Zymeworks Reports 2020 Third Quarter Financial Results

November 3, 2020

VANCOUVER, British Columbia--(BUSINESS WIRE)--Zymeworks Inc. (NYSE: ZYME), a clinical-stage biopharmaceutical company developing multifunctional biotherapeutics, today reported financial results for the quarter ended September 30, 2020.

“Zanidatamab’s clinical development continued to expand this quarter, having opened new sites across the globe for the pivotal trial in HER2-amplified biliary tract cancers toward our first potential BLA submission,” said Ali Tehrani, Ph.D., Zymeworks’ President & CEO. “We are well-resourced to achieve this milestone for zanidatamab, along with advancing the development of ZW49 into expansion cohorts and beyond.”

Third Quarter 2020 Business Highlights and Recent Developments

- **Zanidatamab Pivotal Trial Expands to Europe and Asia-Pacific Region**
  Sites are active and recruiting in North America, Europe, and Asia in the global pivotal trial of single agent zanidatamab in previously-treated HER2 gene-amplified biliary tract cancers. This study aims to support accelerated approval and may enable filing of a Biologics License Application (BLA) as early as 2022.

- **ZW49 Continues Dose Escalation**
  Zymeworks’ second clinical candidate, ZW49, a bispecific antibody-drug conjugate targeting HER2, continues to be evaluated across multiple dosing regimens in the dose-escalation portion of a Phase 1 clinical trial.

- **Zymeworks Implements Expanded Access Program (EAP) for Patients not Eligible for Existing Trials**
  Zymeworks’ EAP or Compassionate Use program will enable critically ill patients who are not eligible for the Company's clinical trials and who may not have options for alternative therapies to be considered for access to Zymeworks' pipeline of investigational medicines. More on Zymeworks' EAP: https://www.zymeworks.com/patients/expanded-access-program.

- **First Patients Dosed in Investigator-Initiated Trial of Zanidatamab in Endometrial Cancers**
  Dr. Vicky Makker at Memorial Sloan Kettering Cancer Center is conducting a Phase 2 trial to evaluate single agent zanidatamab in HER2-overexpressed advanced endometrial cancers and carcinosarcomas. This study is expected to enroll up to 25 patients with the primary endpoint of assessing the overall response rate.

Financial Results for the Quarter Ended September 30, 2020

Revenue of $2.6 million for the three months ended September 30, 2020 related to research support and other payments from our partners. For the same period in 2019, revenue of $7.9 million included $7.5 million for a commercial license option milestone from BMS and $0.4 million in research support payments from our partners.

Research and development expenses were $53.5 million for the three months ended September 30, 2020 compared to $29.3 million for the same period of 2019. The increase related primarily to additional clinical trial activities and associated drug manufacturing for zanidatamab as well as an increase in internal headcount. Expenses also increased during this period due to higher development activity for ZW49, licensing and milestone payments and stock-based compensation expense. Research and development expenses included non-cash stock-based compensation expense of $6.0 million comprised of $3.6 million from equity-classified awards and $2.4 million related to the non-cash mark-to-market revaluation of certain historical liability-classified awards.

General and administrative expenses were $22.8 million for the three months ended September 30, 2020 compared to $12.2 million for the same period in 2019. The change was primarily due to an $8.1 million increase in non-cash stock-based compensation expense. Expenses also increased during this period due to higher headcount and insurance expenses. General and administrative expenses included non-cash stock-based compensation expense of $12.6 million comprised of $4.4 million from equity-classified awards and a $8.2 million expense related to the non-cash mark-to-market revaluation of certain historical liability-classified awards.

Net loss for the three months ended September 30, 2020 was $72.6 million as compared to $30.5 million for the same period of 2019. This was primarily due to the increases in research and development expenses and general and administrative expenses referred to above as well as lower revenue recognized during current period.

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, 2020, Zymeworks had $497.0 million in cash resources consisting of cash, cash equivalents, short-term investments and certain long-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, zanidatamab (ZW25), is a novel Azymetric™ bispecific antibody currently in a registration-enabling clinical trial for refractory HER2+ biliary tract cancer as well as several Phase 2 clinical trials for HER2+ gastroesophageal and breast cancers. 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 zanidatamab with Zymeworks' proprietary ZymeLink™ linker-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 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 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, 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" 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, 2020 (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,	
	2020	**2019**	**2020**	**2019**
Revenue				
Research and development collaborations	$ 2,643	$ 7,860	$ 23,271	$ 27,667
Operating expenses:				
Research and development	53,531	29,251	129,274	70,511
General and administrative	22,806	12,173	43,920	33,937
Impairment on acquired IPR&D	—	—	—	768
Total operating expenses	76,337	41,424	173,194	105,216
Loss from operations	(73,694)	(33,564)	(149,923)	(77,549)
Other income (expense), net	1,089	2,181	7,532	4,276
Loss before income taxes	(72,605)	(31,383)	(142,391)	(73,273)
Income tax expense, net	43	908	(268)	80
Net loss and comprehensive loss	$ (72,562)	$ (30,475)	$ (142,659)	$ (73,193)
Net loss per common share:				
Basic and diluted	(1.43)	(0.70)	(2.85)	(2.03)
Weighted-average common shares outstanding:				
Basic and diluted	50,903,633	43,445,379	50,129,181	36,143,113

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

	September 30, 2020	December 31, 2019
	(unaudited)	
Cash, cash equivalents, short-term investments and certain long-term investments	$ 496,997	$ 298,904
Working capital	390,428	229,278
Total assets	571,719	368,205
Accumulated deficit	(433,368)	(290,709)
Total shareholders' equity	432,354	245,681

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 to exclude 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 performance.

GAAP to Non-GAAP Reconciliations
(Expressed in thousands of U.S. dollars except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Research and development expenses	$ 53,531	$ 29,251	$ 129,274	$ 70,511
Stock based compensation for equity classified instruments	(3,555)	(1,690)	(9,051)	(4,324)
Stock based compensation for liability classified instruments	(2,379)	(888)	(479)	(2,856)
Normalized research and development expenses (Non-GAAP basis)	$ 47,597	$ 26,673	$ 119,744	$ 63,331
General and administrative expenses	$ 22,806	$ 12,173	$ 43,920	$ 33,937
Stock based compensation for equity classified instruments	(4,393)	(1,721)	(10,890)	(4,791)
Stock based compensation for liability classified instruments	(8,195)	(2,781)	(2,395)	(8,908)
Normalized general and administrative expenses (Non-GAAP basis)	$ 10,218	$ 7,671	$ 30,635	$ 20,238
Net loss per common share – Basic	$ (1.43)	$ (0.70)	$ (2.85)	$ (2.03)
Stock based compensation for equity classified instruments	0.16	0.08	0.40	0.25
Stock based compensation for liability classified instruments	0.21	0.08	0.06	0.32
Normalized net loss per common share – Basic (Non-GAAP basis)	$ (1.06)	$ (0.54)	$ (2.39)	$ (1.46)
Net loss per common share – Diluted	$ (1.43)	$ (0.70)	$ (2.85)	$ (2.03)
Stock based compensation for equity classified instruments	0.16	0.08	0.40	0.25
Stock based compensation for liability classified instruments	0.21	0.08	0.06	0.32
Normalized net loss per common share – Diluted (Non-GAAP basis)	$ (1.06)	$ (0.54)	$ (2.39)	$ (1.46)

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