Zymeworks Reports 2021 Second Quarter Financial Results

August 4, 2021

VANCOUVER, British Columbia--(BUSINESS WIRE)--Aug. 4, 2021-- Zymeworks Inc. (NYSE: ZYME), a clinical-stage biopharmaceutical company developing multifunctional biotherapeutics, today reported financial results for the second quarter ended June 30, 2021.

"The second half of 2021 is an exciting time at Zymeworks as we prepare to present important data readouts at upcoming medical conferences in support of the planned launch of our pivotal trial for zanidatamab in first-line HER2-positive gastric cancer," said Ali Tehrani, Ph.D., Zymeworks' President & CEO. "The first data presentation will be at the European Society for Medical Oncology (ESMO) meeting in September and highlights results from our Phase 2 clinical trial evaluating zanidatamab plus chemotherapy in first-line gastric cancer, a setting where the current standard of care is Herceptin® plus chemotherapy. These results will be integral to our goal of establishing zanidatamab as the new foundational HER2-targeted therapy and bring us one step closer to realizing our mission of enabling patients to return home to their loved ones, disease free."

Second Quarter 2021 Business Highlights and Recent Developments

- **Zanidatamab in First-Line Gastroesophageal Adenocarcinoma (GEA) to be Presented at ESMO Annual Meeting**
  The presentation will feature new clinical data for our lead product candidate, zanidatamab, in combination with chemotherapy, as a first-line treatment for patients with HER2-positive GEA. The presentation will be available on Thursday, September 16 at 8:30 AM CEST (Central European Summer Time) on both the ESMO and Zymeworks websites.
- **Enrollment Initiated for First-Line Biliary Tract Cancer and Colorectal Cancer Cohorts in Zanidatamab Phase 2 Clinical Trial**
  The ongoing Phase 2 study is evaluating zanidatamab in combination with standard of care chemotherapy as a first-line treatment for patients with unresectable, locally advanced, recurrent or metastatic HER2-expressing gastrointestinal cancers including biliary tract cancer, colorectal cancer, and GEA. Results from this study are expected to inform future potential pivotal trials.
- **First Patient Dosed with Zanidatamab in Combination with Tukysa® (Tucatinib) and Chemotherapy in Advanced HER2-Positive Breast Cancer**
  The first patient has been dosed in a new cohort of a Phase 1 trial investigating the safety, tolerability, and efficacy of zanidatamab in combination with tucatinib and capecitabine. This new cohort will evaluate HER2-positive breast cancer patients with locally advanced (unresectable) and/or metastatic disease that have received prior therapy with trastuzumab, pertuzumab and T-DM1.
- **First Patient Dosed for Janssen-Developed Bispecific Antibody Utilizing Zymeworks' Azymetric™ and EFECT™ Therapeutic Platforms**
  The new bispecific antibody developed by Janssen, JNJ-78278343, represents Zymeworks' fourth pharmaceutical partnership with programs reaching clinical development. Zymeworks will receive a payment in connection with this milestone under Zymeworks' 2017 licensing agreement with Janssen.
- **ZW49 Cohort Expansion Study Opens New Sites in South Korea and Australia**
  Zymeworks has opened new sites in South Korea and Australia to accelerate the cohort expansion portion of the Phase 1 clinical trial for ZW49. This will support Zymeworks' goal of identifying the recommended Phase 2 dose and schedule by the end of this year. Dose escalation continues in weekly and once every three week schedules while three indication-specific expansion cohorts utilizing the 2.5 mg/kg once every three week regimen are ongoing.

Financial Results for the Quarter Ended June 30, 2021

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 research support and other payments. Revenue for the three months ended June 30, 2021 was $1.8 million compared to $12.4 million for the same period of 2020. Revenue for the second quarter of 2021 related to research support and other payments from our partners. Revenue for the same period in 2020 included recognition of a $12.0 million expansion fee resulting from an amendment to our collaboration agreement with BMS, as well as $0.4 million in research support and other payments from our partners.

For the three months ended June 30, 2021, research and development expenses were $50.7 million compared to $39.8 million for the same period of 2020. The increase was primarily due to higher salaries and benefits expense from additional headcount as well as higher stock-based compensation expense and third-party research and development program expenses. For the three months ended June 30, 2021, research and development expenses included non-cash stock-based compensation expense of $5.8 million from equity-classified equity awards and $0.2 million from the non-cash mark-to-market revaluation of certain historical liability classified equity awards. Excluding stock-based compensation expense, research and development expenses increased by $8.1 million for the three months ended June 30, 2021 compared to the same period in 2020.

For the three months ended June 30, 2021, general and administrative expenses were $19.9 million compared to $12.9 million for the same period in 2020. The increase was primarily due to higher salaries and benefits due to additional headcount, stock-based compensation expense and professional fees. For the three months ended June 30, 2021, general and administrative expenses included non-cash stock-based compensation expense of $5.3 million from equity-classified equity awards and $1.5 million from the non-cash mark-to-market revaluation of certain historical liability-classified equity awards. Excluding stock-based compensation expense, general and administrative expenses increased by $3.9 million for the three months ended June 30, 2021 compared to the same period in 2020.

Net loss for the three months ended June 30, 2021 was $67.5 million compared to $39.0 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 and general and administrative expenses referred to above.

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 June 30, 2021, Zymeworks had $359.8 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, colorectal, 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 development of its product candidates, related clinical trials, anticipated clinical data presentations, potential therapeutic effects of zanidatamab, expected increases in research and development expenditures, anticipated continued receipt of revenue from existing and future partners, Zymeworks' preclinical pipeline, anticipated sufficiency of cash resources to fund Zymeworks' planned operations into the second half of 2022 and potentially beyond, and other information that is not historical information. When used herein, words such as "plan", "expect", "may", "continue", "anticipate", "potential", "will", 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 June 30, 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue				
Research and development collaborations	$ 1,771	$ 12,359	$ 2,415	$ 20,628
Operating expenses:				
Research and development	50,711	39,784	94,994	76,727
General and administrative	19,945	12,924	21,241	20,130
Total operating expenses	70,656	52,708	116,235	96,857
Loss from operations	(68,885)	(40,349)	(113,820)	(76,229)
Other income, net	929	1,324	1,799	6,443
Loss before income taxes	(67,956)	(39,025)	(112,021)	(69,786)
Income tax expense	434	64	(91)	(311)

Net loss and comprehensive loss	$ (67,522)	$ (38,961)	$ (112,112)	$ (70,097)
Net loss per common share:				
Basic	$ (1.31)	$ (0.77)	$ (2.18)	$ (1.41)
Diluted	$ (1.31)	$ (0.77)	$ (2.42)	$ (1.41)
Weighted-average common shares outstanding:				
Basic	51,422,066	50,788,681	51,395,015	49,737,699
Diluted	51,422,066	50,788,681	52,068,506	49,737,699

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

	June 30, 2021	December 31, 2020
	(unaudited)	
Cash, cash equivalents, short-term investments and certain long-term investments	$ 359,811	$ 451,557
Working capital	309,952	369,410
Total assets	471,954	538,376
Accumulated deficit	(583,373)	(471,261)
Total shareholders' equity	321,472	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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development expenses	$ 50,711	$ 39,784	$ 94,994	$ 76,727
Stock-based compensation for equity classified instruments	(5,790)	(3,346)	(10,126)	(5,496)
Stock-based compensation for liability classified instruments	(245)	107	2,268	1,900
Normalized research and development expenses (Non-GAAP basis)	$ 44,676	$ 36,545	$ 87,136	$ 73,131
General and administrative expenses	$ 19,945	$ 12,924	$ 21,241	$ 20,130
Stock-based compensation for equity classified instruments	(5,296)	(4,046)	(9,488)	(6,497)
Stock-based compensation for liability classified instruments	(1,545)	310	11,406	5,799
Normalized general and administrative expenses (Non-GAAP basis)	$ 13,104	$ 9,188	$ 23,159	$ 19,432
Net loss per common share – Basic	$ (1.31)	$ (0.77)	$ (2.18)	$ (1.41)
Stock based compensation for equity classified instruments	0.22	0.15	0.38	0.24
Stock based compensation for liability classified instruments	0.03	(0.01)	(0.27)	(0.15)
Normalized net loss per common share – Basic (Non-GAAP basis)	$ (1.06)	$ (0.63)	$ (2.07)	$ (1.32)
Net loss per common share – Diluted	$ (1.31)	$ (0.77)	$ (2.42)	$ (1.41)
Stock based compensation for equity classified instruments	0.22	0.15	0.38	0.24
Stock based compensation for liability classified instruments	0.03	(0.01)	(0.26)	(0.15)
Normalized net loss per common share – Diluted (Non-GAAP basis)	$ (1.06)	$ (0.63)	$ (2.30)	$ (1.32)

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Investor Inquiries:

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

Jack Spinks
(604) 678-1388
ir@zymeworks.com

Media Inquiries:
Mary Klem
(604) 678-1388
media@zymeworks.com

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