50,680)	(24,739)	(165,323)	(83,280)
Other income, net	38	117	159	1,925
Net loss	<u>\$ (50,642)</u>	<u>\$ (24,622)</u>	<u>\$ (165,164)</u>	<u>\$ (81,355)</u>
Net loss per share, basic and diluted	<u>\$ (1.50)</u>	<u>\$ (0.79)</u>	<u>\$ (4.93)</u>	<u>\$ (2.65)</u>
Weighted-average common shares outstanding, basic and diluted	<u>33,775,358</u>	<u>31,298,264</u>	<u>33,479,782</u>	<u>30,748,280</u>

(1) Amounts include stock-based compensation expense as follows:

Research and development	\$ 4,659	\$ 1,203	\$ 12,264	\$ 4,160
General and administrative	3,889	1,379	13,609	4,294
Total stock-based compensation expense	<u>\$ 8,548</u>	<u>\$ 2,582</u>	<u>\$ 25,873</u>	<u>\$ 8,454</u>

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

	December 31, 2021	December 31, 2020
Cash and investments	\$ 229,542	\$ 366,269
Total assets	298,127	408,632
Accounts payable	5,584	7,924
Accrued liabilities	18,876	6,649
Total liabilities	53,219	26,817
Accumulated deficit	(353,724)	(188,560)
Total stockholders' equity	244,908	381,815