IGM Biosciences Announces Second Quarter 2024 Financial Results and Provides Corporate Update

August 14, 2024

– Enrollment complete in aplitabart randomized colorectal cancer clinical trial; top-line PFS results expected by the end of 1Q25 –

– Second dose cohort cleared in imvotamab rheumatoid arthritis clinical trial –

– First dose cohort cleared in imvotamab systemic lupus erythematosus clinical trial –

MOUNTAIN VIEW, Calif., Aug. 14, 2024 (GLOBE NEWSWIRE) -- IGM Biosciences, Inc. (Nasdaq: IGMS), a clinical-stage biotechnology company creating and developing engineered IgM antibodies, today announced its financial results for the fiscal quarter ended June 30, 2024 and provided an update on recent developments.

"We continue to make significant progress in the clinical development of our two lead product candidates," said Fred Schwarzer, Chief Executive Officer of IGM Biosciences. "We are pleased to have completed enrollment of 127 patients in our randomized study of 3mg/kg of aplitabart plus FOLFIRI and bevacizumab in second line colorectal cancer. We are also pleased to have successfully cleared the first two cohorts of our clinical trial of imvotamab in severe rheumatoid arthritis as well as the first cohort of our clinical trial of imvotamab in severe systemic lupus erythematosus."

Pipeline Updates

Aplitabart (death receptor 5 agonist)

- **Clinical development of aplitabart advances.**
  - **Enrollment completed in randomized colorectal cancer clinical trial.** The Company announced that it has completed enrollment in its randomized clinical trial of 3 mg/kg of aplitabart plus FOLFIRI and bevacizumab in second-line metastatic colorectal cancer. A total of 127 patients, exceeding the trial design target of 110 patients, were enrolled across multiple clinical trial sites in the United States, Asia and Europe. This randomized trial is designed to assess the benefit of 3 mg/kg of aplitabart when administered in combination with FOLFIRI and bevacizumab compared to the current standard of care treatment of FOLFIRI and bevacizumab, with a primary endpoint of progression-free survival (PFS). The release of data from this randomized clinical trial will depend on the timing of PFS events in both the control and the experimental arms of this study. Based on its assumptions as to the timing of PFS events, the Company expects to be able to release top-line PFS results from this study by the end of the first quarter of 2025.

Imvotamab (CD20 x CD3 T cell engager)

- **Clinical development of imvotamab in autoimmune diseases advances.**
  - **First and second dose cohorts in rheumatoid arthritis successfully completed.** The Company announced that it has cleared both the first and second dose cohorts of its placebo-controlled clinical study testing imvotamab in severe rheumatoid arthritis and is currently enrolling the third cohort. This study is designed to evaluate three cohorts of progressively higher dose regimens of imvotamab, with each cohort designed to recruit eight patients, six of whom receive imvotamab and two of whom receive placebo.
  - **First dose cohort in systemic lupus erythematosus successfully completed.** The Company announced that it has cleared the first dose cohort of its open-label clinical study testing imvotamab in severe systemic lupus erythematosus (SLE), with each dose cohort designed to recruit six patients, all of whom are to be treated with imvotamab. The Company is currently enrolling patients in a second dose cohort and plans to enroll a third dose cohort, with each cohort at progressively higher dose regimens of imvotamab.
  - **Enrollment initiated in myositis.** The Company has initiated recruitment of patients in its single arm, open-label clinical study testing imvotamab in moderate-severe idiopathic inflammatory myopathies (myositis).

IGM-2644 (CD38 x CD3 T cell engager)

- **Clinical development of IGM-2644 in autoimmune diseases to be initiated.** The Company has made significant progress towards initiating clinical development of IGM-2644, a CD38 x CD3 T cell engager antibody, in the treatment of autoimmune diseases. The Company currently expects to begin enrolling patients in a single arm, open-label clinical study testing IGM-2644 in generalized myasthenia gravis (gMG) by the end of 2024.

Second Quarter 2024 Financial Results

- **Cash and Investments:** Cash and investments as of June 30, 2024 were $256.4 million, compared to $337.7 million as of December 31, 2023.
- **Collaboration Revenue:** For the second quarter of 2024, collaboration revenues were $1.3 million compared to $0.4 million for the second quarter of 2023.
- **Research and Development (R&D) Expenses:** For the second quarter of 2024, R&D expenses were $42.0 million, compared to $55.7 million for the second quarter of 2023.
- **General and Administrative (G&A) Expenses:** For the second quarter of 2024, G&A expenses were $10.6 million, compared to $13.0 million for the second quarter of 2023.
- **Net Loss:** For the second quarter of 2024, net loss was $47.9 million, or a loss of $0.79 per share, compared to a net loss of $64.4 million, or a loss of $1.43 per share, for the second quarter of 2023.

2024 Financial Guidance

The Company expects full year 2024 GAAP operating expenses of $210 million to $220 million including estimated non-cash stock-based compensation expense of approximately $40 million, and full year collaboration revenue of approximately $2 million related to the Sanofi agreement. The Company expects to end 2024 with a balance of approximately $180 million in cash and investments and for the balance to enable it to fund its operating expenses and capital expenditure requirements into the second quarter of 2026.

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 and autoimmune and inflammatory 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 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, imvotamab, and IGM-2644; IGM's plans and expectations regarding its clinical development efforts and activities; statements regarding the clinical development of aplitabart, imvotamab, and IGM-2644, including with respect to patient enrollment, dosing, and the timing of the release of data; IGM's expectations regarding its financial position and results, including its stock-based compensation expense and collaboration revenue, 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; IGM's ability to obtain additional capital to finance its operations; 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; uncertainties related to IGM's ability to realize the contemplated benefits of its pipeline prioritization efforts and related reduction in force; 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 14, 2024 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Collaboration revenue	$ 1,254	$ 448	$ 1,751	$ 970
Operating expenses:				

Research and development [1]	41,962	55,673	85,777	106,567
General and administrative [1]	10,649	12,983	21,187	25,985
Total operating expenses	52,611	68,656	106,964	132,552
Loss from operations	(51,357)	(68,208)	(105,213)	(131,582)
Other income (expense):				
Interest income	3,455	3,894	7,495	8,066
Other expense	—	—	—	(20)
Total other income (expense)	3,455	3,894	7,495	8,046
Loss before income tax expense	(47,902)	(64,314)	(97,718)	(123,536)
Income tax expense	—	(109)	—	(196)
Net loss	$ (47,902)	$ (64,423)	$ (97,718)	$ (123,732)
Net loss per share, basic and diluted	$ (0.79)	$ (1.43)	$ (1.62)	$ (2.76)
Weighted-average common shares outstanding, basic and diluted	60,434,161	45,122,900	60,274,285	44,796,644

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

Research and development	$ 4,807	$ 8,248	$ 9,169	$ 14,687
General and administrative	3,621	6,061	7,181	10,669
Total stock-based compensation expense	$ 8,428	$ 14,309	$ 16,350	$ 25,356

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

	June 30, 2024	December 31, 2023
Cash and investments	$ 256,381	$ 337,677
Total assets	336,501	423,411
Accounts payable	3,259	1,326
Accrued liabilities	26,461	31,544
Deferred revenue	145,050	146,801
Total liabilities	214,143	220,177
Accumulated deficit	(918,960)	(821,242)
Total stockholders' equity	122,358	203,234

Source: IGM Biosciences, Inc.