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, 2022

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 800, 114 East 4th Avenue, Vancouver, British Columbia, Canada	**V5T 1G4**
(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, 2022, Zymeworks Inc. ("Zymeworks") issued a press release announcing that it presented preliminary results from Zymeworks' Phase 1 clinical trial evaluating zanidatamab zovodotin (ZW49) for the treatment of HER2-positive tumors.

On September 12, 2022, Zymeworks filed this press release with the Canadian securities regulatory authorities on the System for Electronic Document Analysis and Retrieval at www.sedar.com.

A copy of this press release is attached as Exhibit 99.1 hereto.

The information under this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto are being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall such information be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, regardless of the general incorporation language of such filing, except as shall be expressly set forth by specific reference in such filing.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated September 12, 2022.
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 12, 2022

By: /s/ Neil A. Klompas
Name: Neil A. Klompas
Title: President and Chief Operating Officer

Exhibit 99.1

Zymeworks Reports Preliminary Phase 1 Trial Results for Zanidatamab Zovodotin (ZW49) at European Society for Medical Oncology Annual Congress

• Company to hold conference call and webcast on Monday, September 12th at 4:30 PM Eastern Standard Time (EST)

VANCOUVER, British Columbia & SEATTLE - SEPTEMBER 12, 2022—Zymeworks Inc. (NYSE: ZYME), a clinical-stage biopharmaceutical company developing multifunctional biotherapeutics, today presented preliminary results from the company's Phase 1 clinical trial evaluating zanidatamab zovodotin (ZW49) for the treatment of HER2-positive tumors. The presentation, entitled "*Preliminary Results From a Phase 1 Study Using the Bispecific, Human Epidermal Growth Factor 2 (HER2)-targeting Antibody-drug Conjugate (ADC) zanidatamab zovodotin (ZW49) in Solid Cancers"*, was presented by Komal Jhaveri, MD, FACP, medical oncologist, Memorial Sloan Kettering Cancer Center in NYC, in a mini-oral presentation today during the European Society for Medical Oncology Annual Congress at the Paris Expo Porte de Versailles in Paris, France.

A total of 77 patients were enrolled in this first-in-human trial, which was designed to determine the maximum tolerated dose of zanidatamab zovodotin, characterize its safety and tolerability, and evaluate anti-tumor activity in HER2-expressing cancers as monotherapy. The patients represented a variety of HER2-expressing cancers including breast, gastroesophageal, ovarian, endometrial, bladder, biliary tract, anal, colorectal, pancreatic and lung. At the time of the analysis, the maximum tolerated dose had not yet been reached.

Commenting on the data, Dr. Jhaveri noted, "The preliminary results of this trial are very encouraging. Zanidatamab zovodotin dosed on an every three week (Q3W) schedule is active and has a manageable safety profile. I am excited to see further clinical development of zanidatmab zovodotin across a variety of HER2-expressing cancers."

In the trial, zanidatamab zovodotin was shown to have a manageable safety profile with the majority of adverse events being Grade 1 or 2 in severity. In patients with HER2-positive cancers treated with zanidatamab zovodotin at 2.5 mg/kg Q3W (dose escalation + dose expansion), the confirmed objective response rate was 31% and the disease control rate was 72%. The Phase 1 clinical trial is ongoing and continues to enroll patients to study safety, tolerability and activity for an alternate qW dosing regimen. The Company expects to present results of this dosing regimen at a medical meeting in 2023.

"We are grateful to the patients who participated in this trial and appreciate the collaborative efforts and dedication of the outstanding group of clinical investigators who are participating in this Phase 1 study," said Neil Josephson, MD, Chief Medical Officer of Zymeworks. "These promising results provide significant momentum for the further clinical development of zanidatamab zovodotin, as a monotherapy, and in combination with standard of care agents, for the treatment of cancers expressing HER2 or harboring HER2 gene alterations."

Conference Call

Dr. Jhaveri's complete presentation at the ESMO 2022 Congress is available for review on Zymeworks' website. Zymeworks will hold a conference call to discuss Dr. Jhaveri's presentation and future clinical development plans for zanidatamab zovodotin on Monday, September 12th at 4:30 pm EST. Interested parties can access the live webcast via Zymeworks' website at https://ir.zymeworks.com/events-and-presentations. A recorded replay will be accessible after the event through the Zymeworks website.

Disclosure: Dr. Jhaveri has a consulting relationship with Zymeworks.

About Zymeworks Inc.

Zymeworks is a clinical-stage biopharmaceutical company dedicated to the discovery, development and commercialization 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, is a novel Azymetric™ HER2-targeted bispecific antibody currently being evaluated in multiple Phase 1, Phase 2, and pivotal clinical trials globally as a targeted treatment option for patients with solid tumors that express HER2. Zymeworks' second clinical candidate, zanidatamab zovodotin (ZW49), is a novel bispecific HER2 -targeted 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 global biopharmaceutical companies. For more information on our ongoing clinical trials visit www.zymeworksclinicaltrials.com. 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 press release include, but are not limited to, statements that relate to the potential therapeutic effects of zanidatamab, zanidatamab zovodotin and Zymeworks' other product candidates; Zymeworks' clinical development of its product candidates and enrollment in its clinical trials; anticipated clinical data presentations; and other information that is not historical information. When used herein, words such as "will", "plans", "may", "potential", 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: the impact of the COVID-19 pandemic 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, may be more severe and more prolonged than currently anticipated; clinical trials may not demonstrate safety and efficacy of any of Zymeworks' or its collaborators' product candidates; 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; regulatory agencies may impose additional requirements or delay the initiation of clinical trials; the impact of new or changing laws and regulations; market conditions; inability to maintain or enter into new partnerships or strategic collaborations and the factors described under "Risk Factors" in Zymeworks' quarterly and annual reports filed with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for its quarter ended June 30, 2022 (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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