

**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): September 27, 2024

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

(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 2.05 Costs Associated with Exit or Disposal Activities.

On September 27, 2024, IGM Biosciences, Inc. (the “Company”) committed to a strategic pivot and pipeline transformation, pursuant to which the Company has decided to begin taking steps, including a reduction in force, to minimize its future spending on the research and clinical development of aplitabart and its other oncology candidates (the “Strategic Pivot”). The Company is undertaking the Strategic Pivot to prioritize its pipeline of T cell engagers in autoimmune diseases, including ongoing clinical development of invotamab in rheumatoid arthritis, systemic lupus erythematosus, and myositis, while further extending cash runway. The Company will also continue to focus on the development of immunology product candidates under its collaboration with Sanofi. The Company expects that, as a result of the Strategic Pivot, the Company’s existing cash, cash equivalents and investments will be sufficient to fund its operating expenses and capital expenditure requirements into 2027.

The Company is unable to estimate in good faith the amount of all such costs and charges to be incurred as a result of the Strategic Pivot at this time, and in accordance with paragraph (d) of Item 2.05 of Form 8-K, the Company will file an amendment to this Current Report on Form 8-K once it makes a determination of such estimates or range of estimates. The Strategic Pivot activities are expected to be substantially complete in the first quarter of 2025.

A copy of the Company’s press release announcing the Strategic Pivot is attached hereto as Exhibit 99.1.

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Resignation of Chief Executive Officer, President and Director

In connection with the Strategic Pivot, Fred Schwarzer resigned as Chief Executive Officer, President and a member of the board of directors (the “Board”) of the Company, effective as of September 30, 2024 (the “Effective Date”). Mr. Schwarzer confirmed that his resignation from the Board was not the result of any disagreement with or about the Company, its operations, policies or practices.

In connection with Mr. Schwarzer’s resignation, the Company and Mr. Schwarzer entered into a transition and consulting agreement on the Effective Date (the “Schwarzer Consulting Agreement”). Among other things, the Schwarzer Consulting Agreement provides that:

- As of October 1, 2024, Mr. Schwarzer will transition to a consulting role and provide consulting services to the Company through the second anniversary of the Effective Date (the “Schwarzer Scheduled Completion Date,” the actual final day of such consultancy, the “Schwarzer Completion Date,” and the period from the Effective Date through the Schwarzer Completion Date, the “Schwarzer Consulting Period”).
- Through the Schwarzer Scheduled Completion Date, Mr. Schwarzer will be paid \$28,030 for each one-month period in which he is available to provide consulting services, and he will also be paid \$5,500 per month for 18 months to facilitate health care continuation coverage; provided that all such cash payments will cease if the Company terminates the Schwarzer Consulting Agreement for cause.
- Each of Mr. Schwarzer’s outstanding equity awards that would have been eligible to vest based on service during the Schwarzer Consulting Period will continue to vest during the Schwarzer Consulting Period, subject to the terms and conditions of the Company’s Amended and Restated 2018 Omnibus Incentive Plan (the “Plan”) under which the award was granted and the applicable award agreement thereunder. On the Effective Date, the portion of each such outstanding equity award that would not have been eligible to vest based on service during the Schwarzer Consulting Period was irrevocably forfeited.
- Mr. Schwarzer and the Company have agreed to mutual releases of claims.

In addition, pursuant to the Schwarzer Consulting Agreement, if the Company terminates the Schwarzer Consulting Agreement without cause prior to the Schwarzer Scheduled Completion Date, any outstanding equity award held by Mr. Schwarzer will vest as to the portion of those equity awards that were otherwise scheduled to vest through the Schwarzer Scheduled Completion Date, subject to the terms and conditions of the Plan.

The foregoing summary and description of the Schwarzer Consulting Agreement does not purport to be complete and is qualified in its entirety by reference to, and should be read in conjunction with, the full text of the Schwarzer Consulting Agreement, which will be filed as an exhibit to the Company’s next quarterly report on Form 10-Q.

Announcement of New Chief Executive Officer and Director

Mary Beth Harler, M.D. has been appointed as the Company’s Chief Executive Officer, effective as of the Effective Date, and as a member of the Board (initial term ending at the annual stockholder meeting in 2025), effective as of October 1, 2024.

Dr. Harler, who is 59, joined the Company in October 2021 and previously served as the Company’s Head, Research & Autoimmunity. Before joining the Company, Dr. Harler held various roles at Bristol-Myers Squibb from 2010 to 2021, including

Senior Vice President, Head of Immunology and Fibrosis Development from November 2019 to October 2021, as well as Head of Innovative Medicines Development from December 2017 to November 2019 and Head of Innovative Clinical Development in the cardiovascular, fibrosis, immunoscience and genetically-defined diseases group from October 2016 to November 2019. During her time at Bristol-Myers Squibb she oversaw development of multiple assets across a range of diseases including psoriasis (Sotyktu), inflammatory bowel disease, and lupus. She also oversaw development activities for approved medicines within the immunology portfolio, including Orencia, Nulojix, and Zeposia. Prior to joining Bristol-Myers Squibb, Dr. Harler worked in both medical affairs and clinical research at Wyeth Pharmaceuticals (now part of Pfizer). Dr. Harler received a B.S. from Wheeling University and an M.D. from Marshall University. She completed training as a general surgeon at Brown University's Rhode Island Hospital, where she was also a research fellow with a focus on the role of immune cells in wound healing.

There are no arrangements or understandings between Dr. Harler and any other persons pursuant to which she was appointed Chief Executive Officer and director. There are no family relationships between Dr. Harler and any director or executive officer of the Company, and Dr. Harler does not have any direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

Employment Agreement with Dr. Harler

In connection with the appointment of Dr. Harler as the Company's Chief Executive Officer, Dr. Harler entered into an employment agreement with the Company on the Effective Date (the "Harler Employment Agreement"). The Harler Employment Agreement provides the following compensation and other benefits:

- *Base Salary* – Dr. Harler will have an annual base salary of \$640,000.
- *Annual Bonus* – Dr. Harler is eligible to receive a target bonus of 55% of her base salary that is subject to performance and other criteria established by the Board or its Compensation Committee and is subject to continued employment through the date such annual bonus is paid. The annual bonus opportunity for 2024 is pro-rated based on the Effective Date.
- *Equity Awards* – Dr. Harler will be eligible to receive (a) a stock option ("Option") award to purchase 370,000 shares of the Company's common stock at an exercise price equal to the closing price per share on the date of grant and (b) a restricted stock unit ("RSU") award with respect to 185,000 shares of common stock. The shares subject to the Option will vest in equal monthly installments over the course of 48 months following the Effective Date. One third of the shares subject to the RSU shall vest on November 12, 2026, with the remaining shares vesting on a quarterly basis thereafter over the course of 8 quarters following such date.
- *Severance* – Dr. Harler is eligible to participate in the Company's Executive Change in Control and Severance Plan with benefits including payments of one times her salary in the event of certain terminations outside a change of control and one and a half times her salary, one and a half times her target bonus, 18 months of COBRA payments and up to full acceleration of her unvested equity in certain circumstances in connection with a change of control.

The foregoing summary and description of the Harler Employment Agreement does not purport to be complete and is qualified in its entirety by reference to, and should be read in conjunction with, the full text of the Harler Employment Agreement, which will be filed as an exhibit to the Company's next quarterly report on Form 10-Q.

Resignation of Chief Scientific Officer

In connection with the Strategic Pivot, Bruce Keyt, Ph.D., resigned as the Chief Scientific Officer of the Company, effective as of October 1, 2024. In connection with Dr. Keyt's resignation, the Company and Dr. Keyt entered into a transition and consulting agreement on October 1, 2024 (the "Keyt Start Date" and, such agreement, the "Keyt Consulting Agreement"). Among other things, the Keyt Consulting Agreement provides that:

- As of the Keyt Start Date, Dr. Keyt will transition to a consulting role and provide consulting services to the Company through the 18-month anniversary of the Keyt Start Date (the "Keyt Scheduled Completion Date," the actual final day of such consultancy, the "Keyt Completion Date," and the period from the Keyt Start Date through the Keyt Completion Date, the "Keyt Consulting Period").
- Through the Keyt Scheduled Completion Date, Dr. Keyt will be paid \$21,326 for each one-month period in which he is available to provide consulting services, and he will also be paid \$5,500 per month for 18 months to facilitate health care continuation coverage; provided that all such cash payments will cease if the Company terminates the Keyt Consulting Agreement for cause.

- Each of Dr. Keyt’s outstanding equity awards that would have been eligible to vest based on service during the Keyt Consulting Period will continue to vest during the Keyt Consulting Period, subject to the terms and conditions of the Plan under which the award was granted and the applicable award agreement thereunder. On the Keyt Start Date, the portion of each such outstanding equity award that would not have been eligible to vest based on service during the Keyt Consulting Period was irrevocably forfeited.
- Dr. Keyt and the Company have agreed to mutual releases of claims.

In addition, pursuant to the Keyt Consulting Agreement, if the Company terminates the Keyt Consulting Agreement without cause prior to the Keyt Scheduled Completion Date, any outstanding equity award held by Dr. Keyt will vest as to the portion of those equity awards that were otherwise scheduled to vest through the Keyt Scheduled Completion Date, subject to the terms and conditions of the Plan.

The foregoing summary and description of the Keyt Consulting Agreement does not purport to be complete and is qualified in its entirety by reference to, and should be read in conjunction with, the full text of the Keyt Consulting Agreement, which will be filed as an exhibit to the Company’s next quarterly report on Form 10-Q.

Resignation of Chief Medical Officer

On September 27, 2024, Chris H. Takimoto, M.D., Ph.D., F.A.C.P. notified the Company that he will resign as the Chief Medical Officer of the Company, effective October 1, 2024.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements. Such forward-looking statements are not based on historical fact and include, but are not limited to, statements about the nature, timing and scope of the Strategic Pivot, including the expected benefits of the Strategic Pivot, expectations regarding the estimation of the charges and costs of the Strategic Pivot, the expected completion of the Strategic Pivot activities and expectations regarding projected cash runway. 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: the Company’s early stages of clinical drug development; risks related to the use of engineered IgM antibodies, which is a novel and unproven therapeutic approach; the Company’s ability to demonstrate the safety and efficacy of its product candidates; the Company’s ability to successfully and timely advance its product candidates through clinical trials; the Company’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; the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of collaborations with third parties; the Company’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 the Company’s product candidates, and the progress and success of alternative therapeutics currently available or in development; the Company’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 the Company is targeting; the Company’s ability to obtain, maintain and protect its intellectual property rights; developments relating to the Company’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 the Company’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 the Company’s filings with the Securities and Exchange Commission (SEC), including in the Company’s Annual Report on Form 10-K filed with the SEC on March 7, 2024, the Company’s Quarterly Report on Form 10-Q filed with the SEC on August 14, 2024, and any future reports the Company files with the SEC. Any forward-looking statements contained in this Current Report on Form 8-K speak only as of the date hereof, and the Company specifically disclaims any obligation to update any forward-looking statement, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of IGM Biosciences, Inc., dated September 30, 2024
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.

Date: October 3, 2024

By: /s/ Misbah Tahir
Misbah Tahir
Chief Financial Officer



IGM Biosciences Announces Strategic Pivot to Focus Exclusively on Autoimmunity

September 30, 2024

– Company to prioritize its pipeline of T cell engagers in autoimmune diseases, including ongoing clinical development of imvotamab in rheumatoid arthritis and systemic lupus erythematosus –

– Mary Beth Harler, M.D., appointed as Chief Executive Officer and to Board of Directors –

– Cash runway extended into 2027 –

– Company to hold conference call and webcast today at 4:30 p.m. EDT –

MOUNTAIN VIEW, Calif., Sept. 30, 2024 (GLOBE NEWSWIRE) — IGM Biosciences, Inc. (Nasdaq: IGMS), a clinical-stage biotechnology company creating and developing engineered IgM antibodies, today announced a strategic pivot and pipeline transformation to accelerate and deepen its leadership in the development of T cell engaging IgM antibodies for the treatment of autoimmune diseases. The Company's lead candidates include imvotamab, a CD20 x CD3 bispecific T cell engager being developed in rheumatoid arthritis, systemic lupus erythematosus and myositis, and IGM-2644, a CD38 x CD3 bispecific T cell engager, which is expected to enter into a clinical study for generalized myasthenia gravis by the end of 2024.

IGM also announced today that Mary Beth Harler, M.D., an industry veteran with extensive experience in delivering innovative new therapies in autoimmunity, has been appointed as Chief Executive Officer and to the Board of Directors.

Dr. Harler joined IGM in 2021 as President, Autoimmunity and Inflammation following an 11-year career at Bristol Myers Squibb. At Bristol Myers Squibb, Dr. Harler served as Senior Vice President, Head of Immunology and Fibrosis Development, where she successfully led a team of global professionals and oversaw late-stage development of innovative therapies such as SOTYKTU®, ORENCIA® and ZEPOSIA®. Dr. Harler trained as a general surgeon at Brown University's Rhode Island Hospital.

"Mary Beth's experience over the last three years leading our autoimmune research efforts, together with her extensive prior clinical development experience, make her ideally suited to lead IGM as we shift our focus to the development of T cell engagers for autoimmunity and extend the Company's cash runway into 2027," said Felix J Baker, Ph.D., director at IGM Biosciences. "We are excited by Mary Beth's vision and passion to bring forward a new treatment modality to patients suffering from autoimmune diseases and believe she will be a strong leader for IGM."

"Our early pivot to using T cell engagers in autoimmune disease has enabled significant progress on these programs at IGM, and I am excited to lead the Company at this transformational stage," said Dr. Harler. "We've made great progress in our clinical development of imvotamab in autoimmune indications and we believe the clinical, and ultimately commercial, potential of our pipeline of T cell engaging antibodies in treating autoimmune diseases is significant. As we have previously guided, we look forward to sharing initial clinical data from the imvotamab studies later this year or in early 2025."

Pipeline Updates

Aplitabart (death receptor 5 agonist)

- **IGM to minimize future spending on aplitabart and other oncology candidates.** In light of the emerging data from the Company's ongoing randomized clinical trial of aplitabart in second-line metastatic colorectal cancer, together with the significant opportunity in autoimmunity, the Company has decided to immediately begin taking steps, including a reduction in force, to minimize its future spending on the research and clinical development of aplitabart and other oncology candidates. Final data from the randomized clinical trial of aplitabart in second-line metastatic colorectal cancer will be shared in an appropriate forum in the future. As a result of these actions, IGM believes it can extend its current cash runway into 2027.

Corporate Updates

- As part of the Company's strategic pivot to autoimmunity, Fred Schwarzer, Chief Executive Officer, President and Director, and Bruce Keyt, Ph.D., Chief Scientific Officer, will step down from their current roles at the Company. Both Mr. Schwarzer and Dr. Keyt are expected to remain as consultants.
- Chris Takimoto, M.D., Ph.D., F.A.C.P., Chief Medical Officer, is stepping down from his current role to pursue an opportunity outside the Company.

"We deeply thank Fred and Bruce for their vision and leadership of IGM, for their many significant contributions to developing the field of IgM antibodies, and for expanding our understanding of their full clinical potential," said Christina Topsøe, director at IGM Biosciences. "We also want to sincerely thank Chris for his leadership of the clinical development organization as it expanded beyond oncology. We wish each of them the best in their future endeavors."

Conference Call and Webcast

The Company will host a conference call and live webcast to provide an update on its strategic pivot to focus exclusively on the development of T cell engagers for autoimmunity at 4:30 p.m. EDT today, September 30, 2024. To access the call, please dial (646) 357-8785 (U.S. and Canada) or (800)836-8184 (international) at least 10 minutes prior to the start time and asked to be joined to the IGM Biosciences call. A live webcast will be available on the “Events and Presentations” page in the “Investors” section of the Company’s website. A replay of the webcast will be archived on the Company’s website for 90 days following the presentation.

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 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 the timing of clinical study initiation and clinical data; IGM’s expectations regarding its financial position and projected cash runway; statements by Dr. Baker, Dr. Harler and Ms. Topsøe; and expectations that Mr. Schwarzer and Dr. Keyt will remain as consultants. 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; 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 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 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.

Contact:

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Source: IGM Biosciences, Inc.