
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): March 2, 2020

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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 March 2, 2020, Zymeworks Inc. (the "Company") issued a press release announcing its financial results for the fiscal year ended December 31, 2019. A copy of the press release is attached 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**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated March 2, 2020.

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: March 2, 2020

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 Year-End Financial Results

Vancouver, Canada (March 2, 2020) – Zymeworks Inc. (NYSE: ZYME), a clinical-stage biopharmaceutical company developing multifunctional biotherapeutics, today reported financial results for the year ended December 31, 2019.

“We’ve started the year off strong thanks to significant clinical progress in the second half of 2019 and a recent financing that has provided expanded resources to further advance global development of our clinical candidates, ZW25 and ZW49,” said Ali Tehrani, Ph.D., Zymeworks’ President & CEO. “We plan to initiate registration-enabling studies for ZW25 in both biliary tract and gastric cancer, as well as explore additional indications, with a vision toward establishing ZW25 as the new foundational HER2 therapy. We also remain confident in the potential of ZW49 to be transformative in refractory and low HER2-expressing cancers and expect to begin expansion cohorts later this year.”

2019 Business Highlights and Recent Developments

- **Strengthened Balance Sheet**

In January 2020, Zymeworks completed an upsized US\$320.8 million public financing to accelerate and expand global development of its lead clinical candidates, ZW25 and ZW49, and support further advancement of its novel preclinical programs.

- **Robust ZW25 Clinical Data and Initiation of Two Phase 2 Clinical Trials Pave the Way for Upcoming Registration-Enabling Studies**

ZW25 has been well tolerated and has demonstrated promising anti-tumor activity both as a single agent and in combination with chemotherapy, supporting the planned initiation of two registration-enabling trials in refractory HER2-positive biliary tract cancer and first-line HER2-positive gastroesophageal adenocarcinomas. In addition, Zymeworks recently initiated a Phase 2 trial and collaboration with Pfizer to evaluate ZW25 in combination with palbociclib and fulvestrant in HER2-positive, hormone receptor-positive breast cancer.

- **ZW49 Advancing Phase 1 Dose-Escalation and Interim Clinical Update**

Zymeworks’ second product candidate, ZW49, began a Phase 1 clinical trial to evaluate safety and anti-tumor activity, and to establish a recommended dose and schedule for expansion cohorts. A recent update highlighted that there had been no dose-limiting toxicities observed and the maximum tolerated dose had not been reached. The majority of treatment-related adverse events were grade 1 or 2, and were reversible and manageable on an outpatient basis. Preliminary results from these initial dose cohorts included anti-tumor activity.

- **Partner Programs Progress into the Clinic**

In 2019, Eli Lilly entered the clinic with a novel bispecific; Merck, Celgene (now BMS), and Daiichi Sankyo advanced bispecific candidates toward clinical testing; GSK expanded its Azymetric™ partnership; and the first ZymeLink ADC collaboration was signed with Iconic Therapeutics. Zymeworks currently has nine active collaborations that offer up to US\$7.9 billion in potential milestone payments as well as royalties on potential product sales.

Financial Results for the Year Ended December 31, 2019

Revenue in 2019 was \$29.5 million as compared to \$53.0 million in 2018. Revenue for both years was primarily comprised of non-recurring upfront fees, expansion payments and milestone payments from Zymeworks' licensing and collaboration agreements. Revenue for 2019 included \$8.0 million received from Eli Lilly for achievement of a development milestone upon their submission of an IND application, \$7.5 million received upon BMS's exercise of its commercial license option, \$3.5 million received upon Daiichi Sankyo's exercise of a commercial license option, and \$7.0 million received in other development milestones and research support and other payments from our partners. Revenue in 2019 also included recognition of \$3.5 million from deferred revenue relating to the upfront payment received in the prior year from BeiGene under the 2018 licensing and collaboration agreement for development of ZW25.

Revenue for 2018 included recognition of \$23.5 million of the \$60.0 million upfront fee from BeiGene associated with a new licensing agreement, an \$18.0 million upfront fee related to a second licensing agreement with Daiichi Sankyo, a \$5.0 million upfront fee related to a new licensing agreement with LEO Pharma, a \$4.0 million research program expansion fee from BMS and \$2.5 million in other milestones and research support payments from our partners.

For the year ended December 31, 2019, research and development expenses were \$115.9 million as compared to \$56.9 million in the prior year. The change was primarily due to an increase in activities related to the progression and expansion of ZW25 clinical studies and the associated manufacturing costs, as well as development activities for ZW49 in 2019, and an increase in other research and development activities, which include an increase in salaries and benefits expense as a result of an increase in headcount and non-cash stock-based compensation expense compared to the same period in 2018. Research and development expense included non-cash stock-based compensation expense of \$14.3 million, including expense of \$8.4 million related to the mark-to-market revaluation of certain historical liability classified equity awards.

For the year ended December 31, 2019, general and administrative expenses were \$64.2 million as compared to \$29.5 million in the prior year. The change was due to an increase in headcount to support our expanding research and development activities and non-cash stock-based compensation expense. General and administrative expense included non-cash stock-based compensation expense of \$34.2 million including \$27.5 million expense related to the mark-to-market revaluation of certain historical liability classified equity awards.

Net loss for the year ended December 31, 2019 was \$145.4 million as compared to \$36.6 million in 2018. This increase in net loss was primarily due to the variances in revenue, research and development expenses and general and administration expenses noted above.

Zymeworks expects research and development expenditures to increase over time due to the ongoing development of our product candidates and other clinical, preclinical, and regulatory activities. Additionally, Zymeworks anticipates continuing to receive revenue from its existing and future strategic partnerships, including technology access fees, milestones and research support payments. However, Zymeworks' ability to receive these payments is dependent upon either Zymeworks or its collaborators successfully completing specified research and development activities.

As of December 31, 2019, Zymeworks had \$298.9 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 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 press release include, but are not limited to, statements that relate to Zymeworks' clinical and preclinical development of its 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”, “expect”, “plan”, “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, 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.**Consolidated Statements of Loss and Comprehensive Loss****(Expressed in thousands of U.S. dollars except share and per share data)**

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
	(unaudited)	(unaudited)		
Revenue				
Research and development collaborations	\$ 1,877	\$ 28,925	\$ 29,544	\$ 53,019
Operating expenses:				
Research and development	45,389	14,278	115,900	56,926
General and administrative	30,240	6,296	64,177	29,457
Impairment on acquired IPR&D	—	—	768	—
Total operating expenses	75,629	20,574	180,845	86,383
(Loss) income from operations	(73,752)	8,351	(151,301)	(33,364)
Other income (expense), net	1,006	1,267	5,282	(1,021)
(Loss) income before income taxes	(72,746)	9,618	(146,019)	(34,385)
Net income tax recovery (expense)	502	(345)	582	(2,171)
Net (loss) income	\$ (72,244)	\$ 9,273	\$ (145,437)	\$ (36,556)
Net (loss) income per common share:				
Basic	\$ (1.66)	\$ 0.29	\$ (3.83)	\$ (1.26)
Diluted	\$ (1.66)	\$ 0.29	\$ (3.83)	\$ (1.26)
Weighted-average common shares outstanding:				
Basic	43,597,446	31,968,339	38,022,014	29,089,896
Diluted	43,597,446	31,988,216	38,022,014	29,089,896

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

	December 31,	
	2019	2018
Cash, cash equivalents and short-term investments	\$ 298,904	\$ 200,164
Working capital	229,278	174,383
Total assets	368,205	244,477
Accumulated deficit	(290,709)	(145,272)
Total shareholders' equity	245,681	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		Year Ended	
	December 31,		December 31,	
	2019	2018	2019	2018
Research and development expenses	\$ 45,389	\$ 14,278	\$ 115,900	\$ 56,926
Stock based compensation for equity classified instruments	(1,615)	(479)	(5,939)	(2,203)
Stock based compensation for liability classified instruments	(5,502)	(67)	(8,358)	(2,032)
Normalized research and development expenses (Non-GAAP basis)	38,272	13,732	101,603	52,691
General and administrative expenses	30,240	6,296	64,177	29,457
Stock based compensation for equity classified instruments	(1,946)	(935)	(6,737)	(3,693)
Stock based compensation for liability classified instruments	(18,562)	(20)	(27,470)	(5,362)
Normalized general and administrative expenses (Non-GAAP basis)	\$ 9,732	\$ 5,341	\$ 29,970	\$ 20,402

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2019	2018	2019	2018
Net (loss) income per common share – Basic	\$ (1.66)	\$ 0.29	\$ (3.83)	\$ (1.26)
Stock based compensation for equity classified instruments	0.08	0.04	0.33	0.20
Stock based compensation for liability classified instruments	0.52	—	0.91	0.25
Normalized net (loss) income per common share – Basic (Non-GAAP basis)	\$ (1.06)	\$ 0.33	\$ (2.59)	\$ (0.81)
Net (loss) income per common share – Diluted	\$ (1.66)	\$ 0.29	\$ (3.83)	\$ (1.26)
Stock based compensation for equity classified instruments	0.08	0.04	0.33	0.20
Stock based compensation for liability classified instruments	0.52	—	0.91	0.25
Normalized net (loss) income per common share – Diluted (Non-GAAP basis)	\$ (1.06)	\$ 0.33	\$ (2.59)	\$ (0.81)

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