
**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 4, 2022

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)

98-1398788
(IRS Employer Identification No.)

Suite 800, 114 East 4th Avenue, Vancouver, British Columbia, Canada
(Address of principal executive offices)

V5T 1G4
(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 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 May 4, 2022, Zymeworks Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter ended March 31, 2022. 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

Exhibit No.	Description
99.1	Press Release dated May 4, 2022.
104	Cover Page Interactive Data File (embedded as Inline XBRL document)

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: May 4, 2022

By: /s/ Christopher Astle

Name:

Christopher Astle

Title: Senior Vice President and
Chief Financial Officer



Zymeworks Provides Corporate Update and Reports First Quarter 2022 Financial Results

- *Last patient enrolled ahead of expectations in pivotal trial evaluating zanidatamab as monotherapy in 2L biliary tract cancers (BTC)*
- *Two zanidatamab data presentations at ASCO in June: 1L breast cancer and 1L gastroesophageal adenocarcinoma (GEA)*
- *Presented topoisomerase 1 inhibitor (TOPO1i) antibody-drug conjugate (ADC) platform at World ADC London highlighting next-generation ADC capabilities and potential ADC candidates*
- *Completed licensing agreement with Atreca utilizing ZymeLink's auristatin-based ADC platform*
- *ZW49 continues to progress towards anticipated data read-out in 2H22*
- *Will host conference call with Management today at 4:30 PM ET*

Vancouver, Canada (May 4, 2022) – Zymeworks Inc. (NYSE: ZYME), a clinical-stage biopharmaceutical company developing multifunctional biotherapeutics, today reported financial results for the first quarter ended March 31, 2022.

“We are incredibly excited to celebrate the milestone of the last patient enrolled for our pivotal study in second-line biliary tract cancers, as well as the continued progression of multiple zanidatamab clinical studies that we will be presenting over the course of the year starting at ASCO in June,” said Kenneth Galbraith, Chair & CEO. “The completion of enrollment in HERIZON-BTC-01 is an important step forward in our efforts to provide patients with a new HER2-targeted therapy for BTC with the potential to improve on the current standard of care. We completed this clinical milestone ahead of our previously guided timeline set out in January, and hope to continue delivering on our corporate goals and exceeding expectations as we move forward.”

First Quarter 2022 Business Highlights and Recent Developments

- *Completed Enrollment in HERIZON-BTC-01 Pivotal Trial in 2L Biliary Tract Cancers (BTC)*
Enrollment was completed ahead of schedule for the global, pivotal trial (HERIZON-BTC-01) evaluating zanidatamab monotherapy in patients with previously-treated advanced HER2-amplified BTC. The primary endpoint of this pivotal trial is confirmed objective response rate as determined by independent central review and we expect to finalize and present top-line data by early 2023. We expect that full details of the study will be presented at a major medical meeting in 2023.

- ***Unveiled Next-Generation TOPO1i ADC Platform Presentation***
The presentation shown in March at World ADC London highlighted the development of our next-generation TOPO1i ADC payload technology. We anticipate sharing more information on potential therapeutic candidates leveraging this TOPO1i platform at our R&D day in the fourth quarter of this year as we advance towards our goal of submitting two new Investigational New Drug applications by the end of 2024.
- ***Completed Licensing Agreement with Atreca Utilizing Auristatin-Based ADC Platform***
The technology licensing agreement with Atreca provides further validation of our auristatin-based ADC and technology platforms and showcases our ability to generate continued non-dilutive funding opportunities.
- ***ZW49 Enrollment Continues to Advance Toward Anticipated Data Readout in 2H22***
Zymeworks' second clinical-stage asset and first biparatopic HER2-targeting antibody-drug conjugate, ZW49, has completed enrollment of 30 patients in the expansion cohorts targeting 2.5 mg/kg every three weeks. Additionally, the weekly dosing regimen recently expanded enrollment in the 1.5 mg/kg cohort and, in parallel, is now enrolling patients in the 1.75 mg/kg escalation cohort. Enrollment continues to progress well and we remain on target to submit data for presentation at a major medical meeting expected to occur in the second half of this year.

Zanidatamab Update at 2022 American Society of Clinical Oncology (ASCO) Annual Meeting

Zymeworks' Asia-Pacific partner BeiGene will present data at the upcoming ASCO meeting in June on the first-line treatment of patients with HER2+ metastatic breast cancer using zanidatamab plus chemotherapy and on the first-line treatment of patients with HER2+ metastatic GEA using zanidatamab in combination with chemotherapy and tislelizumab. The outcomes of these treatments will be released in abstract form on May 26th, and more detailed information will be discussed at poster presentations on June 4th for first-line GEA and on June 6th for first-line breast cancer. Both presentations will provide further validation of zanidatamab's clinical efficacy and stand to strengthen its position as a leading biparatopic HER2-targeting antibody. We plan to host a conference call to present the clinical results and clinical development strategy for zanidatamab after the ASCO Annual Meeting.

"We look forward to discussing these two important datasets at the ASCO meeting, and how the results will help shape our future development plans for zanidatamab," said Neil Josephson, M.D., Chief Medical Officer. "This will be the first presentation of clinical data with zanidatamab in the first-line treatment of advanced or metastatic HER2-positive breast cancer. The GEA presentation will contain new data from patients treated with standard of care first-line chemotherapy combined with zanidatamab, and the PD-1 inhibitor tislelizumab; a regimen that is being evaluated in the ongoing phase 3 HERIZON-GEA-01 study. We also look forward to additional opportunities available throughout 2022 to provide progress updates and present additional clinical data to support our global development program for zanidatamab."

Financial Results for the Quarter Ended March 31, 2022

Zymeworks' revenue relates primarily to non-recurring upfront fees, expansion payments or milestone payments from collaboration and license agreements, which can vary in timing and amount from period to period, as well as payments for research and development support. Revenue for the three months ended March 31, 2022 was \$1.9 million compared to \$0.6 million for the same period of 2021. Revenue for 2022 related to research support and other payments from our partners including cost sharing arrangements. Revenue for the same period in 2021 was also related to research support and other payments from our partners.

Research and development expense increased by \$18.2 million in the three months ended March 31, 2022 compared to the same period in 2021. Research and development expense in 2022 included non-cash stock-based compensation recovery of \$3.2 million, comprised of a \$2.7 million recovery from equity classified awards and a \$0.5 million recovery related to the non-cash mark-to-market revaluation of certain historical liability classified awards, as well as \$5.5 million from restructuring expenses. Excluding stock-based compensation expense and restructuring expenses, research and development expense increased on a Non-GAAP basis by \$17.7 million in 2022 compared to 2021. The increase related primarily to higher clinical trial expenses for zanidatamab, increased drug manufacturing expenses, severance and other expenses incurred due to the Company's restructuring program, partly offset by lower clinical trial expense for ZW49.

We expect research and development expenditures to fluctuate over time in line with the advancement, expansion and completion of the clinical development of our product candidates, as well as our ongoing preclinical research activities.

Excluding the impact of stock-based compensation and restructuring expenses, general and administrative expense increased on a Non-GAAP basis by \$3.2 million in 2022 compared to 2021. This increase was primarily due to severance and other expenses incurred due to the Company's restructuring program in 2022 as well as a non-recurring sales tax refund recognized in 2021, which offset expenses in the prior year.

Net loss for the three months ended March 31, 2022 was \$72.6 million compared to \$44.6 million for the same period of 2021. This was primarily due to increase in research and development expenses and general and administrative expenses referred to above.

"We continue to make progress upon our goal of improving our financial position and have successfully completed the first steps with the reduction in anticipated spending through prioritization of R&D programs and the previously announced new equity issuance closed in January," said Chris Astle, Ph.D., SVP and Chief Financial Officer. "We remain committed to further improving our cash position through non-dilutive capital and executing on the framework laid out in January, and we look forward to reporting on these initiatives in the coming months."

As of March 31, 2022, Zymeworks had \$300.5 million in cash resources consisting of cash, cash equivalents and short-term investments. Based on our current operating plan, we believe that our current cash resources, and proceeds from certain existing collaboration payments we anticipate receiving, will enable us to fund our planned operations into the second half of 2023 and potentially beyond. Further, we continue to make good progress towards our previously announced goal of executing on new partnerships and collaborations in order to provide additional non-dilutive sources of funding for our operations beyond 2023.

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 therapeutic platforms and its fully integrated drug development engine enable precise engineering of highly differentiated product candidates. Zymeworks' lead clinical candidate, zanidatamab, is a novel Azymetric™ HER2-targeted bispecific antibody currently being evaluated in multiple Phase 1, Phase 2, and pivotal clinical trials globally as a targeted treatment option for patients with solid tumors that express HER2. Zymeworks' second clinical candidate, ZW49, is a novel bispecific HER2-targeted antibody-drug conjugate currently in Phase 1 clinical development and combines the unique design and antibody framework of zanidatamab with Zymeworks' proprietary ZymeLink™ linker and cytotoxin. 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 global biopharmaceutical companies. For more information on our ongoing clinical trials visit www.zymeworksclinicaltrials.com. For additional information about Zymeworks, visit www.zymeworks.com and follow [@ZymeworksInc](https://twitter.com/ZymeworksInc) on Twitter.

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' expectations regarding implementation of its corporate goals, Zymeworks' clinical development of its product candidates, related clinical trials, anticipated clinical data presentations, potential therapeutic effects of zanidatamab and its other product candidates, expected financial performance and future financial position, the commercial potential of technology platforms and product candidates, anticipated continued receipt of revenue from existing and future partners, Zymeworks' preclinical pipeline, anticipated sufficiency of cash resources and other potential sources of cash to fund Zymeworks' planned operations into the second half of 2023 and potentially beyond, Zymeworks' ability to execute new collaborations and partnerships and other information that is not historical information. When used herein, words such as “plan”, “hope”, “believe”, “expect”, “may”, “continue”, “anticipate”, “potential”, “will”, “progress”, “look forward”, 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: the impact of the COVID-19 pandemic on Zymeworks' business, research and clinical development plans and timelines and results of operations, including impact on its clinical trial sites, collaborators, and contractors who act for or on Zymeworks' behalf, may be more severe and more prolonged than currently anticipated; clinical trials may not demonstrate safety and efficacy of any of Zymeworks' or its collaborators' product candidates; any of Zymeworks' or its partners' product candidates may fail in development, may not receive required regulatory approvals, or may be delayed to a point where they are not commercially viable; regulatory agencies may impose additional requirements or delay the initiation of clinical trials; the impact of new or changing laws and regulations; market conditions; Zymeworks' assumptions regarding its financial condition or future financial performance may be incorrect; Zymeworks may not recognize the anticipated cost savings of its reduction in workforce;

inability to maintain or enter into new partnerships or strategic collaborations; and the factors described under “Risk Factors” in Zymeworks’ quarterly and annual reports filed with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for its quarter ended March 31, 2022, which the Company anticipates filing on or about the date hereof (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 and Comprehensive Loss**
(Expressed in thousands of U.S. dollars except share and per share data) (unaudited)

	Three Months Ended March 31,	
	2022	2021
Revenue		
Research and development collaborations	\$ 1,916	\$ 644
Operating expenses:		
Research and development	62,510	44,283
General and administrative	12,092	1,296
Total operating expenses	74,602	45,579
Loss from operations	(72,686)	(44,935)
Other income (expense), net	(13)	870
Loss before income taxes	(72,699)	(44,065)
Income tax recovery (expense)	74	(525)
Net loss and comprehensive loss	\$ (72,625)	\$ (44,590)
Net loss per common share:		
Basic	\$ (1.18)	\$ (0.87)
Diluted	\$ (1.19)	\$ (0.87)
Weighted-average common shares outstanding:		
Basic	61,367,368	51,367,663
Diluted	61,378,170	51,367,663

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

	March 31,	December 31,
	2022	2021
	(unaudited)	
Cash, cash equivalents and short-term investments	\$ 300,534	\$ 252,608
Working capital	244,051	216,367
Total assets	429,977	389,132
Accumulated deficit	(755,729)	(683,104)
Total shareholders' equity	282,444	249,094

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 adjusted expenses and adjusted loss per share, which are non-GAAP financial measures. Adjusted expenses and adjusted 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, other companies, including companies in our industry, may calculate similarly titled non-GAAP or adjusted measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of our adjusted expenses measures as tools for comparison. 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, adjusted 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 as well as expenses incurred in relation the restructuring program implemented in 2022.

Adjusted expenses are a non-GAAP measure that Zymeworks believes may be helpful to investors because they provide consistency and comparability with past financial performance.

GAAP to Non-GAAP Reconciliations

(Expressed in thousands of U.S. dollars except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2022	2021
Research and development expenses	\$ 62,510	\$ 44,283
Stock-based compensation recovery / (expense) for equity classified instruments (*)	2,747	(4,336)
Stock-based compensation recovery / (expense) for liability classified instruments (*)	474	2,513
Restructuring expenses	(5,542)	—
Adjusted research and development expenses (Non-GAAP basis)	\$ 60,189	\$ 42,460
General and administrative expenses	\$ 12,092	\$ 1,296
Stock-based compensation recovery / (expense) for equity classified instruments (*)	2,232	(4,192)
Stock-based compensation recovery / (expense) for liability classified instruments (*)	2,876	12,951
Restructuring expenses	(3,935)	—
Adjusted general and administrative expenses (Non-GAAP basis)	\$ 13,265	\$ 10,055
Net loss per common share – Basic	\$ (1.18)	\$ (0.87)
Stock-based compensation recovery	(0.13)	(0.13)
Restructuring expenses	0.15	—
Adjusted net loss per common share – Basic (Non-GAAP basis)	\$ (1.16)	\$ (1.00)
Net loss per common share – Diluted	\$ (1.19)	\$ (0.87)
Stock-based compensation recovery	(0.13)	(0.13)
Restructuring expenses	0.15	—
Adjusted net loss per common share – Diluted (Non-GAAP basis)	\$ (1.17)	\$ (1.00)

(*): Research and development expenses and general and administrative expenses include stock-based compensation recovery related to the restructuring of \$5,516 and \$4,865, respectively, for the three months ended March 31, 2022.

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