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Zymeworks Reports 2020 Year-End Financial Results

February 24, 2021

VANCOUVER, Canada--(BUSINESS WIRE)-- Zymeworks Inc. (NYSE: ZYME), a clinical-stage biopharmaceutical company developing multifunctional biotherapeutics, today reported financial results for the year ended December 31, 2020 and provided a summary of recent business and clinical highlights.

"Throughout 2020, we initiated and advanced several clinical trials and achieved important regulatory milestones for zanidatamab and ZW49," said Ali Tehrani, Ph.D., Zymeworks' President & CEO. "This has set up 2021 to be a data-rich year for both of our lead clinical assets as well as new preclinical candidates and therapeutic platforms, and we are well resourced to deliver on our priorities."

2020 Business Highlights and Recent Developments

- **Clinical Data Continues to Support Goal of Establishing Zanidatamab as the Foundational HER2 Targeted Therapy Across Multiple HER2-Positive Cancers**

Updated clinical data was recently presented at the American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium for zanidatamab, in both HER2-expressing biliary tract cancer (BTC) and gastroesophageal adenocarcinoma (GEA). Overall zanidatamab was well tolerated with the majority of treatment-related adverse events being mild or moderate in severity. With respect to antitumor activity, both refractory BTC and GEA compare favorably to current standard of care and emerging treatments. These data support zanidatamab's broad therapeutic potential as a foundational therapy across multiple HER2-expressing cancers.

- **Zanidatamab Advances in Accelerated Pivotal Trial Paving the Way for Commercialization**

The U.S. Food and Drug Administration granted Breakthrough Therapy designation to zanidatamab for BTC, enabling an Accelerated Approval pathway for the global pivotal trial (HERIZON-BTC-01) for zanidatamab monotherapy in patients with previously treated HER2 gene-amplified BTC and submission of a Biologics License Application (BLA) as early as 2022. A second pivotal trial evaluating zanidatamab as first-line treatment for advanced HER2-positive GEA is on track to launch mid-2021. Zanidatamab received additional drug review special designations in the U.S. and the European Union that are expected to help to expedite clinical development of both trials.

- **ZW49 Demonstrates Antitumor Activity and Differentiated Safety Profile; Expansion Cohorts Enrolling while Dose Escalation Continues**

ZW49, a bispecific antibody-drug conjugate targeting HER2, has begun enrolling patients into the expansion cohort portion of the ongoing Phase 1 clinical trial. Interim data were recently presented and showed no dose limiting toxicities or treatment-related hematologic, pulmonary, or liver toxicity. The majority of treatment-related adverse events were mild or moderate in severity with the most common being keratitis, fatigue, and diarrhea. ZW49 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., and dose escalation is continuing at 3 mg/kg once every three weeks. 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 to better ascertain antitumor activity in more homogeneous patient populations.

- **Milestone Payments Received and Deal Values Increase for Partnership Deals**

Throughout 2020, partnerships continued to expand and additional milestones were achieved upon BeiGene initiating multiple clinical studies with zanidatamab, Merck and BMS expanding Azymetric™ and EFECT™ collaborations, and Iconic/Exelixis entering into a licensing deal for a ZymeLink™ ADC. Zymeworks has nine active collaborations that could result in up to \$8.6 billion in potential milestone payments in addition to royalties on potential product sales.

- **Strengthened Balance Sheet**

In January 2020, Zymeworks completed an upsized \$320.8 million public financing to accelerate and expand global

development of its lead clinical candidates, zanidatamab and ZW49, and support further advancement of its novel preclinical programs.

Financial Results for the Year Ended December 31, 2020

Revenue was \$39.0 million in 2020 compared to \$29.5 million in 2019. For both years, revenue related to non-recurring upfront fees, milestone payments, option fees, research support and other payments under our licensing and collaboration agreements. Revenue for 2020 included \$15.0 million from BeiGene for development milestones, \$12.0 million from BMS for an expansion fee and \$12.0 million from other partners for research support, partner revenue, drug supply and other payments. Revenue for 2019 included \$8.0 million from Lilly for achievement of a development milestone, \$7.5 million and \$3.5 million from BMS and Daiichi Sankyo, respectively, for exercise of commercial license options, \$3.5 million for recognition of deferred revenue relating to our licensing and collaboration agreement with BeiGene, and \$7.0 million from our partners for other development milestones, research support and other payments.

Research and development expense was \$168.5 million in 2020 compared to \$115.9 million in 2019. The \$52.6 million increase related primarily to additional clinical trial activities and associated drug manufacturing costs for zanidatamab, as well as an increase in salaries and benefits expense resulting from a higher headcount. Expenses also increased in 2020 for higher development activity for ZW49 and an increase in-licensing and milestone payments for discovery and research activities. Research and development expense included non-cash stock-based compensation expense of \$12.3 million in 2020 and \$14.3 million in 2019.

General and administrative expense was \$57.9 million in 2020 compared to \$64.2 million in 2019. General and administrative expense included non-cash stock-based compensation expense of \$16.1 million in 2020 and \$34.2 million in 2019. Excluding stock-based compensation expense, general and administrative expense increased by \$11.9 million year over year primarily due to an increase in salaries and benefits expense resulting from a higher headcount, as well as higher insurance and professional services expenses.

Net loss was \$180.6 million in 2020 compared to \$145.4 million in 2019. The increase in net loss was primarily due to the increases in research and development expenses referred to above partially offset by lower general and administrative expense and higher revenue and other 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 December 31, 2020, Zymeworks had \$451.6 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 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](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 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' Annual Report on Form 10-K for its fiscal year ended December 31, 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.

Consolidated Statements of Loss and Comprehensive Loss

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

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Revenue	(unaudited)	(unaudited)		
Research and development collaborations	\$ 15,680	\$ 1,877	\$ 38,951	\$ 29,544

Operating expenses:				
Research and development	39,260	45,389	168,534	115,900
General and administrative	13,965	30,240	57,885	64,177
Impairment on acquired IPR&D	—	—	—	768
Total operating expenses	53,225	75,629	226,419	180,845
Loss from operations	(37,545)	(73,752)	(187,468)	(151,301)
Other (expense) income, net	(187)	1,006	7,345	5,282
Loss before income taxes	(37,732)	(72,746)	(180,123)	(146,019)
Income tax (expense) recovery, net	(161)	502	(429)	582
Net loss and comprehensive loss	\$ (37,893)	\$ (72,244)	\$ (180,552)	\$ (145,437)
Net loss per common share:				
Basic and diluted	(0.74)	(1.66)	(3.58)	(3.83)
Weighted-average common shares outstanding:				
Basic and diluted	51,136,942	43,597,446	50,382,497	38,022,014

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

	December 31, 2020	December 31, 2019
Cash, cash equivalents, short-term investments and certain long-term investments	\$ 451,557	\$ 298,904
Working capital	369,410	229,278
Total assets	538,376	368,205
Accumulated deficit	(471,261)	(290,709)
Total shareholders' equity	409,922	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 December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Research and development expenses	\$ 39,260	\$ 45,389	\$ 168,534	\$ 115,900
Stock based compensation for equity-classified instruments	(3,619)	(1,616)	(12,299)	(5,939)
Stock based compensation for liability-classified instruments	485	(5,501)	6	(8,358)
Normalized research and development expenses (Non-GAAP basis)	\$ 36,126	\$ 38,272	\$ 156,241	\$ 101,603
General and administrative expenses	\$ 13,965	\$ 30,240	\$ 57,885	\$ 64,177
Stock based compensation for equity-classified instruments	(3,942)	(1,946)	(14,645)	(6,737)
Stock based compensation for liability-classified instruments	980	(18,562)	(1,416)	(27,470)
Normalized general and administrative expenses (Non-GAAP basis)	\$ 11,003	\$ 9,732	\$ 41,824	\$ 29,970
Net loss per common share – Basic and diluted	\$ (0.74)	\$ (1.66)	\$ (3.58)	\$ (3.83)
Stock based compensation for equity-classified instruments	0.15	0.08	0.53	0.33
Stock based compensation for liability-classified instruments	(0.03)	0.52	0.03	0.91
Normalized net loss per common share – Basic and diluted (Non-GAAP basis)	\$ (0.62)	\$ (1.06)	\$ (3.02)	\$ (2.59)



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