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): January 12, 2020

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

British Columbia, Canada	**001-38068**	**47-2569713**
(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 January 12, 2020, Zymeworks Inc. issued a press release announcing the initiation of a Phase 2 trial evaluating ZW25 combination therapy and an agreement with Pfizer which advances the study. On January 13, 2020, this press release was filed 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.

On January 13, 2020, Zymeworks Inc. issued a press release highlighting its key accomplishments in 2019, providing updated corporate priorities, and announcing multiple clinical program advances for its lead candidates, ZW25 and ZW49. On January 13, 2020, this press release was filed with the Canadian securities regulatory authorities in Canada on SEDAR at www.sedar.com. A copy of this press release is attached as exhibit 99.2 hereto.

The information provided under this Item (including exhibits 99.1 and 99.2, 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 January 12, 2020.
99.2	Press Release dated January 13, 2020.

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: January 13, 2020

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

Zymeworks Announces Agreement with Pfizer and Initiation of a New Phase 2 Trial Evaluating ZW25 in Combination with Ibrance® (palbociclib)

- *Potential for a Novel Chemotherapy-Free Treatment Option for People with Advanced HER2-positive, HR-positive Breast Cancer*

VANCOUVER, British Columbia (January 12, 2020) – Zymeworks Inc. (NYSE: ZYME), a clinical-stage biopharmaceutical company developing multifunctional therapeutics, today announced the initiation of a Phase 2 trial evaluating ZW25 combination therapy and an agreement with Pfizer which advances the study. Zymeworks' HER2-targeted bispecific antibody ZW25 is being evaluated in combination with Pfizer's Ibrance® (palbociclib), an oral CDK4/6 inhibitor, and the hormone therapy fulvestrant in patients with previously-treated locally advanced and/or metastatic HER2-positive, HR-positive breast cancer. Zymeworks will sponsor the study, and Pfizer will provide palbociclib.

"The initiation of this Phase 2 trial and collaboration with Pfizer mark significant milestones in our progress towards establishing ZW25 as the foundational HER2 therapy in multiple regimens across breast and other cancers," said Diana Hausman, M.D., Chief Medical Officer at Zymeworks. "Together, ZW25 and palbociclib have the potential to improve anti-tumor activity and minimize side effects for people living with advanced HER2-positive, HR-positive breast cancer."

This Phase 2 clinical trial is a multicenter, open-label, two-part study (clinicaltrials.gov: NCT04224272). Part one of the study will evaluate the safety and tolerability of ZW25 in combination with palbociclib and fulvestrant and identify the recommended doses (RD) of ZW25 and palbociclib. Part two of the study will evaluate anti-tumor activity at the RD level. The trial will enroll up to 76 patients at sites in the United States and Canada, and expansion to Spain is planned.

ZW25 is being evaluated within a broad clinical development program in multiple HER2-expressing cancers, including biliary tract, gastroesophageal adenocarcinoma (GEA), breast, colorectal, and gynecologic cancers. In an ongoing Phase 1 clinical trial, Zymeworks is evaluating ZW25 as a single agent and in combination with chemotherapy as potential treatments for patients with HER2-expressing cancers (clinicaltrials.gov: NCT02892123). For patients with HER2-positive GEA, ZW25 is being studied in a Phase 2 trial as a first-line treatment in combination with standard of care chemotherapy (clinicaltrials.gov: NCT03929666). Zymeworks plans to initiate a registration-enabling Phase 2 trial in previously-treated or recurrent HER2-positive biliary tract cancer in 2020.

About Breast Cancer

Breast cancer occurs when cells of the breast grow uncontrollably. According to the World Health Organization, each year, over 2 million new cases of breast cancer are diagnosed and over 600,000 deaths occur globally. Rates are increasing in nearly every region of the world. For locally advanced or metastatic breast cancer, the American Cancer Society estimates over 271,000 new US cases in men and women this year. About 15 to 20 percent of all breast cancers are positive for human epidermal growth factor receptor 2, or HER2. These cancers make too much HER2 protein, which may cause them to grow more quickly and spread to other parts of the body. Despite the advances with available HER2-targeted therapies, there is still an unmet medical need for people with all HER2-expressing cancers, particularly recurrent or metastatic disease that has progressed after standard of care therapy.

About ZW25

ZW25 is being evaluated in Phase 1 and Phase 2 clinical trials across North America and South Korea. It 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 anti-tumor activity in patients. Zymeworks is developing ZW25 as a HER2-targeted treatment option for patients with solid tumors that express HER2. The FDA has granted Fast Track designation to ZW25 for first-line gastroesophageal adenocarcinoma in combination with standard of care chemotherapy and Orphan Drug designation to ZW25 for the treatment of both gastric and ovarian 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, ZW25, is a novel Azymetric™ bispecific antibody currently in Phase 2 clinical development. Zymeworks' second clinical candidate, ZW49, is a bispecific antibody-drug conjugate currently in Phase 1 clinical development and combines the unique design and antibody framework of ZW25 with Zymeworks' proprietary ZymeLink™ cytotoxic payload. 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 more information, visit www.zymeworks.com.

Cautionary Note Regarding Zymeworks' 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 statements that relate to ZW25 and its potential as an anti-cancer treatment, Zymeworks' collaboration with Pfizer and the potential efficacy of ZW25 in combination with palbociclib, Zymeworks' clinical plans and future results, Zymeworks' technology platform, and other information that is not historical information. When used herein, words such as "will", "believe", "may", "plan", 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 the three month period ended September 30, 2019 (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. You 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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Zymeworks Highlights 2019 Achievements and Announces Corporate Priorities

Vancouver, Canada (January 13, 2020) – Zymeworks Inc. (NYSE: ZYME), a clinical-stage biopharmaceutical company developing multifunctional biotherapeutics, today highlighted its key accomplishments in 2019 and updated its corporate priorities. Zymeworks also announced multiple clinical program advances for its lead candidates, ZW25 and ZW49.

Recent ZW25 and ZW49 Program Advances

- Zymeworks initiated a Phase 2 clinical trial evaluating ZW25 in combination with Ibrance® (palbociclib), an oral CDK4/6 inhibitor, and the hormone therapy fulvestrant with the goal of providing a chemotherapy-free treatment option to people with advanced HER2-positive, hormone receptor-positive breast cancer. Zymeworks entered into a clinical collaboration with Pfizer to advance the study.
- ZW25 achieved two additional regulatory milestones, recently being granted Fast Track and Orphan Drug Designations by the FDA in refractory biliary tract cancer (BTC). These were ZW25's second Fast Track and third Orphan Drug Designations. ZW25 already holds a Fast Track Designation for 1st line gastroesophageal adenocarcinoma (GEA) and Orphan Drug Designations for GEA and ovarian cancer.
- An interim update from the ongoing ZW49 Phase 1 dose-escalation study highlighted that there have been no dose-limiting toxicities observed and the maximum tolerated dose has not been reached. With over ten patients treated, the majority of treatment-related adverse events have been grade 1 or 2, and were reversible and manageable on an outpatient basis. Importantly, preliminary results from these initial dose cohorts include anti-tumor activity.

"Our significant achievements in 2019 demonstrate that we are executing on our vision to establish ZW25 as the foundational HER2 therapy across the spectrum of HER2-expressing cancers and lines of therapy," said Ali Tehrani, Ph.D., President and CEO at Zymeworks. "As our second therapeutic candidate, ZW49, continues to advance in the clinic, we are excited about its transformative potential for both patients with HER2-expressing cancers and for the development of future antibody-drug conjugate therapies. With a visionary leadership team, key hires company-wide, and a strong financial position, we are ready to deliver on our clinical programs and partnering priorities for 2020."

2019 Achievements

ZW25 Single Agent and Chemotherapy Combination Data Presented at Multiple Medical Meetings; Data Support Plans for Multiple Registration-Enabling Studies

- ZW25 demonstrated robust single agent anti-tumor activity and durable disease control across multiple HER2-expressing tumors that have progressed after standard-of-care (SOC) therapies, including HER2-targeted agents. These data support the initiation of a registration-enabling Phase 2 trial evaluating single agent ZW25 in refractory HER2-positive BTC followed by additional HER2-expressing tumor types.

- ZW25 plus chemotherapy showed durable anti-tumor activity for patients with heavily pretreated GEA, which supports the ongoing Phase 2 trial of ZW25 plus SOC chemotherapy and a planned registration-enabling trial in 1st line HER2-posititve GEA vs Herceptin plus SOC chemotherapy.

ZW49 Enters Phase 1 Clinical Testing for HER2-Expressing Cancers

- ZW49 is a HER2-targeted bispecific antibody-drug conjugate (ADC) that capitalizes on the unique geometry and antibody framework of ZW25, and is armed with Zymeworks' proprietary ZymeLink™ cytotoxin. This design results in enhanced internalization and delivery of the cytotoxin to cancer cells. ZW49 is being evaluated in an ongoing Phase 1 clinical trial.

Partnerships Continue to Advance; Milestone Payments Received

- Zymeworks' pharmaceutical partner Lilly entered the clinic with a novel bispecific, Merck, Celgene, and Daiichi Sankyo advanced bispecific candidates toward clinical testing, GSK expanded its Azymetric™ partnership, and the first ZymeLink ADC collaboration was signed with Iconic Therapeutics. These events resulted in multiple milestone payments and increased future potential milestone payments and royalties for Zymeworks.

Expertise Added to Leadership Team

- Extensive development and commercial experience was added to the executive management team and board of directors. In addition, a Chief People Officer was hired to strategically manage the growth of Zymeworks' human resources.

Balance Sheet Strengthened

- During the year, Zymeworks completed a public financing raising US $201.3 million, and added additional non-dilutive capital from multiple pharmaceutical partners.

Updated Corporate Priorities

- Initiate ZW25 registration-enabling studies in 2nd line HER2-positive BTC and 1st line HER2-positive GEA
- Report ZW49 Phase 1 dose-escalation data and initiate expansion cohorts
- Expand ZW25 clinical development into additional HER2-expressing cancers
- Report ZW25 Phase 2 chemotherapy combination data from 1st line HER2-positive GEA
- Continue building a strong preclinical pipeline through internal R&D and external partnerships

About Zymeworks Inc.

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