

**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): August 03, 2023

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, 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 2.02 Results of Operations and Financial Condition.

On August 3, 2023, IGM Biosciences, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2023. 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 August 3, 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: August 3, 2023

By: /s/ Misbah Tahir

Misbah Tahir
Chief Financial Officer



IGM Biosciences Announces Second Quarter 2023 Financial Results

– Continued progress in clinical development across portfolio –

– Public equity offering and concurrent private placement with gross proceeds of \$120.0 million –

MOUNTAIN VIEW, Calif., August 3, 2023 – 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 quarter ended June 30, 2023.

“We continued to make good progress in the development of our IgM platform in the second quarter, as reflected in our announcement of encouraging data from the clinical trials of IGM-8444, now known as aplitabart, and in the clearance by the FDA of two Investigational New Drug applications to begin clinical trials of imvotamab, our IgM-based CD20 x CD3 bispecific antibody T cell engager, in severe systemic lupus erythematosus and severe rheumatoid arthritis,” said Fred Schwarzer, Chief Executive Officer of IGM Biosciences. “Building on this progress, during the third quarter we expect to initiate these two Phase 1b autoimmune clinical trials and to continue to build enrollment in our randomized clinical trial of aplitabart in combination with standard of care FOLFIRI chemotherapy and bevacizumab in second-line metastatic colorectal cancer patients.”

Pipeline Progress

Aplitabart (IGM-8444) (DR5 agonist)

- **Clinical data with 3 mg/kg of aplitabart plus FOLFIRI from a non-randomized Phase 1 clinical trial.** In June 2023, the Company reported Phase 1 data from a cohort of patients treated with aplitabart, the Company’s IgM agonist antibody targeting death receptor 5 (DR5), in combination with FOLFIRI through a data cut-off date of April 12, 2023.
 - o In 51 CRC patients treated with the combination regimens, no drug related clinically significant hepatotoxicity was observed, with only grade 1 and grade 2 transient liver enzyme elevations noted as of the data cut-off date.
 - o In these predominantly third-line metastatic colorectal cancer patients, the combination of aplitabart dosed at 3 mg/kg and FOLFIRI showed promising activity in terms of progression-free survival.
 - o Multiple confirmed partial responses were observed among the patients treated with 3 mg/kg of aplitabart and FOLFIRI, including some patients who had previously progressed on FOLFIRI treatment.
 - **Clinical development of aplitabart advances.** The Company continues to advance the clinical development of aplitabart.
 - o **Dosing ongoing in the randomized colorectal cancer clinical trial.** The Company is currently enrolling patients in an open-label randomized clinical trial of aplitabart plus FOLFIRI and bevacizumab in second-line metastatic colorectal cancer. This randomized trial will assess the additional benefit of 3 mg/kg of aplitabart with a primary endpoint of progression-free survival (PFS) and secondary endpoints of overall response rate and overall survival as compared to the current standard of care treatment arm of FOLFIRI and bevacizumab. The Company’s goal is to have enrolled approximately 110 patients in the trial by the end of the first quarter of 2024 and to have median PFS data from these patients by the end of 2024.
 - o **Dosing at 10 mg/kg ongoing in the single arm colorectal cancer clinical trial.** The Company has also begun dosing additional colorectal cancer patients at 10 mg/kg of aplitabart in its single arm FOLFIRI combination clinical trial.
 - o **Dosing ongoing in the venetoclax combination.** The Company is currently treating patients with acute myeloid leukemia in its aplitabart plus venetoclax and azacytidine Phase 1 combination cohort.
 - o **Dosing ongoing in birinapant combination.** The Company is also currently treating patients in its aplitabart plus birinapant Phase 1 combination cohort.
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Imvotamab (CD20 x CD3)

- **FDA clearance to begin autoimmune clinical trials.** In the second quarter, the Company received clearance of two Investigational New Drug (IND) applications with the U.S. Food and Drug Administration (FDA) for imvotamab, an IgM-based CD20 x CD3 bispecific antibody T cell engager, which will enable the initiation of two Phase 1b clinical trials, one in severe systemic lupus erythematosus (SLE) and one in severe rheumatoid arthritis (RA), during third quarter 2023.

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

- **Phase 1 trial continues.** The Company continues to enroll patients in a Phase 1 clinical trial exploring the safety, efficacy, and biomarker activity of IGM-7354, an IgM-targeted immunostimulatory IL-15 cytokine, in the treatment of patients with solid tumors.

IGM-2644 (CD38 x CD3)

- **Phase 1 trial initiated.** The Company has initiated a clinical trial exploring the safety and efficacy of IGM-2644, a CD38 x CD3 IgM T cell engaging antibody, in patients with recurrent or refractory multiple myeloma.

Financing

- **Completed underwritten public offering of common stock and concurrent private placement.** As previously announced, the Company recently closed a public offering of its voting and non-voting common stock and concurrent private placement of non-voting common stock, with total gross proceeds of \$120.0 million and net proceeds of \$113.5 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company, of which \$68.5 million had been received by the Company as of June 30, 2023 and \$45.0 million was received on July 3, 2023.

Second Quarter 2023 Financial Results

- **Cash and Investments:** Cash and investments as of June 30, 2023 were \$386.9 million (which amount does not include an additional \$45.0 million from the public equity offering received on July 3, 2023), compared to \$427.2 million as of December 31, 2022.
- **Collaboration Revenue:** For the second quarter of 2023, collaboration revenues were \$0.4 million, compared to \$0.4 million for the same period in 2022.
- **Research and Development (R&D) Expenses:** For the second quarter of 2023, R&D expenses were \$55.7 million, compared to \$47.2 million for the same period in 2022.
- **General and Administrative (G&A) Expenses:** For the second quarter of 2023, G&A expenses were \$13.0 million, compared to \$12.4 million for the same period in 2022.
- **Net Loss:** For the second quarter of 2023, net loss was \$64.4 million, or a loss of \$1.43 per share, compared to a net loss of \$58.6 million, or a loss of \$1.33 per share, for the same period in 2022.

2023 Financial Guidance

The Company expects full year 2023 GAAP operating expenses of \$275 million to \$285 million, including estimated non-cash stock-based compensation expense of approximately \$45 million, and full year collaboration revenue of approximately \$3 million related to the Sanofi agreement. The Company expects to end 2023 with more than \$325 million in cash and investments, and the Company expects its existing cash and investments and anticipated collaboration payments to fund operations into the second half of 2025.

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. IGM'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. IGM 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. Such forward-looking statements are not based on historical fact and include, but are not limited to: the potential of, and expectations regarding, IGM's technology platform and its IgM antibodies and product candidates, including aplitabart and imvotamab; IGM's plans and expectations regarding its clinical development efforts and activities; statements regarding the clinical development of aplitabart, imvotamab, IGM-7354 and IGM-2644, including the timing of initiation of clinical trials, patient enrollment and availability of clinical data; IGM's expectations regarding its financial position and guidance, including collaboration revenue, operating expenses, stock-based compensation expense, ending 2023 cash and investments and projected cash runway; 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: 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 August 3, 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.

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		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
Collaboration revenue	\$ 448	\$ 366	\$ 970	\$ 366
Operating expenses:				
Research and development ⁽¹⁾	55,673	47,218	106,567	86,093
General and administrative ⁽¹⁾	12,983	12,372	25,985	25,453
Total operating expenses	68,656	59,590	132,552	111,546
Loss from operations	(68,208)	(59,224)	(131,582)	(111,180)
Other income (expense):				
Interest income	3,894	760	8,066	814
Other expense	—	(131)	(20)	(123)
Total other income (expense)	3,894	629	8,046	691
Loss before income tax expense	(64,314)	(58,595)	(123,536)	(110,489)
Income tax expense	(109)	—	(196)	—
Net loss	\$ (64,423)	\$ (58,595)	\$ (123,732)	\$ (110,489)
Net loss per share, basic and diluted	\$ (1.43)	\$ (1.33)	\$ (2.76)	\$ (2.84)
Weighted-average common shares outstanding, basic and diluted	45,122,900	43,919,092	44,796,644	38,906,839

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

Research and development	\$ 8,248	\$ 6,335	\$ 14,687	\$ 12,942
General and administrative	6,061	4,951	10,669	9,843
Total stock-based compensation expense	\$ 14,309	\$ 11,286	\$ 25,356	\$ 22,785

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

	June 30, 2023	December 31, 2022
Cash and investments	\$ 386,869	\$ 427,162
Total assets	480,658	513,499
Accounts payable	4,936	2,512
Accrued liabilities	27,737	33,621
Deferred revenue	147,961	148,931
Total liabilities	222,051	226,236
Accumulated deficit	(698,558)	(574,826)
Total stockholders' equity	258,607	287,263

