



zymeworks

Zymeworks Provides Corporate Update and Reports Second Quarter 2023 Financial Results

August 10, 2023

- *Net loss for the first six months of 2023 decreased by 45% as compared to the same period in 2022*
- *Cash resources of \$431.4 million as of June 30, 2023 expected to fund planned operations through at least the end of 2026, and potentially beyond*
- *Presented full clinical results from Phase 2b study of zanidatamab monotherapy in previously treated HER2-amplified biliary tract cancers (BTC) at the Annual Meeting of American Society of Clinical Oncology (ASCO)*
- *Announces next investigational new drug application (IND) candidate, ZW220, a NaPi2b-targeted topoisomerase 1 inhibitor (TOPO1i) antibody drug conjugate (ADC), anticipated for IND filing in 1H-2025*
- *Additional preclinical and clinical data from multiple product candidates in our product pipeline expected to be presented at medical/scientific meetings during 2H-2023*
- *Announced appointment of industry veteran Carlos E. Campoy to board of directors*
- *Will host conference call with management today at 4:30 p.m. Eastern Daylight Time (EDT)*

VANCOUVER, British Columbia, Aug. 10, 2023 (GLOBE NEWSWIRE) -- Zymeworks Inc. (Nasdaq: ZYME), a clinical-stage biotechnology company developing novel multifunctional biotherapeutics, today reported financial results for the three and six months ended June 30, 2023 and provided a summary of recent business highlights.

"During the second quarter of 2023, we made excellent progress in advancing several of our key planned corporate goals for the year," said Kenneth Galbraith, Chair, President and Chief Executive Officer of Zymeworks. "We continue to provide support to our partners, Jazz Pharmaceuticals Ltd. (Jazz) and BeiGene, Ltd. (BeiGene) for their regulatory interactions and initial regulatory submissions of zanidatamab in second-line biliary tract cancer. We look forward to the top-line data readout from the zanidatamab Phase 3 gastroesophageal adenocarcinoma (GEA) pivotal trial (HERIZON-GEA-01) expected in 2024."

"As we move into the second half of the year, we are rapidly progressing our '5 by 5' goal of having five novel therapeutic candidates in clinical studies by 2027. ZW171 and ZW191 currently remain on track for anticipated IND filings in 2024, and we have nominated an additional preclinical development candidate, ZW220, with an expected IND filing in the first half of 2025. We strongly believe that zanidatamab and our early-stage product candidates have the potential to address large unmet needs and potentially improve the standard of care for certain difficult-to-treat cancers."

Recent Highlights and Current Developments

- *Clinical data for zanidatamab presented at ASCO Annual Meeting*
In partnership with Jazz and BeiGene, multiple abstracts for zanidatamab were presented at the ASCO Annual Meeting in Chicago in June 2023. Clinical data from the Phase 2b study of zanidatamab monotherapy in previously treated HER2-amplified BTC patients were exhibited in an oral presentation, sharing [full results from the HERIZON-BTC-01 pivotal trial](#). The results were published simultaneously in [Lancet Oncology](#). Presentations also included updated results from a Phase 1b/2 study of zanidatamab in combination with docetaxel as a first-line therapy for patients with advanced HER2-positive breast cancer.
- *Zanidatamab Clinical Studies to be Presented at the European Society of Medical Oncology (ESMO) Annual Congress*
In partnership with Jazz and BeiGene, multiple abstracts for zanidatamab were accepted for presentation at the ESMO Annual Congress taking place October 20-24 in Madrid, Spain. Updated results from the Phase 1b/2 study of zanidatamab plus chemotherapy and tislelizumab as first-line therapy for patients with advanced HER2-positive gastric/gastroesophageal junction adenocarcinoma will be presented in a poster presentation. Additionally, quality of life outcomes from the Phase 2b HERIZON-BTC-01 study evaluating patients with zanidatamab-treated HER2-positive biliary tract cancer will be presented in a poster presentation.
- *ZW220 named as next IND candidate*
We anticipate filing an IND in the first half of 2025 for ZW220, a NaPi2b-targeted TOPO1i ADC that is built using our proprietary TOPO1i-based payload technology.

- **Strengthened Board of Directors**

With the addition of Carlos E. Campoy to our board of directors, Zymeworks continues to attract industry leaders with the experience and insight necessary to advance our strategic vision and commercial goals. Mr. Campoy has more than 20 years of experience in finance and business development in the pharmaceutical and biotechnology industries and has played leadership roles in commercialization strategies and significant capital transactions. In addition to being a member of our board of directors, Mr. Campoy also serves on Zymeworks' audit committee and nominating and corporate governance committee.

Positive Zanidatamab Clinical Data from HERIZON-BTC-01 presented at ASCO

At the 2023 ASCO Annual Meeting in June, we highlighted the latest progress in our collaboration with Jazz in the development of zanidatamab in HER2-amplified biliary tract cancers. These pivotal HERIZON-BTC-01 study results demonstrated zanidatamab's meaningful clinical benefit, including confirmed objective response rate (cORR) of 41.3%, median duration of response (DOR) of 12.9 months, and median PFS of 5.5 months (median study follow-up time of 12.4 months).

Jazz will continue to lead the development and commercialization programs for zanidatamab in the United States, Europe, Japan and all other territories except for Asia/Pacific territories that Zymeworks previously licensed to BeiGene. With an initial focus in BTC and GEA, zanidatamab has the potential to improve the standard of care in multiple HER2-positive cancers.

'5 by 5' Strategy Strengthened with Nomination of Next IND Candidate

"We are excited to announce the nomination of ZW220, a potential first-in-class ADC targeting NaPi2b-expressing non-small cell lung cancer and ovarian cancer," said Paul Moore, Ph.D., Chief Scientific Officer of Zymeworks. "This marks an important step as we continue progress towards our '5 by 5' strategy and focus on bringing novel medicines into clinical studies starting with ZW191 and ZW171, both on track for regulatory filings to commence initial clinical studies in 2024, and ZW220 anticipated in the first half of 2025."

ZW220 is built on Zymeworks' drug conjugate platform technology, and delivers a potent, bystander-active TOPOli-based payload via a cleavable traceless linker. The monoclonal antibody in ZW220 targeting NaPi2b, a sodium-dependent transporter, was developed in-house and selected based on its favorable binding profile and efficient internalization and payload delivery. The drug-antibody-ratio in ZW220 was selected to balance efficacy and tolerability by incorporating an average of four TOPO1i payloads per antibody.

Financial Results for the Six Months Ended June 30, 2023

Revenue for the six months ended June 30, 2023 was \$42.6 million compared to \$7.4 million for the same period of 2022. Revenue for the six months ended June 30, 2023 included \$40.9 million, net of a credit issued to Jazz for amendments to our partnership agreement, for development support and drug supply revenue from Jazz and \$1.7 million for research support and other payments from our other partners. Revenue for the same period in 2022 included a \$5.0 million research license fee from our Atreca licensing agreement and \$2.4 million in research support and other payments from our other partners.

Research and development expense decreased by \$33.2 million, or 28%, for the six months ended June 30, 2023, compared to the same period in 2022. For the six months ended June 30, 2023, research and development expense included non-cash stock-based compensation recovery of \$0.7 million, comprised of a \$0.7 million recovery from equity classified awards (six months ended June 30, 2022 – \$0.8 million recovery) and a nominal expense related to the non-cash, mark-to-market revaluation of certain historical liability classified awards (six months ended June 30, 2022 - \$0.8 million recovery). Excluding stock-based compensation and 2022 restructuring expense, research and development expense decreased on a non-GAAP basis by \$27.9 million in the six months ended June 30, 2023 compared to the same period of 2022. The decrease was related primarily due to lower manufacturing expenses and a reduction in development costs as a result of the terms of our amended collaboration agreement with Jazz, partially offset by an increase in preclinical expenses compared to the same period in 2022. In addition, salaries and benefits expenses decreased compared to the same period in 2022, due to lower headcount in 2023 and lower non-recurring severance expenses.

General and administrative expense increased by \$11.3 million, or 41%, for the six months ended June 30, 2023 compared to the same period in 2022. For the six months ended June 30, 2023, general and administrative expense included non-cash stock-based compensation expense of \$3.1 million, comprised of a \$4.1 million expense from equity-classified equity awards (six months ended June 30, 2022 – \$1.0 million recovery) and a \$1.0 million recovery related to the non-cash mark-to-market revaluation of certain historical liability-classified equity awards (six months ended June 30, 2022 – \$3.0 million recovery). Excluding stock-based compensation and 2022 restructuring expense, general and administrative expense increased on a non-GAAP basis by \$7.8 million during the six months ended June 30, 2023, compared to same period in 2022. This increase was primarily due to an increase in expenses for professional services in 2023 compared to the same period in 2022. This was partially offset by a decrease in salaries and benefits expenses compared to the same period in 2022 due to lower headcount in 2023 and due to lower non-recurring severance expenses.

Other income, net increased by \$7.7 million for the six months ended June 30, 2023 compared to the same period in 2022. Other income, net for 2023 included \$9.6 million in interest income and \$0.7 million in net foreign exchange loss and other miscellaneous amounts. Other income, net for the six months ended June 30, 2022, included \$0.7 million in interest income and a \$0.4 million net foreign exchange gain and other miscellaneous amounts. This increase was due to an increase in interest income earned on higher cash resources and at higher rates of return.

Net loss for the six months ended June 30, 2023 was \$75.5 million compared to \$137.2 million for the same period of 2022, representing a 45% decrease in net loss. The decrease in net loss was primarily due to revenue from our collaboration agreement with Jazz and an increase in interest income as well as a decrease in research and development expense. This was partially offset by an increase in general and administrative expense and an increase in income tax expense.

"We are happy to report a continued reduction of our operating cash burn and operating losses during 2023 compared to 2022," said Chris Astle, Ph.D., Senior Vice President and Chief Financial Officer of Zymeworks. "Our strategy of building a diverse clinical-stage product pipeline of ADCs and multispecific antibody therapeutics continues to provide a strong foundation for both achieving our net operating cash burn guidance for this year as well as our long-term goal of identifying additional opportunities to develop additional product candidates and seeking valuable partnership options."

As of June 30, 2023, Zymeworks had \$431.4 million of cash, cash equivalents, and marketable securities, comprised of \$142.1 million in cash and cash equivalents and \$289.3 million in marketable securities. Based on current operating plans, we expect to have cash resources to fund planned operations through at least the end of 2026, and potentially beyond. For the calendar year 2023, we now expect a non-GAAP net operating cash burn of between \$110 million and \$130 million, including planned capital expenditures of approximately \$10 million. As we are focused on the long-term cash resource plan to fund our operations, and due to available GAAP measures that convey similar information, we intend to discontinue reporting of our non-GAAP net operating cash burn in future periods.

Non-GAAP Financial Information

In addition to reporting financial information in accordance with U.S. generally accepted accounting principles (“GAAP”) in this press release, we have elected to present selected non-GAAP, or adjusted, financial measures. Reconciliations between historical GAAP and non-GAAP information are contained at the end of this press release following the accompanying financial data. A reconciliation of anticipated net operating cash burn to the most directly comparable GAAP measure is not available without unreasonable effort due to the uncertainty of expenses that may be incurred in the future, and we are also unable to predict the probable significance of such adjusted measures. Accordingly, in reliance on the exception provided by Item 10(e)(1)(i)(B) of Regulation S-K, we have not provided a reconciliation for the net operating cash burn guidance measure provided in this press release.

About Zymeworks Inc.

Zymeworks Inc. (Nasdaq: ZYME) is a global biotechnology company committed to the discovery, development, and commercialization of novel, multifunctional biotherapeutics. Zymeworks' mission is to make a meaningful difference for people impacted by difficult-to-treat cancers and other serious diseases. Zymeworks' complementary therapeutic platforms and fully integrated drug development engine provide the flexibility and compatibility to precisely engineer and develop highly differentiated antibody-based therapeutic candidates. Zymeworks engineered and developed zanidatamab, a HER2-targeted bispecific antibody using Zymeworks' proprietary Azymetric™ technology. Zymeworks has entered into separate agreements with BeiGene, Ltd. (BeiGene) and Jazz Pharmaceuticals Ireland Limited (Jazz), granting each of BeiGene and Jazz with exclusive rights to develop and commercialize zanidatamab in different territories. Zanidatamab is currently being evaluated in global Phase 1, Phase 2, and Phase 3 clinical trials, including certain ongoing pivotal clinical trials as a treatment for patients with HER2-expressing cancers. Zymeworks' next clinical candidate, zanidatamab zovodotin (ZW49), is a HER2-targeted bispecific antibody-drug conjugate (ADC) developed using Zymeworks' proprietary Azymetric™ and ZymeLink™ Auristatin technologies. Zanidatamab zovodotin is currently being evaluated in a Phase 1 clinical trial for patients with a variety of HER2-expressing, HER2-amplified or HER2-mutant cancers. Zymeworks is also advancing a deep pipeline of product candidates based on its experience and capabilities in both ADC and multispecific antibodies (MSAT). In addition to Zymeworks' wholly owned pipeline, its therapeutic platforms have been further leveraged through strategic partnerships with global biopharmaceutical companies. For 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” or information within the meaning of the applicable securities legislation, including Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements in this press release include, but are not limited to, statements that relate to Zymeworks' expectations regarding implementation of its strategic priorities; the anticipated benefits of the collaboration agreement with Jazz, including Zymeworks' ability to receive any future milestone payments and royalties thereunder; the potential addressable market of zanidatamab; the timing of and results of interactions with regulators; Zymeworks' clinical development of its product candidates and enrollment in its clinical trials; anticipated clinical data presentations; expectations regarding future regulatory filings and approvals and the timing thereof; potential therapeutic effects of zanidatamab and Zymeworks' other product candidates; expected financial performance and future financial position; the commercial potential of technology platforms and product candidates; anticipated continued receipt of revenue from existing and future partners; Zymeworks' preclinical pipeline; anticipated sufficiency of cash resources and other potential sources of cash to fund Zymeworks' planned operations through at least the end of 2026, and potentially beyond; Zymeworks' anticipated net operating cash burn and planned capital expenditures in 2023; Zymeworks' ability to execute new collaborations and partnerships and other information that is not historical information. When used herein, words such as “plan”, “believe”, “expect”, “may”, “continue”, “anticipate”, “potential”, “will”, “progress”, 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: any of Zymeworks' or its partners' product candidates may fail in development, may not receive required regulatory approvals, or may be delayed to a point where they are not commercially viable; Zymeworks may not achieve milestones or receive additional payments under its collaborations; regulatory agencies may impose additional requirements or delay the initiation of clinical trials; the impact of new or changing laws and regulations; market conditions; the impact of the pandemic and other health crises on Zymeworks' business, research and clinical development plans and timelines and results of operations, including impact on its clinical trial sites, collaborators, and contractors who act for or on Zymeworks' behalf; clinical trials may not demonstrate safety and efficacy of any of Zymeworks' or its collaborators' product candidates; Zymeworks' assumptions and estimates regarding its financial condition, future financial performance and estimated cash runway may be incorrect; inability to maintain or enter into new partnerships or strategic collaborations; and the factors described under “Risk Factors” in Zymeworks' quarterly and annual reports filed with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for its quarter ended June 30, 2023 (a copy of which may be obtained at www.sec.gov and www.sedar.com). Although Zymeworks believes that such forward-looking statements are reasonable, there can be no assurance they will prove to be correct. Investors should not place undue reliance on forward-looking statements. The above assumptions, risks and uncertainties are not exhaustive. Forward-looking statements are made as of the date hereof and, except as may be required by law, Zymeworks undertakes no 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.

ZYMEWORKS INC.

Condensed Interim Consolidated Statements of Loss and Comprehensive 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,	
	2023	2022	2023	2022
Revenue				
Research and development collaborations	\$ 7,002	\$ 5,442	\$ 42,580	\$ 7,358
Operating expenses:				
Research and development	39,408	56,022	85,320	118,532
General and administrative	21,708	15,243	38,655	27,335
Total operating expenses	61,116	71,265	123,975	145,867
Loss from operations	(54,114)	(65,823)	(81,395)	(138,509)
Other income, net	4,616	1,195	8,934	1,182
Loss before income taxes	(49,498)	(64,628)	(72,461)	(137,327)
Income tax (expense) recovery	(1,654)	9	(3,044)	83

Net loss	\$	(51,152)	\$	(64,619)	\$	(75,505)	\$	(137,244)
Other comprehensive loss:								
Unrealized loss on available for sale securities, net of tax of \$0		(1,874)		—		(1,154)		—
Total other comprehensive loss		(1,874)		—		(1,154)		—
Comprehensive loss	\$	(53,026)	\$	(64,619)	\$	(76,659)	\$	(137,244)
Net loss per common share:								
Basic	\$	(0.76)	\$	(0.97)	\$	(1.13)	\$	(2.15)
Diluted	\$	(0.76)	\$	(0.97)	\$	(1.13)	\$	(2.15)
Weighted-average common stock outstanding:								
Basic		67,281,028		66,353,279		67,011,664		63,874,097
Diluted		67,284,511		66,354,784		67,014,794		63,880,076

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

	June 30, 2023	December 31, 2022
	(unaudited)	
Cash, cash equivalents and marketable securities	\$ 431,438	\$ 492,232
Working capital	326,790	449,081
Total assets	602,054	648,725
Accumulated deficit	(634,268)	(558,763)
Total stockholders' equity	448,919	492,956

NON-GAAP FINANCIAL MEASURES

In addition to reporting financial information in accordance with GAAP in this press release, Zymeworks is also reporting selected non-GAAP, or adjusted, financial measures, including adjusted research and development expenses, adjusted general and administrative expenses, adjusted net loss per share (basic and diluted) and net operating cash burn. These non-GAAP financial measures 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, other companies, including companies in our industry, may calculate similarly titled non-GAAP or adjusted measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of our adjusted measures as tools for comparison. 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, adjusted 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 as well as expenses incurred in relation to the restructuring program implemented in 2022. As defined by Zymeworks, adjusted net loss per share – Basic represents net loss per share – Basic adjusted for non-cash stock-based compensation expenses for equity and liability classified equity instruments on a per share basis as well as restructuring expenses incurred in relation to the restructuring program implemented in 2022 on a per share basis, and adjusted net loss per share – Diluted represents net loss per share – Diluted adjusted for non-cash stock-based compensation expenses for equity and liability classified equity instruments on a per share basis as well as restructuring expenses incurred in relation to the restructuring program implemented in 2022 on a per share basis. As defined by Zymeworks, net operating cash burn represents net operating loss less cash used in the acquisition of property, equipment and intangible assets.

Adjusted expenses and adjusted net loss per share (basic and diluted) are non-GAAP measures that Zymeworks believes may be helpful to investors because they provide consistency and comparability with past financial performance. Net operating cash burn is a non-GAAP measure that Zymeworks believes may be helpful to investors because it provides information about the cash resources used in funding our operations.

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,	
	2023	2022	2023	2022
Research and development expenses	\$ 39,408	\$ 56,022	\$ 85,320	\$ 118,532
Stock-based compensation (expense) / recovery for equity classified instruments (*)	1,081	(1,971)	640	776
Stock-based compensation (expense) / recovery for liability classified instruments (*)	4	300	—	774
Restructuring expense	—	(707)	—	(6,249)
Adjusted research and development expenses (Non-GAAP basis)	\$ 40,493	\$ 53,644	\$ 85,960	\$ 113,833
General and administrative expenses	\$ 21,708	\$ 15,243	\$ 38,655	\$ 27,335
Stock-based compensation (expense) / recovery for equity classified instruments (*)	(1,725)	(1,281)	(4,111)	951
Stock-based compensation (expense) / recovery for liability classified instruments (*)	314	163	968	3,039
Restructuring recovery / (expense)	—	315	—	(3,620)
Adjusted general and administrative expenses (Non-GAAP basis)	\$ 20,297	\$ 14,440	\$ 35,512	\$ 27,705

Three Months Ended June 30, Six Months Ended June 30,

	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Net loss per common share – Basic	\$ (0.76)	\$ (0.97)	\$ (1.13)	\$ (2.15)
Stock-based compensation expense per common share	0.01	0.04	0.04	(0.09)
Restructuring expenses per common share	—	0.01	—	0.15
Adjusted net loss per common share – Basic (Non-GAAP basis)	<u>\$ (0.75)</u>	<u>\$ (0.92)</u>	<u>\$ (1.09)</u>	<u>\$ (2.09)</u>
Net loss per common share – Diluted	\$ (0.76)	\$ (0.97)	\$ (1.13)	\$ (2.15)
Stock-based compensation expense per common share	0.01	0.04	0.04	(0.09)
Restructuring expenses per common share	—	0.01	—	0.15
Adjusted net loss per common share – Diluted (Non-GAAP basis)	<u>\$ (0.75)</u>	<u>\$ (0.92)</u>	<u>\$ (1.09)</u>	<u>\$ (2.09)</u>

(*): Research and development expenses and general and administrative expenses include \$nil stock-based compensation expense related to the 2022 restructuring for the three and six months ended June 30, 2023 (\$0 for the three months ended June 30, 2022; recovery of \$5,516 and \$4,865 for the six months ended June 30, 2022, in research and development expenses and general and administrative expenses, respectively).

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Net loss	\$ (51,152)	\$ (64,619)	\$ (75,505)	\$ (137,244)
Acquisition of property, equipment and intangible assets	(802)	(3,746)	(1,188)	(8,450)
Net operating cash burn (Non-GAAP basis)	<u>\$ (51,954)</u>	<u>\$ (68,365)</u>	<u>\$ (76,693)</u>	<u>\$ (145,694)</u>

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Source: Zymeworks Inc.