
Section 1: 8-K (8-K)

**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):
May 29, 2019

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)

47-2569713
(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 8.01 OTHER EVENTS

The following information is filed pursuant to Item 8.01, "Other Events."

On May 29, 2019, Zymeworks Inc. ("Zymeworks") issued a press release announcing that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to ZW25, a novel Azymetric™ bispecific antibody, for the first-line treatment of patients with HER2overexpressing gastroesophageal adenocarcinoma in combination with standard of care chemotherapy. A copy of this press release is filed as exhibit 99.1 hereto.

Item 9.01. FINANCIAL STATEMENTS AND EXHIBITS**(d) Exhibits**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Zymeworks Inc. on May 29, 2019

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ZYMEWORKS INC.

(Registrant)

Date: May 29, 2019

By: /s/ Neil Klompas
Name: Neil Klompas
Title: Chief Financial Officer

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Section 2: EX-99.1 (EX-99.1)

Exhibit 99.1



Zymeworks' Lead Asset, ZW25, Granted Fast Track Designation from the FDA

Vancouver, Canada (May 29, 2019) – Zymeworks Inc. (NYSE/TSX: ZYME), a clinical-stage biopharmaceutical company developing multifunctional biotherapeutics, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to ZW25, a novel Azymetric™ bispecific antibody, for the first-line treatment of patients with HER2-overexpressing gastroesophageal adenocarcinoma in combination with standard of care chemotherapy.

“Receipt of Fast Track designation from the FDA emphasizes the large unmet need of patients with these types of HER2-expressing cancers,” said Ali Tehrani, Ph.D., Zymeworks’ President & CEO. “This designation is key to our objective of getting important new therapies to patients as quickly as possible. We are pleased with the discussions we’ve had with the FDA thus far and will continue to work together on other opportunities to accelerate the development of ZW25 in additional indications.”

The FDA’s Fast Track designation is designed to facilitate development and expedite the review of therapies to treat a serious diseases where there is a significant unmet medical need. A therapeutic that receives Fast Track designation is eligible for frequent communication with the FDA, accelerated approval and priority review, and rolling submission, which means that a company can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be submitted for review. The primary objective of this program is to accelerate patient access to new and potential lifesaving therapies.

About the Trial

The Phase 2 trial is a two-part open-label study. The primary objectives of this trial are to confirm the safety, tolerability, and anti-tumor activity of ZW25 in combination with global standard of care regimens for gastroesophageal adenocarcinoma, including platinum and fluoropyrimidine-based regimens.

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 the Azymetric™ Platform

The Azymetric platform enables the transformation of monospecific antibodies into bispecific antibodies, giving the antibodies the ability to simultaneously bind two different targets. Azymetric bispecific technology enables the development of multifunctional biotherapeutics that can block multiple signaling pathways, recruit immune cells to tumors, enhance receptor clustering degradation, and increase tumor-specific targeting. These features are intended to enhance efficacy while reducing toxicities and the potential for drug-resistance. Azymetric bispecifics have been engineered to retain the desirable drug-like qualities of naturally occurring antibodies, including low immunogenicity, long half-life, and high stability. In addition, they are compatible with standard manufacturing processes with high yields and purity, potentially significantly reducing drug development costs and timelines.

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 immunoncology 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.

Zymeworks 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, but are not limited to, the speed and outcome of drug development plans, the speed, frequency and outcome of communications with the FDA, patient access to ZW25, and other information that is not historical information. When used herein, words such as “enable”, “plan”, “expect”, “will”, “may”, “eligible”, “continue to” 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 fiscal quarter ended March 31, 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. 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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