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 25, 2026

Zymeworks Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-41535**	**88-3099146**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

108 Patriot Drive, Suite A, Middletown, Delaware	**19709**
(Address of principal executive offices)	**(Zip Code)**

(302) 274-8744
(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:

☐ 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, $0.00001 par value per share	ZYME	The Nasdaq Stock Market LLC

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 7.01 REGULATION FD DISCLOSURES

On August 25, 2026, Zymeworks Inc. ("Company") issued a press release announcing that its partner, Jazz Pharmaceuticals, has received U.S. Food and Drug Administration ("FDA") approval for two Ziihera® (zanidatamab-hrii)-containing regimens for the first-line treatment of adults with unresectable locally advanced or metastatic HER2-positive (HER2+) gastroesophageal adenocarcinoma ("GEA"): Ziihera plus Tevimbra® (tislelizumab-jsgr) and fluoropyrimidine- and platinum-containing chemotherapy (HER2+ IHC 3+ and IHC 2+/ISH+), and Ziihera plus fluoropyrimidine- and platinum-containing chemotherapy (HER2+ IHC 3+). A copy of this press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information provided under this Item 7.01 (including Exhibit 99.1 attached hereto) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

ITEM 8.01 REGULATION FD DISCLOSURES

Zymeworks BC Inc. ("Zymeworks"), a subsidiary of the Company, is a party to an Amended and Restated License and Collaboration Agreement (as amended, the "License and Collaboration Agreement") with Jazz Pharmaceuticals Ireland Limited, a subsidiary of Jazz Pharmaceuticals plc, collectively referred to as "Jazz," granting Jazz exclusive rights to develop and commercialize Zymeworks' proprietary bispecific HER2 antibody product candidate known as zanidatamab throughout the world, but excluding certain territories already covered by Zymeworks' agreement with BeOne Medicines Ltd.

As announced on August 25, 2026, Zymeworks' partner, Jazz, has received FDA approval for two Ziihera® (zanidatamab-hrii)-containing regimens for the first-line treatment of adults with unresectable locally advanced or metastatic HER2-positive (HER2+) GEA: Ziihera plus Tevimbra® (tislelizumab-jsgr) and fluoropyrimidine- and platinum-containing chemotherapy (HER2+ IHC 3+ and IHC 2+/ISH+), and Ziihera plus fluoropyrimidine- and platinum-containing chemotherapy (HER2+ IHC 3+).

Pursuant to the terms of the License and Collaboration Agreement, Zymeworks has earned a milestone payment of $250 million based on the FDA approval in GEA. Zymeworks remains eligible to receive up to $1.3 billion in additional regulatory and commercial milestones, as well as tiered royalties of 10% to 20% on Jazz's net sales of zanidatamab in Jazz's licensed territories.

For additional information regarding the License and Collaboration Agreement, please refer to the Company's Current Reports on Form 8-K, filed with the U.S. Securities and Exchange Commission on October 19, 2022 and on May 16, 2023.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated August 25, 2026
104	Cover Page Interactive Data File (embedded as Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ZYMEWORKS INC.
(Registrant)

Date: August 25, 2026

By: /s/ Kenneth Galbraith

Name: Kenneth Galbraith

Title: Chair, President and Chief Executive Officer

U.S. FDA Approves Ziihera® (zanidatamab-hrii) with and without Tislelizumab plus Chemotherapy in First-Line HER2+ Advanced Gastroesophageal Adenocarcinoma

- *Ziihera plus tislelizumab and chemotherapy approved for first-line treatment of all HER2+ GEA patients (IHC 3+ and IHC 2+/ISH+) regardless of PD-L1 status, providing a new treatment option in front-line GEA*
- *Second FDA approval for zanidatamab in less than two years further validates Zymeworks' proprietary Azymetric™ bispecific antibody platform and internal discovery engine*
- *FDA approval triggers a $250 million milestone payment from Jazz Pharmaceuticals, with Zymeworks remaining eligible for up to $1.3 billion in additional milestones plus tiered royalties of up to 20.0% on net sales*
- *Through its Asia Pacific collaboration with BeOne, Zymeworks remains eligible for up to $144 million in additional milestones plus tiered royalties of up to 19.5% on net sales*
- *Strengthens Zymeworks' diversified cash flow strategy while supporting advancement of its wholly owned pipeline of next-generation trispecific T-cell engagers and antibody-drug conjugates*

Vancouver, British Columbia (August 25, 2026) – Zymeworks Inc. (Nasdaq: ZYME), a biotechnology company managing a portfolio of licensed healthcare assets while developing a diverse pipeline of novel, multifunctional biotherapeutics, today announced that its partner, Jazz Pharmaceuticals, has received U.S. Food and Drug Administration (FDA) approval for two Ziihera® (zanidatamab-hrii)-containing regimens for the first-line treatment of adults with unresectable locally advanced or metastatic HER2-positive (HER2+) gastroesophageal adenocarcinoma (GEA): *Ziihera* plus Tevimbra® (tislelizumab-jsgr) and fluoropyrimidine- and platinum-containing chemotherapy (HER2+ IHC 3+ and IHC 2+/ISH+), and *Ziihera* plus fluoropyrimidine- and platinum-containing chemotherapy (HER2+ IHC 3+).

This is the second FDA approval for zanidatamab in less than two years, further validating Zymeworks' proprietary Azymetric™ platform and its ability to discover and develop differentiated multifunctional antibodies for patients with difficult-to-treat cancers. The FDA approval of zanidatamab in GEA following its accelerated approval in biliary tract cancer, and with additional clinical trials underway by Jazz Pharmaceuticals and BeOne Medicines across other tumor types, together underscores the potential of Zymeworks' partnered drug development and royalty strategy to expand the potential reach of this important medicine to more patients across multiple tumor types. Each additional indication has the potential to increase the clinical impact of zanidatamab, while creating incremental value through our royalty interest and commercial milestone payments. We believe this approach of supporting the development of innovative medicines while leveraging the resources and expertise of our partners, provides a capital-efficient pathway to participate in long-term patient benefit, and value creation for our shareholders.

“This second FDA approval for zanidatamab represents a significant milestone for Zymeworks and reinforces the strength of our scientific innovation engine,” said Kenneth Galbraith, Chair and Chief Executive Officer of Zymeworks. “Zanidatamab was discovered in our Vancouver laboratories using our proprietary Azymetric™ platform and advanced by our development team into late-stage development, and today’s approval demonstrates how our science can translate into meaningful new treatment options for patients around the world. We are grateful to all of the patients and clinical investigators, as well as our partners and others who made it possible for patients with HER2-positive GEA to have a new treatment option. Together with the significant milestone payments and long-term royalty streams associated with this approval, we are well positioned to continue building a more diversified and durable biotechnology company.”

The approval is supported by results from the Phase 3 HERIZON-GEA-01 trial, which demonstrated the benefit of zanidatamab in combination with immunotherapy and chemotherapy in the first-line treatment of HER2+ GEA. Results from the study were published in the *New England Journal of Medicine* and first presented at ASCO GI 2026. The trial remains ongoing, with additional analyses planned.

“This approval represents an important advancement for patients with metastatic HER2-positive gastroesophageal adenocarcinoma, a disease where there remains a significant need for effective treatment options. The median overall survival of more than two years observed with this regimen is encouraging and represents meaningful progress for patients and their families,” said Jaffer A. Ajani, M.D., Professor of Gastrointestinal Medical Oncology, The University of Texas MD Anderson Cancer Center. "Importantly, similar outcomes were observed regardless of PD-L1 status, suggesting that this regimen may provide a treatment option for a broad range of patients with HER2-positive disease.”

Zanidatamab was discovered and engineered by Zymeworks’ research team in Vancouver, Canada, using the Company’s proprietary Azymetric™ platform, which enables a single antibody to simultaneously bind two distinct epitopes on the same target protein. Zymeworks advanced the molecule from discovery through preclinical and clinical development under its own investigational new drug application before entering strategic licensing agreements with BeOne Medicines in 2018 and Jazz Pharmaceuticals in 2022, enabling global development and commercialization across complementary territories.

“Patients with this disease have had far too few options that could truly change the course of their illness, and that reality is what drove our team to engineer and develop zanidatamab. Seeing it now become a treatment option for people with HER2-positive advanced gastroesophageal adenocarcinoma is exactly why we do this work – it’s a profound moment for our team, and most importantly, for the patients we set out to help,” said Dr. Nina Weisser, Ph.D., Executive Director of Multispecific Antibody Therapeutics at Zymeworks.

Under the terms of its collaboration with Jazz Pharmaceuticals, Zymeworks has earned a $250 million milestone payment upon this approval, bringing total upfront and milestone payments received from Jazz to $650 million. The Company remains eligible to receive up to $1.3 billion in additional regulatory and commercial milestones, as well as tiered royalties of 10% to 20% on Jazz’s net sales of zanidatamab in Jazz’s licensed territories. Separately, under its collaboration with BeOne Medicines, Zymeworks has received $81 million in upfront and milestone payments to date and remains eligible for up to $144 million in additional milestones, plus tiered royalties of up to 19.5% on net sales in BeOne’s licensed territories. Together, these collaborations provide significant non-dilutive capital and long-term royalty potential, supporting Zymeworks’ disciplined capital allocation strategy, including investment in its

wholly-owned R&D pipeline, strategic business development opportunities, and return of capital to shareholders.

Beyond zanidatamab, Zymeworks is advancing a growing portfolio of wholly-owned programs, including novel trispecific T-cell engagers and antibody-drug conjugates designed to address significant unmet medical needs.

About Gastroesophageal Adenocarcinoma

GEA, including cancers of the stomach, gastroesophageal junction, and esophagus, is the fifth most common cancer worldwide, and approximately 20% of patients have HER2+ disease.[1,2,3,4] In the United States, more than 31,000 new stomach cancer cases are diagnosed each year.[5] HER2+ GEA has high morbidity and mortality, and patients are urgently in need of new treatment options. The overall prognosis for patients with GEA remains poor, with a global five-year survival rate of less than 10% for patients with metastatic disease.[6]

About Ziihera® (zanidatamab-hrii)

Ziihera (zanidatamab-hrii) is a bispecific HER2-directed antibody that binds to two extracellular sites on HER2. Binding of zanidatamab with HER2 results in internalization leading to a reduction in HER2 expression of the receptor on the tumor cell surface. Zanidatamab induces CDC, ADCC, and ADCP. These mechanisms result in tumor growth inhibition and cell death in vitro and in vivo.[7]

In the United States, *Ziihera* is indicated for adults with HER2-positive locally advanced or metastatic gastroesophageal adenocarcinoma (GEA), including cancers of the stomach, gastroesophageal junction and esophagus, in combination with tislelizumab-jsgr and fluoropyrimidine- and platinum-containing chemotherapy (HER2+ IHC3+ and IHC2+/ISH+ as detected by an FDA-authorized test); and in combination with fluoropyrimidine- and platinum-containing chemotherapy (HER2+ IHC 3+ as detected by an FDA-authorized test).

Ziihera is also indicated for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer (BTC), as detected by an FDA-approved test[7]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).[7]

Zanidatamab is being developed in multiple clinical trials as a targeted treatment option for patients with solid tumors that express HER2. Zanidatamab is being developed by Jazz and BeOne under license agreements from Zymeworks, which first developed the molecule.
The FDA granted three Breakthrough Therapy designations for zanidatamab's development: one as a single agent for previously treated HER2 gene-amplified BTC, one in combination with fluoropyrimidine- and platinum-containing chemotherapy, with or without tislelizumab for first-line HER2+ unresectable locally advanced or metastatic gastric, gastroesophageal junction (GEJ), or esophageal GEA, and one for the treatment of adults with previously treated, locally advanced, unresectable, or metastatic HER2+ colorectal cancer (CRC). The FDA also granted two Fast Track designations for zanidatamab: one as a single agent for refractory BTC and one in combination with standard-of-care chemotherapy for first-line GEA. Additionally, zanidatamab has received Orphan Drug designations from the FDA for the treatment of BTC, gastric (including GEJ) cancer, and esophageal cancer, as well as Orphan Drug designations from the European Medicines Agency for the treatment of

BTC, gastric/gastroesophageal junction cancer, and esophageal cancer. Jazz continues to pursue additional regulatory approvals for zanidatamab in markets worldwide.

More information about Ziihera, the Full Prescribing Information, including Boxed Warning and Patient Information, is available here: https://pp.jazzpharma.com/pi/ziihera.en.USPI.pdf

About Zymeworks Inc.
Zymeworks is a global biotechnology company managing a portfolio of licensed healthcare assets and developing a diverse pipeline of novel, multifunctional biotherapeutics to improve the standard of care for difficult-to-treat diseases, including cancer, inflammation, and autoimmune disease. Zymeworks' asset and royalty aggregation strategy focuses on optimizing positive future cash flows from an emerging portfolio of licensed products such as Ziihera® (zanidatamab-hrii) and other licensed products and product candidates, such as pasritamig. In addition, Zymeworks is building a portfolio of healthcare assets that can generate strong cash flows, while supporting the development of innovative medicines. Zymeworks engineered and developed Ziihera, a HER2-targeted bispecific antibody using Zymeworks' proprietary Azymetric™ technology and has entered into separate agreements with BeOne Medicines Ltd. (formerly BeiGene, Ltd.) and Jazz Pharmaceuticals Ireland Limited granting each exclusive rights to develop and commercialize zanidatamab in different territories. Zymeworks is rapidly advancing a robust pipeline of product candidates, leveraging its expertise in both antibody drug conjugates and multispecific antibody therapeutics targeting novel pathways in areas of significant unmet medical need. Zymeworks' complementary therapeutic platforms and fully integrated drug development engine provide the flexibility and compatibility to precisely engineer and develop highly differentiated antibody-based therapeutics. These capabilities have been further leveraged through strategic partnerships with global biopharmaceutical companies. For information about Zymeworks, visit www.zymeworks.com and follow @ZymeworksInc on X.

Cautionary Note Regarding Forward-Looking Statements

This press release includes "forward-looking statements" or information within the meaning of the applicable securities legislation, including Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements in this press release include, but are not limited to, statements that relate to the conduct of an ongoing HERIZON-GEA-301 Phase 3 confirmatory trial to evaluate the efficacy and safety of zanidatamab and support global registration; ongoing clinical studies and regulatory reviews; the anticipated benefits of the collaboration agreements with Jazz and BeiGene, including Zymeworks' ability to receive any future milestone payments and royalties thereunder; the potential addressable market of zanidatamab; the timing of and results of interactions with regulators; Zymeworks' clinical development of its product candidates and enrollment in its clinical trials; the timing and status of ongoing and future studies and the related data; expectations regarding future regulatory filings and approvals and the timing thereof; potential safety profile and therapeutic effects of zanidatamab and Zymeworks' other product candidates; the commercial potential of technology platforms and product candidates; Zymeworks' ability to satisfy potential regulatory and commercial milestones with existing and future partners; anticipated continued receipt of revenue from existing and future partners; Zymeworks' ability to execute new collaborations and partnerships and other information that is not historical information. When used herein, words such as "plan", "believe", "expect", "may", "anticipate", "potential", "will", "continues", and similar expressions are intended to identify forward-looking statements. In addition, any statements or information that refer to expectations, beliefs, plans, projections, objectives, performance or other characterizations of future

events or circumstances, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon Zymeworks' current expectations and various assumptions. Zymeworks believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. Zymeworks may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various factors, including, without limitation: any of Zymeworks' or its partners' product candidates may fail in development, may not receive required regulatory approvals, or may be delayed to a point where they are not commercially viable; Zymeworks may not achieve milestones or receive additional payments under its collaborations; regulatory agencies may impose additional requirements or delay the initiation of clinical trials; the impact of new or changing laws and regulations; market conditions; the impact of pandemics and other health crises on Zymeworks' business, research and clinical development plans and timelines and results of operations, including impact on its clinical trial sites, collaborators, and contractors who act for or on Zymeworks' behalf; zanidatamab may not be successfully commercialized; clinical trials and any future clinical trials may not demonstrate safety and efficacy of any of Zymeworks' or its collaborators' product candidates; Zymeworks' assumptions and estimates regarding its financial condition, future financial performance and estimated cash runway may be incorrect; and Zymeworks may be unable to maintain or enter into new partnerships or strategic collaborations.

Although Zymeworks believes that such forward-looking statements are reasonable, there can be no assurance they will prove to be correct. Investors should not place undue reliance on forward-looking statements. The above assumptions, risks and uncertainties are not exhaustive. Forward-looking statements are made as of the date hereof and, except as may be required by law, Zymeworks undertakes no obligation to update, republish, or revise any forward-looking statements to reflect new information, future events or circumstances, or to reflect the occurrences of unanticipated events.

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[1]Bray F., et al. Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA: A Cancer Journal for Clinicians. 2024 April; doi.org/10.3322/caac.21834Digital Object Identifier (DOI)

[2]Abrahao-Machado I.F., et al. HER2 testing in gastric cancer: An update WorldJGastroenterol. 2016;22(19):4619-4625.
[3]Van Custem E., et al. HER2 screening data from ToGA: targeting HER2 in gastric and gastroesophageal junction cancer. Gastric Cancer. 2015;18(3):476-484.
[4]Stroes, C.I., et al. A systematic review of HER2 blockade for the curative treatment of gastroesophageal adenocarcinoma: Successes achieved and opportunities ahead. CancerTreatRev. 2021;99:102249.
[5]American Cancer Society. Key Statistics About Stomach Cancer. American Cancer Society. Updated: February 27, 2026. https://www.cancer.org/cancer/types/stomach-cancer/key-statistics.html
[6]Tabernero J., et al. HERIZON-GEA-01: Zanidatamab + chemo ± tislelizumab for 1L treatment of HER2-positive gastroesophageal adenocarcinoma. Taylor & Francis. 2022 July; doi.org/10.2217/fon-2022-0595
[7]ZIIHERA (zanidatamab-hrii) Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.).