# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 8-K**

## **CURRENT REPORT** Pursuant to Rule 13 or 15(d)

of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 14, 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

V6H 3V9 (Zip Code)

(Address of principal executive offices)

(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 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))

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.  $\square$ 

#### ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION

The following information is furnished pursuant to Item 2.02, "Results of Operations and Financial Condition."

On March 14, 2018, Zymeworks Inc. (the "Company") issued a press release announcing its financial results for the fiscal year ended December 31, 2017. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

#### ITEM 8.01 OTHER EVENTS

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

On March 14, 2018, the Company announced that ZW49 is the first product candidate selected for clinical development utilizing technology from the Company's 2016 acquisition of Kairos Therapeutics Inc. and its antibody-drug conjugate platform. The Company will advance ZW49 in lieu of its predecessor product candidate, ZW33. A copy of the press release announcing the Company's decision to advance ZW49 is attached hereto as Exhibit 99.2 and incorporated herein by reference.

#### ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

#### (d) Exhibits

Exhibit No.	Description
99.1	Press Release of financial results issued by Zymeworks Inc. on March 14, 2018
99.2	Press Release issued by Zymeworks Inc. on March 14, 2018

#### 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: March 14, 2018

By: /s/ Neil Klompas

Name: Neil Klompas Title: Chief Financial Officer



## Zymeworks Reports 2017 Year-End Financial Results

**Vancouver, Canada (March 14, 2018)** – Zymeworks Inc. (NYSE/TSX: ZYME), a clinical-stage biopharmaceutical company developing multifunctional therapeutics, today reported financial results for the year ended December 31, 2017.

"2017 was marked by a number of key corporate successes," said Ali Tehrani, Ph.D., Zymeworks' President & CEO. "We continued to generate promising clinical results for ZW25, added a sixth global pharmaceutical partner, and saw important progress in our partners' programs as they advanced compounds utilizing our technology towards the clinic."

#### 2017 Business Highlights and Recent Developments

#### • Expanded Clinical Dataset for ZW25

The Company <u>reported results</u> from the dose-escalation portion of its ongoing Phase 1 clinical trial, showing encouraging tolerability and antitumor activity in heavily pretreated patients with HER2-expressing cancers, including breast and gastric cancers. Zymeworks has increased the number of clinical trial sites in the United States and is in the process of activating multiple sites across Canada.

#### • Established New Corporate Partnership

Zymeworks <u>provided a license</u> to Janssen to develop up to six bispecific antibodies in a transaction potentially worth US\$1.45 billion including a US\$50 million upfront payment, milestones, and tiered royalties on product sales.

#### • Partners' Programs Progress Towards the Clinic

Two long-term partners (Lilly and Merck) have selected lead Azymetric<sup>™</sup> bispecific candidates for advancement towards the clinic, and Daiichi Sankyo's program achieved a significant research milestone resulting in a payment to Zymeworks.

Dr. Tehrani noted, "Looking ahead, we plan to build on the momentum established last year as we create additional value throughout our business. We anticipate achieving the following milestones: complete enrollment in our Phase 1 study and report additional data for ZW25; file an Investigational New Drug (IND) Application for our second clinical compound, ZW49; present preclinical data on our other product candidates; and expand our partnering activities."

#### Financial Results for the Year Ended December 31, 2017

Revenue in 2017 was \$51.8 million as compared to \$11.0 million in 2016. The increase of \$40.8 million was primarily due to the recognition of a \$50.0 million upfront fee received from Janssen and a \$1.0 million milestone payment from Daiichi Sankyo.

For the year ended December 31, 2017, research and development expenditures were \$41.7 million as compared to \$36.8 million in the prior year. The increase was primarily due to clinical costs for ZW25 and development costs for ZW49. General and administrative expenses were \$18.6 million in 2017 and \$12.6 million in 2016. The change between the periods was primarily due to an increase in compensation costs, professional fees, and other administrative expenses.

The net loss for the year ended December 31, 2017, decreased to \$10.4 million as compared to \$33.8 million in 2016, primarily due to increased revenue offsetting research and development expenses as previously noted. Zymeworks expects research and development expenditures to increase over time due to the ongoing development of product candidates and other clinical, preclinical, and regulatory activities.

As of December 31, 2017, Zymeworks had \$87.8 million in cash and cash equivalents and short-term investments. Zymeworks expects to continue receiving revenue from its existing and future corporate collaborations, including technology access fees, research and development fees for services rendered and milestone-based payments. However, its ability to receive these payments is dependent upon either Zymeworks or its collaborators successfully completing specified research and development activities.

#### 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.

#### **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 "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 Zymeworks' planned expansion of clinical trial sites, clinical and preclinical development of Zymeworks' product candidates, future revenue payments, potential milestones, expected research and development expenditures, and other information that is not historical information. When used herein, words such as "anticipate", "plan", "expect", "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' Annual Report on Form 10-K for its fiscal year ended December 31, 2017 (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.

## **ZYMEWORKS INC.**

Condensed Consolidated Statements of Loss (Expressed in thousands of U.S. dollars except share and per share data)

	Three Months Ended December 31, 2017 2016 (unaudited) (unaudited)		2016	Year Ended I 2017		December 31, 2016			
Revenue		,	<b>X</b> -	,					
Research and developmental collaborations	\$	50,071	\$	2,232	\$	51,762	\$	11,009	
Operating expenses:									
Research and development		12,877		8,918		41,749		36,816	
Government grants and credits		(857)		(1,265)		(1,075)		(1,265)	
		12,020		7,653		40,674		35,551	
General and administrative		4,715		5,117		18,550		12,554	
Impairment on acquired IPR&D						1,536		768	
Total operating expenses		16,735		12,770		60,760		48,873	
Income (loss) from operations		33,336		(10,538)		(8,998)		(37,864)	
Other expense, net		(334)		(734)		(964)		(1,020)	
Income (loss) before income taxes		33,002		(11,272)		(9,962)		(38,884)	
Current income tax expense		(232)		(103)		(429)		(430)	
Deferred income tax (expense) recovery		(37)		98		(15)		5,505	
Net income (loss)	\$	32,733	\$	(11,277)	\$	(10,406)	\$	(33,809)	
Net income (loss) per common share:									
Basic	\$	1.29	\$	(0.86)	\$	(0.51)	\$	(2.65)	
Diluted	\$	1.28	\$	(0.86)	\$	(0.64)	\$	(2.65)	
Weighted-average common shares outstanding:									
Basic		25,379,919		13,126,248		21,249,414		12,736,567	
Diluted	25,390,462		13,126,248		21,321,209		12,736,567		

#### ZYMEWORKS INC. Selected Condensed Consolidated Balance Sheet Data (Expressed in thousands of U.S. dollars)

	Decemb	December 31,		
	2017	2016		
Cash, cash equivalents and short-term investments	\$ 87,797	\$ 40,261		
Working capital	77,674	29,928		
Total assets	131,955	93,995		
Accumulated deficit	(108,716)	(97,790)		
Total shareholders' equity	116,428	9,002		

### **Contacts:**

Zymeworks Inc.

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

Media Inquiries: Angela Bitting (925) 202-6211 <u>a.bitting@comcast.net</u>



# Zymeworks Advances Clinical Candidate Incorporating Technology from Kairos Acquisition

Multifunctional Bispecific Antibody-Drug Conjugate; Data Scheduled for Presentation at AACR

Vancouver, Canada (March 14, 2018) – Zymeworks Inc. (NYSE/TSX: ZYME), a clinical-stage biopharmaceutical company developing multifunctional therapeutics, today announced that ZW49 is the first product candidate selected for clinical development utilizing the ZymeLink<sup>™</sup> antibody-drug conjugate (ADC) platform, acquired as part of the Company's 2016 acquisition of Kairos Therapeutics. ZW49 was developed by leveraging ZymeLink in combination with Zymeworks' flagship Azymetric<sup>™</sup> bispecific platform. The Company expects to file an Investigational New Drug (IND) application this year in order to begin clinical trials with ZW49 for patients with HER2-expressing cancers.

ZW49 is a novel bispecific ADC targeting two distinct domains of the HER2 receptor 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. As a result, ZW49 exhibited superior activity when assessed against other approved HER2-targeted therapies and Zymeworks' previous internal ADC candidate, ZW33. Consequently, the Company will advance ZW49 *in lieu* of ZW33. Preclinical data on ZW49 and more generally on the ZymeLink ADC platform will be presented at the annual meeting of the American Association for Cancer Research to be held April 2018 in Chicago. Abstracts for these preclinical data were published today.

"The data generated by ZW49 clearly supported its designation as our second product candidate for clinical evaluation," said Ali Tehrani, Ph.D., President and CEO of Zymeworks. "With the addition of the complementary ZymeLink technology, including proprietary linkers and payloads, we have been able to further leverage the power of our Azymetric platform to create a differentiated molecule that we believe has the potential for best-in-class activity and tolerability."

Zymeworks, whose protein engineering expertise and resulting therapeutic platforms have resulted in a network of global biopharmaceutical partners, is keenly focused on developing its own portfolio of product candidates. Its lead compound, ZW25, is currently being assessed in an adaptive Phase 1 clinical trial and has shown promising single-agent anti-tumor activity in patients with heavily pretreated HER2-expressing cancers that have progressed after standard of care. Zymeworks continues to accelerate the development of ZW25 and is opening several new clinical sites across North America in 2018.

"With the advancement of ZW49, we now have a portfolio of agents with the potential to address the full spectrum of patients with HER2-expressing cancers," said Diana Hausman, M.D., Chief Medical Officer of Zymeworks. "This includes those underserved patients whose tumors express lower levels of HER2 and are ineligible for treatment with HER2-targeted therapies, such as trastuzumab, pertuzumab, and T-DM1."

#### **About ADCs**

Antibody-drug conjugates are a class of anti-cancer therapies intended to precisely target tumor cells in order to avoid the significant toxicities routinely associated with cancer treatments while simultaneously improving their efficacy. An ADC is an antibody connected, or conjugated, to a small molecule drug. It has three critical components: the antibody for targeting of specific cells, the cytotoxin (or payload) being delivered to induce cancer cell death, and the linker, which connects the two components together.

#### About ZW49

ZW49 is a biparatopic (a bispecific antibody that can simultaneously bind two non-overlapping epitopes on a single target) anti-HER2 ADC based on the same framework as ZW25 but armed with the company's proprietary ZymeLink<sup>TM</sup> cytotoxic (potent cancer-cell killing) payload. ZW49 may mediate its therapeutic effect through a combination of mechanisms, including: increased HER2 receptor-antibody clustering and internalization leading to toxin-mediated cytotoxicity; dual HER2 signal blockade; increased binding and removal of HER2 protein from the cell surface; and potent effector function.

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