Section 1: 8-K (8-K)

UNITED STATES
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): November 5, 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 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))

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 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 November 5, 2019, Zymeworks Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended September 30, 2019. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

The information provided under this Form 8-K (including Exhibit 99.1) 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.

The Company makes reference to certain non-GAAP financial measures in the press release. A reconciliation of these non-GAAP financial measures to the most directly comparable GAAP financial measures is contained in the attached press release.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Zymeworks Inc. on November 5, 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: November 5, 2019

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

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Section 2: EX-99.1 (EX-99.1)

Exhibit 99.1

Zymeworks Reports 2019 Third Quarter Financial Results

Vancouver, Canada (November 5, 2019) – Zymeworks Inc. (NYSE: ZYME), a clinical-stage biopharmaceutical company developing multifunctional therapeutics, today reported financial results for the third quarter ended September 30, 2019.

"We recently presented data on our lead asset, ZW25, at two major medical conferences that pave the way for registration-enabling trials in second-line biliary tract cancer (BTC) with single agent ZW25 and in first-line gastroesophageal adenocarcinoma (GEA) with ZW25 in combination with chemotherapy," said Ali Tehrani, Ph.D., Zymeworks' President & CEO. "These clinical plans support our evaluation of ZW25's broad potential in earlier lines of therapy with the goal of establishing ZW25 as a therapeutic option for a greater number of people with HER2-expressing cancers."

Third Quarter 2019 Business Highlights and Recent Developments

- **Single Agent Data for ZW25 Presented at European Society for Medical Oncology (ESMO) Congress**
  Updated Phase 1 clinical data continued to show that ZW25 monotherapy provides anti-tumor activity and durable disease control across multiple tumor types in heavily pretreated patients. Encouraging response rates in BTC support the initiation of a registration-enabling Phase 2 trial evaluating single agent ZW25 as a second-line treatment for patients with HER2-expressing BTC.
- **ZW25 Chemotherapy Combination Data Presented at AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics**
  Phase 1 clinical data demonstrated that the addition of chemotherapy to ZW25 treatment may enhance anti-tumor activity vs. ZW25 alone, and the combination therapy was tolerated in heavily pretreated HER2-expressing GEA patients. These data further support the ongoing Phase 2 trial of ZW25 in combination with standard of care chemotherapy in first-line GEA.
- **Celgene Advances First Azymetric™ Bispecific Towards the Clinic**
  Celgene selected its first lead bispecific antibody candidate built using Zymeworks' Azymetric platform and exercised its option to a commercial license for which Zymeworks received a US$7.5 million payment.

Financial Results for the Quarter Ended September 30, 2019

Revenue for the three months ended September 30, 2019 was $7.9 million as compared to $2.1 million in the same period of 2018. Revenue for the third quarter of 2019 includes $7.5 million recognized upon Celgene's exercise of its commercial license option and $0.4 million in research and support payments from our partners. Revenue in the same period in 2018 was primarily due to a $2.0 million development milestone upon Lilly's submission of an IND application under a licensing agreement with Lilly.

For the three months ended September 30, 2019, research and development expenses were $29.3 million as compared to $14.2 million in the same period of the prior year. The change was primarily due to an increase in clinical trial activity and associated manufacturing costs for ZW25, as well as an increase in other research and discovery activities compared to the same period in 2018. Research and development expenses included non-cash stock-based compensation expense of $1.7 million from equity-classified stock options and a $0.9 million expense related to the non-cash mark-to-market revaluation of certain historical liability-classified stock options.

For the three months ended September 30, 2019, general and administrative expenses were $12.2 million as compared to $7.5 million in the same period in 2018, primarily due to an increase in employee compensation expenses relating to non-cash stock-based compensation, as well as increased head count in 2019 over 2018. General and administrative expenses in 2019 included non-cash stock-based compensation expense of $1.7 million from equity-classified stock options and $2.8 million related to the non-cash mark-to-market revaluation of certain historical liability-classified stock options.

The net loss for the three months ended September 30, 2019, was $30.5 million as compared to $18.8 million in the same period of 2018. This was primarily due to an increase in research and development expenses associated with our lead therapeutic candidates and other programs, as well as an increase in general and administrative expenses in 2019. This increase was partially offset by increased revenue from research and development collaborations, interest and other income in 2019.

Zymeworks expects research and development expenditures to increase over time in line with the advancement and expansion of clinical development of our product candidates, as well as our ongoing preclinical research activities. Additionally, Zymeworks anticipates continuing to receive revenue from our existing and future strategic partnerships, including technology access fees, milestone-based payments and research support payments. However, Zymeworks' ability to receive these payments is dependent upon either Zymeworks or our collaborators successfully completing specified research and development activities.

As of September 30, 2019, Zymeworks had $335.1 million in cash and cash equivalents and short-term investments.

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, but are not limited to, statements that relate to plans to initiate a registration-enabling trial for ZW25, increases in research and development expenditures, planned advancement and expansion of clinical development of Zymeworks' product candidates, anticipated continued receipt of revenue from existing and future partners, and other information that is not historical information. When used herein, words and phrases such as "enable", "may", "expect", "anticipate", "advances", "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, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue				
Research and developmental collaborations	$ 7,860	$ 2,054	$ 27,667	$ 24,094
Operating expenses:				
Research and development	29,251	14,195	70,511	42,648
General and administrative	12,173	7,447	33,937	23,161
Impairment on acquired IPR&D	—	—	768	—
Total operating expenses	41,424	21,642	105,216	65,809
Loss from operations	(33,564)	(19,588)	(77,549)	(41,715)
Other income (expense), net	2,181	886	4,276	(2,288)
Loss before income taxes	(31,383)	(18,702)	(73,273)	(44,003)
Income tax expense (recovery)	908	(49)	80	(1,826)
Net loss and comprehensive loss	$ (30,475)	$ (18,751)	$ (73,193)	$ (45,829)
Net loss per common share:				
Basic	(0.70)	(0.59)	(2.03)	(1.63)
Diluted	(0.70)	(0.59)	(2.03)	(1.63)
Weighted-average common shares outstanding:				
Basic	43,445,379	31,959,206	36,143,113	28,119,872
Diluted	43,445,379	31,959,206	36,143,113	28,119,872

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

	September 30, 2019	December 31, 2018
Cash, cash equivalents and short-term investments	$ 335,103	$ 200,164
Working capital	294,622	174,383
Total assets	400,037	244,363
Accumulated deficit	(218,465)	(145,272)
Total shareholders' equity	309,525	180,490

NON-GAAP FINANCIAL MEASURES

In addition to reporting financial information in accordance with U.S. generally accepted accounting principles ("GAAP") in this press release, Zymeworks is also reporting normalized expenses and normalized loss per share, which are non-GAAP financial measures. Normalized expenses and normalized loss per share are not defined by GAAP and should not be considered as alternatives to net loss, net loss per share or any other indicator of Zymeworks' performance required to be reported under GAAP. In addition, Zymeworks' definitions of normalized expenses and normalized loss per share may not be comparable to similarly titled non-GAAP measures presented by other companies. Investors and others are encouraged to review Zymeworks' financial information in its entirety and not rely on a single financial measure. As defined by Zymeworks, normalized expenses represent total research and development expenses and general and administrative expenses adjusted for non-cash stock-based compensation expenses for equity and liability-classified equity instruments.

Normalized expenses are a non-GAAP measure that Zymeworks believes is useful because it excludes those items that Zymeworks believes are not representative of Zymeworks' operating expenses.

GAAP to Non-GAAP Reconciliations
(Expressed in thousands of U.S. dollars except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development expenses	$ 29,251	$ 14,195	$ 70,511	$ 42,648
Stock based compensation for equity-classified instruments	(1,690)	(691)	(4,324)	(1,724)
Stock based compensation for liability-classified instruments	(888)	(496)	(2,856)	(1,966)
Normalized research and development expenses (Non-GAAP basis)	$ 26,673	$ 13,008	$ 63,331	$ 38,958
General and administrative expenses	$ 12,173	$ 7,447	$ 33,937	$ 23,161
Stock based compensation for equity-classified instruments	(1,721)	(1,093)	(4,791)	(2,758)
Stock based compensation for liability-classified instruments	(2,781)	(1,304)	(8,908)	(5,342)
Normalized general and administrative expenses (Non-GAAP basis)	$ 7,671	$ 5,050	$ 20,238	$ 15,061

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss per common share – Basic	(0.70)	(0.59)	(2.03)	(1.63)
Stock based compensation for equity-classified instruments	0.08	0.06	0.25	0.16
Stock based compensation for liability-classified instruments	0.08	0.06	0.33	0.26
Normalized net loss per common share – Basic (Non-GAAP basis)	(0.54)	(0.47)	(1.45)	(1.21)
Net loss per common share – Diluted	(0.70)	(0.59)	(2.03)	(1.63)
Stock based compensation for equity-classified instruments	0.08	0.06	0.25	0.16
Stock based compensation for liability-classified instruments	0.08	0.06	0.33	0.26
Normalized net loss per common share – Diluted (Non-GAAP basis)	(0.54)	(0.47)	(1.45)	(1.21)

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