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, 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 November 19, 2020, Zymeworks Inc. issued a press release announcing that the European Commission (EC) has granted Orphan Drug designation for zanidatamab, the company's investigational HER2-targeted bispecific antibody, in patients with gastric cancer.

On November 19, 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.

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 November 19, 2020.
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, 2020

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

Zymeworks Receives Orphan Drug Designation from the European Commission for HER2-Targeted Bispecific Antibody Zanidatamab in Patients with Gastric Cancer

Vancouver, British Columbia (November 19, 2020) – Zymeworks Inc. (NYSE: ZYME), a clinical-stage biopharmaceutical company developing multifunctional biotherapeutics, today announced that the European Commission (EC) has granted Orphan Drug designation for zanidatamab, the company's investigational HER2-targeted bispecific antibody, in patients with gastric cancer.

"We are encouraged by the European Commission's and European Medicines Agency's recognition of the benefit that zanidatamab can provide in the treatment of HER2-expressing gastric cancers as we continue to expand our clinical development globally," said Diana Hausman, M.D., Chief Medical Officer at Zymeworks.

The EC grants Orphan Drug designation to therapies that represent a significant benefit over existing treatments, are intended for the treatment, prevention or diagnosis of a life-threatening or chronically debilitating disease, and where prevalence of the condition in the European Union (EU) is less than 5 in 10,000 persons. Orphan drug designation gives companies certain benefits, including 10 years of market exclusivity following regulatory approval, reduced regulatory fees, clinical protocol assistance, and access to research grants.

"While gastric cancer is a rare disease, European countries experience the highest incidence rates among all Western countries" said James Priour, Senior Vice President, Commercial, at Zymeworks. "The European Commission's granting of Orphan Drug designation for zanidatamab represents an important step towards bringing this promising investigational medicine to patients in Europe and around the world."

Zymeworks previously received Orphan Drug designations for zanidatamab in gastric, biliary tract and ovarian cancers from the US FDA, as well as two Fast Track designations from the FDA for zanidatamab.

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. 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 antitumor activity in patients. Zymeworks is developing zanidatamab in multiple Phase 1, Phase 2, and registration-enabling clinical trials globally as a targeted treatment option for patients with solid tumors that express HER2. The US FDA has granted two Fast Track designations to zanidatamab, one as a single agent for refractory BTC and one in combination with standard of care chemotherapy, for first-line Gastroesophageal Adenocarcinoma (GEA). Zanidatamab has also received Orphan Drug designations for the treatment of biliary tract, gastric and ovarian cancers from the US FDA, in addition to Orphan Drug designation for the treatment of gastric cancer from the European Medicines Agency.

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 currently in a registration-enabling clinical trial for refractory HER2+ biliary tract cancer as well as several Phase 2 clinical trials for HER2+ gastroesophageal and breast cancers. 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 zanidatamab with Zymeworks' proprietary ZymeLink™ linker-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 more information, visit www.zymeworks.com.

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 the anticipated benefits of orphan drug designation, the potential therapeutic benefit that zanidatamab can provide, Zymeworks' clinical and preclinical development of its product candidates, and other information that is not historical information. When used herein, words such as "plan", "expect", "may", "can", 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 September 30, 2020 (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.

Contacts:

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

Tiffany Tolmie
(604) 678-1388
ir@zymeworks.com

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