## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

<b>FORM</b>	8-K
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CURRENT REPORT
Pursuant to Rule 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 26, 2018

## **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 of former address, if changed since last report)

Check the appropriate box	x below if the I	Form 8-K filing is ir	itended to simul	taneously satisfy the filing	g obligation of the registra	nt under any of the
following provisions:						
		D 1 405	1 .1 .0	. A . (15 CED 220 425)		

 Written communications	pursuant to Rule	425 under the	Securities Act (1)	(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))

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  $\square$ 

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 1.01 ENTRY INTO A MATERIAL DEFINITIVE AGREEMENT

On November 26, 2018, Zymeworks Inc. ("Zymeworks") entered into the following agreements with BeiGene, Ltd. ("BeiGene"): (i) two license and collaboration agreements (the "ZW25 Agreement" and the "ZW49 Agreement" and together, the "Product Candidate Agreements") granting BeiGene exclusive rights to research, develop, and commercialize Zymeworks' product candidates, ZW25 and ZW49, in Asia (excluding Japan but including the People's Republic of China, South Korea and other countries), Australia and New Zealand (together, the "BeiGene Territory"); and (ii) a research and license agreement granting BeiGene rights to research, and exclusive rights to develop and commercialize globally up to three bispecific antibodies generated through the use of Zymeworks' Azymetric<sup>TM</sup> and EFECT<sup>TM</sup> platforms (the "Platform Agreement" and together with the Product Candidate Agreements, the "BeiGene Agreements"). In connection with the Product Candidate Agreements and the Platform Agreement, Zymeworks will receive upfront payments of \$40.0 million and \$20.0 million, respectively.

Pursuant to the Product Candidate Agreements, Zymeworks is eligible to receive clinical development and commercial milestone payments of up to an aggregate of \$390.0 million for both product candidates, together with tiered royalties from high single-digits up to 20% on annual net sales of each product candidate in the BeiGene Territory, with customary reductions in specified circumstances. Royalties are payable on a product-by-product and country-by-country basis until the latest of (i) the expiration of the last valid patent claim, as specified in the Product Candidate Agreements, (ii) 10 years after the first commercial sale, or (iii) the expiration of regulatory exclusivity of such licensed product in the country of sale. No development or commercial milestones have been received to date. In addition, under the Product Candidate Agreements, Zymeworks and BeiGene have agreed to collaborate on global development of ZW25 and ZW49 in HER2-expressing solid tumors, including gastric and breast cancer, with BeiGene enrolling patients and contributing clinical trial data from the BeiGene Territory. Each of Zymeworks and BeiGene will be generally responsible for development and commercialization costs within their own territories.

The Product Candidate Agreements contain customary representations, warranties and covenants by Zymeworks and BeiGene. Unless earlier terminated, the Product Candidate Agreements will terminate on a licensed product-by-product and country-by-country basis upon the expiration of the royalty term in such country for such licensed product. The Product Candidate Agreements may be terminated by BeiGene upon prior written notice or by either party upon the other party's bankruptcy or uncured material breach.

Under the terms of the Platform Agreement, Zymeworks granted to BeiGene (i) a non-exclusive, world-wide, royalty-free, license to research and (ii) an antibody sequence-pair specific, exclusive, world-wide royalty-bearing license to continue to research, develop, manufacture and commercialize up to three bispecific antibodies generated through the use of the Azymetric<sup>TM</sup> and EFECT<sup>TM</sup> platforms. Pursuant to the Platform Agreement, Zymeworks is eligible to receive development and commercial milestone payments of up to an aggregate of \$702.0 million for up to three product candidates developed under the Platform Agreement, together with tiered royalties on annual net sales of each product candidate, with customary reductions in specified circumstances. Royalties are payable on a product-by-product and country-by-country basis until the later of (i) the expiration of the last valid patent claim, as specified in the Platform Agreement, or (ii) 10 years after the first commercial sale of such licensed product in the country of sale. No development or commercial milestones have been received to date.

The Platform Agreement contains customary representations, warranties and covenants by Zymeworks and BeiGene. Unless earlier terminated, the Platform Agreement will terminate on a licensed product-by-product and country-by-country basis upon the expiration of the royalty term in such country for such licensed product. The Platform Agreement may be terminated by BeiGene upon prior written notice, or by either party upon the other party's uncured material breach.

The foregoing description of the BeiGene Agreements is only a summary and is qualified in its entirety by reference to the BeiGene Agreements, which Zymeworks intends to file as exhibits to an amended Current Report on Form 8-K/A, portions of which will be subject to a confidential treatment request to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

### **Cautionary Note Regarding Forward-Looking Statements**

This current report on Form 8-K includes "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements in this current report on Form 8-K include statements that relate to Zymeworks' potential future milestone payments and royalties, any potential future product sales, proposed research and development activities to be conducted by Zymeworks or BeiGene and other information that is not historical information. When used herein, words such as "believe", "may", "plan", "shall", "will", "estimate", "continue", "anticipate", "potential", "intend", "expect" 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 months ended September 30, 2018 (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

#### ITEM 8.01 OTHER EVENTS

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

On November 27, 2018, Zymeworks issued a press release announcing the BeiGene Agreements, which 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 hereto as Exhibit 99.1.

#### ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

Exhibit No. Description

99.1 <u>Press Release issued jointly by Zymeworks and BeiGene on November 27, 2018.</u>

## **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: November 27, 2018

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





Zymeworks and BeiGene Announce License and Collaboration Agreement for Zymeworks' HER2-Targeted Therapeutic Candidates, ZW25 and ZW49, in Asia-Pacific and Research and License Agreement for Zymeworks' *Azymetric™ and EFECT™* platforms globally

- BeiGene acquires exclusive development and commercial rights to Zymeworks' bispecific candidates, ZW25 and ZW49, in Asia (excluding Japan), Australia, and New Zealand. The companies will collaborate on joint global development for selected indications.
- BeiGene also acquires licenses for Zymeworks' Azymetric™ and EFECT™ platforms to develop and commercialize up to three bispecific antibody therapeutics globally directed to BeiGene's targets.
- Zymeworks will receive total upfront payments of US\$40 million under the ZW25 and ZW49 agreements and US\$20 million under the
  platform agreement and is eligible to receive development and commercial milestone payments plus potential royalties on product sales.

Vancouver, Canada; Beijing, China and Cambridge, MA, (November 27, 2018) – Zymeworks Inc. (NYSE/TSX: ZYME), a clinical-stage biopharmaceutical company developing multifunctional therapeutics, and BeiGene, Ltd. (Nasdaq: BGNE; HKEX: 06160), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, today announced that the two companies have entered into a strategic collaboration for the clinical development and commercialization of Zymeworks' investigational ZW25 and ZW49 HER2-targeted bispecific antibodies. In addition, Zymeworks granted BeiGene a license to Zymeworks' proprietary Azymetric™ and EFECT™ platforms to develop and commercialize globally up to three other bispecific antibodies using the platforms.

## License and Collaboration for ZW25 and ZW49

Under the terms of the license and collaboration agreements for ZW25 and ZW49, Zymeworks has granted BeiGene exclusive rights to develop and commercialize Zymeworks' clinical-stage bispecific antibody candidate ZW25 and its preclinical-stage bispecific antibody drug conjugate (ADC) ZW49 in Asia (excluding Japan), Australia, and New Zealand. BeiGene will be responsible for all clinical development and regulatory submissions in the licensed territories. The companies also plan to collaborate on global development of ZW25 and ZW49 in HER2-expressing solid tumors, including gastric and breast cancer, with BeiGene enrolling patients and contributing clinical trial data from the licensed territories. Zymeworks retains full rights to both ZW25 and ZW49 outside of the specified countries and will continue to lead global development of these drug candidates.

"Partnering with BeiGene was a key component of our development and commercialization strategy for ZW25 and ZW49," said Ali Tehrani, Ph.D., President and CEO of Zymeworks. "This collaboration allows Zymeworks to leverage BeiGene's resources and expertise to accelerate the development of our most advanced product candidates and broaden our reach globally including in a key region of the world."

"Zymeworks' promising candidates ZW25 and ZW49 complement our oncology pipeline and further advance our mission to develop treatments for patients who often have limited options," commented Dr. Xiaobin Wu, General Manager of China and President of BeiGene, Ltd. "Our deep clinical experience in China is an integral part of our business development efforts, as these trial data can be used to support global regulatory filings. We are excited by the clinical prospects of ZW25 and ZW49 in HER2-expressing cancers."

"At Zymeworks we are committed to developing new therapies to help address unmet medical need on a global basis," said Diana Hausman, MD, Zymeworks' Chief Medical Officer. "We are looking forward to collaborating with BeiGene and benefiting from their extensive experience in oncology drug development in China and elsewhere. We expect that this collaboration will accelerate the development of ZW25 and ZW49 as potential new therapies for patients with HER2-expressing solid tumors, including gastric, breast and other cancers."

## License to Zymeworks' Azymetric and EFECT Platforms

In addition to the license and collaboration agreements for ZW25 and ZW49, Zymeworks and BeiGene entered into a separate research and license agreement for Zymeworks' proprietary Azymetric and EFECT platforms, under which BeiGene will have global rights to research, develop and commercialize up to three bispecific antibody therapeutics directed to targets selected by BeiGene. BeiGene will be responsible for all research, development, and commercial activities under this agreement.

#### **Financial Consideration**

Under the terms of the license and collaboration agreements for ZW49 and ZW25, Zymeworks will receive total upfront payments of US\$40 million and is eligible to receive up to US\$390 million in development and commercial milestone payments for both product candidates. In addition, Zymeworks will be eligible to receive tiered royalties on future sales of ZW25 and ZW49 in the licensed territory.

Under the terms of the research and license agreement for the Azymetric and EFECT platforms, Zymeworks will receive an upfront payment of US\$20 million and is eligible to receive up to an aggregate of US\$702 million in development and commercial milestone payments for up to three bispecific product candidates developed under the agreement. In addition, Zymeworks will be eligible to receive tiered royalties on future global sales of bispecific products developed by BeiGene under the agreement.

#### **Zymeworks' Webcast and Conference Call**

Zymeworks will host a webcast and conference call November 27th, at 8:30 a.m. ET (5:30 a.m. PT) to discuss the collaboration and license agreements.

Interested parties can access a live webcast of the presentation via a link from Zymeworks' website at <a href="http://ir.zymeworks.com/events-and-presentations">http://ir.zymeworks.com/events-and-presentations</a>. A recorded replay will also be available on the website shortly after the call concludes.

The live call and Q&A may be accessed by dialing 1-800-319-4610 for North American callers, or 1-604-638-5340 for international callers. Callers should dial in five to ten minutes prior to the scheduled start time and ask to join the "Zymeworks call."

#### About ZW25

ZW25 is being evaluated in a Phase 1 clinical trial in the United States and Canada. 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 Orphan Drug Designation to ZW25 for the treatment of both gastric and ovarian cancers.

#### **About ZW49**

ZW49 is a novel bispecific ADC targeting two non-overlapping epitopes of HER2 resulting in enhanced internalization and delivery of its proprietary ZymeLink cytotoxic payload. ADCs incorporating ZymeLink have demonstrated a greater therapeutic window (range of doses that are both efficacious and tolerable) in preclinical testing than those incorporating the commonly used ADC payloads DM1 or MMAE. Zymeworks is developing ZW49 as a best-in-class HER2-targeting ADC for several indications characterized by HER2 expression, especially those patients whose tumors have progressed or are refractory to HER2-targeted agents, and those that express lower levels of HER2 and are ineligible for treatment with current HER2-targeted therapies. An IND application for ZW49 was recently submitted to the FDA.

## About the Azymetric<sup>TM</sup> 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 the EFECT<sup>TM</sup> Platform

The EFECT platform is a library of antibody Fc modifications engineered to modulate the activity of the antibody-mediated immune response, which includes both the up- and down-regulation of effector functions. This platform, which is compatible with traditional monoclonal as well as Azymetric bispecific antibodies, further enables the customization of therapeutic responses for different diseases.

## About Zymeworks Inc.

Zymeworks is a clinical-stage biopharmaceutical company dedicated to the discovery, development, and commercialization of next-generation multifunctional biotherapeutics. Zymeworks' suite of complementary therapeutic platforms and its fully-integrated drug development engine provide the flexibility and compatibility to precisely engineer and develop highly-differentiated product candidates. Zymeworks' lead product candidate, ZW25, is a novel bispecific antibody currently being evaluated in an adaptive Phase 1 clinical trial. Zymeworks is also advancing a deep pipeline of preclinical product candidates and discovery-stage programs in immuno-oncology and other therapeutic areas. In addition to Zymeworks' wholly-owned pipeline, its therapeutic platforms have been further leveraged through multiple strategic partnerships with global biopharmaceutical companies.

#### About BeiGene, Ltd.

BeiGene is a global, commercial-stage, research-based biotechnology company focused on molecularly-targeted and immuno-oncology cancer therapeutics. With a team of over 1,700 employees in China, the United States, Australia and Switzerland, BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for cancer. BeiGene is also working to create combination solutions aimed to have both a meaningful and lasting impact on cancer patients. BeiGene markets ABRAXANE® (nanoparticle albumin—bound paclitaxel), REVLIMID® (lenalidomide), and VIDAZA® (azacitidine) in China under a license from Celgene Corporation\*.

\*ABRAXANE®, REVLIMID®, and VIDAZA® are registered trademarks of Celgene Corporation.

## **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 "forwardlooking 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 future development activities in accordance with the terms of Zymeworks' agreements with BeiGene, potential payments and/or royalties payable to Zymeworks under these agreements, the speed and outcome of drug development plans, Zymeworks' potential global growth, and other information that is not historical information. When used herein, words such as "enable", "plan", "expect", "allows", "will", "may", "continue", 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, 2018 (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 forwardlooking statements to reflect new information, future events or circumstances or to reflect the occurrences of unanticipated events, except as may be required by law.

## BeiGene Cautionary Note Regarding BeiGene's Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding future research, development and potential commercialization activities under the agreements with Zymeworks, potential payments and/or royalties payable to Zymeworks under these agreements, the speed and outcome of drug development plans, and other information that is not historical information. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed products and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

## **Contacts:**

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