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 12, 2021

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

British Columbia, Canada	**001-38068**	**98-1398788**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

Suite 540, 1385 West 8th Avenue, Vancouver, British Columbia, Canada	**V6H 3V9**
(Address of principal executive offices)	**(Zip Code)**

(604) 678-1388
(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 Shares, no par value per share	**ZYME**	**New York Stock Exchange**

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 DISCLOSURE

On September 12, 2021, Zymeworks Inc. ("Zymeworks") issued a press release announcing the publication of an abstract highlighting new clinical data for zanidatamab, a HER2-targeted bispecific antibody, in first-line HER2-expressing GEA. An updated and expanded data set will be presented at the ESMO Annual Congress taking place virtually on September 16-21, 2021.

On September 13, 2021, Zymeworks filed this press release with the Canadian securities regulatory authorities in Canada on the System for Electronic Document Analysis and Retrieval ("SEDAR") at www.sedar.com. A copy of this press release is attached as Exhibit 99.1 hereto.

The information provided under this Item (including Exhibit 99.1, attached hereto) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (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 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated September 12, 2021.
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: September 13, 2021

By: /s/ Neil A. Klompas
Name: Neil A. Klompas
Title: Executive Vice President, Business Operations and Chief Financial Officer

Exhibit 99.1

Zymeworks Announces Abstract for Zanidatamab in First-line HER2-Expressing Gastroesophageal Cancers (GEA) at the European Society for Medical Oncology (ESMO) Annual Congress

- *Abstract data demonstrate encouraging antitumor activity in first-line GEA*
- *Full ESMO presentation available September 16 at 8:30 am CEST, 2:30 am ET*
- *Conference call and webcast with principal investigator, Dr. Geoffrey Ku, on September 16 at 7:30 am ET*

Vancouver, British Columbia (September 12, 2021) – Zymeworks Inc. (NYSE: ZYME), a clinical-stage biopharmaceutical company developing multifunctional biotherapeutics, today announced the publication of an abstract highlighting new clinical data for zanidatamab, a HER2-targeted bispecific antibody, in first-line HER2-expressing GEA. An updated and expanded data set will be presented at the ESMO Annual Congress taking place virtually on September 16-21, 2021.

Abstract highlights from March 18, 2021 data cut:

- Thirty patients had been treated with zanidatamab in combination with standard of care chemotherapy (either mFOLFOX6, CAPOX, or FP), and 14 patients remained on treatment.
- The confirmed objective response rate was 68.2% and the disease control rate was 90.9% in 22 HER2-positive response-evaluable patients.
- Treatment related adverse events were generally consistent with previous reports of zanidatamab and/or the chemotherapy regimens, with the majority reported as Grade 1 or 2 in severity.

“The initial data from the abstract highlight an encouraging objective response rate for zanidatamab combined with standard of care chemotherapy in patients with metastatic HER2-positive GEA,” said Neil Josephson, M.D., Zymeworks’ Interim Chief Medical Officer. “We’re looking forward to presenting at the Congress the full updated data, which further support zanidatamab’s potential as the new foundational HER2-targeted therapy.”

ESMO Presentation

The abstract is available on the ESMO conference website. The presentation will be available on Thursday, September 16 at 8:30 am CEST, 2:30 am ET, to conference registrants on the ESMO conference website as well as to the general public on the Zymeworks website at https://ir.zymeworks.com/events-and-presentations.

Title: *Phase (Ph) 2 Study of Zanidatamab + Chemotherapy (chemo) in First Line (1L) HER2-expressing Gastroesophageal Adenocarcinoma (GEA)*
Lead Author: Geoffrey Ku, M.D., Memorial Sloan Kettering Cancer Center, New York, NY, US
Abstract: 3678
E-poster: 1380P

Conference Call and Webcast

The company will host a conference call and webcast to discuss the updated data after it is published on September 16. The event will be led by Ali Tehrani, Ph.D., Zymeworks' President and CEO and Neil Josephson, M.D., Zymeworks' Interim Chief Medical Officer, and will include a presentation by medical oncologist and principal investigator, Geoffrey Ku, M.D., Memorial Sloan Kettering Cancer Center. Dr. Ku and members of Zymeworks' executive team will be available to answer questions at the conclusion of the call.

Date: Thursday, September 16th
Time: 7:30 am ET

Interested parties can access the live webcast via the Zymeworks' website at https://ir.zymeworks.com/events-and-presentations. A recorded replay will be accessible after the event through the Zymeworks website.

About Zanidatamab

Zanidatamab is a bispecific antibody, based on Zymeworks' Azymetric™ platform, that can simultaneously bind two non-overlapping epitopes of HER2, known as biparatopic binding. This unique design results in multiple mechanisms of action including dual HER2 signal blockade, increased binding and removal of HER2 protein from the cell surface, and potent effector function leading to encouraging antitumor activity in patients. Zymeworks is developing zanidatamab in multiple Phase 1, Phase 2, and pivotal clinical trials globally as a targeted treatment option for patients with solid tumors that express HER2. The FDA has granted Breakthrough Therapy designation for zanidatamab in patients with previously treated HER2 gene-amplified biliary tract cancer (BTC), and two Fast Track designations to zanidatamab, one as a single agent for refractory BTC and one in combination with standard of care chemotherapy for first-line gastroesophageal adenocarcinoma (GEA). These designations mean zanidatamab is eligible for Accelerated Approval, Priority Review and Rolling Review, as well as intensive FDA guidance on an efficient drug development program. Zanidatamab has also received Orphan Drug designations for the treatment of biliary tract, gastric and ovarian cancers from the FDA, as well as Orphan Drug designation for the treatment of biliary tract and gastric cancer from the European Medicines Agency.

About Zymeworks Inc.

Zymeworks is a clinical-stage biopharmaceutical company dedicated to the development of next-generation multifunctional biotherapeutics. Zymeworks' suite of therapeutic platforms and its fully integrated drug development engine enable precise engineering of highly differentiated product candidates. Zymeworks' lead clinical candidate, zanidatamab (ZW25), is a novel Azymetric™ bispecific antibody which has been granted Breakthrough Therapy designation by the FDA and is currently enrolling in a pivotal clinical trial for refractory HER2-amplified biliary tract cancer (HERIZON-BTC-01) as well as several Phase 2 clinical trials for HER2-expressing gastroesophageal, colorectal, and breast cancers. Zymeworks' second clinical candidate, ZW49, is a novel bispecific HER2-targeting antibody-drug conjugate currently in Phase 1 clinical development and combines the unique design and antibody framework of zanidatamab with Zymeworks' proprietary ZymeLink™ linker and cytotoxin. Zymeworks is also advancing a deep preclinical pipeline in oncology (including immuno-oncology agents) and other therapeutic areas. In addition, its therapeutic platforms are being leveraged through strategic partnerships with nine biopharmaceutical companies. For additional information about Zymeworks, visit www.zymeworks.com and follow @ZymeworksInc on Twitter.

Cautionary Note Regarding Forward-Looking Statements

This press release includes “forward-looking statements” within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and “forward-looking information” within the meaning of Canadian securities laws, or collectively, forward-looking statements. Forward-looking statements in this news release include, but are not limited to, statements that relate to Zymeworks’ clinical development of its product candidates, related clinical trials, anticipated clinical data presentations, potential therapeutic effects of zanidatamab, Zymeworks’ preclinical pipeline, and other information that is not historical information. When used herein, words such as “potential”, “will”, 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, market conditions and the factors described under “Risk Factors” in Zymeworks’ Quarterly Report on Form 10-Q for its quarter ended June 30, 2021 (a copy of which may be obtained at www.sec.gov and www.sedar.com). Consequently, forward-looking statements should be regarded solely as Zymeworks’ current plans, estimates and beliefs. Investors should not place undue reliance on forward-looking statements. Zymeworks cannot guarantee future results, events, levels of activity, performance or achievements. Zymeworks does not undertake and specifically declines any 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, except as may be required by law.

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