
**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 6, 2021

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:

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 May 6, 2021, IGM Biosciences, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 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.

Exhibit No.	Description
99.1	Press Release of IGM Biosciences, Inc., dated May 6, 2021.

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: May 6, 2021



IGM Biosciences Announces First Quarter 2021 Financial Results and Provides Corporate Update

– Recommended Phase 2 Dose of IGM-2323 Expected in 2021 –

– Initial Data from Phase 1 Trial of IGM-8444 in Solid Cancers Expected in 2021 –

– IND Filing for IGM-7354 Planned in 2021 –

MOUNTAIN VIEW, Calif., May 6, 2021 – 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 first quarter ended March 31, 2021 and provided an update on recent developments.

“We are very pleased with the progress we made in the first quarter towards achieving our clinical and pipeline goals for 2021,” said Fred Schwarzer, Chief Executive Officer of IGM Biosciences. “We look forward to announcing a recommended Phase 2 dose for IGM-2323, presenting initial data from the dose escalation portion of the Phase 1 trial of IGM-8444 and filing an IND for IGM-7354 during 2021.”

Pipeline Updates

IGM-2323

- **Recommended Phase 2 dose expected in 2021.** IGM continues to advance the clinical development of IGM-2323, the Company’s IgM-based CD20 x CD3 bispecific antibody, for the treatment of non-Hodgkin’s lymphoma (NHL) and potentially other CD20-expressing hematologic malignancies, including chronic lymphocytic leukemia (CLL). IGM has cleared the titration dose cohorts of 50/100 mgs, 50/300 mgs and 50/600 mgs in the ongoing Phase 1 clinical trial of IGM-2323, and is currently enrolling patients in what is expected to be its top titration dose cohort, 50/1000 mgs. IGM is also currently enrolling patients in the expansion dose cohorts of 50/100 mgs, 50/300 mgs and 50/600 mgs. IGM expects to complete enrollment in the dose escalation portion of the Phase 1 clinical trial and select a recommended Phase 2 dose in 2021.

IGM-8444

- **Phase 1 data expected in the second half of 2021.** IGM also continues to advance the clinical development of IGM-8444, the Company’s IgM Death Receptor 5 (DR5) agonist, for the treatment of a potentially broad range of solid tumors and hematologic malignancies. IGM has cleared its second dose escalation dose cohort, 1 mg/kg, in the ongoing Phase 1 trial, and is currently dosing patients in its third dose escalation cohort, 3 mg/kg, with every two week dosing. IGM has also begun dosing patients in its first combination with FOLFIRI dose cohort and its first weekly dosing cohort. IGM expects to report initial data from the dose escalation portion of the Phase 1 trial in the second half of 2021.
- **Clinical testing of birinapant in combination with IGM-8444 expected to begin this year.** As previously announced, during the first quarter of 2021, IGM entered into an exclusive license agreement with Medivir AB, by which IGM received global, exclusive development and commercialization rights for birinapant. IGM remains on track to begin clinical testing of birinapant in combination with IGM-8444 this year.

IGM-7354

- **Investigational New Drug (IND) application expected to be filed this year.** IGM also plans to file an IND application with the U.S. Food and Drug Administration (FDA) for IGM-7354, the Company's IL-15 x PD-L1 bispecific IgM antibody, before the end of 2021 in order to begin clinical testing initially in solid tumors, followed by hematologic malignancies.

Corporate Updates

- **George Gauthier appointed to the newly created position of Chief Commercial Officer.** Mr. Gauthier brings twenty years of experience in global commercial strategy, marketing and product development. Most recently, Mr. Gauthier was Vice President of Global Product Strategy for Breast and Gynecological Cancers at Genentech, where he led a global team in the creation and execution of commercial and product development strategies.

First Quarter 2021 Financial Results

- **Cash and Investments:** Cash and investments as of March 31, 2021 were \$331.7 million, compared to \$366.3 million as of December 31, 2020.
- **Research and Development (R&D) Expenses:** For the first quarter of 2021, R&D expenses were \$23.6 million, compared to \$14.6 million for the same period in 2020.
- **General and Administrative (G&A) Expenses:** For the first quarter of 2021, G&A expenses were \$8.1 million, compared to \$4.0 million for the same period in 2020.
- **Net Loss:** For the first quarter of 2021, net loss was \$31.6 million, or a loss of \$0.95 per share, compared to a net loss of \$17.6 million, or a loss of \$0.58 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 for the treatment of multiple diseases. 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, its antibody drug candidates and birinapant; statements regarding IGM's Phase 1 clinical trials of IGM-2323 and IGM-8444; the anticipated timing of the selection of a recommended Phase 2 dose for IGM-2323, the reporting of initial data from the dose escalation portion of the Phase 1 trial of IGM-8444, the initiation of clinical testing of birinapant in combination with IGM-8444 and an IND filing for IGM-7354; IGM's expectations regarding its financial position, including operating expenses and cash and investments; and statements by the Chief Executive Officer of IGM. 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 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 risk that all necessary regulatory approvals cannot be obtained; the risk that the potential benefits of combination therapies do not outweigh their costs; 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 May 6, 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	
	March 31,	
	2021	2020
Operating expenses:		
Research and development (1)	\$ 23,572	\$ 14,583
General and administrative (1)	8,134	3,990
Total operating expenses	31,706	18,573
Loss from operations	(31,706)	(18,573)
Other income, net	62	949
Net loss	\$ (31,644)	\$ (17,624)
Net loss per share, basic and diluted	\$ (0.95)	\$ (0.58)
Weighted-average common shares outstanding, basic and diluted	33,328,994	30,491,463

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

Research and development	\$ 1,865	\$ 666
General and administrative	3,639	657
Total stock-based compensation expense	\$ 5,504	\$ 1,323

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

	March 31, 2021	December 31, 2020
Cash and investments	\$ 331,674	\$ 366,269
Total assets	380,474	408,632
Accounts payable	5,661	7,924
Accrued liabilities	5,826	6,649
Total liabilities	24,864	26,817
Accumulated deficit	(220,204)	(188,560)
Total stockholders' equity	355,610	381,815