Zymeworks Reports 2021 Third Quarter Financial Results

November 3, 2021

VANCOUVER, British Columbia--(BUSINESS WIRE)--Nov. 3, 2021-- Zymeworks Inc. (NYSE: ZYME), a clinical-stage biopharmaceutical company developing multifunctional biotherapeutics, today reported financial results for the third quarter ended September 30, 2021.

“This year, we delivered upon our goal of presenting data showcasing the potential of zanidatamab to be the new foundational HER2-targeted therapy in first-line gastroesophageal adenocarcinoma (GEA),” said Ali Tehrani, Ph.D., Zymeworks’ President & CEO. “These data support the launch of our second pivotal study, HERIZON-GEA-01, and we look forward to continuing our recent clinical success with upcoming catalysts for zanidatamab in early- and late-line metastatic breast cancer as well as in combination with Ibrance, Tukysa, tislelizumab, and agents targeting the CD47 pathway.”

Third Quarter 2021 Business Highlights and Recent Developments

- **Clinical Data Supports Zanidatamab as Potential New Standard of Care in 1L HER2+ GEA**
  In September, we presented Phase 2 clinical data for zanidatamab in combination with chemotherapy in first-line metastatic HER2-positive GEA at the European Society for Medical Oncology Annual Congress. The data support zanidatamab as a potential new standard of care in 1L HER2-positive GEA and the initiation of a global, randomized Phase 3 trial scheduled to launch in the fourth quarter of 2021. Further information relating to the pivotal trial design and commercial strategy in gastrointestinal cancers will be provided on a webcast on Tuesday, November 9, 2021 at 4:15 p.m. ET (1:15 p.m. PT). Interested parties can access a live webcast via Zymeworks’ website.
- **Zanidatamab Plus Chemotherapy in Late-Line Breast Cancer to be Presented at San Antonio Breast Cancer Symposium**
  The presentation will feature new clinical data for zanidatamab, in combination with chemotherapy, as a late-line treatment for patients with HER2-positive breast cancer. The presentation will be available on Wednesday, December 8, 2021.
- **First Patient Dosed in Clinical Trial of Zanidatamab and Anti-CD47 Evorpacept (ALX148)**
  The Phase 1b/2 clinical trial is designed to evaluate the safety and efficacy of zanidatamab in combination with ALX148 (anti-CD47) in patients with advanced HER2-positive breast cancer, HER2-low breast cancer, and additional non-breast HER2-expressing solid tumors.
- **Study Commences in Investigator-Initiated Trial of Zanidatamab as Neoadjuvant Treatment in HER2-Positive Breast Cancer**
  A Phase 2 open-label trial to evaluate zanidatamab monotherapy as neoadjuvant treatment in patients with newly diagnosed HER2-positive early breast cancer is being co-lead by Dr. Vincent Valero and Dr. Funda Meric-Bernstam at the University of Texas MD Anderson Cancer Center. The primary endpoint of this study is to assess efficacy by pathologic complete response.
- **ZW49 Program Update**
  The ZW49 program continues to advance in the weekly and once every three week dosing schedules. Expansion cohorts evaluating 2.5 mg/kg every three weeks have enrolled 29 patients and are expected to complete enrollment (30 patients) prior to year end. In parallel, the weekly dose regimen has enrolled 14 patients and continues to dose escalate as the maximum tolerable dose has not been reached. No dose-limiting toxicities have been observed to date. The results of these studies will inform the recommended Phase 2 dose and schedule with safety and efficacy data expected to be presented at a medical conference in 2022.

Financial Results for the Quarter Ended September 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 payments for research and development support. Revenue for the three months ended September 30, 2021 was $4.4 million compared to $2.6 million for the same period of 2020. Revenue for the third quarter of 2021 included a development milestone and research and development support under cost sharing arrangements. Revenue for the same period in 2020 included research and development support under cost sharing arrangements.

For the three months ended September 30, 2021, research and development expenses were $49.9 million compared to $54.4 million for the same period of 2020. The decrease was primarily due to lower third-party manufacturing expenses for zanidatamab which were partially offset by higher salary and benefit expenses from additional headcount as well as higher preclinical and other research and development program expenses. For the three months ended September 30, 2021, research and development expenses included non-cash stock-based compensation expense of $5.6 million from equity-classified equity awards and a $1.0 million recovery from the non-cash mark-to-market revaluation of certain historical liability-classified equity awards. Excluding stock-based compensation, research and development expenses decreased by $3.3 million for the three months ended September 30, 2021 compared to the same period in 2020.

For the three months ended September 30, 2021, general and administrative expenses were $15.5 million compared to $21.9 million for the same

period in 2020. For the three months ended September 30, 2021, general and administrative expenses included non-cash stock-based compensation expense of $4.8 million from equity-classified equity awards and a $3.6 million recovery from the non-cash mark-to-market revaluation of certain historical liability-classified equity awards. Excluding stock-based compensation, general and administrative expenses increased by $4.9 million for the three months ended September 30, 2021 compared to the same period in 2020 primarily due to higher salary and benefit expenses from additional headcount, and professional fees.

Net loss for the three months ended September 30, 2021 was $60.6 million compared to $72.6 million for the same period of 2020. This was primarily due to the decrease in research and development and general and administrative expenses and the increase in revenue referred to above, which was partially offset by a decrease in interest income.

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 September 30, 2021, Zymeworks had $307.8 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, combined with the collaboration payments we anticipate receiving, will enable us to fund our planned operations into late 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 product 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 product 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 late 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 September 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue				
Research and development collaborations	$ 4,395	$ 2,643	$ 6,810	$ 23,271
Operating expenses:				
Research and development	49,893	54,401	144,887	131,128
General and administrative	15,466	21,936	36,707	42,066
Total operating expenses	65,359	76,337	181,594	173,194
Loss from operations	(60,964)	(73,694)	(174,784)	(149,923)
Other income, net	1,149	1,089	2,948	7,532
Loss before income taxes	(59,815)	(72,605)	(171,836)	(142,391)
Income tax expense	(764)	43	(855)	(268)

Net loss and comprehensive loss	$ (60,579)	$ (72,562)	$ (172,691)	$ (142,659)
Net loss per common share:				
Basic	$ (1.17)	$ (1.43)	$ (3.35)	$ (2.85)
Diluted	$ (1.25)	$ (1.43)	$ (3.66)	$ (2.85)
Weighted-average common shares outstanding:				
Basic	51,657,371	50,903,633	51,483,428	50,129,181
Diluted	52,238,901	50,903,633	52,125,929	50,129,181

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

	September 30, 2021	December 31, 2020
	(unaudited)	
Cash, cash equivalents, short-term investments and certain long-term investments	$ 307,757	$ 451,557
Working capital	261,336	369,410
Total assets	420,360	538,376
Accumulated deficit	(643,952)	(471,261)
Total shareholders' equity	278,929	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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development expenses	$ 49,893	$ 54,401	$144,887	$131,128
Stock-based compensation for equity classified instruments	(5,562)	(3,389)	(15,688)	(8,680)
Stock-based compensation for liability classified instruments	916	(2,379)	3,185	(479)
Normalized research and development expenses (Non-GAAP basis)	$ 45,247	$ 48,633	$132,384	$121,969
General and administrative expenses	$ 15,466	$ 21,936	$ 36,707	$ 42,066
Stock-based compensation for equity classified instruments	(4,773)	(4,311)	(14,260)	(10,703)
Stock-based compensation for liability classified instruments	3,600	(8,195)	15,006	(2,395)
Normalized general and administrative expenses (Non-GAAP basis)	$ 14,293	$ 9,430	$ 37,453	$ 28,968
Net loss per common share – Basic	$ (1.17)	$ (1.43)	$ (3.35)	$ (2.85)
Stock based compensation for equity classified instruments	0.20	0.15	0.58	0.39
Stock based compensation for liability classified instruments	(0.09)	0.21	(0.35)	0.06
Normalized net loss per common share – Basic (Non-GAAP basis)	$ (1.06)	$ (1.07)	$ (3.12)	$ (2.40)
Net loss per common share – Diluted	$ (1.25)	$ (1.43)	$ (3.66)	$ (2.85)
Stock based compensation for equity classified instruments	0.20	0.15	0.57	0.39
Stock based compensation for liability classified instruments	(0.09)	0.21	(0.35)	0.06
Normalized net loss per common share – Diluted (Non-GAAP basis)	$ (1.14)	$ (1.07)	$ (3.44)	$ (2.40)

View source version on businesswire.com: https://www.businesswire.com/news/home/20211103006081/en/

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

Source: Zymeworks Inc.