



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

November 8, 2024

– *Imvotamab (CD20 x CD3) trials in rheumatoid arthritis, systemic lupus erythematosus and myositis ongoing; initial clinical data expected by mid-2025 –*

– *IGM-2644 (CD38 x CD3) expected to enter clinical study for generalized myasthenia gravis by year-end 2024 –*

– *Cash runway expected to fund operations into 2027 –*

MOUNTAIN VIEW, Calif., Nov. 08, 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 September 30, 2024 and provided an update on recent developments.

"The third quarter was transformative for IGM, punctuated by the announcement of our strategic pivot to focus exclusively on autoimmunity," said Mary Beth Harler, M.D., Chief Executive Officer of IGM Biosciences. "Our near-term focus for imvotamab remains generating robust initial data sets in rheumatoid arthritis, systemic lupus erythematosus and myositis. Based on enrollment timing, we expect to have sufficient information by the middle of 2025 to present initial imvotamab data at an appropriate venue as well as determine next steps to advance imvotamab in autoimmune indications."

Pipeline Updates

Imvotamab (CD20 x CD3 T cell engager)

- **Clinical development of imvotamab in autoimmune diseases advances, with initial clinical data disclosure expected by mid-2025.**
 - **Third dose cohort in rheumatoid arthritis successfully completed.** The Company has cleared the third dose cohort of its placebo-controlled clinical study testing imvotamab in severe rheumatoid arthritis.
 - **Enrollment in second dose cohort in systemic lupus erythematosus ongoing.** The Company has cleared the first dose cohort of its open-label clinical study testing imvotamab in severe systemic lupus erythematosus (SLE) and is currently enrolling patients in a second dose cohort.
 - **First patient dosed in myositis.** The Company has dosed the first patient in its single arm, open-label clinical study testing imvotamab in moderate-severe idiopathic inflammatory myopathies (myositis). Enrollment is ongoing in this study, which is being conducted in collaboration with Stanford University.
- **Imvotamab preclinical data selected for poster presentation at ACR Convergence 2024.** The Company will present a poster titled "Imvotamab, a CD20-Targeted Bispecific IgM T Cell Engager, Effectively Depletes Low-Expressing CD20+ B Cells in Preclinical Models of Autoimmune Disease" at the American College of Rheumatology's annual meeting, ACR Convergence 2024, taking place in Washington, D.C., on November 17, 2024.

IGM-2644 (CD38 x CD3 T cell engager)

- **Clinical development of IGM-2644 in autoimmune diseases to be initiated.** The Company continues to make 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 expects to enter IGM-2644 into a single arm, open-label clinical study for generalized myasthenia gravis (gMG) by the end of 2024.

Corporate Updates

- **Peer-reviewed article titled "Cutting-edge Approaches to B-cell Depletion in Autoimmune Diseases" published in *Frontiers in Immunology*.** IGM co-authored this article with Bill Robinson, M.D., Ph.D., et al. and the article can be found online [here](#). Dr. Robinson is Chief of the Division of Immunology and Rheumatology at Stanford University.
- **Eric Humke, M.D., Ph.D., Senior Vice President, appointed as Head of Clinical Research and Development.** Dr. Humke joined IGM in 2019 as Vice President, Clinical Development. Prior to IGM, he spent eight years at Genentech, most recently serving as Senior Medical Director, where he led the early clinical development of multiple first-in-human therapeutics. Prior to joining Genentech, he was an Instructor of Medicine at the Stanford University School of Medicine, where he conducted basic science research and cared for patients.

Third Quarter 2024 Financial Results

- **Cash and Investments:** Cash and investments as of September 30, 2024 were \$218.8 million, compared to \$337.7 million as of December 31, 2023.
- **Collaboration Revenue:** For the third quarter of 2024, collaboration revenues were \$0.5 million, compared to \$0.5 million for the third quarter of 2023.
- **Research and Development (R&D) Expenses:** For the third quarter of 2024, R&D expenses were \$46.1 million, compared to \$54.8 million for the third quarter of 2023. R&D expenses for the third quarter of 2024 included \$5.5 million in one-time expenses related to the strategic pivot to focus exclusively on autoimmunity.
- **General and Administrative (G&A) Expenses:** For the third quarter of 2024, G&A expenses were \$18.8 million, compared to \$12.5 million for the third quarter of 2023. G&A expenses for the third quarter of 2024 included \$8.5 million in one-time expenses related to the strategic pivot to focus exclusively on autoimmunity.
- **Net Loss:** For the third quarter of 2024, net loss was \$61.4 million, or a loss of \$1.01 per share, compared to a net loss of \$62.0 million, or a loss of \$1.04 per share, for the third quarter of 2023.

2024 Financial Guidance

The Company expects full year 2024 GAAP operating expenses of \$215 million to \$225 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 2027.

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 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 imvotamab and IGM-2644; IGM's plans and expectations regarding its clinical development efforts and activities; statements regarding the clinical development of 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 operating expenses, stock-based compensation expense, 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; uncertainties related to IGM's ability to realize the contemplated benefits of its strategic pivot and pipeline transformation 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 November 8, 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.

This press release contains hyperlinks to information that is not deemed to be incorporated by reference into this press release.

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2024	2023	2024	2023
Collaboration revenue	\$ 516	\$ 509	\$ 2,267	\$ 1,479

Operating expenses:				
Research and development ⁽¹⁾	46,142	54,762	131,919	161,329
General and administrative ⁽¹⁾	18,761	12,507	39,948	38,492
Total operating expenses	64,903	67,269	171,867	199,821
Loss from operations	(64,387)	(66,760)	(169,600)	(198,342)
Other income (expense):				
Interest income	2,957	5,011	10,452	13,077
Other expense	—	—	—	(20)
Total other income (expense)	2,957	5,011	10,452	13,057
Loss before income tax expense	(61,430)	(61,749)	(159,148)	(185,285)
Income tax expense	—	(240)	—	(436)
Net loss	\$ (61,430)	\$ (61,989)	\$ (159,148)	\$ (185,721)
Net loss per share, basic and diluted	\$ (1.01)	\$ (1.04)	\$ (2.63)	\$ (3.73)
Weighted-average common shares outstanding, basic and diluted	60,657,797	59,580,402	60,403,056	49,778,716

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

Research and development	\$ 5,792	\$ 7,391	\$ 14,961	\$ 22,078
General and administrative	10,410	4,563	17,591	15,232
Total stock-based compensation expense	\$ 16,202	\$ 11,954	\$ 32,552	\$ 37,310

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

	September 30,	December 31,
	2024	2023
Cash and investments	\$ 218,787	\$ 337,677
Total assets	304,508	423,411
Accounts payable	3,545	1,326
Accrued liabilities	31,071	31,544
Deferred revenue	144,534	146,801
Total liabilities	225,561	220,177
Accumulated deficit	(980,390)	(821,242)
Total stockholders' equity	78,947	203,234



Source: IGM Biosciences, Inc.