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): October 5, 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 October 5, 2021, Zymeworks Inc. (“Zymeworks”) and ALX Oncology Inc. (“ALX”) issued a press release announcing the first patient has been dosed in an open-label, multi-center Phase 1b/2 clinical trial conducted by Zymeworks of zanidatamab (Zymeworks’ lead HER2-targeted bispecific antibody) in combination with evorpacept (ALX’s CD47 blocker).

On October 5, 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

Exhibit No.	Description
99.1	Press Release dated October 5, 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: October 5, 2021

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

Zymeworks and ALX Oncology Announce First Patient Dosed in Phase 1b/2 Clinical Trial of Zanidatamab and Evorpacept (ALX148) in Patients with Advanced HER2-Expressing Breast Cancer and Other Solid Tumors

Vancouver, Canada and South San Francisco, California (October 5, 2021) – Zymeworks Inc. (NYSE: ZYME), a clinical-stage biopharmaceutical company developing multifunctional biotherapeutics, and ALX Oncology Holdings Inc. (NASDAQ: ALXO), a clinical-stage immuno-oncology company developing therapies that block the CD47 checkpoint pathway, today announced the first patient has been dosed in an open-label, multi-center Phase 1b/2 clinical trial conducted by Zymeworks.

The trial is designed to evaluate the safety and efficacy of zanidatamab, Zymeworks' lead HER2-targeted bispecific antibody, in combination with evorpacept (ALX148), ALX's CD47 blocker, in patients with advanced HER2-positive breast cancer, HER2-low breast cancer and additional non-breast HER2-expressing solid tumors.

This collaboration builds on the promising antitumor activity observed in clinical trials of evorpacept combined with a HER2-targeted antibody in patients with advanced HER2-positive gastric or gastroesophageal junction cancer. The addition of CD47 blockade is designed to enhance zanidatamab's immunotherapeutic effects and has the potential to provide benefit to a broad population of patients, including those with advanced HER2-expressing breast cancer and potentially other HER2-expressing cancers.

About the Zanidatamab-Evorpacept Combination

Zanidatamab is designed to have multiple mechanisms of action, including immune clearance of HER2-expressing tumor cells by macrophages through antibody-dependent cellular phagocytosis (ADCP). CD47 is a "don't eat me" signal that acts as a checkpoint inhibitor to macrophages. Cancer cells that express CD47 are resistant to immune clearance even when targeted with therapeutic antibodies. Treatment with zanidatamab plus evorpacept has the potential to increase the immune clearance of HER2-expressing cancer cells by combining a biparatopic antibody capable of binding at higher density than monospecific antibodies with a molecule that blocks CD47 on the same targeted cancer cells.

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 Evorpacept

Evorpacept is a next-generation CD47 blocking therapeutic that combines a high-affinity CD47 binding domain with an inactivated, proprietary Fc domain. Evorpacept is designed to avoid the limitations caused by hematologic toxicities inherent in other CD47 blocking approaches, and to leverage the immune activation of broadly used anti-cancer agents through combination strategies. ALX Oncology is developing evorpacept in multiple Phase 1 and Phase 2 clinical trials globally across a range of hematologic and solid malignancies in combination with a number of leading anti-cancer agents. The FDA has granted two Fast Track designations to evorpacept, one for the first-line treatment of patients with head and neck squamous cell carcinoma, and one for the second-line treatment of patients with HER2-positive gastric or gastroesophageal junction carcinoma. The FDA's Fast Track designation provides the opportunity for more frequent meetings with the FDA over the course of drug development and allows for eligibility for Accelerated Approval and Priority Review if relevant criteria are met, as well as for Rolling Review.

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.

About ALX Oncology

ALX Oncology is a publicly traded, clinical-stage immuno-oncology company focused on helping patients fight cancer by developing therapies that block the CD47 checkpoint pathway and bridge the innate and adaptive immune system. ALX Oncology's lead product candidate, evorpacept, has demonstrated promising clinical responses across a range of hematologic and solid malignancies in combination with a number of leading anti-cancer agents. ALX Oncology intends to continue clinical development of evorpacept for the treatment of multiple solid tumor indications and hematologic malignances, including acute myeloid leukemia and myelodysplastic syndrome. ALX Oncology has entered into strategic partnerships with multiple biopharmaceutical companies to support indications that entail large unmet medical needs. For additional information about ALX Oncology, visit www.alxoncology.com and follow @AlxOncology on Twitter.

Zymeworks 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 Zymeworks’ expectations regarding the beneficial characteristics, safety, and therapeutic effects of zanidatamab, its trial combining zanidatamab and evorpacept, the potential benefits of that combination, and other information that is not historical information. When used herein, words such as “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, 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.

ALX Oncology Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements regarding future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, plans and objects of management for future operations, as well as statements regarding industry trends. Such forward-looking statements are based on ALX Oncology’s beliefs and assumptions and on information currently available to it on the date of this press release. Forward-looking statements may involve known and unknown risks, uncertainties and other factors that may cause ALX Oncology’s actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. These and other risks are described more fully in ALX Oncology’s filings with the Securities and Exchange Commission (“SEC”), including ALX Oncology’s Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other documents ALX Oncology files with the SEC from time to time. Except to the extent required by law, ALX Oncology undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Zymeworks Inc.

Investor Inquiries:
Ryan Dercho, Ph.D.
(604) 678-1388
ir@zymeworks.com

Jack Spinks
(604) 678-1388
ir@zymeworks.com

Media Inquiries:
Mary Klem
(604) 678-1388
media@zymeworks.com

ALX Oncology

Investor Inquiries

Peter Garcia
Chief Financial Officer, ALX Oncology
(650) 466-7125 Ext. 113
peter@alxoncology.com

Argot Partners
(212)-600-1902
alx@argotpartners.com

Media Inquiries

Karen Sharma
MacDougall
(781) 235-3060
alx@macbiocom.com