

**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): November 19, 2021

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

British Columbia, Canada
(State or other jurisdiction
of incorporation)

001-38068
(Commission
File Number)

98-1398788
(IRS Employer
Identification No.)

Suite 540, 1385 West 8th Avenue, Vancouver, British Columbia, Canada
(Address of principal executive offices)

V6H 3V9
(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 November 19, 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.

On November 19, 2021, Zymeworks filed this press release with the Canadian securities regulatory authorities 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated November 19, 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: November 19, 2021

By: /s/ Neil A. Klompas

Name: Neil A. Klompas

Title: Executive Vice President, Business
Operations and Chief Financial Officer



Zymeworks Announces Abstract for Zanidatamab in Late-Line HER2-Positive Breast Cancer at the San Antonio Breast Cancer Symposium (SABCS)

- Full presentation available December 8 at 5:00 pm Central Time (CT)

Vancouver, Canada (November 19, 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. Zanidatamab in combination with chemotherapy was well tolerated, with encouraging and durable antitumor activity in heavily pretreated patients with HER2-positive breast cancer. A poster with an updated and expanded data set will be presented at SABCS taking place in San Antonio, Texas and virtually on December 7-10, 2021. In addition, Zymeworks will present a *Trial in Progress* poster detailing the ongoing clinical trial evaluating zanidatamab in combination with the CD47-blocker, evorpacept (ALX148).

SABCS Data Presentation

Abstract highlights from May 3, 2021 data cut:

- Twenty heavily pretreated HER2-positive breast cancer patients had been treated with zanidatamab in combination with standard of care chemotherapy (either vinorelbine, capecitabine, or paclitaxel).
- The confirmed objective response rate was 37.5% and the disease control rate was 81.3% in 16 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 abstract is available on the SABCS conference website. The presentation will be available on Wednesday, December 8 at 5:00 pm CT to conference registrants on the SABCS conference website as well as to the general public on the [Zymeworks website](#).

Title: *Zanidatamab (ZW25), a HER2-targeted bispecific antibody, in combination with chemotherapy (chemo) for HER2-positive breast cancer (BC): Results from a phase 1 study* Lead Author: Philippe L. Bedard, M.D., Princess Margaret Cancer Center, Toronto, ON Canada Abstract: #93
Program Number: P2-13-07

Trials in Progress Presentation

The abstract is available on the SABCS conference website. The presentation will be available on Wednesday, December 8 at 5:00 pm CT to conference registrants on the SABCS conference website as well as to the general public on the [Zymeworks website](#).

Title: *Zanidatamab in combination with ALX148 in advanced Human Epidermal Growth Factor Receptor 2 (HER2)-expressing cancers, including breast cancer: a phase 1b/2, multicenter, open-label, dose-finding and cohort-expansion study (ZWI-ZW25-204)*

Lead Author: Sara A. Hurvitz, M.D., University of California, Los Angeles; Jonsson Comprehensive Cancer Center, Los Angeles, CA, US

Abstract: #182

Program Number: OT1-14-01

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. Zanidatamab's unique binding properties result in multiple mechanisms of action including HER2-receptor clustering, internalization, and downregulation; inhibition of growth factor- dependent and -independent tumor cell proliferation; antibody-dependent cellular cytotoxicity and phagocytosis; and complement-dependent cytotoxicity. 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 monotherapy 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 from the FDA as well as the European Medicines Agency for the treatment of biliary tract and gastric cancers.

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, is a novel Azymetric™ HER2-targeted bispecific antibody which is currently enrolling in two pivotal clinical trials, one for HER2-positive gastroesophageal adenocarcinoma (HERIZON-GEA-01) and one for refractory HER2-amplified biliary tract cancer (HERIZON-BTC-01) for which it has been granted Breakthrough Therapy designation by the FDA. Zanidatamab is also being evaluated in 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](https://twitter.com/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, potential therapeutic effects of zanidatamab, Zymeworks' preclinical pipeline, and other information that is not historical information. When used herein, words such as “will”, “developing”, “is eligible

for”, 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 factors described under “Risk Factors” in Zymeworks’ Quarterly Report on Form 10-Q for its quarter ended September 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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