Zymeworks Reports 2020 Second Quarter Financial Results

August 5, 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 June 30, 2020.

“Among many notable accomplishments in the past quarter, I am particularly excited about the transition of our lead therapeutic program, zanidatamab, into late stage clinical development, providing a clear path for Zymeworks to seek its first potential approval in biliary tract cancer in 2022,” said Ali Tehrani, Ph.D., Zymeworks’ President & CEO. “Looking ahead, with zanidatamab in five active Phase 2 programs and ZW49 advancing in its dose-escalation study, we anticipate a number of important data readouts over the next six to twelve months. We are proud of everything that we have accomplished and are well positioned to strategically execute on our mission of sending patients home to their loved ones, disease free.”

Second Quarter 2020 Business Highlights and Recent Developments

- **Zanidatamab (ZW25) Advances into Global Registration-Enabling Study**
  Zymeworks initiated a global Phase 2 registration-enabling study of single agent zanidatamab in patients with previously-treated HER2 gene amplified biliary tract cancer (BTC). This study is designed to support accelerated approval based on a primary endpoint of objective response rate, and secondary endpoints of duration of response and safety and may enable filing of a Biologics License Application (BLA) as early as 2022.

- **Zanidatamab Data Updates Support Advancement in First Line Gastric Cancer**
  In addition to BTC, updated data were also presented from single agent zanidatamab and zanidatamab in combination with chemotherapy in patients with refractory HER2-expressing gastroesophageal adenocarcinomas (GEA). Zanidatamab continues to demonstrate promising single agent anti-tumor activity with response rates and durability that further improved when zanidatamab was combined with either paclitaxel or capecitabine. Zymeworks plans to initiate its second registration-enabling study for zanidatamab as first line treatment for advanced HER2+ GEA.

- **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. In the first half of the year, Zymeworks initiated recruitment at five additional clinical sites bringing the total to 11 across North America.

- **Merck Signs New Partnership to Develop Additional Azymetric™ Multispecific Antibodies**
  Long-term partner Merck signed a new licensing agreement to develop and commercialize up to three new multispecific antibodies toward Merck’s therapeutic targets in human health. Zymeworks is eligible to receive up to $411.0 million in option exercise fees and clinical development and regulatory approval milestone payments and up to $480.0 million in commercial milestone payments, as well as tiered royalties on worldwide sales.

- **Bristol-Myers Squibb Expands Partnership and Adds EFECT™ Platform**
  BMS (formerly Celgene) expanded its Azymetric collaboration with Zymeworks, gaining access to the EFECT platform and extending its research term, resulting in a $12.0 million upfront payment to Zymeworks. Milestones remain at up to $1.7 billion plus tiered royalties on global sales.

- **Strengthens Clinical Drug Development Expertise**
  Pamela Farmer, MD, joins Zymeworks as Vice President, Pharmacovigilance to provide medical oversight and ensure comprehensive and timely risk-benefit assessments of Zymeworks safety data. Dr. Farmer has held various leadership roles in drug safety and pharmacovigilance at major pharmaceutical companies including Prothena, Amgen, Genentech, and BioMarin, working on multiple regulatory submissions including Rituxan®, Actemra® and Vimizim®.

Financial Results for the Quarter Ended June 30, 2020

Revenue for the three months ended June 30, 2020 was $12.4 million as compared to $7.9 million in the same period of 2019. Revenue for the three months ended June 30, 2020 included recognition of a $12.0 million expansion fee resulting from the BMS collaboration agreement expansion, as well as $0.4 million in research support and other payments from our partners. Revenue for the same period in 2019 included a $3.5 million commercial license option exercise fee from Daiichi Sankyo, $3.0 million in development milestone payments from our partners, as well as $1.4 million in research support and other payments from our partners.

For the three months ended June 30, 2020, research and development expenses were $39.2 million as compared to $23.8 million in the same period of 2019. The change was primarily due to an increase in clinical trial activity and associated drug manufacturing costs for zanidatamab, an increase in development activity for ZW49, an increase in licensing fee expenses as well as an increase in salaries and benefits expense from additional research and development headcount in 2020 as compared to the same period in 2019. Research and development expenses also included non-cash stock-based compensation expense of $3.2 million comprised of $3.3 million from equity classified equity awards and a $0.1 million recovery related to the non-cash mark-to-market revaluation of certain historical liability classified equity awards.

For the three months ended June 30, 2020, general and administrative expenses were $13.5 million as compared to $12.8 million in the same period in 2019. The change was primarily due to an increase in salaries and benefits expense resulting from an increase in headcount to support our expanding research and development activities and higher insurance expenses offset by lower non-cash stock-based compensation expense in 2020, compared to 2019. General and administrative expenses included non-cash stock-based compensation expense of $3.7 million comprised of $4.0 million from equity classified equity awards and a $0.3 million recovery related to the non-cash mark-to-market revaluation of certain historical liability classified equity awards.

Net loss for the three months ended June 30, 2020 was $39.0 million as compared to $29.1 million in 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, partially offset by an increase in revenue.

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, 2020, Zymeworks had $512.0 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, anticipated data readouts, 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 June 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue				
Research and development collaborations	$ 12,359	$ 7,882	$ 20,628	$ 19,807
Operating expenses:				
Research and development	39,217	23,785	75,743	41,260
General and administrative	13,491	12,761	21,114	21,764
Impairment on acquired IPR&D	—	768	—	768
Total operating expenses	52,708	37,314	96,857	63,792
Loss from operations	(40,349)	(29,432)	(76,229)	(43,985)
Other income (expense), net	1,324	990	6,443	2,095

Loss before income taxes	(39,025)	(28,442)	(69,786)	(41,890)
Income tax expense, net	64	(635)	(311)	(828)
Net loss and comprehensive loss	$ (38,961)	$ (29,077)	$ (70,097)	$ (42,718)
Net loss per common share:				
Basic and diluted	(0.77)	(0.89)	(1.41)	(1.32)
Weighted-average common shares outstanding:				
Basic and diluted	50,788,681	32,837,975	49,737,699	32,431,464

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

	June 30, 2020	December 31, 2019
	(unaudited)	
Cash, cash equivalents, short-term investments and certain long-term investments	$ 512,049	$ 298,904
Working capital	398,517	229,278
Total assets	606,853	368,205
Accumulated deficit	(360,806)	(290,709)
Total shareholders' equity	491,253	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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development expenses	$ 39,217	$ 23,785	$ 75,743	$ 41,260
Stock based compensation for equity classified instruments	(3,346)	(1,507)	(5,496)	(2,633)
Stock based compensation for liability classified instruments	107	(1,548)	1,900	(1,968)
Normalized research and development expenses (Non-GAAP basis)	$ 35,978	$ 20,730	$ 72,147	$ 36,659
General and administrative expenses	$ 13,491	$ 12,761	$ 21,114	$ 21,764
Stock based compensation for equity classified instruments	(4,046)	(1,579)	(6,497)	(3,070)
Stock based compensation for liability classified instruments	310	(4,800)	5,799	(6,127)
Normalized general and administrative expenses (Non-GAAP basis)	$ 9,755	$ 6,382	$ 20,416	$ 12,567
Net loss per common share – Basic	$ (0.77)	$ (0.89)	$ (1.41)	$ (1.32)
Stock based compensation for equity classified instruments	0.15	0.09	0.24	0.18
Stock based compensation for liability classified instruments	(0.01)	0.19	(0.15)	0.24
Normalized net loss per common share – Basic (Non-GAAP basis)	$ (0.63)	$ (0.61)	$ (1.32)	$ (0.90)
Net loss per common share – Diluted	$ (0.77)	$ (0.89)	$ (1.41)	$ (1.32)
Stock based compensation for equity classified instruments	0.15	0.09	0.24	0.18
Stock based compensation for liability classified instruments	(0.01)	0.19	(0.15)	0.24
Normalized net loss per common share – Diluted (Non-GAAP basis)	$ (0.63)	$ (0.61)	$ (1.32)	$ (0.90)

Contacts

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

Tiffany Tolmie
(604) 678-1388
ir@zymeworks.com

Media Inquiries:
Kavita Shah, Ph.D.
(604) 678-1388
media@zymeworks.com