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 28, 2019

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 8.01 OTHER EVENTS

On September 28, 2019, Zymeworks Inc. (“Zymeworks”) issued a press release announcing updated data from the ongoing multi-center Phase 1 clinical trial evaluating ZW25 in patients with HER2-expressing solid tumors, including biliary tract cancer (BTC), colorectal cancer (CRC), gynecological cancers, and gastroesophageal adenocarcinoma (GEA), in a poster discussion presentation at the ESMO 2019 Congress, taking place September 27 – October 1 in Barcelona, Spain.

On September 30, 2019 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. Additionally, on September 30, 2019, Zymeworks filed a material change report regarding this matter with the Canadian securities regulatory authorities on SEDAR at www.sedar.com. Copies of this press release and material change report are respectively filed as exhibits 99.1 and 99.2 hereto.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated September 28, 2019.
99.2	Material Change Report dated September 30, 2019.

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 30, 2019

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

Zymeworks Announces Updated Single Agent Data for HER2-Targeted Bispecific Antibody ZW25 at European Society for Medical Oncology (ESMO) Congress

- *Single Agent Activity and Durable Disease Control Across Multiple Tumor Types*
- *Data Support the Initiation of a Registration-Enabling Phase 2 Trial Evaluating Single Agent ZW25 in Second-Line HER2-Expressing Biliary Tract Cancers*

Barcelona, Spain (September 28, 2019) – Zymeworks Inc. (NYSE/TSX: ZYME), a clinical-stage biopharmaceutical company developing multifunctional therapeutics, today announced updated data from the ongoing multi-center Phase 1 clinical trial evaluating ZW25 in patients with HER2-expressing solid tumors, including biliary tract cancer (BTC), colorectal cancer (CRC), gynecological cancers, and gastroesophageal adenocarcinoma (GEA), in a poster discussion presentation at the ESMO 2019 Congress, taking place September 27 – October 1 in Barcelona, Spain.

“The data presented today at ESMO confirm previous findings that ZW25 monotherapy can provide durable disease control in patients with a variety of HER2-expressing solid tumors that have progressed following standard of care therapies, including HER2-targeted agents,” said Diana Hausman, M.D., Chief Medical Officer at Zymeworks. “Notably, the single agent objective response rate in biliary tract cancer is highly encouraging given the poor prognosis and limited treatment options for these patients. We are working closely with regulatory agencies to initiate a registration-enabling Phase 2 trial in second-line HER2-expressing biliary tract cancer with the goal of bringing ZW25 to patients as quickly as possible.”

Based on the data from the ongoing Phase 1 study, Zymeworks has initiated a broad clinical development program for ZW25 in multiple HER2-expressing cancers. In addition to the Phase 2 BTC trial announced today, Zymeworks is continuing to evaluate ZW25 as a potential treatment for patients with other HER2-expressing cancers, including CRC and gynecological cancers (Phase 1; NCT02892123). For patients with HER2-expressing GEA, ZW25 is being developed as a first-line treatment in combination with standard of care chemotherapy (Phase 2; NCT03929666). Zymeworks also plans to initiate a Phase 2 study of ZW25 in combination with a CDK4/6 inhibitor and hormone therapy in third-line HER2-expressing, HR-positive breast cancer.

ZW25 Clinical Results Presented Today

The Safety, Efficacy and Biomarker Results of the HER2-Targeted Bispecific Antibody ZW25 in HER2-Expressing Solid Tumors (Abstract# 3575, Poster Discussion on Saturday, September 28 at 4:30 pm CEST)

Findings from this ongoing Phase 1 study of ZW25 in patients with HER2-expressing solid tumors were last presented at the 2018 EORTC-NCI-AACR Symposium. The updated results were presented today by Dr. Funda Meric-Bernstram, M.D., Clinical Investigator and Chair of the Department of Investigational Cancer Therapeutics at The University of Texas MD Anderson Cancer Center.

Data were reported from 58 patients diagnosed with HER2-expressing solid tumors other than breast cancer who received ZW25 at the recommended dose of either 10 mg/kg weekly or 20 mg/kg every other week. Patients had a median age of 61 years and received a median of four prior therapies. Thirty-two (55%) patients received prior HER2-targeted therapies including 87% of GEA patients. Of all patients, 23 were diagnosed with GEA, 13 with CRC, nine with BTC, and 13 with other HER2-expressing cancers, including endometrial, ovarian, pancreatic, and salivary gland.

At the time of data cut-off, 46 of 58 patients were response evaluable. Overall, the majority of patients experienced a decrease in their target lesions with a disease control rate of 72%, comprising 16 (35%) patients with partial responses and 17 (37%) with stable disease. The objective response rate in the six evaluable biliary tract cancer patients was 67%, with the majority of patients experiencing disease control greater than six months. In the 11 CRC and 19 GEA patients, the objective response rates were 36% and 32%, respectively. The overall median progression-free survival was 5.2 months, with 27 (47%) of the 58 total patients still on study at the time of data cut-off.

Among all patients, ZW25 was well tolerated as an outpatient therapy. The most common adverse events were diarrhea, infusion-related reaction, and nausea. All treatment-related adverse events occurring in 10% or more of patients were Grade 1 or 2.

About the Phase 1 Clinical Trial

Zymeworks' Phase 1 study has three parts. From part one of the study (the dose-escalation phase), the recommended single-agent dose was determined to be 20 mg/kg once every two weeks or 10 mg/kg weekly. In the second part of the study (the cohort expansion phase), additional patients are being enrolled to further assess ZW25's single-agent tolerability and anti-tumor activity against a variety of cancer types in different settings. The third part of the study (the combination phase) is underway and evaluating ZW25 in combination with selected chemotherapy agents in gastroesophageal and breast cancer patients with HER2 high or lower HER2 expression levels.

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 any solid tumor that expresses 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 immuno-oncology 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' clinical plans and future results, Zymeworks' technology platform, and other information that is not historical information. When used herein, words such as "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 June 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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FORM 51-102F3
MATERIAL CHANGE REPORT

Item 1: Name and Address of Company

Zymeworks Inc. ("**Zymeworks**" or the "**Company**")
1385 West 8th Avenue, Suite 540
Vancouver, BC, Canada
V6H 3V9

Item 2: Date of Material Change

September 28, 2019

Item 3: News Release

A news release announcing the material change was disseminated through the facilities of Business Wire on September 28, 2019 and a copy was filed on the Company's profile at www.sedar.com.

Item 4: Summary of Material Change

On September 28, 2019, Zymeworks announced updated data from the ongoing multi-center Phase 1 clinical trial evaluating ZW25 in patients with HER2-expressing solid tumors, including biliary tract cancer (BTC), colorectal cancer (CRC), gynecological cancers, and gastroesophageal adenocarcinoma (GEA), in a poster discussion presentation at the ESMO 2019 Congress, taking place September 27 – October 1 in Barcelona, Spain.

Item 5: Full Description of Material Change

5.1 Full Description of Material Change

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Z25 Clinical Results Presented on September 28, 2019

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5.2 Disclosure of Restructuring Transactions

Not applicable.

Item 6: Reliance on subsection 7.1(2) of National Instrument 51-102

Not applicable.

Item 7: Omitted Information

Not applicable.

Item 8: Executive Officer

For further information, please contact Neil Klompas, Executive Vice President, Business Operations and Chief Financial Officer of the Company at (604) 678-1388.

Item 9: Date of Report

September 30, 2019

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