# Zymeworks Reports 2021 First Quarter Financial Results

May 5, 2021

VANCOUVER, British Columbia--(BUSINESS WIRE)-- Zymeworks Inc. (NYSE: ZYME), a clinical-stage biopharmaceutical company developing multifunctional biotherapeutics, today reported financial results for the first quarter ended March 31, 2021.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20210505006039/en/


FDA cleared the IND for Zanidatamab's first randomized Phase 3 trial in first line HER2-positive gastric cancer. (Photo: Business Wire)

“As we look ahead over the next 12 months, Zymeworks is focused on delivering several key clinical data presentations highlighting the significant potential of zanidatamab and ZW49, as well as driving continued value creation from our preclinical assets and partnerships,” said Ali Tehrani, Ph.D., Zymeworks’ President & CEO. “Recently, the FDA cleared the IND for zanidatamab's first randomized Phase 3 trial in first line HER2-positive gastric cancer, which represents a significant corporate milestone. This will also be the second pivotal trial for zanidatamab, in addition to our ongoing trial in refractory HER2-amplified biliary tract cancer. We look forward to presenting the supportive Phase 2 data at an upcoming medical meeting this year.”

**First Quarter 2021 Business Highlights and Recent Developments**

- **Zanidatamab Advances in Pivotal Trial in Biliary Tract Cancer (BTC)**
  Enrollment continues at sites across North and South America, Europe, and Asia for the global, pivotal trial for zanidatamab (a HER2-targeted bispecific antibody) monotherapy in patients with previously treated HER2 gene-amplified BTC (HERIZON-BTC-01). This trial was initiated based on encouraging data, recently updated at the American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium in January, which highlighted a 40% confirmed objective response rate for zanidatamab monotherapy in BTC. Zanidatamab development is also supported by a number of special designations in the U.S. and European Union, including Breakthrough Therapy designation for BTC from the U.S. Food and Drug Administration (FDA).
- **FDA Clears Zanidatamab Phase 3 Pivotal Trial in First Line HER2-positive Gastroesophageal Adenocarcinoma (GEA)**
  Zymeworks recently received clearance from the FDA for its first randomized Phase 3 clinical trial for zanidatamab. HERIZON-GEA-01 is a randomized, multicenter study of zanidatamab in combination with chemotherapy with or without BeiGene’s PD-1-targeted antibody, tislelizumab, as a first line treatment for patients with HER2-positive unresectable locally advanced or metastatic GEA. Supportive clinical data from an ongoing Phase 2 clinical trial evaluating zanidatamab with chemotherapy in first line HER2-positive GEA are expected to be presented at a medical conference in the second half of the year.
- **ZW49 Continues Enrollment in Dose-Escalation and Expansion Cohorts**
  In January, interim data was presented for ZW49, a bispecific antibody-drug conjugate targeting HER2, which demonstrated antitumor activity and a differentiated safety profile. Specifically, there have been no dose limiting toxicities,

no treatment-related hematologic, pulmonary, or liver toxicity, and no treatment-related deaths. Over 90% of treatment-related adverse events have been mild or moderate in severity, with the most common being keratitis, fatigue, and diarrhea, which have been reversible and manageable in an outpatient setting. ZW49 has demonstrated antitumor activity at all dose levels evaluated in the once every three week regimen, including confirmed partial responses and stable disease per RECIST 1.1. Dose escalation is continuing in both the weekly and once every three week schedules and three indication-specific expansion cohorts (HER2-positive breast cancer, HER2-positive GEA, and a basket cohort of other HER2-positive cancers) utilizing the 2.5 mg/kg once every three week regimen have also been initiated. The objective of these studies is to identify a recommended Phase 2 dose and schedule by the end of this year.

- **Preclinical Assets, Including New Therapeutic Platform, ProTECT™, and Zanidatamab Mechanisms of Action Showcased at AACR Annual Meeting**
  Data presented at the American Association for Cancer Research (AACR) in April highlighted preclinical data that reveal new insights into the unique mechanisms of action of lead clinical candidate, zanidatamab, introduce Zymeworks' fourth therapeutic platform, ProTECT™, and describe two new preclinical assets focused on both the cytokine, IL-12, and the immune-oncology target, 4-1BB.
- **Expanded Commercial and Clinical Leadership**
  As zanidatamab advances in late-stage clinical development, Zymeworks continues to build its clinical and commercial leadership team in preparation for potential commercial launch. In January, James Priour, former Senior Vice President, Commercial, was promoted to Chief Commercial Officer and named to the Company's Executive Committee. The Commercial team also recruited Manny Duenas as Vice President, Global Value & Access. The clinical team was strengthened with the recent additions of Dr. Jonas Hylton as Vice President, Medical and Scientific Affairs and Dr. Kaycia Wilde as Vice President, Clinical Operations.

**Financial Results for the Quarter Ended March 31, 2021**

Revenue for the three months ended March 31, 2021 was $0.6 million compared to $8.3 million for the same period of 2020. Revenue for the first quarter of 2021 related to research support and other payments from our partners. Revenue for the same period in 2020 included $5.0 million from BeiGene for a development milestone and $3.3 million from our partners for research support, drug supply and other payments.

For the three months ended March 31, 2021, research and development expenses were $44.3 million compared to $36.9 million for the same period of 2020. The increase was primarily due to higher salaries and benefits expense from additional headcount and an increase in lab and consulting expenses partly offset by slightly lower third-party research and development program expenses. For the three months ended March 31, 2021, research and development expenses included non-cash stock-based compensation expense of $4.3 million from equity-classified equity awards and a $2.5 million recovery related to the non-cash mark-to-market revaluation of certain historical liability classified equity awards.

For the three months ended March 31, 2021, general and administrative expenses were $1.3 million compared to $7.2 million for the same period in 2020. The decrease was primarily due to a $5.7 million increase in stock-based compensation recovery. For the three months ended March 31, 2021, general and administrative expenses included non-cash stock-based compensation expense of $4.2 million from equity-classified equity awards and a $13.0 million recovery related to the non-cash mark-to-market revaluation of certain historical liability-classified equity awards. Excluding stock-based compensation, general and administrative expense decreased by $0.2 million in the three months ended March 31, 2021 compared to the same period in 2020.

Net loss for the three months ended March 31, 2021 was $44.6 million compared to $31.1 million for the same period of 2020. This was primarily due to the decrease in revenue and interest income and increase in research and development expenses referred to above, partially offset by lower general and administrative expenses.

Zymeworks expects research and development expenditures to increase over time in line with the advancement and expansion of the Company's clinical development of its product candidates, as well as its ongoing preclinical research activities. Additionally, Zymeworks anticipates continuing to receive revenue from its existing and future strategic partnerships, including technology access fees and milestone-based 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 March 31, 2021, Zymeworks had $411.5 million in cash resources consisting of cash, cash equivalents and short-term investments. We anticipate this will enable us to fund our planned operations into the second half of 2022 and potentially beyond.

**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, zanidatamab (ZW25), is a novel Azymetric™ bispecific antibody which has been granted Breakthrough Therapy designation by the FDA and is currently enrolling in a pivotal clinical trial for refractory HER2-amplified biliary tract cancer (HERIZON-BTC-01) as well as several Phase 2 clinical trials for HER2-expressing gastroesophageal and breast cancers. Zymeworks' second clinical candidate, ZW49, is a novel bispecific HER2-targeting 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 nine biopharmaceutical companies. For additional information about Zymeworks, visit www.zymeworks.com and follow @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 news release include, but are not limited to, statements that relate to Zymeworks' clinical and preclinical development of its product candidates, related clinical trials and regulatory filings, anticipated clinical data presentations, potential commercial launch, expected increases in research and development expenditures, anticipated continued receipt of revenue from existing and future partners, and other information that is not historical information. When used herein, words such as "plan", "expect", "may", "continue", "anticipate", "potential" 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 March 31, 2021 (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) (unaudited)**

| | Three Months Ended March 31, | |
|---|---|---|
| | 2021 | 2020 |
| Revenue | | |
| Research and development collaborations | $ 644 | $ 8,269 |
| Operating expenses: | | |
| Research and development | 44,283 | 36,943 |
| General and administrative | 1,296 | 7,206 |
| Total operating expenses | 45,579 | 44,149 |
| Loss from operations | (44,935) | (35,880) |
| Other income, net | 870 | 5,119 |
| Loss before income taxes | (44,065) | (30,761) |
| Income tax expense | (525) | (375) |
| Net loss and comprehensive loss | $ (44,590) | $ (31,136) |
| Net loss per common share: | | |
| Basic and diluted | $ (0.87) | $ (0.64) |
| Weighted-average common shares outstanding: | | |
| Basic and diluted | 51,367,663 | 48,686,718 |

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

| | March 31, 2021 | December 31, 2020 |
|---|---|---|
| | (unaudited) | |
| Cash, cash equivalents, short-term investments and certain long-term investments | $ 411,474 | $ 451,557 |
| Working capital | 362,523 | 369,410 |
| Total assets | 490,059 | 538,376 |
| Accumulated deficit | (515,851) | (471,261) |
| Total shareholders' equity | 377,145 | 409,922 |

**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 March 31, | |
|---|---|---|
| | 2021 | 2020 |
| Research and development expenses | $ 44,283 | $ 36,943 |
| Stock-based compensation for equity classified instruments | (4,336) | (2,016) |
| Stock-based compensation for liability classified instruments | 2,513 | 1,794 |
| Normalized research and development expenses (Non-GAAP basis) | $ 42,460 | $ 36,721 |
| | | |
| General and administrative expenses | $ 1,296 | $ 7,206 |
| Stock-based compensation for equity classified instruments | (4,192) | (2,228) |
| Stock-based compensation for liability classified instruments | 12,951 | 5,379 |

| | | | | |
|---|---|---|---|---|
| Normalized general and administrative expenses (Non-GAAP basis) | $ | 10,055 | $ | 10,357 |
| | | | | |
| Net loss per common share – Basic and Diluted | $ | (0.87) | $ | (0.64) |
| Stock based compensation for equity classified instruments | | 0.17 | | 0.09 |
| Stock based compensation for liability classified instruments | | (0.30) | | (0.15) |
| Normalized net loss per common share – Basic (Non-GAAP basis) | $ | (1.00) | $ | (0.70) |

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