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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2025

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 001-41535

ZYMEWORKS INC.
(Exact name of registrant as specified in its charter)

Delaware	**88-3099146**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

108 Patriot Drive, Suite A
Middletown, Delaware 19709
(Address of principal executive offices, including zip code)

(302) 274-8744
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00001 par value per share	ZYME	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes ☐ No ☒

The number of outstanding shares of common stock of the registrant, $0.00001 par value per share, as of May 6, 2025 was 69,683,492.

ZYMEWORKS INC.

QUARTERLY REPORT ON FORM 10-Q

For the Quarter Ended March 31, 2025

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q includes "forward-looking statements" or information within the meaning of applicable securities legislation, including Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934 as amended (the "Exchange Act"). Forward-looking statements include statements that may relate to our plans, objectives, goals, strategies, future events, future revenue or performance, capital expenditures, financing needs and other information that is not historical information. Many of these statements appear, in particular, under the headings "Business", "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations". Forward-looking statements can often be identified by the use of terminology such as "subject to," "believe," "anticipate," "plan," "expect," "intend," "estimate," "on track," "project," "may," "will," "should," "would," "could," "can," the negatives thereof, variations thereon and similar expressions, or by discussions of strategy. 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. In particular, these forward-looking statements include, but are not limited to, statements about:

- the size of our addressable markets and our ability to commercialize product candidates;
- the achievement of advances in and expansion of our therapeutic platforms and antibody engineering expertise;
- the likelihood of product candidate development and clinical trial progression, initiation or success; and
- our ability to predict and manage government regulation.

All forward-looking statements, including, without limitation, those related to our examination of historical operating trends, are based upon our current expectations and various assumptions. Certain assumptions made in preparing the forward-looking statements include:

- our ability to manage our growth effectively;
- the absence of material adverse changes in our industry or the global economy;
- our ability to understand and predict trends in our industry and markets;
- our ability to enter into and maintain good business relationships with our strategic partners;
- our ability to comply with current and future regulatory standards;
- our ability to protect our intellectual property rights;
- our continued compliance with third-party license terms and the non-infringement of third-party intellectual property rights;
- our ability to manage and integrate any acquisitions we may pursue;
- our ability to retain key personnel; and
- our ability to raise sufficient debt, equity, or non-dilutive financing to support our continued growth.

We believe there is a reasonable basis for our expectations and beliefs, but they are inherently uncertain. We may not realize our expectations, and our beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements. The following uncertainties and factors, among others (including those referred to in the section titled "Risk Factors"), could affect future performance and cause actual results to differ materially from those matters expressed in or implied by forward-looking statements:

- our or our partners' ability to obtain regulatory approval for product candidates without significant delays;
- the predictive value of our current or planned clinical trials;
- delays with respect to the development and commercialization of our product candidates, which may cause increased costs or delay receipt of product revenue;
- our or any of our partners' ability to enroll subjects in clinical trials and thereby complete trials on a timely basis;
- the design or our execution of clinical trials may not support regulatory approval, including where clinical trials are conducted outside the United States;
- our ability to achieve milestones and receive associated milestone payments and royalties pursuant to the terms of our collaboration agreements, including the Amended Jazz Collaboration Agreement (as defined below);

- the extent to which our business may be adversely affected by pandemics or other health crises;
- global economic and political conditions, including as a result of the Russian invasion of Ukraine and the conflicts in Israel and the broader Middle East, as well as social and political unrest in the locations where our clinical trials are held, and the related impact on our business and the markets generally;
- unanticipated tax consequences in connection with the Redomicile Transactions (as defined below);
- the possibility that the Fast Track and Breakthrough Therapy designations for any of our product candidates may not expedite regulatory review or approval;
- the U.S. Food and Drug Administration's (the "FDA") refusal to accept data from trials we conduct outside the United States;
- disruptions at the FDA and other government agencies caused by funding shortages, global health concerns or changes implemented by the current U.S. Presidential administration;
- changes in regulations and customs, tariffs and trade barriers;
- our discretion to discontinue or reprioritize the development of any of our product candidates;
- the potential for our product candidates to have undesirable side effects;
- that no regulatory agency has made a determination that any of our product candidates are safe or effective for use by the general public or for any indication;
- our ability to face significant competition, including biosimilar products;
- the likelihood of broad market acceptance of our product candidates;
- our ability to obtain Orphan Drug Designation or exclusivity for some or all of our product candidates;
- our ability to commercialize products outside of the United States;
- the outcome of reimbursement decisions by third-party payors relating to our products;
- our expectations with respect to the market opportunities for any product that we or our strategic partners develop;
- our ability to pursue product candidates that may be profitable or have a high likelihood of success;
- our ability to use and expand our therapeutic platforms to build a pipeline of product candidates;
- our ability to meet the requirements of ongoing regulatory review;
- the threat of product liability lawsuits against us or any of our strategic partners;
- changes in product candidate manufacturing or formulation that may result in additional costs or delay;
- the potential disruption of our business and dilution of our shareholdings associated with acquisitions and joint ventures;
- the potential for foreign governments to impose strict price controls;
- the risk of security breaches and incidents or data loss, which could compromise sensitive business or health information;
- current and future legislation that may increase the difficulty and cost of commercializing our product candidates;
- economic, political, regulatory and other risks associated with international operations;
- our exposure to legal and reputational penalties as a result of any of our current and future relationships with various third parties;
- our ability to comply with export control and import laws and regulations;
- our history of significant losses since inception;
- our ability to generate revenue from product sales and achieve profitability;
- our requirement for substantial additional funding;
- the potential dilution to our stockholders associated with future financings;
- restrictions on our ability to seek financing, which may be imposed by future debt;
- unstable market and economic conditions;

- currency fluctuations and changes in foreign currency exchange rates;
- our ability to maintain existing and future strategic partnerships;
- our ability to realize the anticipated benefits of our strategic partnerships;
- our ability to secure future strategic partners;
- our or a third party's ability to successfully develop any companion diagnostic tests for our product candidates without significant delays;
- our reliance on third-party manufacturers to produce our product candidate supplies and on other third parties to monitor and transport bulk drug substance and drug product;
- our reliance on third parties to oversee clinical trials of our product candidates and, in some cases, maintain regulatory files for those product candidates;
- risks related to the manufacture of product candidates and difficulties in production;
- our reliance on third parties for various operational and administrative aspects of our business including our reliance on third parties' cloud-based software platforms;
- our reliance on the performance of independent clinical investigators and contract research organizations ("CROs");
- our ability to operate without infringing the patents and other proprietary rights of third parties;
- our ability to obtain and enforce patent protection for our product candidates and related technology;
- our patents could be found invalid or unenforceable if challenged;
- our intellectual property rights may not necessarily provide us with competitive advantages;
- our potential involvement in expensive and time-consuming patent lawsuits;
- the risk that the duration of our patents will not adequately protect our competitive position;
- our ability to obtain protection under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments") and similar foreign legislation;
- our ability to protect the confidentiality of our proprietary information;
- our ability to comply with procedural and administrative requirements relating to our patents;
- the risk of claims challenging the inventorship of our patents and other intellectual property;
- our dependency on the abilities of third parties to assert and defend our intellectual property rights for some of our product candidates;
- patent reform legislation and court decisions can diminish the value of patents in general, thereby impairing our ability to protect our products;
- our ability to protect our intellectual property rights throughout the world;
- that we will require FDA approval for any proposed product candidate names and any failure or delay associated with such approval which may adversely affect our business;
- our election to rely on certain reduced reporting and disclosure requirements available to smaller reporting companies may make our common stock less attractive to investors;
- the risk of employee misconduct including noncompliance with regulatory standards and insider trading;
- our ability to market our products in a manner that does not violate the law and subject us to civil or criminal penalties;
- potential adverse effects to our business from any non-compliance with laws regulating the protection of the environment and health and human safety;
- our ability to retain key executives and attract and retain qualified personnel;
- our ability to manage any organizational growth;
- our exposure to potential securities class action litigation; and

- the possibility that our share price and trading volume could decline if securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business.

Consequently, forward-looking statements should be regarded solely as our current plans, estimates and beliefs. You should not place undue reliance on forward-looking statements. We cannot guarantee future results, events, levels of activity, performance or achievements. We do not undertake and specifically decline any obligation to update, republish or revise forward-looking statements to reflect future events or circumstances or to reflect the occurrences of unanticipated events, except as required by law. Our Risk Factors are not guarantees that no such conditions exist as of the date of this report and should not be interpreted as an affirmative statement that such risks or conditions have not materialized, in whole or in part.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

We own or have rights to trademarks, service marks or trade names that we use in connection with the operation of our business. In addition, our names, logos and website names and addresses are our service marks or trademarks. Our registered trademarks include Azymetric, Zymeworks, ZymeCAD, EFECT, ZymeLink and the phrase "Building Better Biologics". The other trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. Solely for convenience, the trademarks, service marks, tradenames and copyrights referred to in this Quarterly Report on Form 10-Q are listed without the ©, ® and TM symbols, but we will assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks and tradenames.

We express all amounts in this Quarterly Report on Form 10-Q in U.S. dollars, except where otherwise indicated. References to "$" and "US$" are to U.S. dollars and references to "C$" are to Canadian dollars.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Zymeworks Inc.

Index to Interim Condensed Consolidated Financial Statements (unaudited)

As of and for the three months ended March 31, 2025

ZYMEWORKS INC.
Condensed Consolidated Balance Sheets
(Expressed in thousands of U.S. dollars except share data)

	March 31, 2025	December 31, 2024
Assets	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 76,204	$ 66,103
Short-term marketable securities (note 5)	189,083	159,673
Accounts receivable	24,594	55,815
Prepaid expenses and other current assets	16,586	18,860
Total current assets	306,467	300,451
Long-term marketable securities (note 5)	56,324	98,428
Long-term prepaids and other assets	9,096	8,919
Deferred tax asset	4,849	4,385
Property and equipment, net	16,685	17,650
Operating lease right-of-use assets	16,723	16,666
Intangible assets, net	3,362	4,576
Goodwill (note 6)	12,016	12,016
Total assets	$ 425,522	$ 463,091
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (note 7)	$ 38,223	$ 59,838
Income tax payable	127	128
Current portion of operating lease liability (note 11)	3,258	2,740
Deferred revenue (note 9)	23,495	25,588
Total current liabilities	65,103	88,294
Long-term portion of operating lease liability (note 11)	15,174	15,738
Deferred revenue (note 9)	14,607	14,607
Other long-term liabilities (note 7)	856	923
Deferred tax liability	4,815	4,761
Total liabilities	100,555	124,323
Stockholders' equity:		
Common stock, $0.00001 par value; 900,000,000 authorized shares at March 31, 2025 and December 31, 2024, respectively; 69,584,811 and 68,964,319 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively (note 8a)	1,021,950	1,015,618
Preferred shares, $0.00001 par value; 100,000,000 authorized shares of preferred stock, out of which, one share of preferred stock is a share of Special Voting Preferred Stock and outstanding as of March 31, 2025 and December 31, 2024 (note 8a).	—	—
Exchangeable shares, no par value, 569,902 and 570,637 issued and outstanding shares at March 31, 2025 and December 31, 2024, respectively (note 8a)	8,178	8,188
Additional paid-in capital	154,216	152,249
Accumulated other comprehensive loss	(6,406)	(6,952)
Accumulated deficit	(852,971)	(830,335)
Total stockholders' equity	324,967	338,768
Total liabilities and stockholders' equity	$ 425,522	$ 463,091
Research collaboration and licensing agreements (note 9)		
Commitments and contingencies (note 13)		

The accompanying notes are an integral part of these financial statements.

ZYMEWORKS INC.
Condensed Consolidated Statements of Loss and Comprehensive Loss
(Expressed in thousands of U.S. dollars except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2025	2024
Revenue		
Research and development collaborations (note 9)	$ 27,110	$ 10,030
Operating expenses:		
Research and development	35,738	32,042
General and administrative	16,985	15,790
Total operating expenses	52,723	47,832
Loss from operations	(25,613)	(37,802)
Other income:		
Interest income	3,424	5,920
Other income, net (note 10)	49	304
Total other income, net	3,473	6,224
Loss before income taxes	(22,140)	(31,578)
Income tax expense	(496)	(75)
Net loss	(22,636)	(31,653)
Other comprehensive income (loss):		
Unrealized income (loss) on available for sale securities, net of tax of nil (note 5)	546	(1,121)
Total other comprehensive income (loss)	546	(1,121)
Comprehensive loss	$ (22,090)	$ (32,774)
Net loss per common share (note 4):		
Basic	$ (0.30)	$ (0.42)
Diluted	$ (0.30)	$ (0.42)
Weighted-average common stock outstanding (note 4):		
Basic	75,171,020	76,214,833
Diluted	75,226,387	76,248,158

The accompanying notes are an integral part of these financial statements.

ZYMEWORKS INC.
Condensed Consolidated Statement of Changes in Stockholders' Equity
(Expressed in thousands of U.S. dollars except share data)
(unaudited)

	Preferred stock		Exchangeable shares		Common stock		Accumulated deficit	Accumulated other comprehensive loss	Additional paid-in capital	Total stockholders' equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at January 1, 2025	1	$ —	570,637	$ 8,188	68,964,319	$ 1,015,618	$ (830,335)	$ (6,952)	$ 152,249	$ 338,768
Issuance of common stock on exercise of options	—	—	—	—	84,863	1,208	—	—	(437)	771
Issuance of common stock through employee stock purchase plan	—	—	—	—	74,274	724	—	—	—	724
Issuance of common stock upon vesting of restricted stock units ("RSUs")	—	—	—	—	460,620	4,390	—	—	(4,390)	—
Issuance of common stock for retracted exchangeable shares (note 8a)	—	—	(735)	(10)	735	10	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	6,794	6,794
Net loss	—	—	—	—	—	—	(22,636)	—	—	(22,636)
Other comprehensive income	—	—	—	—	—	—	—	546	—	546
Balance at March 31, 2025	1	$ —	569,902	$ 8,178	69,584,811	$ 1,021,950	$ (852,971)	$ (6,406)	$ 154,216	$ 324,967

	Preferred stock		Exchangeable shares		Common stock		Accumulated deficit	Accumulated other comprehensive loss	Additional paid-in capital	Total stockholders' equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at January 1, 2024	1	$ —	651,219	$ 9,345	70,115,997	$ 997,227	$ (677,437)	$ (6,603)	$ 142,274	$ 464,806
Issuance of common stock on exercise of options	—	—	—	—	203,518	2,581	—	—	(626)	1,955
Issuance of common stock through employee stock purchase plan	—	—	—	—	52,905	577	—	—	—	577
Issuance of common stock upon vesting of RSUs	—	—	—	—	224,104	1,939	—	—	(1,939)	—
Issuance of common stock for retracted exchangeable shares (note 8a)	—	—	(80,582)	(1,157)	80,582	1,157	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	3,435	3,435
Net loss	—	—	—	—	—	—	(31,653)	—	—	(31,653)
Other comprehensive loss	—	—	—	—	—	—	—	(1,121)	—	(1,121)
Balance at March 31, 2024	1	$ —	570,637	$ 8,188	70,677,106	$ 1,003,481	$ (709,090)	$ (7,724)	$ 143,144	$ 437,999

The accompanying notes are an integral part of these financial statements

ZYMEWORKS INC.
Condensed Consolidated Statements of Cash Flows
(Expressed in thousands of U.S. dollars)
(unaudited)

	Three Months Ended March 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (22,636)	$ (31,653)
Items not involving cash:		
Depreciation of property and equipment	981	1,061
Amortization of intangible assets	1,617	702
Stock-based compensation expense	6,402	3,552
Amortization of operating lease right-of-use assets	707	549
Deferred income tax recovery	(410)	(38)
Change in fair value of contingent consideration liability	—	(700)
Unrealized foreign exchange gain	(32)	(487)
Changes in non-cash operating working capital:		
Accounts receivable	31,219	(11,468)
Prepaid expenses and other current assets	2,872	(227)
Accounts payable and accrued liabilities	(21,219)	2,278
Operating lease liabilities	(814)	(1,035)
Deferred revenue and other consideration	(2,093)	(259)
Income taxes payable	(1)	50
Net cash used in operating activities	(3,407)	(37,675)
Cash flows from financing activities:		
Issuance of common stock on exercise of stock options	772	1,743
Issuance of common stock through employee stock purchase plan	544	386
Net cash provided by financing activities	1,316	2,129
Cash flows from investing activities:		
Purchases of marketable securities	(34,032)	(66,509)
Proceeds from marketable securities	46,552	59,847
Acquisition of property and equipment	(16)	(185)
Acquisition of intangible assets	(322)	(469)
Net cash provided by (used in) investing activities	12,182	(7,316)
Effect of exchange rate changes on cash and cash equivalents	10	119
Net change in cash and cash equivalents	10,101	(42,743)
Cash and cash equivalents, beginning of period	66,103	157,557
Cash and cash equivalents, end of period	$ 76,204	$ 114,814
Supplemental cash flow information:		
Net cash paid during the period for income taxes	$ 387	$ —
Supplemental disclosure of non-cash investing and financing items:		
Leased assets obtained in exchange for operating lease liabilities	$ 765	$ —
Acquisition of property and equipment and intangible assets in accounts payable and accrued liabilities	81	—

The accompanying notes are an integral part of these financial statements.

ZYMEWORKS INC.
Notes to the Interim Condensed Consolidated Financial Statements
(unaudited)
(Expressed in thousands of U.S. dollars except share and per share data)

1. Nature of Operations

Zymeworks Inc. together with its subsidiaries (collectively the "Company" or "Zymeworks") is a clinical-stage biopharmaceutical company dedicated to the development of next-generation multifunctional biotherapeutics. Zymeworks BC Inc. ("Zymeworks BC"), (previously known as "Zymeworks Inc.") was incorporated on September 8, 2003 under the laws of the Canada Business Corporations Act. On October 22, 2003, the Company was registered as an extra-provincial company under the Company Act (British Columbia). On May 2, 2017, the Company continued under the Business Corporations Act (British Columbia).

Since its inception, the Company has devoted substantially all of its resources to research and development activities, including developing its therapeutic platforms and identifying and developing potential product candidates by undertaking preclinical studies and clinical trials. The Company supports these activities through general and administrative support, as well as by raising capital, conducting business planning and protecting its intellectual property.

On October 13, 2022, the Company completed an internal reorganization transaction resulting in a Delaware incorporated entity becoming the listed company (the "Redomicile Transactions"). Prior to the Redomicile Transactions, the shares of Zymeworks BC Inc. (formerly known as Zymeworks Inc.) were publicly listed. Unless the context otherwise requires or otherwise expressly states, all references in the accompanying interim condensed consolidated financial statements to "Zymeworks," the "Company," "we," "us" and "our" (i) for periods until completion of the Redomicile Transactions, refer to Zymeworks BC Inc. and its subsidiaries and (ii) for periods after completion of the Redomicile Transactions, refer to Zymeworks Inc. (formerly known as Zymeworks Delaware Inc.) and its subsidiaries.

To effect the Redomicile Transactions, the Company conducted a share exchange, pursuant to which holders of the Company's common shares exchanged their common shares in the Company for shares of common stock of Zymeworks Inc. (formerly known as Zymeworks Delaware Inc.) or, at their election with respect to all or a portion of their common shares in the Company and subject to applicable eligibility criteria and an overall cap, exchangeable shares (the "Exchangeable Shares") in the capital of a newly formed indirect subsidiary of Zymeworks Inc. A special meeting of Company security holders was held on October 7, 2022 to approve the Redomicile Transactions. The Redomicile Transactions were governed by a transaction agreement dated July 14, 2022, as restated and amended on August 18, 2022 (the "Restated and Amended Transaction Agreement"), by and among the Company and its direct or indirect subsidiaries Zymeworks Inc., Zymeworks CallCo ULC ("CallCo") and Zymeworks ExchangeCo Ltd., ("ExchangeCo") including a plan of arrangement included as Exhibit A to the Restated and Amended Transaction Agreement (the "Plan of Arrangement").

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying interim condensed consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP") and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, these financial statements do not include all the information and footnotes required for complete financial statements and should be read in conjunction with the audited consolidated financial statements of the Company and the accompanying notes thereto for the year ended December 31, 2024.

These unaudited interim condensed consolidated financial statements reflect all adjustments, consisting solely of normal recurring adjustments, which, in the opinion of management, are necessary for a fair presentation of results for the interim periods presented. The results of operations for the three months ended March 31, 2025 and 2024 are not necessarily indicative of results that can be expected for a full year. These unaudited interim condensed consolidated financial statements follow the same significant accounting policies as those described in the notes to the audited consolidated financial statements of the Company for the year ended December 31, 2024.

All amounts expressed in the interim condensed consolidated financial statements of the Company and the accompanying notes thereto are expressed in thousands of U.S. dollars, except for share and per share data and where otherwise indicated. References to "$" are to U.S. dollars and references to "C$" are to Canadian dollars.

Certain prior period amounts have been reclassified for consistency with the current period presentation. These reclassifications had no effect on the reported results of operations.

Use of Estimates

The preparation of interim condensed consolidated financial statements in accordance with U.S. GAAP requires the Company to make estimates and judgments in certain circumstances that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, the Company evaluates its estimates, most notably those related to revenue recognition including estimated timing of completion of performance obligations required to meet revenue recognition criteria, accrual of expenses including clinical and preclinical study expense accruals, stock-based compensation, valuation allowance for deferred taxes, measurement of contingent consideration liabilities, and other contingencies. Management bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. Actual results could differ from these estimates.

3. Recent Accounting Pronouncements

Recent accounting pronouncements not yet adopted

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. The amendments require disclosure of specific categories in the rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold and further disaggregation of income taxes paid for individually significant jurisdictions. The ASU is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. However, these disclosures are not required for interim periods. The standard is to be applied on a prospective basis, with the option for retrospective application. The Company is currently evaluating the impact of adoption of the standard on its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, Income Statement Reporting – Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40), Disaggregation of Income Statement Expenses. The standard update improves the disclosures about a public business entity's expenses by requiring more detailed information about the types of expenses (including purchases of inventory, employee compensation, depreciation and amortization) included within income statement expense captions. The guidance will be effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The standard updates are to be applied prospectively with the option for retrospective application. The Company is currently evaluating the impact of adoption of the standard update on its consolidated financial statements.

4. Net loss per share

Net loss per share for the three months ended March 31, 2025 and 2024 was as follows:

	Three Months Ended March 31,	
	2025	2024
Numerator:		
Net loss attributable to common stockholders:		
Basic	$ (22,636)	$ (31,653)
Adjustment for change in fair value of liability classified stock options	(177)	(209)
Diluted	$ (22,813)	$ (31,862)
Denominator:		
Weighted-average common stock outstanding:		
Basic	75,171,020	76,214,833
Adjustment for dilutive effect of liability classified stock options	55,367	33,325
Diluted	75,226,387	76,248,158
Net loss per common share – basic	$ (0.30)	$ (0.42)
Net loss per common share – diluted	$ (0.30)	$ (0.42)

Weighted average number of shares of common stock used in the basic and diluted earnings per share calculations include Exchangeable Shares and the pre-funded warrants issued in connection with the Company's December 2023 private placement as the warrants were exercisable at any time for nominal cash consideration. The Company's potentially dilutive securities, which include stock options and RSUs, have been excluded from the computation of diluted net loss per share for the three months ended March 31, 2025 and 2024 as the effect would be to reduce the net loss per share.

5. Cash, Cash Equivalents and Marketable Securities

The following table summarizes the Company's marketable securities as of March 31, 2025:

	March 31, 2025		
	Amortized Cost	Unrealized Gain	Fair Value
Short-term marketable securities:			
Contractual maturity of one year or less:			
Guaranteed investment certificates ("GICs") and mutual funds	$ 37,512	$ —	$ 37,512
U.S. Treasury notes	87,151	105	87,256
Corporate debt securities	64,277	38	64,315
	188,940	143	189,083
Long-term marketable securities:			
Contractual maturity of one to three years:			
Corporate debt securities	39,870	49	39,919
Contractual maturity of three to four years:			
Corporate debt securities	16,344	61	16,405
	56,214	110	56,324
	$ 245,154	$ 253	$ 245,407

The following table summarizes the Company's marketable securities as of December 31, 2024:

	December 31, 2024		
	Amortized Cost	Unrealized Gain (Loss)	Fair Value
Short-term marketable securities:			
Contractual maturity of one year or less:			
GICs and mutual funds	$ 37,166	$ —	$ 37,166
U.S. Treasury notes	71,500	72	71,572
Corporate debt securities	50,993	(58)	50,935
	159,659	14	159,673
Long-term marketable securities:			
Contractual maturity of one to three years:			
U.S. Treasury notes	14,979	2	14,981
Corporate debt securities	65,461	(153)	65,308
Contractual maturity of three to four years:			
Corporate debt securities	18,295	(156)	18,139
	98,735	(307)	98,428
	$ 258,394	$ (293)	$ 258,101

The following tables present information about the Company's assets that are measured at fair value on a recurring basis, and indicate the fair value hierarchy of the valuation techniques used to determine such fair value:

	March 31, 2025				December 31, 2024			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Cash and cash equivalents:								
Cash				$ 58,830				$ 34,620
Cash equivalents:								
Money market funds	$ 17,374	$ —	$ —	$ 17,374	$ 16,398	$ —	$ —	$ 16,398
GICs	—	—	—	—	15,085	—	—	15,085
	$ 17,374	$ —	$ —	$ 76,204	$ 31,483	$ —	$ —	$ 66,103
Marketable securities:								
GICs and mutual funds	$ 37,512	$ —	$ —	$ 37,512	$ 37,166	$ —	$ —	$ 37,166
U.S. Treasury notes	87,256	—	—	87,256	86,553	—	—	86,553
Corporate debt securities	—	120,639	—	120,639	—	134,382	—	134,382
	$ 124,768	$ 120,639	$ —	$ 245,407	$ 123,719	$ 134,382	$ —	$ 258,101
	$ 142,142	$ 120,639	$ —	$ 321,611	$ 155,202	$ 134,382	$ —	$ 324,204

6. Goodwill

The Company performed its most recent annual impairment test of goodwill as of December 31, 2024. As part of the evaluation of the recoverability of goodwill, the Company identified only one reporting unit to which the total carrying amount of goodwill has

been assigned. As at December 31, 2024, the Company performed a qualitative assessment for its annual impairment test of goodwill after concluding that it was not more likely than not that the fair value of the reporting unit was less than its carrying value. Consequently, a quantitative impairment test was not required. The Company concluded that there were no impairment indicators related to goodwill as of March 31, 2025.

7. Liabilities

Accounts payable and accrued liabilities consisted of the following:

	March 31, 2025	December 31, 2024
Trade payables	$ 5,223	$ 3,903
Accrued research and development expenses	25,867	43,114
Goods and services tax payable	5	1,250
Employee compensation and related accruals	2,653	6,222
Fair value of liability classified stock options	707	1,264
Accrued legal, professional fees and other	3,768	4,085
	$ 38,223	$ 59,838

Other long-term liabilities consisted of the following:

	March 31, 2025	December 31, 2024
Liability from in-licensing agreements	$ 447	$ 447
Finance lease liability (note 11)	28	28
Other	381	448
	$ 856	$ 923

8. Stockholders' Equity

a. Authorized Share Capital and Preferred Stock

The Company's authorized share capital consists of 1,000,000,000 shares of stock, consisting of (i) 900,000,000 shares of common stock, par value $0.00001 per share, and (ii) 100,000,000 shares of preferred stock, par value $0.00001 per share.

In connection with the Plan of Arrangement, the Company issued to Computershare Trust Company of Canada, a trust company existing under the laws of Canada (the "Share Trustee"), one share of the Company's preferred stock, par value $0.00001 per share, which has certain variable voting rights in proportion to the number of Exchangeable Shares outstanding (the "Special Voting Preferred Stock"), enabling the Share Trustee to exercise voting rights for the benefit of the Exchangeable Shareholders.

Immediately prior to the completion of the Redomicile Transactions, there were 61,699,387 Zymeworks BC common shares issued and outstanding. In connection with the consummation of the Plan of Arrangement, 60,274,854 shares of Common Stock and 1,424,533 Exchangeable Shares were issued to former Zymeworks BC shareholders. As of March 31, 2025, there were 569,902 Exchangeable Shares held by former Zymeworks BC shareholders (December 31, 2024: 570,637). The Company will issue shares of its common stock as consideration when a holder of Exchangeable Shares calls for Exchangeable Shares to be retracted by ExchangeCo, when ExchangeCo redeems Exchangeable Shares from the holder, or when CallCo purchases Exchangeable Shares from the Exchangeable Shareholder under CallCo's overriding call rights. These Exchangeable Shares and the Special Voting Preferred Stock, when taken together, are similar in substance to the Company's common stock and are treated as such in calculation of basic net loss per share.

b. Stock Repurchase Program

On August 1, 2024, the board of directors of the Company authorized a stock repurchase program (the "Repurchase Program"), whereby the Company may repurchase up to $60,000 of the Company's outstanding common stock, par value $0.00001 per share.

As part of the Repurchase Program, the Company adopted an accounting policy whereby the par value of each share is deducted from common stock and the remainder of the repurchase price is debited to accumulated deficit.

During the year ended December 31, 2024, the Company repurchased 2,545,402 shares of its common stock for a cost of $30,000, and incurred commission expense of $51, under the Repurchase Program, which have been recorded against accumulated deficit. The Company's share repurchases in excess of issuances are subject to a 1% excise tax enacted by the Inflation Reduction Act of $152. During the year ended December 31, 2024, the Company retired all 2,545,402 shares repurchased. These shares were returned to the status of authorized and unissued shares.

The following table presents the Company's Repurchase Program activity:

	Total number of shares purchased	Average price paid per share	Approximate value of shares purchased
Year Ended December 31, 2024	2,545,402	$ 11.79	$ 30,000

c. Pre-Funded Common Share Warrants

In connection with the private placement completed on December 28, 2023, the Company issued a total of 5,086,521 pre-funded warrants which granted holders of warrants the right to purchase up to 5,086,521 common shares of the Company, at an exercise price of $0.0001 per share.

The pre-funded warrants are exercisable by the holders at any time on or after the original issue date. The pre-funded warrants do not expire unless they are exercised or settled in accordance with the pre-funded warrant agreement. As the pre-funded warrants meet the condition for equity classification, proceeds from issuance of the pre-funded warrants, net of any transaction costs, are recorded in additional paid-in capital. Upon exercise of the pre-funded warrants, the historical costs recorded in additional paid-in capital along with exercise price collected from holders will be recorded in common shares. As the amounts required to exercise the warrants are nominal, these instruments are considered in the calculation of basic net loss per share.

As of March 31, 2025, there were 5,086,521 pre-funded warrants outstanding (December 31, 2024: 5,086,521).

d. Stock-Based Compensation

In connection with Redomicile Transactions in 2022, Zymeworks BC. assigned to the Company, and the Company assumed, all of Zymeworks BC's rights and obligations under each of the stock-based compensation plans, as described below, and such plans became the Company's stock-based compensation plans, with each outstanding award assumed by the Company and deemed exchanged for equivalent awards of the Company, except that the security issuable upon exercise or settlement, as applicable, will be shares of common stock of the Company rather than common shares of Zymeworks BC.

Original Stock Option Plan

On July 14, 2006, the shareholders of the Company approved an employee stock option plan (the "Original Plan"). The total number of options outstanding is not to exceed 20% of the issued common shares of the Company. Options granted under the Original Plan are exercisable at various dates over their 10-year life. The exercise prices of the Company's stock options under the Original Plan are denominated in Canadian dollars. Upon the effectiveness of the Company's New Plan described below, no further options were issuable under the Original Plan. However, all outstanding options granted under the Original Plan remain outstanding, subject to the terms of the Original Plan and the applicable grant documents, until such outstanding options are exercised or they terminate or expire by their terms.

New Plan and Inducement Plan

On April 10, 2017, the Company's shareholders approved a new stock option plan, which became effective immediately prior to the consummation of the Company's initial public offering ("IPO"). This plan allows for the grant of options, and also permitted the Company to grant incentive stock options ("ISOs"), within the meaning of Section 422 of the Internal Revenue Code, to its employees, until the shares reserved for issuance of ISOs were depleted. On June 7, 2018, the Company's shareholders approved an amendment and restatement of this plan (this plan, as amended and restated, the "New Plan"), which includes an article that allows the Company to grant restricted shares, RSU and other share-based awards, in addition to stock options. As of March 31, 2025, 5,326,769 shares of common stock were available for future award grants under the New Plan (December 31, 2024: 5,196,630 shares of common stock).

On January 5, 2022, the board of directors approved the Zymeworks Inc. Inducement Stock Option and Equity Compensation Plan (the "Inducement Plan") and reserved 750,000 of the Company's common shares for issuance pursuant to equity awards granted thereunder. On July 19, 2024, the board of directors approved an amendment and restatement of the Inducement Plan, which increased the number of shares of the Company's common stock available for future issuance pursuant to equity awards granted under the Inducement Plan by 700,000 shares. As a result of this increase, a total of 1,450,000 shares will have been available for issuance pursuant to equity awards granted under the Inducement Plan since the inception of the Inducement Plan in January 2022. As of March 31, 2025, 390,000 shares of common stock were available for future award grants under this plan (December 31, 2024: 390,000).

RSUs

The following table summarizes the Company's RSU activity under the New Plan since December 31, 2024:

	Number of RSUs	Weighted-average grant date fair value ($)
Outstanding, December 31, 2024	1,293,970	9.69
Granted	1,176,475	13.22
Vested and settled	(460,620)	9.53
Forfeited, expired	(31,004)	11.56
Outstanding, March 31, 2025	1,978,821	11.80

As of March 31, 2025, there was $11,678 of unamortized RSU expense that will be recognized over a weighted average period of 1.58 years.

Stock Options

The following table summarizes the Company's stock options granted in Canadian dollars under the Original Plan and the New Plan:

	Number of Options	Weighted-Average Exercise Price (C$)	Weighted-Average Exercise Price ($)	Weighted-Average Contractual Term (years)	Aggregate intrinsic value (C$)	Aggregate intrinsic value ($)
Outstanding, December 31, 2024	1,082,835	20.36	14.15	4.73	6,485	4,509
Granted	—	—	—			
Exercised	(14,177)	8.77	6.11			
Forfeited, expired	(3,266)	24.31	16.90			
Outstanding, March 31, 2025	1,065,392	20.50	14.25	4.45	3,970	2,760

The following table summarizes the Company's stock options granted in U.S. dollars under the New Plan and the Inducement Plan:

	Number of Options	Weighted-Average Exercise Price ($)	Weighted-Average Contractual Term (years)	Aggregate intrinsic value ($)
Outstanding, December 31, 2024	7,331,084	12.01	7.97	30,459
Granted	1,551,225	13.18		
Exercised	(70,686)	8.28		
Forfeited	(64,997)	12.18		
Outstanding, March 31, 2025	8,746,626	12.25	8.09	14,571

During the three months ended March 31, 2025, the Company received cash proceeds of $772 from stock options exercised.

The stock options outstanding at March 31, 2025 expire at various dates from October 1, 2025 to March 9, 2035.

The estimated fair values of options granted to officers, directors, employees and consultants are amortized over the relevant vesting periods. Stock-based compensation expense for equity classified instruments, RSUs, as well as the financial statement impact of the amortization and periodic revaluation of liability classified instruments, are recorded in research and development expense and general and administration expense as follows:

	Three Months Ended March 31,	
	2025	2024
Research and development expense	$ 3,161	$ 1,925
General and administrative expense	3,113	1,534

The amounts above include stock-based compensation expense relating to RSUs of $2,280 for the three months ended March 31, 2025 (2024: $1,022).

The estimated fair value of stock options granted under the New Plan was determined using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Three Months Ended March 31,	
	2025	2024
Dividend yield	0 %	0 %
Expected volatility	63.1 %	65.0 %
Risk-free interest rate	4.58 %	4.01 %
Expected average life of options	6.06 years	6.04 years

The weighted-average Black-Scholes option pricing assumptions for liability classified stock options outstanding at March 31, 2025 and 2024 are as follows:

	Three Months Ended March 31,	
	2025	2024
Dividend yield	0 %	0 %
Expected volatility	47.0 %	49.1 %
Risk-free interest rate	2.30 %	4.10 %
Expected average option term	0.63 years	0.77 years
Number of liability classified stock options outstanding	272,330	369,096

At March 31, 2025, the unamortized compensation expense related to unvested options was $18,105. The remaining unamortized compensation expense as of March 31, 2025 will be recognized over a weighted-average period of 1.78 years.

9. Research, Collaboration and Licensing Agreements

Revenue recognized from the Company's strategic partnerships. which includes amounts from Jazz Pharmaceuticals Ireland Limited or Jazz Pharmaceuticals, Inc. (subsidiaries of Jazz Pharmaceuticals plc, collectively referred to as "Jazz") is summarized as follows:

	Three Months Ended March 31,	
	2025	2024
Jazz:		
Development support payments	$ 4,493	$ 2,066
Drug supply for ongoing studies	2,957	6,218
Other drug supply	2,150	1,578
Royalties	202	—
BeiGene, Ltd. ("BeiGene"):		
Drug supply	208	—
GlaxoSmithKline Intellectual Property Development Ltd. ("GSK"):		
Milestone revenue	14,000	—
Daiichi Sankyo, Co., Ltd. ("Daiichi Sankyo"):		
Milestone revenue	3,100	—
Research support and other payments from other partners	—	168
	$ 27,110	$ 10,030

Since December 31, 2024, there have not been any material changes to the key terms of our collaboration and license agreements.

In January 2025, the Company recognized $14,000 of milestone revenue associated with a clinical milestone under the Company's 2016 licensing agreement with GSK.

In March 2025, the Company recognized $3,100 of milestone revenue from Daiichi Sankyo following the first patient dosed in a clinical trial related to the 2018 license agreement between the Company and Daiichi Sankyo.

Contract Assets and Liabilities

As at March 31, 2025, contract assets from research, collaboration and licensing agreements were $197 (December 31, 2024: $100) and contract liabilities were $38,102 (December 31, 2024: $40,195). As at March 31, 2025 and December 31, 2024, $23,495 and $25,588 respectively, of the contract liabilities is classified as short-term. Contract liabilities relate to deferred revenue from the BeiGene and Jazz agreements.

10. Other income, net

Other income, net, consists of the following:

	Three Months Ended March 31,	
	2025	2024
Foreign exchange (loss) gain, net	$ (2)	$ 285
Other	51	19
	$ 49	$ 304

11. Leases

The lease for the Company's office and laboratory spaces in Vancouver, British Columbia, which we entered into in January 2019, has an initial term expiring in February 2032, with two five-year extension options. In addition, the Company leases office spaces in Bellevue, Washington and in Redwood City, California with lease terms expiring between June 2026 and August 2027. None of the optional extension periods have been included in the determination of the right-of-use assets or the lease liabilities for operating leases as the Company did not consider it reasonably certain that the Company would exercise any such options.

The Company also leases office equipment under capital lease agreements.

The balance sheet classification of the Company's lease liabilities was as follows:

	March 31, 2025	December 31, 2024
Operating lease liabilities:		
Current portion	$ 3,258	$ 2,740
Long-term portion	15,174	15,738
Total operating lease liabilities	18,432	$ 18,478
Finance lease liabilities:		
Current portion included in other current liabilities	5	28
Long-term portion included in other long-term liabilities	28	28
Total finance lease liabilities	33	56
Total lease liabilities	$ 18,465	$ 18,534
Weighted average remaining lease term:		
Operating leases	6.1 years	6.4 years
Weighted average discount rate:		
Operating leases in U.S. dollars	5.4 %	5.4 %
Operating leases in Canadian dollars	4.8 %	4.8 %

Cash paid for amounts included in the measurement of operating lease liabilities for fixed payments for the three months ended March 31, 2025 and 2024 was $1,048 and $1,341, respectively, and were included in net cash used in operating activities in the consolidated statement of cash flows.

As of March 31, 2025, the maturities of the Company's operating lease liabilities were as follows:

	Operating leases
Within 1 year	$ 4,042
1 to 2 years	3,659
2 to 3 years	3,202
3 to 4 years	2,960
4 to 5 years	2,582
Thereafter	4,733
Total operating lease payments	21,178
Less:	
Imputed interest	(2,746)
Operating lease liabilities	$ 18,432

The cost components of the operating leases were as follows for the three months ended March 31, 2025 and 2024:

	Three Months Ended March 31,	
	2025	2024
Lease expenses:		
Operating lease expense	$ 776	$ 422
Variable lease expense	616	418
	$ 1,392	$ 840

12. Financial Instruments

The Company evaluates financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level of classification each reporting period. This determination requires the Company to make subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the fair value hierarchy.

Fair Value Measurements

The Company measures certain financial instruments and other items at fair value.

To determine fair value, the Company uses a fair value hierarchy that prioritizes the inputs, assumptions and valuation techniques used to measure fair value. The three levels of the fair value hierarchy are as follows:

- Level 1 inputs are unadjusted quoted market prices for identical instruments available in active markets.
- Level 2 inputs are inputs other than Level 1 prices, such as prices for a similar asset or liability that are observable either directly or indirectly. If the asset or liability has a contractual term, the input must be observable for substantially the full term. An example includes quoted market prices for similar assets or liabilities in active markets.
- Level 3 inputs are unobservable inputs for the asset or liability and will reflect management's assessment about market assumptions that would be used to price the asset or liability.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. Changes in the observability of valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy.

The Company's financial instruments consist of cash and cash equivalents, short-term and long-term investments in marketable and other securities, accounts receivable, accounts payable and accrued liabilities, contingent consideration, finance and operating lease obligations, and other long-term liabilities.

The carrying values of cash and cash equivalents, accounts receivable and accounts payable and accrued liabilities approximate their fair values due to the near-term maturities of these financial instruments. All marketable securities are classified as available-for-sale and are recorded at fair value. As at March 31, 2025, long-term investments in equity securities of private entities are accounted for as available for sale at their fair values. Other long-term liabilities for contingent consideration related to business

acquisitions are recorded at fair value on the acquisition date and are adjusted quarterly for changes in fair value. Changes in the fair value of contingent consideration liabilities can result from changes in anticipated milestone payments and changes in assumed discount periods and rates. These inputs are unobservable in the market and therefore categorized as level 3 inputs as defined above.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash and cash equivalents, short-term and long-term marketable securities and accounts receivable. Cash and cash equivalents and investments in marketable securities are invested in accordance with the Company's cash investment policy with the primary objective being the preservation of capital and maintenance of liquidity. The cash investment policy includes guidelines on the quality of financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk. The Company limits its exposure to credit loss by placing its cash and cash equivalents and investments with high credit quality financial institutions.

At March 31, 2025, the maximum exposure to credit risk for accounts receivable was $24,594, 57% of which was from GSK (December 31, 2024: 95% of receivables from Jazz) and all accounts receivable are due within the next 12 months. As at March 31, 2025 and December 31, 2024, the Company has recognized nominal amounts of provision for expected credit losses in relation to accounts receivable.

Liquidity Risk

Liquidity risk is the risk that the Company will encounter difficulty in meeting the obligations associated with its financial liabilities that are settled by delivering cash or another financial asset. The Company's short-term cash requirements are primarily to settle its financial liabilities, which consist primarily of accounts payable and accrued liabilities falling due within 45 days and current portion of lease obligations falling due within the next 12 months, with medium term requirements to invest in property and equipment and research and development. The Company's principal sources of liquidity to settle its financial liabilities are cash, cash equivalents, short-term and long-term investments, collection of accounts receivable relating to research collaboration and license agreements and additional public equity offerings as required. The Company believes that these principal sources of liquidity are sufficient to fund its operations for at least the next 12 months.

Foreign Currency Risk

The Company incurs certain operating expenses in currencies other than the U.S. dollar and accordingly is subject to foreign exchange risk due to fluctuations in exchange rates. The Company does not use derivative instruments to hedge exposure to foreign exchange risk and therefore assumes the risk of future gains or losses in its consolidated statements of loss. At March 31, 2025, the Company's net monetary liabilities denominated in Canadian dollars were $2,358 (C$3,392), and in Euros were $4,273 (€3,950).

The operating results and financial position of the Company are reported in U.S. dollars in the Company's interim condensed consolidated financial statements. The fluctuation of the U.S. dollar relative to the Canadian dollar and other foreign currencies will have an impact on the reported balances for net assets, net loss and stockholders' equity in the Company's interim condensed consolidated financial statements.

13. Commitments and Contingencies

Commitments

The Company has entered into research collaboration agreements with strategic partners in the ordinary course of operations that may include contractual milestone payments related to the achievement of pre-specified research, development, regulatory and commercialization events and indemnification provisions, which are common in such agreements. Pursuant to the agreements, the Company is obligated to make research and development and regulatory milestone payments upon the occurrence of certain events and royalty payments based on net sales. The maximum amount of potential future indemnification is unlimited, however, the Company currently holds commercial and product liability insurance that limits the Company's liability and may enable it to recover a portion of any future amounts paid. Historically, the Company has not made any indemnification payments under such agreements and believes that the fair value of these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to indemnification obligations for any period presented in the interim condensed consolidated financial statements.

Contingencies

From time to time, the Company may be subject to various legal proceedings and claims related to matters arising in the ordinary course of business. The Company does not believe it is currently subject to any material matters where there is at least a reasonable possibility that a material loss may be incurred.

14. Business Segments

The Company operates and manages its business in a single reportable segment, which is the discovery, development and commercialization of next-generation multifunctional biotherapeutics (the "biotherapeutics segment"). The biotherapeutics segment revenue consists of collaboration revenue, including amounts recognized relating to upfront non-refundable payments for licenses or options to obtain future licenses, research and development funding, milestone payments and royalties earned under collaboration and license agreements and is managed on a consolidated basis. The accounting policies of the biotherapeutics segment are the same as those described in the summary of significant accounting policies.

The Company's Chief Operating Decision Maker ("CODM") is the Chair of the Board of Directors and Chief Executive Officer. The CODM assesses performance for the biotherapeutics segment and decides how to allocate resources to our development pipeline based on the results of our strategic planning, with segment (loss) income being used to monitor performance against the budgeted costs of that strategy. The measure of segment assets is reported on the balance sheet as total consolidated assets.

Revenue and net income for the Company's biotherapeutics segment are shown below:

	Three Months Ended March 31,	
	2025	2024
Revenue from research and development collaborations	$ 27,110	$ 10,030
Segment expenses:		
Zanidatamab	1,403	3,388
ZW171	2,226	2,298
ZW191	1,706	2,726
ZW220	2,199	3,367
ZW251	3,951	607
Zanidatamab zovodotin	349	2,649
Expense for other preclinical and research programs	5,726	2,810
Salaries and benefits	13,840	13,348
Other research and development expense	4,848	3,741
Other general and administrative expense	7,475	8,283
Total segment expenses	43,723	43,217
Segment loss	(16,613)	(33,187)
Reconciling items:		
Depreciation and amortization	(2,598)	(1,763)
Stock-based compensation expense	(6,402)	(3,552)
Change in contingent consideration	—	700
Interest income	3,424	5,920
Other income, net	49	304
Income tax expense	(496)	(75)
Net loss	$ (22,636)	$ (31,653)

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion should be read in conjunction with the attached financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q, as well as our audited financial statements and related notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2024 included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on March 5, 2025 and with the securities commissions in all provinces and territories of Canada on March 5, 2025. This Quarterly Report on Form 10-Q, including the following sections, contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. As a result of many factors, including without limitation those set forth under "Risk Factors" under Item 1A of Part II below, and elsewhere in this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements. We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Quarterly Report on Form 10-Q. We undertake no obligation to update forward-looking statements which reflect events or circumstances occurring after the date of this Quarterly Report on Form 10-Q, except as required by law.

Overview

Zymeworks is a clinical-stage biotechnology company developing a diverse pipeline of novel, multifunctional biotherapeutics to improve the standard of care for difficult-to-treat diseases such as cancer and autoimmune and inflammatory diseases ("AIID"). 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 from preclinical candidate screening through to registrational clinical trials.

Our first internally developed product candidate, zanidatamab, is a novel bispecific antibody that targets two distinct domains of the human epidermal growth factor receptor 2 ("HER2"). Through rigorous scientific investigation, innovative protein engineering, and our proprietary Azymetric bispecific platform technology, we developed the unique binding mechanism of zanidatamab which enables it to bind to two extracellular sites on HER2. Zanidatamab's unique binding properties result in multiple mechanisms of action that may enable it to address unmet need in patient populations with HER2-expressing cancers. We have entered into separate agreements with BeiGene, Ltd. ("BeiGene") and Jazz Pharmaceuticals Ireland Limited (a subsidiary of Jazz Pharmaceuticals plc, collectively referred to as "Jazz"), granting to each of BeiGene and Jazz exclusive rights to develop and commercialize zanidatamab in different territories. Zanidatamab is currently being evaluated in multiple global clinical trials as a potential best-in-class treatment for patients with HER2-expressing cancers.

In 2024, the FDA granted accelerated approval of Ziihera® (zanidatamab-hrii) 50mg/mL for injection for intravenous use for the treatment of adults with previously-treated, unresectable or metastatic HER2-positive ("HER2+") (IHC 3+) second-line biliary tract cancer ("BTC"). Ziihera® is the first and only dual HER2-targeted bispecific antibody approved for HER2+ BTC in the United States. A Biologics License Application ("BLA") submitted by our partner, BeiGene, has also been accepted for review by the Center for Drug Evaluation (the "CDE") of the National Medical Products Administration (the "NMPA") in China. The European Medicines Agency (the "EMA") has validated our partner Jazz's marketing authorization application for zanidatamab in second-line BTC, and the EMA Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending the conditional marketing authorization of zanidatamab as monotherapy for the treatment of adults with unresectable locally advanced or metastatic HER2+ (IHC 3+) BTC previously treated with at least one prior line of systemic therapy. The CHMP's recommendation will be reviewed by the European Commission. With initial uptake in BTC in the United States, we look forward to reporting on the outcomes of the European Commission's review in the European Union (the "EU"), following the positive opinion from the CHMP, and pending regulatory action in China as early as 2Q-2025 with our partners Jazz Pharmaceuticals and BeiGene, as well as the top-line results from the HERIZON-GEA-01 study of Ziihera® expected in 2H-2025. Zanidatamab is also under development for multiple HER2-expressing indications. For additional information regarding these agreements with BeiGene and Jazz, see the section titled "Strategic Partnerships and Collaborations" below.

We commenced operations in 2003 and have since devoted substantially all of our resources to research and development activities including developing our therapeutic platforms, identifying and developing potential product candidates and undertaking preclinical studies and clinical trials. Additionally, we have supported our research and development activities with general and administrative support, as well as by raising capital, conducting business planning and protecting our intellectual property. Other than the receipt of royalties on sales of zanidatamab and regulatory milestone payments relating to the regulatory approval of zanidatamab, we have not generated any revenue related to product approvals or the sale of approved products as of March 31, 2025, and, other than the anticipated receipt of additional royalties and potential regulatory milestone payments relating to future regulatory decisions and sales of zanidatamab, we do not expect to do so until such time as we obtain regulatory approval and

commercialize one or more of our product candidates. We cannot be certain of the timing or success of approval of our product candidates.

Since our initial public offering ("IPO") in 2017, we have funded our operations primarily through follow-on public offerings, including the issuance of pre-funded warrants, and payments received under our license and collaboration agreements. Payments received or receivables from our license and collaboration agreements include upfront fees, milestone and royalty payments, as well as research support and reimbursement payments. Prior to our IPO, we also received financing from private equity placements and the issuance of convertible debt, which was subsequently converted into equity securities, and a credit facility. From inception to March 31, 2025, we received $1,004.3 million, net of equity issuance costs, from these sources of financing including proceeds from exercises of stock options and employee stock purchase plans. As of March 31, 2025, we had $321.6 million of cash resources consisting of cash, cash equivalents and marketable securities.

Although it is difficult to predict our funding requirements, based upon our current operating plan, we anticipate that our existing cash and cash equivalents and marketable securities as of March 31, 2025 will enable us to fund our operating expenditures and capital expenditure requirements for at least the next twelve months from the date of this Quarterly Report on Form 10-Q is filed with the SEC.

We reported a net loss of $22.6 million for the three months ended March 31, 2025 and through March 31, 2025, we had an accumulated deficit of $853.0 million. Over the next several years, we expect to continue to incur losses as we increase our research and development expenditures in connection with the ongoing development of our product candidates and other clinical, preclinical and regulatory activities.

Wholly-Owned Pipeline

Our wholly-owned programs include novel antibody drug conjugate ("ADC") and multispecific antibody therapeutics ("MSAT") candidates, such as T cell engagers ("TCEs"), focusing on highly-expressed targets which provide opportunities for benchmarking in preclinical development and expected clinical differentiation. Our ADC candidates exploit our proprietary topoisomerase 1 inhibitor ("TOPO1i") payload, ZD06519, while exploring alternate mechanisms of action for longer-term development and leveraging validated peptide-cleavable linkers and stochastic conjugations. With potential for enhanced activity compared to combination therapy, our current MSAT candidates are developed with 2+1 bispecific or trispecific (with co-stimulation or checkpoint inhibition) TCE engineering. These approaches are designed to optimize tumor cell engagement and enhance T cell activation to increase anti-tumor activity while also minimizing cytokine release and off-tumor toxicities.

Solid Tumors in Oncology: Antibody Drug Conjugates (ADCs)

ZW191: A clinical-stage ADC that targets folate receptor α ("FRα")-expressing tumors including ovarian cancer, endometrial cancer, and non-small cell lung cancer ("NSCLC"), is built using our novel, bystander active, TOPO1i payload technology, ZD06519. The FRα-targeting monoclonal antibody incorporated in ZW191 was selected based on compelling internalization characteristics to enable targeting of high, mid, and low levels of FRα expression. A drug-antibody-ratio ("DAR") of eight was selected due to the restricted expression profile of FRα in normal tissues and to enhance our ability to deliver payload to tumors with lower levels of FRα. FRα is a clinically validated target, found in approximately 75% of high-grade serous ovarian carcinomas, 50% of endometrial cancers, and in 70% of NSCLC. Preclinical data demonstrate strong ZW191 activity across a range of FRα-expressing patient-derived xenografts, including models with low levels of FRα. The ability to target lower levels of FRα is in part due to the DAR-eight format and the observed superior internalization, payload delivery, and tissue penetration derived from the ZW191 monoclonal antibody compared to other FRα monoclonal antibodies used in ADCs currently or previously in development. In a good laboratory practices ("GLP") toxicology study, ZW191 achieved a highest non-severely toxic dose ("HNSTD") in non-human primates of 60 mg/kg, which presents a compelling profile and enables the expectation of potentially achieving an efficacious dose level in the Phase 1 clinical trial. We are optimistic about the prospects of ZW191 and we believe the design features and preclinical profile support the potential of ZW191 to target cancers with lower levels of FRα. This would allow ZW191 to potentially unlock efficacy for both ovarian cancer patients who are unable to receive Elahere, as it is only approved in FRα-high platinum-resistant ovarian cancer ("PROC"), and other indications including endometrial and NSCLC which typically express lower levels of FRα. We are currently recruiting patients in an ongoing global Phase 1, open-label, multicenter study of ZW191, registered under NCT06555744 on clinicaltrials.gov. The study aims to enroll 145 participants with advanced solid tumors, including ovarian, endometrial, and non-small cell lung cancers, across North America, Europe, and the Asia-Pacific region. The study is designed to evaluate the safety, tolerability, pharmacokinetics, and preliminary anti-tumor activity of ascending doses of ZW191.

ZW251: A potential first-in-class ADC molecule designed for the treatment of glypican 3 ("GPC3")-expressing hepatocellular carcinoma ("HCC"), incorporates the same Zymeworks proprietary bystander-active TOPO1i payload utilized in ZW191 (anti-FRα) and ZW220 (anti-sodium-dependent phosphate transporter 2b ("NaPi2b")), ZD06519. The GPC3-targeting monospecific antibody incorporated in ZW251 was selected based on favorable binding and internalization properties to enable targeting of a range of GPC3-expressing tumors. A DAR of four was selected for this program as a lower DAR potentially could unlock a broader range of dose levels, a potential benefit as HCC patients are commonly challenged by impairment of liver function as a result of chronic liver disease and cirrhosis. GPC3, a glycosylphosphatidylinositol ("GPI")-anchored cell surface oncofetal antigen, is over-expressed in most HCC patients (>75%), and displays minimal normal adult tissue expression, making it an appealing ADC target. In preclinical studies, anti-tumor activity for ZW251 was observed in multiple patient-derived xenograft models of HCC reflecting a range of GPC3 over-expression. In non-GLP non-human primate studies, ZW251 was tolerated at doses up to 120 mg/kg, suggesting the potential for high doses in humans. We are encouraged by published research demonstrating the potential of targeting GPC3 with an antibody in HCC patients as evidenced by tumor localization of iodine radio-labeled condrituzumab, a clinical-stage anti-GPC3 monoclonal antibody, and believe that ADC-based targeting of GPC3 could enable a novel and effective approach to treatment of HCC. We expect to submit an IND to commence Phase 1 clinical studies for ZW251 by mid-2025, with equivalent non-U.S. applications to be submitted thereafter.

ZW220: An ADC that targets NaPi2b-expressing NSCLC and ovarian cancer, is built, like ZW191, using our proprietary bystander active TOPO1i payload technology, ZD06519. The strong and persistent bystander effect of the ZD06519 payload that we have observed in preclinical studies may help overcome NaPi2b heterogeneity across different cancers. The NaPi2b-targeting monospecific antibody incorporated in ZW220 was selected based on a favorable binding profile and enhanced internalization properties to enable targeting of both Napi2b-high and NaPi2b-low expressing tumors. Distinct from ZW191, ZW220 utilizes a DAR-four format paired with mutations in the fragment crystallizable ("Fc") region to attenuate binding to Fc-gamma family receptors. These features were incorporated in ZW220 with the goal of minimizing potential toxicities associated with expression of NaPi2b in normal lung tissue. NaPi2b is expressed in approximately 83% of ovarian (serous) cancer, 81% of endometrial cancer, and 77% of adenocarcinoma NSCLC. Preclinical data demonstrate that ZW220 is active in models of ovarian cancer and NSCLC with strong anti-tumor activity observed in patient-derived xenograft models and growth inhibition observed in three-dimensional spheroid models. ZW220 is tolerated at high doses in non-GLP animal studies with a maximum tolerated dose ("MTD") ≥90 mg/kg in non-human primates and ≥200 mg/kg in rats, suggesting the potential for high doses in humans. NaPi2b is a compelling ADC target, and we believe the design of ZW220 may overcome some of the challenges encountered with other NaPi2b-targeted ADCs, including Lifa-V, UpRi, and XMT-1592, and may potentially provide a safe and meaningful benefit to patients with NaPi2b-expressing tumors. We have paused the preparations for the commencement of a Phase 1 study of ZW220 to help facilitate the accelerated development of ZW251. However, we believe ZW220 remains a highly differentiated, IND-ready asset with strong clinical, commercial, and partnership potential.

Solid Tumors in Oncology: Multispecific Antibody Therapeutics (MSATs)

ZW171: A clinical-stage multispecific antibody built using our Azymetric platform, is a novel 2 + 1 format TCE targeting mesothelin ("MSLN")-expressing cancers. ZW171 has a unique geometry, with two single-chain fragment variable arms targeting MSLN and one Fab arm targeting the cluster of differentiation 3 protein ("CD3") component of the T cell receptor, to redirect the body's natural immune system to fight cancer cells. Preclinical data demonstrated in vivo anti-tumor activity, with engagement in high-expressing cells but not low-expressing cells, mitigating the risk of on-target, off-tumor toxicities. MSLN has strong expression in ovarian cancer (~84%), with moderate to strong expression in NSCLC (~36%), making it an appealing target for therapeutic development with our proprietary TCE technology. In preclinical studies, ZW171 has demonstrated potent preferential killing of tumor cells expressing relatively medium to high thresholds of MSLN while sparing cell line models representative of normal tissue MSLN expression, demonstrating reduced potential for on-target-off tumor toxicity. Incorporation of a low affinity anti-CD3 binding domain further mitigates the risk of peripheral T cell activation and cytokine release syndrome. Preclinical data demonstrated that ZW171 exhibits greater anti-tumor activity compared to benchmark in MSLN-expressing tumor models and is well tolerated in cynomolgus monkeys up to 30 mg/kg. We are actively recruiting patients in the global Phase 1, open-label, multicenter study of ZW171, registered under NCT06523803 on clinicaltrials.gov. The study aims to enroll 160 adult patients with advanced MSLN-expressing cancers in North America, Europe, and the Asia-Pacific region. The study is designed to evaluate the safety, tolerability, pharmacokinetics, and preliminary anti-tumor activity of ascending doses of ZW171.

ZW209: A novel trispecific T cell engager ("TriTCE") targeting Delta-like ligand 3 ("DLL3")-expressing tumor cells, is designed using our clinically validated Azymetric and EFECT platforms. By leveraging obligate cis-T cell binding and conditional cluster of differentiation 28 ("CD28") engagement, this potentially first-in-class molecule has been designed to prevent unintended T cell activation, while enabling tumor-targeted cytotoxicity. The innovative design has demonstrated differentiated long-term cytotoxicity in vitro at low E:T (effector to target) ratios, with enhanced T cell proliferation and survival, offering significant potential to increase durability of responses in DLL3-expressing cancers. We expect to submit an IND to commence Phase 1 clinical studies for ZW209 in 1H-2026, with equivalent non-U.S. applications to be submitted thereafter.

Autoimmune and Inflammatory Diseases (AIID)

ZW1528: Our first program in AIID, is a novel IL-4Rα x IL-33 bispecific molecule designed to address respiratory inflammation such as mixed-type chronic obstructive pulmonary disease ("COPD") by inhibiting multiple pathways. By blocking three cytokines (IL-4, IL-13 and IL-33) in a single biologic, ZW1528 offers a unique approach to inhibit clinically validated pathways. The bispecific antibody is designed to provide complete, prolonged IL-4Rα blockade with simultaneous blockade of IL-33. Based on non-clinical in vitro studies, the bispecific can independently suppress IL-13, IL-4 and IL-33 driven cell signaling equivalent to that achieved with anti-IL-4Rα monoclonal antibody ("mAb") or anti-IL-33 clinical benchmarks mAbs. Furthermore, in preclinical studies, ZW1528-mediated blockade of cytokine-driven activation of human epithelial cells was superior to that achieved with mAbs targeting either IL-4Rα or IL-33, indicating potential benefits of dual blockade. Additionally, preclinical studies with human peripheral blood mononuclear cells ("PBMCs") demonstrate ZW1528 provides blockade of IL-33 mediated effects beyond that achievable with an anti-IL33 benchmark mAb. With native Immunoglobulin G ("IgG")-like geometry, ZW1528 demonstrates the potential for high manufacturability and incorporates half-life extending Fc modifications. We expect to submit a non-U.S. regulatory filing to commence Phase 1 clinical studies for ZW1528 in 2H-2026, with further non-U.S. applications to be submitted thereafter.

Continued Pipeline Development

We continue to develop and advance additional product candidates in multiple different product formats for selected therapeutic indications in solid tumors, hematological cancers, and AIID, with further potential IND applications in 2027 and beyond. With these candidates, we intend to continue innovating with increased novelty in targets and unique mechanisms of action through bispecific or biparatopic ADCs, dual-payload ADCs, multi-specific immune cell engagers and immune-oncology.

Our Proprietary Therapeutic Platforms

Our proprietary capabilities and technologies include several modular, complementary therapeutic platforms that can be used in combination with each other and with existing approaches. This ability to layer technologies without compromising manufacturability enables us to engineer next-generation biotherapeutics with multifunctional activity, which we believe will result in improved patient outcomes. Our platforms include:

- Azymetric, our multispecific antibody platform, which enables therapeutic antibodies to simultaneously bind multiple distinct locations on a target (known as an epitope) or to multiple targets. This is achieved by tailoring multiple configurations of the antibody's Fc and Fab regions (locations on the antibody to which epitopes bind);
- Drug Conjugate Platforms, used to develop ADC candidates, are comprised of cytotoxins and the linker technologies used to couple these cytotoxins to tumor-targeting antibodies or proteins. These platforms can be used in conjunction with our other therapeutic platforms, including our multispecific antibody platform, to increase safety and efficacy as compared to existing ADC technologies;
- EFECT, which enables finely tuned modulation (both up and down) of immune cell recruitment and function; and
- ProTECT, which enables tumor-specific activity that may reduce systemic toxicity and simultaneously enhances localized immune co-stimulation or checkpoint modulation that may increase efficacy.

Our protein engineering expertise and proprietary structure-guided molecular modeling capabilities enable these therapeutic platforms. Together with our internal antibody discovery and generation technologies, we have established a fully integrated drug development engine and toolkit capable of rapidly delivering a steady pipeline of next-generation product candidates in oncology and other therapeutic areas.

Recent Developments

Wholly-Owned Programs

In April 2025, we presented six preclinical posters at the American Association for Cancer Research ("AACR") annual meeting, highlighting progress across our multispecific T cell engager ("TCE") and ADC platforms. Poster presentations included:

- ZW171, a differentiated 2+1 T cell-engaging bispecific antibody with antitumor activity in a range of mesothelin expressing cancers;
- ZW209, a DLL3 targeted trispecific T cell engager with integrated CD28 co-stimulation, demonstrates safety and potent preclinical efficacy in models of small cell lung cancer;

- ZW327, a novel Ly6E-targeting antibody-drug conjugate bearing a TOPO1i payload; and
- Design and development of biparatopic antibody-drug conjugates against protein tyrosine kinase 7.

Zymeworks scientists coauthored two additional AACR poster presentations leveraging technologies to aid further in design and characterizations of ADCs:

- High throughput quantitative molecular characterization of cytotoxic antibody-drug conjugates in spheroid models for improved functional characterization, screening and candidate selection; and
- In vitro assays for prediction of ADC hematological toxicity: contribution of antibody, linker, and payload.

An abstract highlighting results from recent preclinical research on ZW1528, a novel IL-4Rα x IL-33 bispecific molecule, was accepted for poster presentation at the upcoming American Thoracic Society annual meeting:

- Title: ZW1528, A Bispecific Antibody Targeting IL-4Ra And IL-33, Potently Inhibits Key Mediators Of Airway Inflammation (Abstract: 12571)
- Session Category: B33 (Poster Board: P1567)
- Date and Time: May 19, 2025 at 11:30 AM – 13:15 PM PDT

We will be presenting a trial-in-progress poster at the American Society of Clinical Oncology annual meeting on the ongoing first-in-human Phase 1 study for ZW171 (ZWI-ZW171-101):

- Title: Design of a First-in-Human Multicenter Open-Label Study of ZW171, a Mesothelin x CD3 Targeting Bispecific T Cell Engager, in Participants With Advanced Solid Tumors: ZWI-ZW171-101 (Poster Board: 473b)
- Session Category: Developmental Therapeutics - Molecularly Targeted Agents and Tumor Biology
- Date and Time: June 2, 2025 at 13:30 PM – 16:30 PM CDT

We will also be presenting a trial-in-progress poster at the ESMO GynaecologicalCancers Congress annual meeting on the ongoing first-in-human Phase 1 study for ZW191 (ZWI-ZW191-101):

- Title: Design of a First-in-Human Multicenter Open-Label Study of ZW191, a Folate Receptor α–Targeting Antibody-Drug Conjugate Utilizing a Novel TOPO1i Payload, in Participants With Advanced Solid Tumors ZWI-ZW191-101 (Poster Board: 125TiP)
- Session Category: Ovarian Cancer
- Date and Time: June 20, 2025 at 12:40 PM – 13:30 PM CEST

Zanidatamab Clinical Program

In April 2025, our partner Jazz announced that the EMA Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending the conditional marketing authorization of zanidatamab as monotherapy for the treatment of adults with unresectable locally advanced or metastatic HER2+ (IHC 3+) BTC previously treated with at least one prior line of systemic therapy. The CHMP's recommendation will be reviewed by the European Commission, which has the authority to approve medicines in all EU member states, Iceland, Norway and Liechtenstein. A final decision is expected in the coming months.

In April 2025, our partner Jazz presented two encore trials-in-progress presentations for zanidatamab at the AACR annual meeting titled:

- HERIZON-BTC-302: A phase 3 trial of zanidatamab with standard-of-care ("SOC") therapy vs SOC therapy alone for first-line treatment of human epidermal growth factor receptor 2 (HER2)-positive advanced/metastatic biliary tract cancer; and
- EmpowHER-303: A phase 3 study of zanidatamab vs trastuzumab with physician's choice of chemotherapy in patients with HER2+ metastatic breast cancer whose disease progressed on trastuzumab deruxtecan.

In April 2025, our partner Jazz announced their participation at the 2025 American Society of Clinical Oncology annual meeting with three zanidatamab abstracts accepted for presentation. Details of the accepted abstracts as well as presentation dates are as follows:

- Long-term outcomes and overall survival (OS) for zanidatamab + chemotherapy in HER2- positive (HER2+) advanced or metastatic gastroesophageal adenocarcinoma (mGEA): 4-year follow-up of a phase 2 trial. The presentation is scheduled to take place on Monday, June 2, 2025, 11:30 AM CDT, Rapid Oral Abstract – Gastrointestinal Cancer—Gastroesophageal, Pancreatic, and Hepatobiliary
- Concordance Analysis Between HER2 Immunohistochemistry (IHC) and In Situ Hybridization (ISH) and a Translational Analysis of Plasma ctDNA in Patients With Biliary Tract Cancer (BTC): An Exploratory Analysis From Phase 2 HERIZON-BTC-01 Trial. The presentation is scheduled to take place on Saturday, May 31, 2025, 9:00 AM CDT, Poster Session – Gastrointestinal Cancer—Gastroesophageal, Pancreatic, and Hepatobiliary
- Survival outcomes for zanidatamab compared with chemotherapy in HER2-positive biliary tract cancer (BTC): HERIZON BTC-01 vs a real-world (RW) external control arm (ECA). The presentation is scheduled to take place on Saturday, May 31, 2025, 9:00 AM CDT, Poster Session – Gastrointestinal Cancer—Gastroesophageal, Pancreatic, and Hepatobiliary

Ziihera® net product sales by Jazz were $2.0 million in the three months ended March 31, 2025. In the three months ended March 31, 2025, our royalties from net sales by Jazz were $0.2 million and have been reflected in our financial statements.

Other Matters

In January 2025, we recognized $14.0 million in milestone revenue from GSK in relation to a clinical milestone under our 2016 platform technology transfer and license agreement with GSK, which milestone was achieved in January 2025 and paid in April 2025. Following receipt of this $14.0 million milestone in April 2025, we remain eligible to receive up to $203.5 million in research and development milestone payments, up to $867.0 million in commercial milestone payments, and tiered royalties in the low to mid-single digits on product sales.

In March 2025, we recognized and received $3.1 million in milestone revenue from Daiichi Sankyo following the first patient dosed in a clinical trial related to our 2018 license agreement with Daiichi Sankyo. Following receipt of this $3.1 million milestone, we remain eligible to receive up to $60.3 million in development milestone payments, up to $170.0 million in commercial milestone payments, and tiered royalties ranging from the low single digits up to 10% on future product sales.

In April 2025, we announced the appointment of Sabeen Mekan, M.D., as Senior Vice President, Clinical Development.

Strategic Partnerships and Collaborations

Our novel product candidates, together with our combination of proprietary protein engineering capabilities and resulting therapeutic platform technologies, have enabled us to enter into a number of strategic partnerships, many of which were subsequently expanded in scope. Our strategic partnerships and collaborations provide us with the ability to accelerate clinical development of our product candidates in certain geographical regions and provide our strategic partners with access to components of our proprietary therapeutic platforms for their own therapeutics development. In addition, these strategic partnerships have provided us with non-dilutive funding as well as access to proprietary therapeutic assets, which increase our ability to rapidly advance our product candidates while maintaining commercial rights to our own therapeutics.

Through collaboration agreements with Jazz and BeiGene relating to our programs for zanidatamab and zanidatamab zovodotin, we have received $471.0 million through March 31, 2025 in the form of non-refundable upfront payments and milestone payments. In addition, through these partnerships with Jazz and BeiGene with respect to zanidatamab, as of March 31, 2025, we remain eligible to receive up to $1.53 billion in potential regulatory, development and commercial milestone payments, as well as tiered royalties on potential future product sales, pending receipt of applicable regulatory approvals. These partnerships have provided us with a significant source of non-dilutive funding and provide for additional future funding for our lead asset, zanidatamab. These partnerships also leverage our partners' commercial infrastructure, helping accelerate the development and expanding the potential reach of our lead product candidates.

In addition to the payments we have received through our collaboration agreements with Jazz and BeiGene relating to zanidatamab and zanidatamab zovodotin, as of March 31, 2025, we have received approximately $186.6 million in the form of non-refundable upfront and milestone payments from platform partnership and collaboration agreements. We continue to have revenue-generating strategic partnerships and collaborations with respect to our Azymetric, EFECT and drug conjugate therapeutic platforms with the following pharmaceutical companies: Celgene Corporation (now a Bristol-Myers Squibb company,

"BMS"), GlaxoSmithKline Intellectual Property Development Limited ("GSK"), Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo"), Janssen Biotech, Inc. (now known as J&J Innovative Medicine,"J&J"), and Merck Sharp & Dohme Research GmbH ("Merck"). Through these strategic partnerships and collaborations, as of March 31, 2025, we remain eligible to receive up to $1.03 billion in preclinical and development milestone payments and up to $3.08 billion in commercial milestone payments, as well as tiered royalties on potential future product sales, pending regulatory approval. It is possible, however, that our strategic partners' programs will not advance as currently contemplated, which would negatively affect the amount of development and commercial milestone payments and royalties on potential future product sales we may receive. Importantly, these partnerships include predominantly non-target-exclusive licenses for any of our therapeutic platforms, so we maintain the ability to develop therapeutics directed to many high-value targets using our platforms. There have not been any material changes to the key terms of any of our licensing and collaboration agreements since December 31, 2024. For further information on the terms and conditions of our existing collaboration and license agreements, please refer to "Item 1. Business - Strategic Partnerships and Collaborations" of our Annual Report on Form 10-K for the year ended December 31, 2024.

Financial Operations Overview

Revenue

Our revenue consists of collaboration revenue, including amounts recognized relating to upfront non-refundable payments for licenses or options to obtain future licenses, research and development funding, milestone payments and royalties earned under collaboration and license agreements. We expect that collaboration revenue from our strategic partnerships will be our primary source of revenue for the foreseeable future.

Operating Expenses

Our operating expenses consist primarily of research and development expenses and general and administrative expenses. Personnel costs, including salaries, benefits, bonuses and stock-based compensation expense, comprise a significant component of research and development and general and administrative expenses. We allocate certain indirect expenses associated with our facilities, information technology, depreciation and other overhead costs between research and development and general and administrative categories based on employee headcount and the nature of work performed by each employee.

Research and Development Expense

Research and development expenses consist of expenses incurred in performing research and development activities such as conducting clinical trials and preclinical research studies, technical and manufacturing operations, regulatory affairs and other indirect expenses in support of advancing our product candidates and therapeutic platforms. Research and development expenses include third-party program costs, internal personnel costs and other indirect costs as follows:

- fees paid to CROs, consultants, subcontractors and other third-party vendors for work performed for our clinical trials, preclinical studies and regulatory activities;
- fees paid to third-party manufacturers to produce our product candidate supplies;
- amounts paid to vendors and suppliers for laboratory supplies;
- fees, milestone payments and other expenses incurred in connection with license agreements and amendments;
- employee-related expenses such as salaries and benefits and stock-based compensation;
- depreciation of laboratory equipment, computers and leasehold improvements; and
- overhead expenses such as facilities, information technology and other allocated items.

It is difficult to determine with certainty the duration and completion costs of our current or future clinical trials and preclinical programs of our product candidates, or if, when or to what extent we will generate revenue other than zanidatamab royalties from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our current or future product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of clinical trials and preclinical studies, uncertainties in clinical trial enrollment rates and significant and changing government regulation, tariffs and trade policies. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each

product candidate's commercial potential. We expect our research and development expenses to increase in the future, subject to periodic fluctuations, as we continue to advance, expand and complete the clinical development of our product candidates, support our ongoing collaborations, and conduct our ongoing preclinical research activities.

General and Administrative Expense

General and administrative expenses consist of salaries, benefits and stock-based compensation costs for employees in our executive, finance, legal, intellectual property, business development, human resources and other support functions, as well as legal and professional fees, business insurance, facilities and information technology costs and other expenses. Our general and administrative expenses may increase in the future as we expand or modify our infrastructure to support our ongoing research and development activities.

Other Income (Expense)

Other income (expense) primarily consists of interest income and foreign exchange gain (loss).

Critical Accounting Policies and Significant Judgments and Estimates

Our critical accounting policies are those policies that require the most significant judgments and estimates in the preparation of our interim condensed consolidated financial statements. A summary of our critical accounting policies is presented in note 2 of our annual consolidated financial statements for the year ended December 31, 2024.

Our management's discussion and analysis of financial condition and results of operations is based on our interim condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these interim condensed consolidated financial statements requires us to make estimates, judgments and assumptions that are inherently uncertain that affect the amounts reported in the interim condensed consolidated financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable. We review and evaluate these estimates on an ongoing basis. These assumptions and estimates form the basis for making judgments about the carrying values of assets and liabilities and amounts that have been recorded as revenue and expenses. Actual results and experiences may differ from these estimates. The results of any material revisions would be reflected in the interim condensed consolidated financial statements prospectively from the date of the change in estimate.

There have been no material changes in our critical accounting policies and significant judgments and estimates during the three months ended March 31, 2025 as compared to what has been described in our most recent annual consolidated financial statements.

Recent Accounting Pronouncements

A summary of recent accounting pronouncements is presented in note 3 of our interim condensed consolidated financial statements for the quarter ended March 31, 2025 within this Quarterly Report on Form 10-Q.

Results of Operations for the Three Months Ended March 31, 2025 and 2024

Revenue

(dollars in millions)	Three Months Ended March 31, 2025	2024	Increase/ (Decrease)	
Revenue from research and collaborations	$ 27.1	$ 10.0	$ 17.1	171 %

Our revenue relates primarily to non-recurring upfront fees, expansion payments or milestone payments from our licensing and collaboration agreements.

Total revenue increased by $17.1 million in the three months ended March 31, 2025 compared to the same period in 2024. Revenue for the three months ended March 31, 2025 included $14.0 million of milestone revenue from GSK in relation to a

clinical milestone under our 2016 platform technology transfer and license agreement, $3.1 million of milestone revenue from Daiichi Sankyo following the first patient dosed in a clinical trial related to the 2018 license agreement, $9.6 million for development support and drug supply revenue and $0.2 million royalty revenue from Jazz, and $0.2 million of drug supply revenue from BeiGene. Revenue for the same period in 2024 included $9.9 million for development support and drug supply revenue from Jazz and $0.2 million from our other partners for research support and other payments.

Research and Development Expense

(dollars in millions)	Three Months Ended March 31, 2025	2024	Increase/ (Decrease)	
Third-party research and development program expenses:				
Zanidatamab	$ 1.4	$ 3.4	$ (2.0)	(59)%
Zanidatamab zovodotin	0.3	2.6	(2.3)	(88)%
ZW171	2.2	2.3	(0.1)	(4)%
ZW191	1.7	2.7	(1.0)	(37)%
ZW220	2.2	3.4	(1.2)	(35)%
ZW251	4.0	0.6	3.4	567 %
Other preclinical and research programs	5.7	2.8	2.9	104 %
	17.5	17.8	(0.3)	(2)%
Unallocated departmental research and development expenses:				
Salaries and benefits	9.5	8.6	0.9	10 %
Stock-based compensation expense	3.3	2.0	1.3	65 %
Other unallocated expenses	5.4	3.6	1.8	50 %
Research and development expense	$ 35.7	$ 32.0	$ 3.7	12 %

Research and development expense increased by $3.7 million for the three months ended March 31, 2025 compared to the same period in 2024. The increase in research and development expense in 2025 was primarily due to an increase in expenses for ZW251 for IND enabling studies and other preclinical and research activities, primarily due to preclinical development expenses for ZW209 and increased discovery work towards identifying novel targets and therapeutic areas. These were partially offset by a decrease in expenses for ZW191 as an IND-enabling toxicology study was completed during the three months ended March 31, 2024, by a decrease in expenses for ZW220 as cell line and CMC process development was completed in 2024, by a decrease in expenses for zanidatamab, due to reduced manufacturing and clinical support following BLA approval in 2024, and by a decrease in expenses for zanidatamab zovodotin, due to our decision to discontinue the zanidatamab zovodotin clinical development program. Increase in salaries and benefits in 2025 was primarily due to severance costs while stock-based compensation expense in 2025 increased primarily due to new stock award grants during 2025. Increase in other expenses were primarily due to increase in rent and consulting expenses, as well as the recovery due to the reversal of a contingent liability in 2024.

General and Administrative Expense

(dollars in millions)	Three Months Ended March 31, 2025	2024	Increase/ (Decrease)	
Salaries and benefits	$ 4.4	$ 4.8	$ (0.4)	(8)%
Stock-based compensation expense	3.1	1.6	1.5	94 %
Professional fees, consulting and business insurance	4.9	5.4	(0.5)	(9)%
Other general and administrative expenses	4.6	4.0	0.6	15 %
General and administrative expense	$ 17.0	$ 15.8	$ 1.2	8 %

General and administrative expense increased by $1.2 million for the three months ended March 31, 2025 compared to the same period in 2024. The increase in general and administrative expense was primarily due to an increase in stock-based compensation expense as a result of new stock award grants in 2025 and an increase in amortization expense of capitalized software and software subscription expenses. This was partially offset by a decrease in salaries and benefits due to a decrease in severance costs and external consulting expenses for information technology compared to the same period in 2024.

Other Income, net

(dollars in millions)	Three Months Ended March 31, 2025	2024	Increase/ (Decrease)	
Other income, net	$ 3.5	$ 6.2	$ (2.7)	(44)%

Other income, net decreased by $2.7 million for the three months ended March 31, 2025 compared to the same period in 2024. Other income, net for 2025 included $3.4 million in interest income. Other income, net for the three months ended March 31, 2024 included $5.9 million in interest income and a $0.3 million net foreign exchange gain and other miscellaneous amounts. The decrease in interest income was due to a reduction in the balances of our cash, cash equivalents and marketable securities, due to operating cash requirements, and due to a decrease in the average yield of these investments compared to the same period in 2024.

Income Tax

(dollars in millions)	Three Months Ended March 31, 2025	2024	Increase/ (Decrease)	
Income tax expense	$ 0.5	$ 0.1	$ 0.4	400 %

Income tax expense increased by $0.4 million for the three months ended March 31, 2025, compared to the same period in 2024. The increase was primarily due to withholding taxes incurred on revenue recognized in the period.

Liquidity and Capital Resources

Sources of Liquidity

Since our IPO in 2017, we have funded our operations primarily through follow-on public offerings, including the issuance of pre-funded warrants, as well as from upfront fees, milestone payments, and research support payments generated from our strategic collaborations and licensing agreements.

In August 2024, we entered into a sales agreement (the "Cowen Sales Agreement") with TD Securities (USA) LLC. ("TD Cowen") to sell shares of our common stock subject to a maximum aggregate dollar amount registered pursuant to an applicable prospectus supplement, from time to time, through an "at-the-market" equity offering program under which TD Cowen will act as our sales agent. Sales of shares of common stock through TD Cowen, if any, will be made by any method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415(a)(4) under the Securities Act. As of the date of this report, no shares of our common stock have been sold under the Cowen Sales Agreement. As part of the ongoing management of our operations and related funding needs, we evaluate various financing vehicles, including "at-the-market" equity offering programs, and may enter into similar "at-the-market" equity offering programs in the future, as well as other financing transactions.

As of March 31, 2025, we had $321.6 million of cash, cash equivalents, and marketable securities, comprised of $76.2 million in cash and cash equivalents and $245.4 million in marketable securities.

Cash Flows

The following table represents a summary of our cash flows for the three months ended March 31, 2025 and 2024:

	Three Months Ended March 31,	
	2025	2024
	(dollars in millions)	
Net cash (used in) provided by:		
Operating activities	$ (3.4)	$ (37.7)
Financing activities	1.3	2.1
Investing activities	12.2	(7.3)
Effect of exchange rate changes on cash and cash equivalents	—	0.1
Net change in cash and cash equivalents	$ 10.1	$ (42.7)

Operating Activities

During the three months ended March 31, 2025, cash used in operating activities was $3.4 million compared to $37.7 million for the same period in 2024. The decrease in net cash used in operating activities was primarily due to favorable movements in working capital compared to the same period in the prior year.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2025 included net proceeds of $0.8 million from stock option exercises and $0.5 million from the issuance of shares of common stock under our employee stock purchase plan. Net cash provided by financing activities for the three months ended March 31, 2024 included net proceeds of $1.7 million from stock option exercises and $0.4 million from the issuance of shares of common stock in relation to our employee stock purchase plan.

Investing Activities

Net cash provided by investing activities for the three months ended March 31, 2025 primarily related to net proceeds from marketable securities of $12.5 million partially offset by cash outflows of $0.3 million for the expenditures for software implementation. Net cash used in investing activities for the three month period ended March 31, 2024 primarily related to net purchases of marketable securities of $6.7 million and cash outflows of $0.7 million for the expenditures for software implementation and acquisition of property and equipment in our office and laboratory spaces in Canada and the United States.

Funding Requirements

In the quarter ended December 31, 2024, we began recognizing royalty revenue from sales of zanidatamab by our partner Jazz. However, we have not generated revenue from sales of any of our wholly-owned product candidates as of March 31, 2025 and we do not expect to do so until such time as we obtain regulatory approval and commercialize one or more of our current or future product candidates. As we are currently in the clinical and preclinical stages of development, it will be some time before we expect to achieve this, and it is uncertain that we ever will. We expect that we will continue to increase our operating expenses,

subject to periodic fluctuations, in connection with ongoing clinical trials and preclinical activities and the development of product candidates in our pipeline. In addition, inflation generally may affect us by increasing our cost of labor, outside services, manufacturing and clinical trial expenses. Our funding requirements in the short-term and long-term will consist of the operational, capital, and manufacturing expenditures, a portion of which contain contractual or other obligations including future minimum lease payments under non-cancelable operating leases as presented in note 11 and other commitments and contingencies as presented in note 13 to the interim condensed consolidated financial statements. Because of the inherent risks and uncertainties associated with the development and commercialization of our drug candidates, it is difficult to predict the amounts of capital outflows and operating expenditures associated with our current and anticipated clinical trials and preclinical studies.

Although it is difficult to predict our funding requirements, based on our current operating plan, we anticipate that our existing cash and cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months from the date this Quarterly Report on Form 10-Q is filed with the SEC. We have based these estimates on assumptions and plans which may change and which could impact the magnitude and/or timing of operating expenses, capital expenditures and our cash runway. The successful development of our product candidates and the achievement of milestones by our strategic partners is uncertain, and therefore it is difficult to predict the actual funds we will require to complete the research, development and commercialization of product candidates. See Part II, Item 1A, “Risk Factors – Risks Related to Our Business and the Development and Commercialization of Our Product Candidates” and “Risk Factors – Risks Related to Our Dependence on Third Parties.”

Additionally, on August 1, 2024, our board of directors authorized the Repurchase Program, under which we may repurchase up to $60.0 million of our common stock. As of the date of this report, there is $30.0 million of remaining capacity under the Repurchase Program. The shares may be repurchased from time to time in open market transactions, or other means in accordance with Rule 10b5-1 of the Exchange Act and Rule 10b-18 of the Exchange Act. As of March 31, 2025, we have repurchased 2,545,402 shares of our common stock under the Repurchase Program. The timing, number of shares repurchased, and prices paid for any additional shares of the stock repurchased under this program will depend on general business and market conditions as well as corporate and regulatory limitations, prevailing stock prices, and other considerations. The Repurchase Program may be suspended or discontinued at any time and does not obligate us to acquire any additional shares of common stock.

We will need substantial additional funding to support our continuing operations and pursue our long-term business plans. Accordingly, our future funding requirements will depend on many factors, including but not limited to:

- the scope, rate of progress, results and costs of our clinical trials, preclinical studies and other related activities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements as well as our ability to enter into new arrangements;
- the timing and the costs of obtaining regulatory approvals for any of our current or future drug candidates;
- the cost of commercialization activities if any of our current or future drug candidates are approved for sale, including marketing, sales and distribution costs;
- the amount of royalties and sales-based milestones, if any, received from our collaboration partners for commercial sales of drug candidates, for any such drug candidates that receive marketing approval; and
- the amount of revenue, if any, received from commercial sales of our drug candidates, should any of our drug candidates receive marketing approval.

If adequate funds are not available at favorable terms, we may be required to reduce operating expenses, delay or reduce the scope of our product development and commercial expansion programs, obtain funds through arrangements with others that may require us to relinquish rights to certain of our technologies or products that we would otherwise seek to develop or commercialize ourselves or cease operations. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders’ rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. A deterioration in the equity or credit markets may make any necessary debt or equity financing more difficult, more costly and more dilutive.

Segment Reporting

We view our operations and manage our business in one segment, which is the development of next-generation multifunctional biotherapeutics.

Outstanding Share Data

Our authorized share capital consists of 1,000,000,000 shares of stock, consisting of 900,000,000 shares of common stock, par value $0.00001 per share, and 100,000,000 shares of preferred stock, par value 0.00001 per share. As of May 6, 2025, 69,683,492 shares of common stock were issued and outstanding. In addition, as of May 6, 2025, we had 5,086,521 shares of common stock issuable pursuant to 5,086,521 pre-funded warrants, 4,787,713 shares of common stock issuable pursuant to 4,787,713 exercisable outstanding stock options, 4,909,448 shares of common stock issuable pursuant to 4,909,448 outstanding options that were not exercisable at that date, and 1,895,565 shares of common stock issuable upon vesting of outstanding restricted stock units.

In connection with the Plan of Arrangement, we issued to the Share Trustee one share of our preferred stock, par value $0.00001 per share, which has certain variable voting rights in proportion to the number of Exchangeable Shares outstanding, enabling the Share Trustee to exercise voting rights for the benefit of the holders of Exchangeable Shares. In connection with the consummation of the Plan of Arrangement, 1,424,533 Exchangeable Shares were issued to former Zymeworks BC shareholders. We will issue shares of our common stock as consideration when a holder of Exchangeable Shares calls for Exchangeable Shares to be retracted by ExchangeCo, when ExchangeCo redeems Exchangeable Shares from the holder, or when CallCo purchases Exchangeable Shares from the holder of Exchangeable Shares under CallCo's overriding call rights. For additional information and meaning of defined terms referenced in this paragraph, please see notes 1 and 8a of our interim condensed consolidated financial statements as of and for the quarter ended March 31, 2025, within this Quarterly Report on Form 10-Q.

As of May 6, 2025, 854,631 Exchangeable Shares have been exchanged on a one-to-one basis for 854,631 shares of our common stock and 569,902 Exchangeable Shares are held by former Zymeworks BC shareholders and are exchangeable on a one-to-one basis, subject to adjustment, for up to 569,902 shares of our common stock.

Item 3. Quantitative and Qualitative Disclosure About Market Risk.

As a "smaller reporting company," as defined by Rule 12b-2 of the Exchange Act, and pursuant to Item 305 of Regulation S-K, we are not required to provide quantitative and qualitative disclosures about market risk.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Quarterly Report on Form 10-Q, our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the design and operating effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports that the Company files or submits under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Any such information is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on our evaluation of our disclosure controls and procedures as of March 31, 2025, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were, in design and operation, effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our fiscal quarter ended March 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. As of March 31, 2025, we are not a party to any legal proceedings that, in the opinion of our management, would reasonably be expected to have a material adverse effect on our business, financial condition, operating results or cash flows if determined adversely to us. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

You should carefully consider the following risk factors, in addition to the other information contained in this Quarterly Report on Form 10-Q, including our interim condensed consolidated financial statements and related notes. If any of the events described in the following risk factors occurs, our business, operating results and financial condition could be seriously harmed. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Quarterly Report on Form 10-Q. See "Cautionary Note Regarding Forward-Looking Statements." The risks below are not the only risks facing our company. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations, and/or prospects. Our Risk Factors are not guarantees that no such conditions exist as of the date of this report and should not be interpreted as an affirmative statement that such risks or conditions have not materialized, in whole or in part.

Summary of Risk Factors

Below is a summary of the principal factors that make an investment in shares of our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the SEC, before making an investment decision regarding shares of our common stock.

- We have a limited number of product candidates, which are still in preclinical or clinical development. If we do not obtain regulatory approval of our product candidates, or experience significant delays in doing so, our business will be materially adversely affected.
- Clinical trials are expensive, time consuming, difficult to design and implement, and involve uncertain outcomes. Furthermore, the results of previous preclinical studies and clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or comparable regulatory authorities outside the United States.
- Our long-term prospects depend in part upon discovering, developing and commercializing additional product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.
- Our product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.
- We face significant competition, and if our competitors develop and market products that are more effective, safer and/or less expensive than our product candidates, our commercial opportunities will be negatively impacted.
- If zanidatamab or any of our product candidates that receives regulatory approval in the future does not achieve broad market acceptance among physicians, patients, the medical community and third-party payors, revenue generated from royalties or sales would be limited.
- We may not be successful in our efforts to use our therapeutic platforms to build a pipeline of product candidates.
- If any product liability lawsuits are successfully brought against us or any of our strategic partners, we may incur substantial liabilities and commercialization efforts of zanidatamab or our product candidates may need to be limited.
- Security breaches and incidents, loss of data and other disruptions could compromise sensitive information related to our business or protected health information or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

- Current and future legislation may increase the difficulty and cost for us or our strategic partners to commercialize any approved products that we or our strategic partners develop and affect the prices that may be obtained.
- We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We have only one product approved for commercial sale, and, as of March 31, 2025, we have not received any revenue or profit from product sales, other than the receipt of royalties relating to sales of zanidatamab. We may never achieve or sustain profitability.
- We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back, or cease our product development programs or operations.
- Our effective tax rate may change in the future.
- We depend on our collaborative relationship with Jazz to further develop and commercialize zanidatamab, and if our relationship is not successful or is terminated, we may be delayed in or unable to effectively develop and/or commercialize zanidatamab, which could have a material adverse effect on our business.
- Our existing strategic partnerships are important to our business, and future strategic partnerships will likely also be important to us. If we are unable to maintain our strategic partnerships, or if these strategic partnerships are not successful, our business could be adversely affected.
- We rely on third-party manufacturers to produce our product candidates and on other third parties to provide supplies and store, monitor and transport bulk drug substance and drug product. We and our third-party partners may encounter difficulties with respect to these activities that could delay or impair our ability to initiate or complete our clinical trials or commercialize products.
- We rely on third parties to monitor, support, conduct and oversee clinical trials of the product candidates that we are developing and, in some cases, to maintain regulatory files for those product candidates. We may not be able to obtain regulatory approval for our product candidates or commercialize any products that may result from our development efforts if we are not able to maintain or secure agreements with such third parties on acceptable terms, if these third parties do not perform their services as required, or if these third parties fail to timely transfer any regulatory information held by them to us.
- If we are unable to obtain, maintain and enforce patent and trade secret protection for our product candidates and related technology, our business could be materially harmed.
- If we are unable to protect the confidentiality of our proprietary information, the value of our technology and products could be adversely affected.
- Our stock price is likely to be volatile and the market price of our common stock may drop below the price paid by stockholders.
- Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws might delay, discourage or prevent a change in control of Zymeworks or changes in our management, thereby depressing the market price of our common stock.

Risk Factors

Risks Related to Our Business and the Development and Commercialization of Our Product Candidates

We have a limited number of product candidates, which are still in preclinical or clinical development. If we do not obtain regulatory approval of our product candidates, or experience significant delays in doing so, our business will be materially adversely affected.

Our strategic partner Jazz has received accelerated approval from the FDA for Ziihera® (zanidatamab-hrii) for the treatment of adults with previously-treated, unresectable or metastatic HER2+ BTC. Ziihera® is the first product candidate from one of our therapeutic platforms to receive regulatory approval. Our other product candidates are in preclinical or clinical development and we have not submitted an application, or received marketing approval, for any other product candidates, and we may never be able to achieve such regulatory approval. In addition, although Jazz is developing zanidatamab for regulatory approval in additional indications, such regulatory approval may never be achieved.

Obtaining regulatory approval and commercializing any approved product candidates depends on many factors, including:

- successfully completing clinical trials that demonstrate the pre-specified efficacy endpoints and acceptable safety profile of the product candidate in the indication for which approval is sought;
- preparation and submission to the appropriate regulatory authorities of an application for marketing approval that includes substantial evidence of safety, purity and potency from results of nonclinical testing and clinical trials;
- establishing adequate commercial manufacturing arrangements and maintaining a consistent, quality supply of product or establishing our own commercial manufacturing capabilities or reliable arrangements with third-party contract manufacturers;
- potential pre-approval audits of nonclinical sites, clinical trial sites, and third-party manufacturing sites that generated the data and product in support of the marketing application; and
- launching commercial sales, marketing and distribution operations.

Many of these factors are wholly or partially beyond our control, including clinical advancement, the regulatory submission process and changes in the competitive landscape. If we do not achieve one or more of these factors in a timely manner, we could experience significant delays or an inability to develop our product candidates at all.

Clinical trials are expensive, time consuming, difficult to design and implement, and involve uncertain outcomes. Furthermore, the results of previous preclinical studies and clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or comparable regulatory authorities outside the United States.

Although our strategic partner Jazz has submitted a BLA with respect to zanidatamab, we have not submitted a BLA to the FDA or similar marketing applications to foreign health authorities with respect to any of our other product candidates. A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety, purity and efficacy for each desired indication. The BLA must also include significant information regarding the manufacturing controls for the product. The novel nature of our product candidates may introduce uncertain, complex, expensive and lengthy challenges that could impact regulatory approval. Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA or foreign health authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested.

There is typically an extremely high rate of attrition from the failure of product candidates proceeding through preclinical studies and clinical trials. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. Our clinical trials may produce negative or inconclusive results, and we or any of our current and future strategic partners may decide, or regulators may require us, to conduct additional clinical or preclinical testing. In some instances, there can be significant variability in safety or efficacy results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates also may experience side effects or adverse events that are unrelated to our product candidates but may still impact the success of our clinical trials. The inclusion of patients with significant co-morbidities in our clinical trials may result in deaths or other adverse medical events due to an underlying condition or other therapies or medications that such patients may be using. Any of these events could prevent us from obtaining regulatory approval or achieving or maintaining market acceptance and impair our ability to commercialize our product candidates.

Moreover, success in preclinical studies or early-stage clinical trials does not mean that future clinical trials or registrational clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and comparable regulatory authorities outside the United States, despite having progressed through preclinical studies and initial clinical trials. Product candidates that have shown promising results in early clinical trials may suffer significant setbacks in subsequent clinical trials or registrational clinical trials. Similarly, interim results of a clinical trial do not necessarily predict final results. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including:

- the FDA or foreign health authorities may disagree with the design, implementation or data analyses of clinical trials;

- the FDA or foreign health authorities may determine that the product candidate(s) do not have adequate risk-benefit ratio or have undesirable or unintended side effects, toxicities or other characteristics that preclude obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which approval is sought;
- the FDA or foreign regulators may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of the product candidates may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or foreign health authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers providing our clinical and commercial supplies; and
- the approval policies or regulations of the FDA or foreign health authorities may significantly change in a manner rendering clinical data insufficient for approval.

We have conducted, and may in the future conduct, clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA and its determination that the trials complied with all applicable U.S. laws and regulations. If the FDA does not accept the data from any clinical trials conducted outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or halt development of any future product candidates.

Even if regulatory approval is obtained for a particular indication, there is no guarantee that additional indications will be approved, which could materially limit the commercial potential of any approved product. For example, while Jazz intends to seek approval of zanidatamab in additional indications, we cannot be certain that such approvals will be obtained. If additional indications are not approved, our ability to achieve additional milestone payments and royalties on sales of zanidatamab will be materially and negatively impacted.

If clinical trials for product candidates are prolonged, delayed or stopped, we may be unable to obtain regulatory approval and commercialize product candidates on a timely basis, or at all, which could require us to incur additional costs and delay our receipt of any product revenue.

We currently have two clinical-stage product candidates, ZW171 and ZW191. We have licensed zanidatamab to our strategic partner Jazz, which has been responsible for completing its clinical development in the United States and other jurisdictions not covered by our license to BeiGene. In November 2024, Jazz announced the FDA granted accelerated approval for Ziihera® for injection for intravenous use for the treatment of adults with previously treated, unresectable or metastatic HER2+ (IHC 3+) BTC. Jazz is conducting the confirmatory trial for Ziihera® related to the accelerated approval. If the confirmatory trial fails to demonstrate a clinical benefit, the FDA may remove Ziihera® from the market, which would negatively impact our ability to earn milestone payments and royalties under our arrangement with Jazz.

Following the transfer of the zanidatamab development program to Jazz and the discontinuation of our zanidatamab zovodotin clinical development program following a strategic business review, we have been focused on the development of our early-stage product candidates and general discovery efforts. We are currently recruiting patients in ongoing global Phase 1, open-label, multicenter studies of ZW191 and ZW171 in North America, Europe, and the Asia-Pacific region.

The commencement or completion of ongoing or planned clinical trials could be substantially delayed, prevented or suspended by many factors, including:

- further discussions with the FDA or other regulatory agencies regarding the scope or design of our clinical trials;
- the limited number of, and competition for, suitable sites and patients required to conduct our clinical trials, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication as our product candidates;
- any delay or failure to obtain approval or agreement to commence a clinical trial in any of the countries where enrollment is planned;
- inability to obtain sufficient funds required for a clinical trial;
- inability to recruit clinical operations personnel and other personnel with later-stage development experience;

- clinical holds on, or other regulatory objections to, a new or ongoing clinical trial;
- delay or failure to manufacture sufficient supplies of the product candidate for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different sites or CROs;
- delay or failure to obtain institutional review board ("IRB") approval to conduct a clinical trial at a prospective site;
- slower than expected rates of patient recruitment and enrollment;
- failure of patients to complete the clinical trial or to be lost to follow up;
- the inability to enroll a sufficient number of patients in studies to ensure adequate statistical power to detect statistically significant treatment effects;
- unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by patients, including possible deaths;
- lack of efficacy during clinical trials;
- termination of our clinical trials by one or more clinical trial sites;
- inability or unwillingness of patients or clinical investigators to follow our clinical trial protocols;
- inability to monitor patients adequately during or after treatment by us or our CROs;
- our CROs or clinical study sites failing to comply with the trial protocol or regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a study;
- the inability to address any noncompliance with regulatory requirements or safety concerns that arise during the course of a clinical trial;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or foreign health authorities for violations of applicable regulatory requirements;
- delays in the testing, validation, manufacturing and delivery of our product candidates to the clinical trial sites, including due to a facility manufacturing any of our product candidates or any of their components being ordered by the FDA or foreign health authorities to temporarily or permanently shut down due to violations of cGMP regulations or other applicable requirements, or cross-contaminations of product candidates in the manufacturing process;
- inconclusive or negative results or unforeseen complications in clinical trials;
- a breach or suspension or termination pursuant to the terms of any agreement with, or for any other reason by, current or future strategic partners that have responsibility for the clinical development of any of our product candidates;
- failure to conduct our clinical trials in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or foreign health authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial; and
- receiving untimely or unfavorable feedback from applicable regulatory authorities regarding the trial or requests from regulatory authorities to modify the design of a trial.

If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

Changes in regulatory requirements, policies and guidelines may also occur and we may need to significantly amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. These changes may require us to renegotiate terms with CROs or resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or us.

Any failure or significant delay in commencing or completing clinical trials would adversely affect our ability to obtain regulatory approval, and our commercial prospects and ability to generate product revenue will be diminished. Even if trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or foreign health authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. We cannot guarantee that the FDA or foreign health authorities will view any of our product candidates as having adequate safety and efficacy profiles even if favorable results are observed in these clinical trials, and we may receive unexpected or unfavorable feedback from the FDA or foreign health authorities regarding satisfaction of safety, purity and potency (including clinical efficacy), amongst other factors. To the extent the results of the trials are not satisfactory to the FDA or foreign health authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

Our long-term prospects depend in part upon discovering, developing and commercializing additional product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.

Our future operating results are dependent in part on our ability to successfully discover, develop, obtain regulatory approval for and commercialize product candidates beyond zanidatamab and the product candidates we currently have in clinical and preclinical development. A product candidate can unexpectedly fail at any stage of preclinical and clinical development. Our investments in our early-stage research and development efforts may not yield any promising product candidates. Even if our research and development efforts yield product candidates that advance into clinical studies, the historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from preclinical testing or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later stage clinical trials of the product candidate.

The success of other product candidates we may develop will depend on many factors, including generating sufficient data to support the initiation or continuation of clinical trials and obtaining regulatory permission to initiate clinical trials. Even if we successfully advance any other product candidates into clinical development, their success will be subject to the clinical, regulatory and commercial risks described elsewhere in this “Risk Factors” section. We cannot assure you that we will ever be able to discover, develop, obtain regulatory approval of, commercialize or generate significant revenue from our other product candidates.

If we, or any of our strategic partners, are unable to enroll patients in clinical trials, we will be unable to complete these trials on a timely basis or at all.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of subjects to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, ability to obtain and maintain patient consents, risk that enrolled subjects will drop out before completion, competing clinical trials and clinicians’ and patients’ perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. In particular, we are developing certain of our product candidates for the treatment of rare diseases, which have limited pools of patients from which to draw for clinical testing. If we, or any of our strategic partners that perform clinical tests for our product candidates, are unable to enroll a sufficient number of patients to complete clinical testing, we will be unable to gain marketing approval for such product candidates and our business will be harmed. Additionally, projections of addressable patient populations that have the potential to benefit from treatment with our or our strategic partners’ product candidates are based on estimates, and, if such estimates are inaccurate, could have an adverse material impact on our business.

In addition, the U.S. federal Right to Try Act, among other things, provides a framework for patients to access certain investigational new drug products that have completed a Phase 1 clinical trial. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA approval under the FDA expanded access program. While there is no obligation to make product candidates available to eligible patients as a result of the Right to Try Act, new and emerging legislation regarding expanded access to unapproved drugs could negatively impact enrollment in our clinical trials and our business in the future.

The design or our execution of clinical trials may not support regulatory approval.

The design or execution of a clinical trial can determine whether its results will support regulatory approval, and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced. In some instances, there

can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any Phase 2, Phase 3 or other clinical trials we or any of our strategic partners may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

Further, the FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether regulatory approval will be obtained for any of our product candidates. Our product candidates may not be approved even if they achieve their primary endpoints in any Phase 3 clinical trials or registration trials. The FDA or other non-U.S. regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 clinical trial that has the potential to result in FDA or other agencies' approval. In addition, any of these regulatory authorities may approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or other non-U.S. regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

Interim, preliminary or top-line data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, preliminary or top-line data from clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or top-line data previously published. As a result, interim, preliminary and top-line data should be viewed with caution until the final data is available. Adverse differences between interim, preliminary or top-line data and final data could significantly harm our reputation and business prospects. Moreover, preliminary, interim and top-line data are subject to the risk that one or more of the clinical outcomes may materially change as more patient data become available when patients mature on study, patient enrollment continues or as other ongoing or future clinical trials with a product candidate further develop. Past results of clinical trials may not be predictive of future results.

The information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically more extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. Similarly, even if we are able to complete our planned and ongoing preclinical studies and clinical trials of our product candidates according to our current development timeline, the positive results from such preclinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical and other nonclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical, nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or other regulatory approval.

The Fast Track and Breakthrough Therapy designations received for zanidatamab may not result in faster development, regulatory review or approval process.

The FDA has granted Fast Track designations to zanidatamab for the first-line treatment of patients with HER2-overexpressing GEA in combination with standard of care chemotherapy and for previously treated or recurrent gene-amplified BTC. While the FDA granted accelerated approval in November 2024 for Ziihera® for injection for intravenous use for the treatment of adults with previously treated, unresectable or metastatic HER2+ BTC (IHC 3+), these Fast Track designations do not ensure that zanidatamab will experience a faster development, regulatory review or approval process compared to conventional FDA procedures or that zanidatamab will ultimately obtain regulatory approval for additional indications. The FDA may withdraw Fast

Track designation if it believes that the designation is no longer supported by data from the zanidatamab clinical development program. The FDA also granted Breakthrough Therapy designation for zanidatamab for treatment of patients with previously treated HER2 gene-amplified locally advanced/unresectable or metastatic BTC. Designation as a Breakthrough Therapy is within the discretion of the FDA and the FDA may decide to rescind a Breakthrough Therapy designation if it believes that a designated product candidate no longer meets the conditions for qualification of this program. If a clinical development program is suspended, terminated, or put on clinical hold due to unexpected adverse events or other issues, including clinical supply issues, the benefits associated with the Fast Track or Breakthrough Therapy designations may not be realized by us or our strategic partners. Furthermore, Fast Track designation does not change the standards for approval, and the designation alone does not guarantee qualification for the FDA's priority review procedures. Zanidatamab has also been granted Breakthrough Therapy designation from the CDE in China for treating patients with BTC who have failed prior systemic therapies. This designation alone does not guarantee faster approval of zanidatamab in China.

Development of product candidates in combination with other therapies could expose us to additional risks.

We are subject to risks that the FDA, the EMA or other comparable foreign regulatory authorities could revoke approval of any therapies with which zanidatamab or any other product candidate that receives marketing approval is approved for use. We are also subject to the risk that safety, efficacy, manufacturing or supply issues could arise with such therapies. In addition, it is possible that existing therapies with which zanidatamab or our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment, which could result in such products being removed from the market or being less successful commercially. We may also evaluate our product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved therapies that do not ultimately obtain marketing approval. If the FDA, EMA or other comparable foreign regulatory authorities do not approve or revoke their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any other product candidate, we may be unable to obtain approval of or successfully market any one or all of the product candidates we develop.

Additionally, if the third-party providers of therapies or therapies in development with which zanidatamab or our product candidates is approved for use are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the cost of combination therapies is prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

If we are unable to successfully develop any required companion diagnostic tests for our product candidates, or experience significant delays in doing so, or rely on third parties in the development of such companion diagnostic tests, we may not realize the full commercial potential of our product candidates.

If we develop a product candidate for which there are no commercially available diagnostic tests for identifying the appropriate patient population to ensure safe and effective use of such candidate, the FDA may require us to develop a companion diagnostic plan in conjunction with clinical development and regulatory approval for our product candidate. Lack of a reliable commercially available companion diagnostic can introduce uncertainties in the regulatory process for our product candidate. Developing a companion diagnostic or working with a third party to develop such companion diagnostic for our product candidate will require more resources and could expose us to additional liabilities related to government regulation of companion diagnostics. If the FDA expects to review and approve simultaneously marketing submissions for a therapeutic candidate and its companion diagnostic, any delay in obtaining the appropriate marketing authorization for a companion diagnostic or laboratory-developed test could delay the drug approval.

We may rely on third parties for the design, development and manufacture of companion diagnostic tests for our product candidates that require such tests. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. If we or such third parties are unable to successfully develop companion diagnostics, or experience delays in doing so, we may be unable to enroll enough patients for our current and planned clinical trials, the development of our product candidates may be adversely affected or we may not obtain marketing approval, and we may not realize the full commercial potential of our product candidates.

Disruptions at the FDA and other government agencies could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified product candidates from being developed, or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and clear or approve new product candidates can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities. If funding shortages, staffing limitations or other factors hinder or prevent the FDA from conducting their regular inspections, reviews or other regulatory activities, there could be a significant impact on the ability of the FDA to timely review and process our regulatory submissions, which could have a material impact on our business.

Successful development of our current and future product candidates is uncertain and we may discontinue or reprioritize the development of any of our product candidates at any time, at our discretion.

Before obtaining regulatory approval for the commercial distribution of our product candidates, we must conduct, at our own expense, extensive preclinical tests and clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Additionally, the results from nonclinical testing or early clinical trials of a product candidate may not predict the results that will be obtained in subsequent human clinical trials of that product candidate. There is a high failure rate for drugs proceeding through clinical studies. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and any such setbacks in any future clinical development could have a material adverse effect on our business and operating results. Alternatively, management may elect to discontinue development of certain product candidates to accommodate a shift in corporate strategy, despite positive clinical results. Based on our operating results and business strategy, among other factors, we may discontinue the development of any of our other product candidates under development or reprioritize our focus on other product candidates at any time and at our discretion.

Because we have limited financial and managerial resources, we focus on research programs, therapeutic platforms and product candidates that we identify for specific indications. As a result, we may forgo or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

Our product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved by regulatory authorities, after the approved product has been marketed. As our product candidates are evaluated in clinical trials, the results of such clinical trials may show that our product candidates cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities with restrictive label warnings, limited patient populations or potential product liability claims. Even if we believe that our clinical trials and preclinical studies demonstrate the safety and efficacy of our product candidates, only the FDA and other comparable regulatory agencies may ultimately make such determination.

If we or others later identify undesirable or unacceptable side effects caused by zanidatamab or other product candidates that receive marketing approval:

- regulatory authorities may require the approved product to be taken off the market;

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies, or impose a risk evaluation and mitigation strategy that includes restrictions and conditions on product distribution, prescribing and/or dispensing;
- we or our partners may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we or our partners may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or our current or future strategic partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating revenue from the sale of any future products.

We face significant competition, and if our competitors develop and market products that are more effective, safer and/or less expensive than our product candidates, our commercial opportunities will be negatively impacted.

The life sciences industry is highly competitive and subject to rapid and significant technological change. We are developing biotherapeutics that will compete with other drugs and therapies that currently exist or are being developed. Products we may develop in the future are also likely to face competition from other drugs and therapies, some of which we may not currently be aware. We have competitors in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of these factors, our competitors may succeed in obtaining patent protection or FDA approval or discovering, developing and commercializing products in our field before we do. Specifically, there are a large number of companies developing or marketing treatments for cancer and AIID, including many major pharmaceutical and biotechnology companies. These treatments consist both of small-molecule drug products, as well as biologics that work by using various antibody therapeutic platforms to address specific targets.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, more convenient or less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market.

Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

We expect to compete with biosimilar versions of already approved products, and even if additional product candidates achieve marketing approval, they may be challenged to achieve a price premium over competitive biosimilar products and will compete for market share with them.

The Biologics Price Competition and Innovation Act of 2009, which is included in the 2010 Patient Protection and Affordable Care Act (“PPACA”), authorized the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. Under the PPACA, a manufacturer may submit an application for licensure of a biologic product that is “biosimilar to” or “interchangeable with” a previously approved biologic product or “reference product.” Manufacturers may not submit an

application for a biosimilar to the FDA until four years following approval of the reference product, and the FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if our product candidates, if approved, are deemed to be reference products eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. Additionally, from time to time, there are proposals to repeal or modify the PPACA, including proposals that could significantly shorten the exclusivity period for biologics.

If zanidatamab or any of our product candidates that receives regulatory approval in the future does not achieve broad market acceptance among physicians, patients, the medical community and third-party payors, revenue generated from royalties or sales would be limited.

The commercial success of zanidatamab or our product candidates will depend upon their acceptance among physicians, patients and the medical community. The degree of market acceptance of zanidatamab or our product candidates will depend on a number of factors, including:

- limitations or warnings contained in the approved labeling;
- changes in the standard of care for the targeted indications;
- limitations in the approved clinical indications;
- demonstrated clinical safety and efficacy compared to other products;
- sales, marketing and distribution support;
- availability of coverage and the extent of access and reimbursement from managed care plans and other third-party payors;
- timing of market introduction and perceived effectiveness of competitive products;
- availability of alternative therapies at similar or lower cost;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular diseases;
- whether the product can be used effectively with other therapies to achieve higher response rates;
- adverse publicity about the product or favorable publicity about competitive products;
- convenience and ease of administration of the product; and
- potential product liability claims.

If zanidatamab or any of our product candidates that are approved in the future do not achieve an adequate level of acceptance by physicians, patients and the medical community, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of zanidatamab or our product candidates may require significant resources and may never be successful.

We or our strategic partners may be unable to obtain orphan drug exclusivity in specific indications for zanidatamab or in future product candidates that we may develop. If our competitors are able to obtain orphan product exclusivity for their products in specific indications, we may not be able to have competing products approved in those indications by the applicable regulatory authority for a significant period of time.

The FDA granted Orphan Drug Designation to zanidatamab for the treatment of BTC and gastric cancer, including cancer of the gastroesophageal junction, the EMA granted Orphan Drug Designation to zanidatamab for the treatment of gastric cancer and BTC, and we or our strategic partners may seek Orphan Drug Designation for zanidatamab or other product candidates for additional indications in the future. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. Generally, if a product candidate with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the "same drug", as defined under the FDA orphan drug regulation, for the same indication for that time

period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for Orphan Drug Designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition. The loss of Orphan Drug Designation could have a negative effect on our ability to successfully commercialize our product candidates, earn revenues and achieve profitability.

Aside from the orphan drug exclusivity for zanidatamab, even if we obtain orphan drug exclusivity for other product candidates that receive an Orphan Drug Designation in the future, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Further, in the United States, even after an orphan drug is approved, the FDA can subsequently approve the "same drug" for the same condition submitted by a competitor if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. If we or our strategic partners are unable to manufacture sufficient supply of a product to meet the needs of patients, the FDA can withdraw orphan exclusive marketing rights or approve another marketing application for the "same drug" product before the expiration of the exclusivity period.

Further, in Catalyst Pharms., Inc. v. Becerra, 14 F.4th 1299 (11th Cir. 2021), the court disagreed with the FDA's longstanding position that the orphan drug exclusivity only applies to the approved use or indication within an eligible disease, and not to all uses or indications within the entire disease or condition. In January 2023, the FDA published a notice in the Federal Register to clarify that while the FDA complies with the court's order in Catalyst, the FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the Catalyst order – that is, the agency will continue tying the scope of orphan drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. The U.S Supreme Court's June 2024 Chevron decision may invite lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, including the FDA's statutory interpretations of market exclusivities, which could undermine the FDA's authority, lead to uncertainty in the industry, and disrupt the FDA's normal operations. Further, the current U.S. Presidential administration, along with new leadership at the FDA, may issue new policies and regulations. Executive actions under the current U.S. Presidential administration, such as layoffs, a hiring freeze and budget cuts, may also disrupt the normal operations of federal agencies. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity.

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such product candidates outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs and may require additional preclinical studies or clinical trials, which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. Our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. Zanidatamab is the only product developed using our therapeutic platforms to have received FDA approval, and as of the date of this report, no approvals in international markets have been obtained. Such approval was received by our strategic partner Jazz, and we do not have experience in obtaining regulatory approval in the United States or international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

Our ability to eventually generate significant revenues from product sales will depend on a number of factors, including:

- successful completion of preclinical studies;
- submission of IND and non-U.S. applications, or other regulatory applications, for our planned clinical trials or future clinical trials and authorizations from regulators to initiate clinical studies;
- successful enrollment in, and completion of, clinical trials;

- achieving favorable results from clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing and maintaining sufficient manufacturing capabilities, for clinical and commercial supply;
- obtaining pricing, reimbursement, and hospital formulary access;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in combination with other products;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials and commercialization activities;
- effectively competing with other therapies;
- developing and implementing successful marketing and reimbursement strategies;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates; and
- maintaining a continued acceptable safety profile of any product following approval, if any.

If we do not achieve one or more of these requirements in a timely manner, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. To become and remain profitable, we must develop, obtain approval for and eventually commercialize products, if approved, that generate significant revenue. Even if we obtain approval and begin commercializing one or more of our product candidates, we may never generate revenue that is significant or large enough to achieve profitability.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development, manufacturing and other expenditures to develop and market additional product candidates. Our failure to become or remain profitable would decrease the value of the Company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our products, it is less likely that our products will be widely used.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. Many countries require approval of the sale price of a drug before it can be marketed. The pricing review period begins after marketing or product licensing approval is granted in most cases. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenues we are able to generate from the sale of the product in that country. In many countries, particularly those in the EU, prescription drug pricing and reimbursement is subject to governmental control. In those countries that impose price controls, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our strategic partners may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. If we are not currently capturing the scientific and clinical data that will be required for reimbursement approval, we may be required to conduct additional trials, which may delay or suspend reimbursement approval. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of a product candidate that receives regulatory approval to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Even if our product candidates are approved for sale by the appropriate regulatory authorities, market acceptance and sales of these products will depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will reimburse and establish payment levels. We cannot be certain that reimbursement will be available for any products that we develop. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any approved products.

We expect to experience pricing pressures in connection with the sale of any products that we develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single-source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Only high-expenditure single-source drugs that have been approved for at least seven years (11 years for single-source biologics) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. Various industry stakeholders have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. The impact of these judicial challenges, future challenges in view of the U.S. Supreme Court's overruling of the Chevron doctrine, changes in the leadership of the federal agencies, legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA, EMA or other regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our and any collaborator's costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that currently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our or any collaborator's inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we or our strategic partners develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates and our overall financial condition.

We may not be successful in our efforts to use our therapeutic platforms to build a pipeline of product candidates.

We intend to use our therapeutic platforms to build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of a variety of diseases. Although our research and development efforts have resulted in a pipeline of product candidates directed at various cancers and AIID, we may not be able to develop product candidates that are safe and effective. Although we expect that our therapeutic platforms will allow us to develop further product candidates, they may not prove to be successful at doing so. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop and begin to commercialize product candidates, we will face difficulty in obtaining product revenue in future periods, which could result in significant harm to our financial position and adversely affect our stock price.

Even if we receive regulatory approval to commercialize any of the product candidates that we develop, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense.

Any regulatory approvals we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or subject to certain conditions of approval, and may contain requirements for potentially costly post-approval trials, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the marketed product. For example, in November 2024 the FDA granted accelerated approval for Ziihera® for the treatment of adults with

previously treated, unresectable or metastatic HER2+ (IHC 3+) BTC. However, continued approval for this indication is contingent upon verification and description of clinical benefit in a confirmatory trial.

For any approved product, we will be subject to ongoing regulatory obligations and extensive oversight by regulatory authorities, including with respect to manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product. These requirements include submissions of safety and other post-approval information and reports, as well as continued compliance with cGMP and good clinical practice ("GCP"), for any clinical trials that we or our strategic partners conduct after approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product;
- withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA, EMA or another applicable regulatory authority to approve pending applications or supplements to approved applications filed by us or our strategic partners, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

Occurrence of any of the foregoing could have a material and adverse effect on our business and results of operations. Our business also may be impacted by new policies and leadership at the FDA and other federal agencies under the current U.S. Presidential administration. Such changes may delay our interactions and submissions with the FDA, our clinical development timeline, or result in increased compliance costs. Further, the FDA's or other ex-U.S. regulators' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We also cannot predict the full impact of the U.S. Supreme Court's decision overruling the Chevron doctrine, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

The FDA strictly regulates manufacturers' promotional claims of drug products. In particular, a drug product may not be promoted by manufacturers for uses that are not approved by the FDA, as reflected in FDA-approved labeling, although healthcare professionals are permitted to use drug products for off-label uses. The FDA, among other government agencies, actively enforces the laws and regulations prohibiting manufacturers' promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including large civil and criminal fines, penalties, and enforcement actions. The FDA has also imposed consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed for companies that engaged in such prohibited activities. If we cannot successfully manage the promotion of any approved product candidates, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

If any product liability lawsuits are successfully brought against us or any of our strategic partners, we may incur substantial liabilities and commercialization efforts of zanidatamab or our product candidates may need to be limited.

We face an inherent risk of product liability lawsuits related to the testing of our product candidates in seriously ill patients, and face an even greater risk as a result of commercialization of any approved product candidates. Product liability claims may be brought against us or our strategic partners by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling any of our current or future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities. Regardless of their merit or eventual outcome, liability claims may result in:

- decreased demand for any current or future approved products;
- injury to our reputation;
- limitations placed on our promotional activities;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;

- increased regulatory scrutiny;
- significant litigation costs;
- substantial monetary awards to, or costly settlement with, patients or other claimants;
- product recalls or a change in the indications for which they may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize approved products.

We may need to have in place increased product liability coverage when we begin the commercialization of any product candidates. Insurance coverage is becoming increasingly expensive and we may be unable to maintain or obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. A successful product liability claim or series of claims brought against us, particularly if judgments exceed any insurance coverage we may have, could decrease our cash resources and adversely affect our business, financial condition and results of operation.

Patients with cancer and other diseases targeted by zanidatamab and our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to zanidatamab or our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end the opportunity to receive or maintain regulatory approval to market zanidatamab or our product candidates, or require us or our strategic partners to suspend or abandon commercialization efforts. Even in circumstances in which we do not believe that an adverse event is related to zanidatamab or our product candidates, the investigation into the circumstance may be time-consuming or inconclusive, and may result in reputational harm. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals zanidatamab or our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

If we, our strategic partners or any of our third-party manufacturers encounter manufacturing difficulties, our ability to provide supply of our product candidates for clinical trials or any approved products for patients could be delayed or prevented.

The manufacture of biological drug products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques, process and quality controls. Manufacturers of biologic products often encounter difficulties in production and sourcing, particularly in scaling up or out, validating the production process and assuring high reliability of the manufacturing processes (including the absence of contamination), in light of variations and supply constraints of key components. These problems include logistics and shipping, difficulties with production costs and yields, quality control, including consistency, stability, purity and efficacy of the product, product testing, operator error and availability of qualified personnel, as well as compliance with applicable federal, state and foreign regulations. Prolonged uncertainty in trade relationships could result in supply chain disruptions, packaging issues, delayed shipments, or increased operational complexity, which could also adversely affect our business, results of operations and cash flows. While we are evaluating steps to mitigate any impacts of tariffs or other impacts resulting from changes in trade policy, our ability to do so may be limited by operational and supply chain constraints, especially in the short term. Additionally, if contaminants are discovered in the supply of our products or product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability, purity, and efficacy failures, deficiencies, or other issues relating to the manufacture of our products or product candidates will not occur in the future. Even if any of our product candidates is approved, these manufacturing difficulties and supply chain risks will persist and an inability to source sufficient commercial supply would materially and negatively impact our commercialization efforts and financial results. Our research and development activities also involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. While we currently outsource all manufacturing to third parties, we and our manufacturers are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures relating to these laws comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury, and any related liability, resulting from medical or hazardous materials. In addition, manufacturing methods and formulation changes for product candidates advancing towards commercialization carry the risk that such product candidates may perform differently and

affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. While such changes are common and intended to help optimize processes and results during the development process, any of these changes could increase costs, cause delays and impact our ability, or our strategic partners' ability, to commence product sales and generate revenue.

Strategic transactions could disrupt our business, cause dilution to our stockholders and otherwise harm our business.

We actively evaluate various strategic transactions on an ongoing basis. For example, we may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, investments in complementary businesses, out-licensing and in-licensing agreements, divestitures or other transactions. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with existing strategic partners or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees;
- diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals;
- increases in our expenses and reductions in our cash available for operations and other uses; and
- possible write-offs or impairment charges relating to acquired businesses.

Also, the anticipated benefit of any strategic transaction may not materialize or such strategic transaction may be prohibited. Any future acquisitions or dispositions could result in dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of any future strategic alliances, joint ventures, investments, acquisitions, divestitures or other strategic transactions, or the effect that any such transactions might have on our operating results.

Security breaches and incidents, loss of data and other disruptions could compromise sensitive information related to our business or protected health information or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we and our CROs and other service providers collect, store and otherwise process petabytes of sensitive data, including legally protected health information, personal information, intellectual property and proprietary business information owned or controlled by ourselves or our strategic partners. We manage and maintain our applications and data by using a combination of on-site systems, managed data center systems and cloud-based data center systems. These applications and data encompass a wide variety of business-critical information, including research and development information, commercial information and business and financial information. We face four primary risks relative to protecting this critical information: loss of access risk, inappropriate disclosure risk, inappropriate modification risk and the risk of being unable to adequately monitor our controls over the first three risks.

Although we take measures designed to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure and those that our CROs and our other third-party service providers may use in the past have been subject to, and may be vulnerable to, attacks by hackers or other third parties, viruses, ransomware or other malicious code, vulnerabilities or other means of causing breaches, incidents, outages, interruptions or compromises due to causes such as inadvertent or intentional actions by our employees, contractors, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including supply chain cyber-attacks or the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of systems or information). The risks of these types of incidents and other matters occurring may be heightened in connection with geopolitical events. Any such incident or other matter could compromise systems and networks used in our business and lead to system and other operational outages, interruptions and disruptions and the loss, destruction, alteration, disclosure or dissemination of, or prevention of access, damage or unauthorized access to, our data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information) or data that is

maintained or otherwise processed on our behalf, or other assets, which could result in financial, legal, business and reputational harm to us. Any such event could result in legal claims, demands and litigation or governmental investigations or other proceedings, liability under laws and regulations, including those that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), and regulatory penalties and other liabilities.

Although we have implemented security measures and a formal enterprise security program designed to prevent unauthorized access to sensitive data, and make use of third-party service providers to perform certain operational and security functions on our behalf, there is no guarantee that we or our third-party service providers can, or have been able to, protect our systems or networks or other systems or networks used in our business from security breaches, incidents, outages, interruptions, compromises, or vulnerabilities, or that we or they have been or will be able to identify, identify the cause of or otherwise respond to any actual or potential security breach, incident, outage, interruption, compromise or vulnerability. We have engaged in efforts to improve our security measures, and we expect to continue to incur additional expenses in further efforts to do so, whether in response to actual or perceived security breaches or incidents, compromises, outages, interruptions, vulnerabilities or otherwise. Any loss, destruction, alteration, disclosure or dissemination of, or prevention of access, damage or unauthorized access to, our data or other data that is processed or maintained on our behalf could also disrupt our operations (including our ability to conduct our analyses, pay providers, conduct research and development activities, collect, process and prepare company financial information, provide information about any future products and manage the administrative aspects of our business) and damage our reputation, any of which could adversely affect our business.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing regulations, impose certain requirements relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Penalties for HIPAA violations can be significant, and criminal and monetary penalties, as well as injunctive relief, may be imposed for HIPAA violations. Most drug manufacturers are not directly subject to HIPAA, but prosecutors increasingly are using HIPAA-related theories of liability against drug manufacturers and their agents and we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Furthermore, HIPAA regulations impose specific reporting requirements to regulators, individuals impacted by the breach, as defined by HIPAA, and, in some cases, the media. Issuing such notifications can be costly, time and resource intensive, and can generate significant negative publicity. In addition to HIPAA, other applicable data privacy and security obligations may require us to notify relevant stakeholders of any security breaches or incidents that result in the unauthorized disclosure or dissemination of personal information. Such disclosures are costly, and the disclosures or the failure to comply with such requirements, could lead to adverse impacts.

Furthermore, the loss, corruption or unavailability of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems or otherwise relating to their collection, storage or processing of data could also have a material adverse effect on our business.

We are subject to stringent and changing obligations related to privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm and other adverse business consequences.

U.S. states have enacted and are considering enacting laws relating to the protection of personal information (including health and other data of patients, research subjects, and other individuals), which may be more rigorous than, or impose additional requirements beyond those required by, HIPAA. For example, the California Consumer Privacy Act ("CCPA"), which became effective in January 2020, gives California consumers expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation) as well as a limited private right of action in connection with certain data breaches. The California Privacy Rights Act of 2020, which went into effect in January 2023, expanded the CCPA in numerous ways and established a new California Privacy Protection Agency to implement and enforce the law. Many other privacy and security laws have been proposed at the federal level and in other states, certain of which impose obligations similar to the CCPA. Other privacy and security laws address specific subject matter, such as Washington's My Health, My Data Act, which, among other things, provides for a private right of action. While exemptions to some of these laws may apply to portions of our business, these laws' enactment and evolving interpretations may increase our compliance costs and potential liability. These or other proposed or enacted laws relating to privacy and security could similarly increase our compliance obligations and costs in the future.

We may also become subject to laws and regulations in non-U.S. countries covering privacy and security and the protection of health-related and other personal information. In particular, the European Economic Area ("EEA"), the UK and Switzerland have adopted laws and regulations addressing privacy, data protection and security that impose significant compliance obligations. These laws and regulations are subject to frequent revisions and differing interpretations and have generally become more stringent over time.

The General Data Protection Regulation 2016/679 ("GDPR") applies to the processing of personal information and imposes numerous requirements, including, for example, high standards for obtaining consent, requirements for more robust disclosures to individuals and strengthened individual data rights, required data breach notifications, limitations on retention and secondary use of information, increased requirements pertaining to health data and pseudonymized (i.e., key-coded) data and additional obligations when contracting third-party data processors. The GDPR allows EEA countries to make additional laws and regulations further limiting the processing of genetic, biometric or health data. The GDPR provides for fines of up to the greater of €20.0 million or up to 4% of the total worldwide annual turnover of the preceding financial year and other administrative penalties; further, the GDPR permits other forms of relief and recovery, and other national and local data protection laws provide for additional penalties and relief. Adverse publicity relating to actual or alleged GDPR noncompliance also could cause a loss of goodwill, which could have an adverse effect on our reputation, brand, business and financial condition. The UK has implemented legislation similar to the GDPR, referred to as the UK GDPR, which provides for fines of up to the greater of £17.5 million or 4% of global turnover.

Certain jurisdictions, including the EEA, have enacted laws and regulations governing cross-border personal information transfer and providing for data localization in certain cases. For example, absent appropriate safeguards or other circumstances, the GDPR and laws in Switzerland and the UK generally restrict the transfer of personal information to countries outside the EEA, Switzerland and the UK, such as the United States. In July 2023, the European Commission adopted its adequacy decision for the EU-U.S. Data Privacy Framework, and generally permits personal information to flow from the EU to the United States by companies participating in the EU-U.S. Data Privacy Framework. We are not certified under the EU-U.S. Data Privacy Framework, and instead rely on other data transfer tools such as the EU standard contractual clauses ("EU SCCs") and the UK addendum to the EU SCCs to transfer personal information to third countries outside the EEA and the UK, taking into consideration related obligations. To the extent we transfer personal information from other jurisdictions to the United States, we may not be able to implement or maintain an appropriate data transfer mechanism to continue such transfers. The U.S. Department of Justice also has issued rules regarding certain bulk sensitive personal data transfers. The interpretation of data transfer requirements, regulatory guidance and opinions, and other developments relating to cross-border data transfer may require us to implement additional contractual and technical safeguards for any personal information transferred out of the EEA, Switzerland, the UK, the United States, or other regions, which may increase compliance costs, lead to increased regulatory scrutiny or liability, and may require additional contractual negotiations, which may adversely impact our business, financial condition, and operating results.

We expect an increase in regulatory requirements relating to privacy, data protection and cybersecurity that may apply to our business. For instance, the EU has enacted numerous laws and regulations addressing cybersecurity, including substantial revisions to its Network and Information Security directive that EU member states are required to reflect in national law. Requirements for hosting health data will vary by jurisdiction within EEA countries and the UK, and we may be or become subject to other national healthcare regulations or regulatory requirements. For example, France requires hosts of health data to obtain a prior certification with the competent certification body.

The interpretation and application of consumer, health-related and privacy, data protection and security laws in the United States, the EEA, Switzerland, the UK and elsewhere are often uncertain, contradictory and in flux. Any failure or perceived failure to comply with federal, state or foreign laws or regulations, contractual or other legal obligations related to privacy or security may result in claims, warnings, communications, requests or investigations from individuals, supervisory authorities or other legal or regulatory authorities in relation to our processing of personal information, and regulatory investigations or other proceedings. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. These privacy regulations vary between states, may differ from country to country, and may vary based on whether testing is performed in the United States or in the local country. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

Current and future legislation may increase the difficulty and cost for us or our strategic partners to commercialize any approved products that we or our strategic partners develop and affect the prices that may be obtained.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change healthcare systems in ways that could affect our or our strategic partners' ability to sell any of our product candidates profitably, if such product candidates are approved for sale. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In March 2010, the PPACA became law in the United States. The PPACA may affect the operational results of companies in the pharmaceutical industry, including us, by imposing on them additional costs. For example, effective January 2010, PPACA increased the minimum Medicaid drug rebates for pharmaceutical companies and imposed an annual fee on certain branded prescription drugs and biologics. Since the enactment of PPACA, there have been executive, judicial and Congressional challenges to certain aspects of the PPACA, including judicial challenges in the Fifth Circuit Court and the U.S. Supreme Court. In June 2021, the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the PPACA, dismissing the case without specifically ruling on the constitutionality of the PPACA. Accordingly, the PPACA remains in effect in its current form. It is unclear how future litigation or healthcare measures promulgated by the current U.S. Presidential administration will impact our business, financial condition and results of operations. Complying with any new legislation or changes in healthcare regulation could be time-intensive and expensive, resulting in a material adverse effect on our business.

Other legislative changes have been proposed and adopted since the PPACA was enacted. For example, the Bipartisan Budget Act of 2018, among other things, amended the PPACA, effective January 2019, to close the coverage gap in most Medicare drug plans. The Budget Control Act of 2011, which calls for aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, began in 2013 and, due to subsequent legislative amendments, will remain in effect through 2032 unless Congress takes further action. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on potential customers for zanidatamab or our product candidates, if approved, and, accordingly, our future financial operations. We are unable to predict the future course of federal or state health care legislation or foreign regulations relating to the marketing, pricing and reimbursement of pharmaceutical products.

There have been U.S. Congressional inquiries, presidential executive orders, and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, under the American Rescue Plan Act of 2021, effective January 1, 2024, Medicaid statutory rebates are no longer be capped at 100% of AMP (average manufacturer price). Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. As discussed above, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single-source Medicare drugs. The implementation of cost containment measures, including the prescription drug provisions under the Inflation Reduction Act, as well as other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

Further, many states have proposed or enacted legislation and administrative actions that seek to indirectly or directly regulate pharmaceutical drug pricing, such as by requiring biopharmaceutical manufacturers to publicly report proprietary pricing information or to place a maximum price ceiling on pharmaceutical products purchased by state agencies. For example, the FDA has authorized Florida to develop a drug importation program to import certain prescription drugs from Canada for a limited period to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. Additionally, a number of states are considering or have enacted state drug price transparency and reporting laws that could substantially increase compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products candidates. We cannot be sure of the extent of these and future legislative and regulatory efforts, whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. Increased

scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval and subject us to more stringent product labeling and post-marketing testing and other requirements. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate, if approved, is prescribed or used.

In the EU similar political, economic and regulatory developments may affect our ability to profitably commercialize any future products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Our future products, if any, might not be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, an adequate level of reimbursement might not be available for such products, and third-party payors' reimbursement policies might adversely affect our or our strategic partners' ability to sell any future products profitably.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or elsewhere. If we or our strategic partners are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our strategic partners are not able to maintain regulatory compliance, any approved products may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Our business may become subject to economic, political, regulatory and other risks associated with international operations.

Our business, financial condition, and stock price may be adversely affected by economic downturns, a volatile business environment, or large-scale unpredictable or unstable or unfavorable market conditions, including a prolonged government shutdown, geopolitical events, or a global pandemic. If events like these occur, our business may be materially and adversely impacted, including making any necessary debt or equity financing more difficult, more costly and more dilutive.

Our business is subject to risks associated with conducting business internationally. We have physical operations and personnel in North America, Europe and Asia, and some of our suppliers and collaborative and clinical trial relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic instability or weakness, including inflation, reduced growth, diminished credit availability, weakened consumer confidence or increased unemployment;
- instability in the international geopolitical environment, including as a result of the Russian invasion of Ukraine and the conflicts in Israel and the broader Middle East;
- sociopolitical instability in particular foreign economies and markets;
- differing regulatory requirements for drug approvals in foreign countries;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in U.S. or non-U.S. regulations and customs, tariffs and trade barriers, including any changes that nations may impose as a result of political tensions, including tensions between Canada and China or the United States and China;
- changes in non-U.S. currency exchange rates and currency controls;
- fluctuations in the U.S. dollar, particularly a weakening of the U.S. dollar against foreign currencies;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- restrictions on cross-border data exchanges;
- differing reimbursement regimes, including price controls;
- negative consequences from changes in tax laws;
- workforce uncertainty in countries where labor unrest is more common than in the United States;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities outside the United States;
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires; and
- supply and other disruptions resulting from the impact of public health epidemics on our strategic partners, third-party manufacturers, suppliers and other third parties upon which we rely.

In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, treatment of intellectual property, taxes, and other limitations on cross-border operations, including but not limited to the provision of services and the exchange of data. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, there have been legislative proposals that would limit the extension of certain specific types of government contracts or renewals, loans, or grants to companies that may do business with select Chinese biotechnology equipment or service providers. If enacted, such legislation will preclude certain U.S. biotechnology companies from using equipment or services produced or provided by those Chinese biotechnology companies when performing on specified types of agreements with the U.S. government. Others in Congress have advocated for the use of existing executive branch authorities to limit certain Chinese service providers' ability to engage in business in the United States. We cannot predict whether any proposed legislation will be enacted, what executive actions may implicate these kinds of service relationships, or what other actions may ultimately be taken with respect to trade relations between the United States and China or other countries, including countries which the U.S. government has identified as a foreign adversary that poses national security risks to the United States.

Relatedly, the United States has recently enacted significant new tariffs on a number of countries, including China. The current U.S. Presidential administration has directed various federal agencies to further evaluate key aspects of U.S. trade policy and there has been ongoing discussion and commentary regarding potential significant changes to U.S. trade policies, treaties and tariffs. There continues to exist significant uncertainty about the future relationship between the United States and other countries with respect to such trade policies, treaties and tariffs. These developments, or the perception that any of them could occur, have caused and may continue to cause significant volatility in global financial markets and may have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global trade and, in particular, trade between the impacted nations and the United States. Additionally, these developments and their direct and indirect impacts could also weaken the U.S. dollar against foreign currencies, which may adversely affect our business, including as a result of increased costs for goods and services denominated in currencies other than the U.S. dollar. These effects may also negatively impact our partners. Any of these factors could depress economic activity and restrict our access to third party services as well as disrupt the supply chain for the sourcing of our product candidates. For example, the early-stage clinical supplies for our internal pipeline are currently sourced from China, and while we are actively monitoring tariffs and evaluating other locations for future clinical product requirements, our mitigation efforts may not be successful and our business may be adversely affected. We also run a portion of our global clinical studies and utilize clinical trial sites in non-U.S. locations; we cannot predict how these non-U.S. locations may be impacted by tariffs or a broader trade war among different nations. If we or our partners are unable to obtain or use services from existing service providers, unable to source supplies of product candidates or approved drugs, or unable to export or sell approved products or export or sell approved products at competitive prices, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

In addition, the U.S. Presidential administration has indicated that it views foreign pharmaceutical manufacturing as a national security concern. As a result, the Department of Commerce has initiated an investigation into imports of pharmaceuticals and pharmaceutical products. If a threat is determined to exist, the U.S. Presidential administration could impose new and/or additional pharmaceutical-specific tariffs or take other actions. While we cannot predict the outcome of this investigation and whether or not it will result in the imposition of additional tariffs, if additional tariffs are imposed, it could materially increase our costs and also further complicate our supply chain for the manufacture and importation of our product candidates.

Our business has been in the past and may in the future be adversely affected by public health outbreaks and pandemics.

Our business has been in the past and may in the future be adversely affected by public health outbreaks and pandemics. If a public health outbreak or pandemic, including a resurgence of COVID-19 cases, leads to disruptions in our industry or to our service providers, particularly in regions where we or our strategic partners and suppliers do business, we could experience disruptions that could significantly impact our current and planned clinical trials, preclinical research and other business activities, including:

- disruption to and delays in preclinical research activities due to extended closure or reduced capacity of lab facilities;

- delays or difficulties in enrolling patients in our ongoing and planned clinical trials;
- patients discontinuing their treatment or follow-up visits;
- delays or difficulties in clinical site initiation, including limitations on access to sites, limitations to site initiation activities that can be carried out remotely, and limitations on the number of clinical site staff on site from time to time;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- shortages, disruptions in supply, logistics or other activities related to the procurement of materials and other supplies, which could have a negative impact on our ability to conduct preclinical research, initiate or complete our clinical trials or commercialize our product candidates;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of clinical trials;
- interruption of key business activities due to illness and/or quarantine of key individuals and delays associated with recruiting, hiring and training new temporary or permanent replacements for such key individuals, both internally and at our third-party service providers and strategic partners;
- limitations in resources that would otherwise be focused on the conduct of our business or our current or planned clinical trials or preclinical research, including because of sickness, the desire to avoid contact with large groups of people, restrictions on travel, or prolonged stay-at-home or similar working arrangements;
- delays in receiving approvals from regulatory authorities to initiate our planned clinical trials;
- changes in regulations as part of a response to public health outbreaks, pandemics, or a resurgence of COVID-19 cases and related disruptions, which may require us to change the ways in which our clinical trials are conducted and incur unexpected costs, or require us to discontinue clinical trials altogether;
- delays in necessary interactions with regulators (including the FDA), ethics committees and other important agencies and contractors due to limitations in employee resources or furlough of government or contractor personnel;
- disruptions to our strategic partners' operations, which could delay the development of our product candidates in certain geographical regions and thereby affect the timing of development and commercial milestone payments and royalties on potential future product sales we may receive; and
- limitations on our ability to recruit any necessary preclinical research, clinical, regulatory and other professional staff on the timeframe required to support our research and development programs.

The impact of such disruptions would be highly uncertain and would depend on factors such as the location, duration and severity, travel restrictions and social distancing, business closures or disruptions, and the effectiveness of actions taken to contain and treat the disease and to address its impact, including on financial markets. Public health outbreaks, pandemics, and related disruptions could disrupt the global financial markets, reducing our ability to access capital, which could negatively affect our liquidity and could heighten the volatility of the financial markets, which could adversely impact the value of our common stock.

Our business and current and future relationships with customers and third-party payors in the United States and elsewhere will be subject, directly or indirectly, to applicable federal and state anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of zanidatamab and any product candidates for which we obtain marketing approval.

Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers, and third-party payors and other entities may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including the federal Anti-Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we conduct clinical research on product candidates and market, sell and distribute any approved products. In addition, we may be subject to transparency laws and patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, impose criminal or civil penalties, as applicable, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government (including the Medicare and Medicaid programs) or other third-party payor claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA established the federal offense of health care fraud, which among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g. public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by HITECH, and its implementing regulations, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law, such as health plans, healthcare clearinghouses and healthcare providers and their respective business associates and their covered subcontractors;
- the federal Open Payments program under the Physician Payments Sunshine Act, created under Section 6002 of the PPACA and its implementing regulations, requires applicable group purchasing organizations and manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to HHS information related to "payments or other transfers of value" made in the previous year to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as nurse practitioners and physician assistants) and teaching hospitals, and information regarding ownership and investment interests held by physicians or their immediate family members; and
- analogous and similar state and foreign laws and regulations, including: state anti-kickback and false claims laws that may apply to our business practices (including research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by state governmental and non-governmental third-party payors, including private insurers); state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government; state laws that require drug manufacturers to track gifts and other remuneration and items of value provided to healthcare professionals and entities and file reports relating to pricing and marketing information; and state and foreign laws that govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of any available statutory exceptions and safe harbors, it is possible that some of our current and future business activities could be subject to challenge under one or more of such laws.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. Any failure or perceived failure by us to comply with such laws, regulations, or case law may result in governmental investigations or enforcement actions, litigation, claims and other proceedings, harm our reputation, and could result in significant liability. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other providers or entities with whom we expect to do business, including our strategic

partners, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations that can harm our business.

In addition to potential risks discussed above at the risk factor entitled "*Our business may become subject to economic, political, regulatory and other risks associated with international operations*", we are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, the USA PATRIOT Act, the UK Bribery Act 2010, the Proceeds of Crime Act 2002, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We currently engage third parties for clinical trials outside of the United States and we may in the future engage third parties to sell our products outside of the United States once we enter a commercialization phase, or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violation of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Third-party manufacturers may not be able to comply with U.S. export control regulations, cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in a necessity to replace current third parties, resulting in the possibility of supply delays, clinical holds on our trials, sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or medicines, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business, financial condition, results of operations and growth prospects.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We have only one product approved for commercial sale, and, as of March 31, 2025, we have not received any revenue or profit from product sales, other than the receipt of royalties relating to sales of zanidatamab. We may never achieve or sustain profitability.

We have incurred significant losses since our inception. Our net losses for the years ended December 31, 2024 and 2023 were $122.7 million and $118.7 million, respectively, while our net loss for the three months ended March 31, 2025 was $22.6 million. As of March 31, 2025, our accumulated deficit was $853.0 million. Our revenue as of March 31, 2025 has been primarily revenue from the license of our proprietary therapeutic platforms for the development of product candidates by others or revenue from our strategic partners. We do not anticipate being net income positive on a regular basis for the foreseeable future. We expect to continue to incur losses for the foreseeable future as we continue our research and development of, and seek regulatory approvals for, our product candidates, prepare for and begin to commercialize any approved product candidates and add infrastructure, which may include personnel, to support our product development efforts. In addition, inflationary pressure could adversely impact our financial results. The net losses and negative cash flows incurred as of March 31, 2025, together with expected future losses, have had, and likely will continue to have, an adverse effect on our stockholders' deficit and working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue, including through the receipt of royalties from our strategic partners. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability.

We have devoted substantially all of our financial resources and efforts to developing our proprietary therapeutic platforms, identifying potential product candidates and conducting preclinical studies and clinical trials. Zanidatamab is the only product candidate developed with our therapeutic platforms that has received regulatory approval, and we and our strategic partners are

still developing other product candidates. To become and remain profitable, we or our strategic partners must succeed in developing and commercializing product candidates with significant market potential. This will require us to be successful in a range of challenging activities for which we are only in the preliminary stages, including developing product candidates, obtaining regulatory approval for such product candidates, and manufacturing, marketing and selling those product candidates for which we may obtain regulatory approval. We may never succeed in these activities and may never generate revenue from product sales or royalties that is significant enough to achieve profitability. While we are receiving royalties from sales of zanidatamab, we do not anticipate generating revenue from sales of our wholly-owned product candidates in the near term. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates, or continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back, or cease our product development programs or operations.

We currently have two clinical-stage product candidates, ZW171 and ZW191. We have licensed zanidatamab to our strategic partner Jazz, which has been responsible for completing its clinical development in the United States and other jurisdictions not covered by our license to BeiGene. In November 2024, Jazz announced the FDA granted accelerated approval for Ziihera® for injection for intravenous use for the treatment of adults with previously treated, unresectable or metastatic HER2+ (IHC 3+) BTC. Jazz is conducting the confirmatory trial for Ziihera® related to the accelerated approval. If the confirmatory trial fails to demonstrate a clinical benefit, the FDA may remove Ziihera® from the market, which would negatively impact our ability to earn milestone payments and royalties under our arrangement with Jazz. We are focused on the development of our early-stage product candidates and general discovery efforts. Following the clearance of our IND applications for both ZW171 and ZW191, we have received approvals to proceed in selected non-U.S. countries in relation to our Phase 1 study sites in Europe and the Asia-Pacific region.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. In order to obtain regulatory approval, we will be required to conduct clinical trials for each indication for each of our product candidates. Although our collaboration agreements with Jazz and BeiGene provide for additional future funding for zanidatamab, we will continue to require additional funding to advance and complete the development of our other product candidates, and such funding may not be available on acceptable terms or at all. If sufficient funds on acceptable terms are not available when needed, or at all, we could be forced to significantly reduce operating expenses and delay, scale back or eliminate one or more of our development programs or our business operations.

Our future funding requirements will depend on many factors, including:

- the number and characteristics of other product candidates that we pursue;
- the scope, progress, timing, cost and results of research, preclinical development, and clinical trials;
- the costs, timing and outcome of seeking and obtaining FDA and non-U.S. regulatory approvals;
- the costs associated with manufacturing our product candidates and establishing sales, marketing and distribution capabilities;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;
- our ability to hire when needed additional management, scientific and medical personnel;
- the effect of competing products that may limit market penetration of our product candidates;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing of and success of our existing strategic partnerships, and any collaboration, asset monetization, licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through a combination of public and private equity offerings, debt financings, asset monetization, strategic partnerships and grant funding.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish substantial rights.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect our stockholders' rights as common stockholders. For example, in August 2024, we entered into the Cowen Sales Agreement with TD Cowen as sales agent to sell shares of our common stock from time to time through an "at-the-market" equity offering program, subject to a maximum aggregate dollar amount registered pursuant to an applicable prospectus supplement. As part of the ongoing management of our operations and related funding needs, we evaluate various financing vehicles, including "at-the-market" equity offering programs, and may enter into similar "at-the-market" equity offering programs in the future, as well as other financing transactions. Debt financing, if available at all, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional funds through partnerships, collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates, or future revenue streams, or grant licenses on terms that are not favorable to us. We cannot assure that we will be able to obtain additional funding if and when necessary. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, scale back or eliminate one or more of our development programs or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our effective tax rate may change in the future.

We are subject to U.S. federal income taxes on our earnings and the earnings of our non-U.S. subsidiaries in a manner that may adversely impact our effective tax rate. For example, we have had to include additional amounts in income (such as interest income) under the so-called "global intangible low-taxed income" regime and may be required to do so in the future under the "global intangible low-taxed income" regime or as a result of the application of "controlled foreign corporation" rules. The United States has enacted the Inflation Reduction Act, which, among other changes, imposes a 1% excise tax on certain stock buybacks and an alternative minimum tax on adjusted financial statement income. In addition, our Canadian tax attributes (including net operating loss and tax credit carryforwards and deductible Scientific Research and Experimental Development Expenditure carryforwards) will generally not be available to offset U.S. income and may be subject to limitation. Further, our future operations and business structure may result in increased tax burden. For example, changes in our clinical development plans and business or commercialization strategies may result in an increased effective tax rate. Taxation of international business operations and intercompany transactions, including transactions between us and non-U.S. subsidiaries, is complicated and our expenses may increase as a result of any steps we take to enhance our compliance efforts. Any changes in the U.S. or non-U.S. taxation of such activities may increase our worldwide effective tax rate and harm our business, financial condition, and results of operations.

Risks Related to Our Dependence on Third Parties

We depend on our collaborative relationship with Jazz to further develop and commercialize zanidatamab, and if our relationship is not successful or is terminated, we may be delayed in or unable to effectively develop and/or commercialize zanidatamab, which could have a material adverse effect on our business.

In October 2022, Zymeworks BC entered into a License and Collaboration Agreement (the "Original Jazz Collaboration Agreement") with Jazz, under which Jazz obtained development and commercialization rights of zanidatamab throughout the world, but excluding certain territories already covered by Zymeworks BC's agreement with BeiGene. In April 2023, certain of our subsidiaries entered into a stock and asset purchase agreement with Jazz Inc. (as amended, the "Transfer Agreement"). Pursuant to the terms of the Transfer Agreement, we took a series of steps designed to simplify, focus, and potentially expedite the clinical development and commercialization of zanidatamab in partnership with Jazz by transferring certain assets, contracts and employees associated with our zanidatamab development program to Jazz and its affiliates (the "Program"). As part of the transactions contemplated by the Transfer Agreement, at the closing of the Transfer Agreement in May 2023, Zymeworks BC and Jazz amended and restated the Original Jazz Collaboration Agreement to reflect the transfer of responsibility for the Program (as amended, the "Amended Jazz Collaboration Agreement"). Under the Amended Jazz Collaboration Agreement, the financial terms of the Original Jazz Collaboration Agreement, as previously disclosed, were unchanged, except that the costs of the Program (including ongoing costs related to the service providers transferred to Jazz pursuant to the Transfer Agreement) incurred following the closing of the Transfer Agreement are directly borne by Jazz instead of being incurred by us and charged back to Jazz for reimbursement, though Zymeworks BC remains eligible for reimbursement of certain costs for activities where Zymeworks BC maintains responsibility under the Amended Jazz Collaboration Agreement. Other material terms in the Amended

Jazz Collaboration Agreement also remain substantially similar to the terms of the Original Jazz Collaboration Agreement, including commercialization, term and termination, and certain other customary terms and conditions, including mutual representations and warranties, indemnification, and confidentiality provisions. We cannot be certain that our amended arrangement with Jazz will simplify, focus, or potentially expedite the clinical development and commercialization of zanidatamab in partnership with Jazz. We continue to depend on Jazz to collaborate with us to develop and commercialize zanidatamab in the territories covered by the Amended Jazz Collaboration Agreement and, as a result, the eventual success or commercial viability of zanidatamab is largely beyond our control. Any future financial returns to us depend in large part on achievement of regulatory and commercialization milestones, plus a share of any revenue from sales. Therefore, our success, and any associated financial returns to us and our investors, will depend in significant part on Jazz's performance under the Amended Jazz Collaboration Agreement.

We are subject to a number of additional specific risks associated with our dependence on our collaborative relationship with Jazz, including:

- adverse decisions by Jazz regarding the development and commercialization of zanidatamab;
- Jazz's ability to manufacture, directly or through third parties, commercially required quantities of zanidatamab in a timely manner or at all;
- Jazz's compliance with ongoing post-marketing obligations, including completion of the confirmatory trial for zanidatamab;
- possible disagreements as to the timing, nature and extent of development plans, including clinical trials or regulatory approval strategy;
- loss of significant rights if we fail to meet our obligations under the agreement;
- changes in key management personnel at Jazz;
- possible disagreements with Jazz regarding the agreement, for example, with regard to ownership of intellectual property rights or program costs and reimbursement matters; and
- Jazz may not perform its obligations as expected.

In November 2024, Jazz announced the FDA granted accelerated approval for Ziihera® for injection for intravenous use for the treatment of adults with previously treated, unresectable or metastatic HER2+ (IHC 3+) BTC. Jazz is conducting the confirmatory trial for Ziihera® related to the accelerated approval. If the confirmatory trial fails to demonstrate a clinical benefit, the FDA may remove Ziihera® from the market, which would negatively impact our ability to earn milestone payments and royalties under our arrangement with Jazz. In addition, although Jazz is developing zanidatamab for regulatory approval in additional indications, such regulatory approval may never be achieved. If additional indications are not approved, our ability to achieve additional milestone payments and royalties on sales of zanidatamab will be materially and negatively impacted. Jazz is also subject to the risks relating to development and commercialization of product candidates or approved products discussed elsewhere in this "Risk Factors" section, which could restrict Jazz's ability to further develop and commercialize zanidatamab and negatively impact our ability to achieve milestone payments and royalties.

If either we or Jazz fail to perform our respective obligations, any clinical trial, regulatory approval or development progress could be significantly delayed or halted, could result in costly or time-consuming litigation or arbitration and could have a material adverse effect on our business. In addition, we depend on Jazz to provide certain information to us regarding the Program, and any delay by Jazz in fulfilling its information-sharing obligations under the Amended Collaboration Agreement could impact our understanding of the status of the Program, as well as result in potential delays or inaccuracies in our disclosures relating to the Program.

Decisions by Jazz to emphasize other drug candidates currently in its portfolio ahead of zanidatamab, or to add competitive agents to its portfolio could result in a decision to terminate the agreement, in which event, among other things, we may be responsible for paying any remaining costs of ongoing or future clinical trials. If Jazz decides to terminate the Amended Jazz Collaboration Agreement, we may be delayed in or unable to effectively develop and/or commercialize zanidatamab, which could have a material adverse effect on our business. Any of the above discussed scenarios could adversely affect the timing and extent of the development and commercialization activities related to zanidatamab, which could materially and adversely impact our business.

Our existing strategic partnerships are important to our business, and future strategic partnerships will likely also be important to us. If we are unable to maintain our strategic partnerships, or if these strategic partnerships are not successful, our business could be adversely affected.

We have limited capabilities for drug development and commercialization of our product candidates, if approved. Accordingly, we have entered into strategic partnerships with other companies that we believe can provide such capabilities, including our collaboration and license agreements with Jazz, BeiGene, BMS, GSK, Daiichi Sankyo, J&J and Merck. These relationships also have provided us with non-dilutive funding for our wholly-owned pipeline and therapeutic platforms and we expect to receive additional funding under these strategic partnerships in the future. Our existing strategic partnerships, and any future strategic partnerships we enter into, may pose a number of risks, including the following:

- strategic partners have significant discretion in determining the efforts and resources that they will apply to these partnerships;
- strategic partners may not perform their obligations as expected;
- strategic partners may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the partners' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- strategic partners may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- strategic partners could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the strategic partners believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than our product candidates;
- product candidates discovered in collaboration with us may be viewed by our strategic partners as competitive with their own product candidates or products, which may cause strategic partners to cease to devote resources to the commercialization of our product candidates;
- a strategic partner with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidates;
- disagreements with strategic partners, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- we may be dependent on strategic partners to provide certain information to us regarding the development of product candidates, and any delay by our strategic partners to full information-sharing obligations could impact our understanding of such development, as well as result in potential delays or inaccuracies in our disclosures;
- strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- strategic partners may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- strategic partnerships may be terminated for the convenience of the partner and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates (for example, each of our collaboration and license agreements with Jazz, BeiGene, BMS, GSK, Daiichi Sankyo, J&J and Merck may be terminated for convenience upon the completion of a specified notice period);
- we may elect to enter into additional licensing or collaboration agreements to partner our product candidates in territories we currently retain, and in the event we grant exclusive rights to such partners, we would be precluded from potential commercialization of our product candidates within the territories in which we have a partner; and
- strategic partners may not have the ability or the development capabilities to perform their obligations as expected, including as a result of the impact of a pandemic or epidemic on our strategic partners' operations or business.

In addition, our strategic partners are subject to the risks relating to development and commercialization of product candidates discussed elsewhere in this "Risk Factors" section, which could limit their ability to develop and commercialize product candidates and negatively impact our ability to achieve milestone, royalty or other contractual payments.

If our strategic partnerships do not result in the successful development and commercialization of product candidates or if one of our partners terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under our strategic partnership agreements, our development of our therapeutic platforms and product candidates could be delayed and we may need additional resources to develop product candidates and our therapeutic platforms.

We face significant competition in seeking new strategic partners.

For some of our product candidates, we may in the future determine to collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the strategic partner's resources and expertise, the terms and conditions of the proposed collaboration and the proposed strategic partner's evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The strategic partner may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Strategic partnerships are complex and time-consuming to negotiate and document. In addition, there have been and may continue to be a significant number of business combinations among large pharmaceutical companies that have resulted in and may in the future result in a reduced number of potential strategic partners. If we are unable to reach agreements with suitable strategic partners on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay one or more of our other development programs, delay potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into strategic partnerships and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our therapeutic platforms and our business may be materially and adversely affected.

We rely on third-party manufacturers to produce our product candidates and on other third parties to provide supplies and store, monitor and transport bulk drug substance and drug product. We and our third-party partners may encounter difficulties with respect to these activities that could delay or impair our ability to initiate or complete our clinical trials or commercialize products.

We do not currently own or operate any manufacturing facilities. We rely on our strategic partners to manufacture product candidates licensed to them or work with multiple third-party contract manufacturers to produce sufficient quantities of materials required for the manufacture of our product candidates for preclinical testing and clinical trials, in compliance with applicable regulatory and quality standards, and intend to do so for the commercial manufacture of our products. If we are unable to arrange for such third-party manufacturing sources, or fail to do so on commercially reasonable terms, we may not be able to successfully produce sufficient supply of product candidate or we may be delayed in doing so. Such failure or substantial delay could materially harm our business.

The manufacture of biopharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. The process of manufacturing our product candidates is susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the third-party manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. All of our engineered antibodies are

manufactured in accordance with cGMP by utilizing cells that are stored in a cell bank. We have one master cell bank and one working cell bank for zanidatamab and one master cell bank for each of ZW191 and ZW171. Should any cell bank be lost in a catastrophic event, it is possible that we could lose part of a cell bank and have our manufacturing potentially impacted by the need to replace the cell bank. Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

Furthermore, reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality control and assurance, volume production, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to manufacture our product candidates in accordance with our product specifications) and the possibility of termination or nonrenewal of the agreement by the third party at a time that is costly or damaging to us. In addition, the FDA, EMA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Pharmaceutical manufacturers and their subcontractors are required to register their facilities or products manufactured at the time of submission of the marketing application and then annually thereafter with the FDA and certain state and foreign agencies. They are also subject to periodic unannounced inspections by the FDA, state and other foreign authorities. Any subsequent discovery of problems with a product, or a manufacturing or laboratory facility used by us or our strategic partners, may result in restrictions on the product or on the manufacturing or laboratory facility, including marketed product recall, suspension of manufacturing, product seizure, or a voluntary withdrawal of the drug from the market. We may have little to no control regarding the occurrence of third-party manufacturer incidents. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates.

In addition to third-party manufacturers, we rely on other third parties to store, monitor and transport bulk drug substance and drug product. If we are unable to arrange for such third-party sources, or fail to do so on commercially reasonable terms, we may not be able to successfully supply sufficient product candidate or we may be delayed in doing so. Such failure or substantial delay could materially harm our business.

In addition, disruptions to ports and other shipping infrastructure may result in shortages or delays impacting the availability of materials and other supplies, which could negatively impact our manufacturers, suppliers and other third parties on whom we rely. While we have not suffered any direct, material negative impacts from supply chain disruptions to date, we cannot be certain that we will not be impacted by any such disruptions in the future, which could increase our costs or negatively impact our development timelines.

We rely on third parties to monitor, support, conduct and oversee clinical trials of the product candidates that we are developing and, in some cases, to maintain regulatory files for those product candidates. We may not be able to obtain regulatory approval for our product candidates or commercialize any products that may result from our development efforts if we are not able to maintain or secure agreements with such third parties on acceptable terms, if these third parties do not perform their services as required, or if these third parties fail to timely transfer any regulatory information held by them to us.

We rely on entities outside of our control, which may include academic institutions, CROs, hospitals, clinics and other third-party strategic partners, to monitor, support, conduct and oversee preclinical studies and clinical trials of our current and future product candidates. We also rely on third parties to perform clinical trials on our current and future product candidates when they reach that stage. As a result, we have less control over the timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials with our own personnel.

If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated prematurely, we may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate. In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by our contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our product candidates. These third parties, in turn, may face their own constraints in obtaining the resources and personnel needed to perform the work for which we engage them. If these third parties fail to meet expected deadlines, fail to transfer to us any regulatory information in a timely manner, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then clinical trials of our product

candidates may be extended or delayed with additional costs incurred, or our data may be rejected by the FDA, EMA or other regulatory agencies.

Ultimately, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with GCP regulations and guidelines enforced by the FDA, the competent authorities of the member states of the EU and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of our CROs fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed or the FDA may require us to perform additional clinical trials before approving our marketing applications. Upon inspection, the FDA could determine that any of our clinical trials fail or have failed to comply with applicable GCP regulations. In addition, our clinical trials must be conducted with product produced under the cGMP regulations enforced by the FDA, and our clinical trials may require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and increase our costs. Moreover, our business may be implicated if any of our CROs violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If any of our clinical trial sites terminate for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. Further, if our relationship with any of our CROs is terminated, we may be unable to enter into arrangements with alternative CROs on commercially reasonable terms, or at all.

Switching or adding CROs or other suppliers can involve substantial cost and require extensive management time and focus, and there is a natural transition period when a new CRO or supplier commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. If we are required to seek alternative supply arrangements, the resulting delays and potential inability to find a suitable replacement could materially and adversely impact our business.

We rely on third parties for various operational and administrative aspects of our business, including for certain cloud-based software platforms, which impact our financial, operational and research activities. If any of these third parties fail to provide timely, accurate and ongoing service or if the cloud-based platforms suffer outages that we are unable to mitigate, our business may be adversely affected.

We currently rely upon third-party consultants and contractors to provide certain operational and administrative services, including external financial, legal, information technology, clinical and research consultation. The failure of any of these third parties to provide accurate and timely service may adversely impact our business operations. In addition, if such third-party service providers were to cease operations, temporarily or permanently, face financial distress or other business disruption, or increase their fees, or if our relationships with these providers deteriorate, we could suffer increased costs until an equivalent provider could be found, if at all, or we could develop internal capabilities, if ever. If we are unsuccessful in choosing or finding high-quality partners, if we fail to negotiate cost-effective relationships with them, or if we ineffectively manage these relationships, it could have an adverse impact on our business and financial performance.

Further, our operations depend on the continuing and efficient operation of our information technology and communications systems and infrastructure, and specifically on “cloud-based” platforms. These platforms are vulnerable to damage or interruption from earthquakes, vandalism, sabotage, terrorist attacks, floods, fires, power outages, telecommunications failures, and computer viruses or other deliberate attempts to harm the systems. The occurrence of a natural or intentional disaster, any decision to close a facility we are using without adequate notice, or particularly an unanticipated problem at our cloud-based virtual server facility, could result in harmful interruptions in our service, resulting in adverse effects to our business.

Risks Related to Our Intellectual Property

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our future

approved products or impair our competitive position. For example, certain patents and patent applications held by third parties cover Fab and Fc region engineering methods for bispecific antibodies, and antibodies having mutations in Fab heavy and light chain regions and Fc regions to generate correctly paired bispecific antibodies. In addition, we are aware of certain third-party patents and patent applications that generally encompass topoisomerase 1 inhibitors. If our or our strategic partners' product candidates or products are covered by any claims of these patents or patents that may issue from these applications, and if licenses for them are not available on commercially reasonable terms or at all, we or our strategic partners are unable to invalidate or render unenforceable those patents, or we or our strategic partners are unable to reengineer such product candidates or products, our business could be materially harmed.

There is no assurance that there are not third-party patents or patent applications of which we are aware, but which we do not believe are relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position.

Patents that we may ultimately be found to infringe could be issued to third parties. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. Our failure to obtain a license to any patent covering any technology that we require may materially harm our business, financial condition and results of operations. Moreover, our failure to maintain a license to any patent covering any technology that we require may also materially harm our business, financial condition and results of operations. Furthermore, we would be exposed to a threat of litigation.

In the pharmaceutical industry, significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights are commonplace. Any such lawsuits and proceedings could be costly and could affect our results of operations and divert the attention of our management and scientific personnel. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. There is a risk that a court would decide that we or our strategic partners are infringing a third party's patents and would order us or our strategic partners to stop the activities or stop the manufacture, use, or sale of any product covered by the patents. In that event, we or our strategic partners may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected product candidate or cease commercialization of an approved product. In addition, there is a risk that a court would order us or our strategic partners to pay third-party damages or some other monetary award, depending upon the jurisdiction. An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third parties, potentially including treble damages and attorneys' fees if we are found to have willfully infringed, and we may be required to cease using the technology at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. Any of these outcomes could have a material adverse effect on our business.

If we are unable to obtain, maintain and enforce patent and trade secret protection for our product candidates and related technology, our business could be materially harmed.

Our strategy depends on our ability to identify and seek patent protection for our discoveries. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we have licensed from third parties. Therefore, our owned or in-licensed patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current and future product candidates in the United States or in other countries.

Moreover, the patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has been the subject of much litigation. The issuance of a patent does not ensure that it is valid or enforceable. Third parties may challenge the validity, enforceability or scope of our issued patents, and such patents may be narrowed, invalidated, circumvented, or deemed unenforceable. In addition, changes in law may introduce uncertainty in the enforceability or scope of patents owned by biotechnology companies. If our patents are narrowed, invalidated or held unenforceable, third parties may be able to commercialize our technology or products and compete directly with us without payment to us. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, and such prior art could potentially invalidate one or more of our patents or prevent a patent from issuing from one or more of our pending patent applications. There

is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim.

Additionally, recent reforms and changes at government agencies of the United States and those of non-U.S. jurisdictions could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications, and the maintenance, enforcement, or defense of our issued patents. For example, the ability of the U.S. Patent and Trademark Office ("USPTO") and other applicable patent authorities to properly administer their functions is highly dependent on the levels of funding available to the agency and their ability to retain key personnel and fill key leadership appointments, among various factors. Termination of employees or delays in replacing or hiring for key positions could significantly impact the ability of the USPTO and other applicable patent authorities to fulfill their functions and could greatly impact our ability to timely and adequately prosecute or maintain our patent applications, and our ability to timely and adequately maintain, enforce, or defend our issued patents.

Furthermore, even if our patents are unchallenged, they may not adequately protect our intellectual property, provide exclusivity for our product candidates, prevent others from designing around our claims or provide us with a competitive advantage. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of other countries may not allow us to protect our inventions with patents to the same extent as the laws of the United States. Because patent applications in the United States and many other jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the issuance, validity, enforceability, scope and commercial value of our patents in the United States and in other countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

Our patents covering one or more of our products or product candidates could be found invalid or unenforceable if challenged.

Any of our intellectual property rights could be challenged or invalidated despite measures we take to obtain patent and other intellectual property protection with respect to our product candidates and proprietary technology. These challenges could be initiated in the courts or administratively in various patent offices. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable or file an administrative action to invalidate our patent. In patent litigation in the United States and in some other jurisdictions, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith. The outcome following such a challenge is unpredictable.

With respect to challenges to the validity of our patents, for example, there might be invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. The cost of defending such a challenge, and any resulting loss of patent protection, could have a material adverse impact on one or more of our product candidates and our business.

Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend and could require us to pay substantial damages, cease the use, manufacture, or sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at

all). Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel.

Our intellectual property rights will not necessarily provide us with competitive advantages.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we or our strategic partners own or have exclusively licensed;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may obtain patents for certain compounds many years before we obtain marketing approval for products containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited;
- our competitors might conduct research and development activities in countries where we do not have patent rights and use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may fail to develop additional proprietary technologies that are patentable;
- the laws of certain countries may not protect our intellectual property rights to the same extent as the laws of the United States, or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and
- the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our product candidates for one or more indications.

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

We may become involved in lawsuits to protect or enforce our patents and trade secrets, which could be expensive, time consuming and unsuccessful.

Third parties may seek to market biosimilar versions of any approved products. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our product candidates. In these circumstances, we may need to defend or assert our patents, including by filing lawsuits alleging patent infringement. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid or unenforceable. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Even after they have issued, our patents and any patents that we license may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited or will expire prior to the commercialization of our product candidates, other companies may be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The following are examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patents or patents licensed to us:

- we or our strategic partners may initiate litigation or other proceedings against third parties to enforce our patent or trade secret rights;
- third parties may initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us;

- third parties may initiate opposition or reexamination proceedings challenging the validity or scope of our patent rights, requiring us or our strategic partners and/or licensors to participate in such proceedings to defend the validity and scope of our patents;
- there may be a challenge or dispute regarding inventorship or ownership of patents or trade secrets currently identified as being solely or co-owned by us or by a licensor who has granted a license to us;
- the USPTO may initiate an interference between patents or patent applications owned by or licensed to us and those of our competitors, requiring us or our strategic partners and/or licensors to participate in an interference proceeding to determine the priority of invention, which could jeopardize our patent rights; or
- third parties may seek approval to market biosimilar versions of our future approved products prior to expiration of relevant patents owned by or licensed to us, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

These lawsuits and proceedings would be costly and could affect our results of operations and divert the attention of our managerial and scientific personnel. Adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors can. There is a risk that a court or administrative body would decide that our patents are invalid, unenforceable or not infringed or trade secrets not misappropriated by a third party's activities, or that the scope of certain issued claims must be further limited. An adverse outcome in a litigation or proceeding involving our own patents or trade secrets could limit our ability to assert our patents or trade secrets against these or other competitors, affect our ability to receive royalties or other licensing consideration from our licensees, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition.

We may not be able to prevent, alone or with our licensors or licensees, infringement or misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to develop a platform that is similar to, or better than, ours in a way that is not covered by the claims of our patents;
- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by patents or pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or
- we may not develop additional proprietary technologies that are patentable or that afford meaningful trade secret protection.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with

sufficient rights to exclude others from commercializing products similar or identical to ours. Further, judicial decisions in the United States raised questions regarding the award of patent term adjustment ("PTA") for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will be viewed in the future and whether patent expiration dates may be impacted.

If we do not obtain protection under the Hatch-Waxman Amendments and similar legislation in other countries for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

If we are unable to protect the confidentiality of our proprietary information, the value of our technology and products could be adversely affected.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information. For example, we treat our confidential and proprietary computational technologies, including unpatented know-how and other proprietary information, as trade secrets. We enter into confidentiality agreements with our employees, consultants, strategic partners and others upon the commencement of their relationships with us. These agreements provide that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. We cannot guarantee that we have entered into such agreements with each party that has or may have had access to, or houses or hosts, our trade secrets or proprietary information or that has been involved in the development of intellectual property. Further, despite such agreements, such inventions or confidential information may become disclosed or assigned to third parties. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in such technology or know-how or in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems and cloud storage sources, but such security measures may be breached, including through cyber-hacking or cyberattacks, and we may not have adequate remedies for any breach.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor,

or if we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced and our business and competitive position could be harmed. Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously or concurrently employed at research institutions and/or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. Such trade secrets or other proprietary information could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by regulations and governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents or applications. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

Although we are not currently experiencing any claims challenging the inventorship or ownership of our patents, we may in the future be subject to claims that former employees, strategic partners or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. For example, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, or we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Patent protection and patent prosecution for some of our product candidates may be dependent on, and the ability to assert patents and defend them against claims of invalidity may be maintained by, third parties.

There may be times when certain patents that relate to our product candidates or any approved products are controlled by our licensees or licensors. Although we may, under such arrangements, have rights to consult with our strategic partners on actions taken as well as back-up rights of prosecution and enforcement, we have in the past and may in the future relinquish rights to prosecute and maintain patents and patent applications within our portfolio as well as the ability to assert such patents against infringers.

If any current or future licensee or licensor with rights to prosecute, assert or defend patents related to our product candidates fails to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, or if patents covering any of our product candidates are asserted against infringers or defended against claims of invalidity or unenforceability in a manner that adversely affects such coverage, our ability to develop and commercialize any such product candidate may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our products.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or found to be enforceable in our patents, in our strategic partners' patents or in third-party patents. U.S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this has created uncertainty with respect to the validity, scope and value of patents, once obtained.

In September 2011, the Leahy-Smith America Invents Act, also known as the America Invents Act ("AIA"), was signed into law. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties disclosing or claiming the same invention. A third party that has filed, or files a patent application in the USPTO after March 16, 2013, but before us, could be awarded a patent covering a given invention, even if we had made the invention before it was made by the third party. This requires us to be cognizant of the time from invention to filing of a patent application.

Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future. For example, the U.S. Supreme Court held in Amgen v. Sanofi (2023) that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the Patent Act. As such, any of our patent rights with functional claims may be vulnerable to third party challenges seeking to invalidate these claims for lacking enablement or adequate support in the specification.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our current or future products, if any, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. U.S. Supreme Court cases have narrowed the scope of what is considered patentable subject matter, for example, in the areas of software and diagnostic methods involving the association between treatment outcome and biomarkers. This could impact our ability to patent certain aspects of our technology in the United States.

Many companies have encountered significant problems in protecting and defending intellectual property rights in jurisdictions other than the United States. The legal systems of certain countries do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

The requirements for patentability may differ in certain countries, which may make it more difficult for us to obtain sufficient claim scope to protect our products in those jurisdictions. India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue

opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors or licensees and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors or licensees. For example, in March 2025, the Chinese government issued regulations for implementation of the 2021 Anti-Foreign Sanctions Act. These regulations expand the Chinese government's ability to seize certain assets, including intellectual property, of foreign entities in response to foreign sanctions, including those by the United States. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

As another example, the complexity and uncertainty of European patent laws have increased in recent years. In Europe, a new unitary patent system was introduced on June 1, 2023, which will significantly impact European patents, including those granted before the introduction of this system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which is subject to the jurisdiction of the Unitary Patent Court (the "UPC"). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC are potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

We use open source software in connection with our internal research and development programs, which could negatively affect our ability to develop products and subject us to litigation or other actions.

We use open source software in connection with our internal research and development programs. The terms of many open source licenses have not been interpreted by U.S. courts or courts outside of the United States, and there is a risk that these licenses could be construed in a way that could impose unanticipated conditions or restrictions on our ability to use this software. As a result, we could be subject to lawsuits by parties claiming ownership of what we believe to be open source software, or claiming that software we developed using such open source software is a derivative work of open source software and demanding the release of portions of our source code, or otherwise seeking to enforce the terms of the applicable open source license. Litigation could be costly for us to defend, have a negative effect on our financial condition and results of operations or require us to devote additional research and development resources to change our platform and offerings.

If we were to combine our proprietary software with open source software in a certain manner, we could, under certain open source licenses, be required to release the source code of our proprietary software to the public. If we inappropriately use open source software, or if the license terms for open source software that we use change, we may be required to re-engineer our platform, incur additional costs, discontinue the use of some or all of our platform or take other remedial actions.

In addition to risks related to license requirements, usage of open source software can lead to greater risks than use of third-party commercial software, because open source licensors generally do not provide warranties or assurance of title or controls on origin of the software.

Many of the risks associated with usage of open source software, such as the lack of warranties or assurances of title, cannot be eliminated, and if not properly addressed, could have an adverse effect on our business, financial condition and results of operations.

We will need to obtain FDA approval for any proposed product candidate names, and any failure or delay associated with such approval may adversely affect our business.

Any proprietary name or trademark we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product candidate names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies certain medical claims or contributes to an overstatement of efficacy. If the FDA objects to any product candidate names we propose, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we would lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Risks Related to Additional Legal and Compliance Matters

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, insider trading, and noncompliance with our policies and procedures.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state health care fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Conduct and Business Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. In addition, employees may become subject of allegations of gender discrimination and other misconduct that are not in compliance with our policies and procedures, which, regardless of the ultimate outcome, may result in adverse publicity that could materially harm our brand, reputation and business.

If we or our contractors or agents market products in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws and transparency laws, we may be subject to civil or criminal penalties.

In addition to FDA restrictions on the marketing of pharmaceutical products, federal and state healthcare laws restrict certain business practices in the biopharmaceutical industry. If our product candidates are approved and we begin commercialization, we will be subject to additional healthcare laws and regulations enforced by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. These state and federal healthcare laws, commonly referred to as “fraud and abuse” laws, have been applied to restrict certain marketing practices in the pharmaceutical industry, and include anti-kickback, false claims, data privacy and security and transparency statutes and regulations.

Federal false claims laws prohibit, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. Most states also have statutes or regulations similar to the federal anti-kickback law and federal false claims laws, which may apply to items such as pharmaceutical products and services reimbursed by private insurers. Administrative, civil and criminal sanctions may be imposed under these federal and state laws.

The federal civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

HIPAA created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of, or payment for, healthcare benefits, items or services.

We may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business, including HIPAA, as amended by HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable information. In addition, state laws govern the

privacy and security of health information in certain circumstances, many of which differ from each other in significant ways. These state laws may not have the same effect and often are not preempted by HIPAA, thus complicating compliance efforts.

The PPACA also included the federal Physician Payments Sunshine Act, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually information related to certain payments or other transfers of value made in the previous year to covered recipients, including physicians and teaching hospitals, including certain ownership and investment interests held by physicians or their immediate family members. Failure to comply with the required reporting requirements could subject applicable reporting entities such as manufacturers to substantial civil monetary penalties.

Many states have similar healthcare statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Certain states require pharmaceutical companies to implement a comprehensive compliance program that includes a limit or outright ban on expenditures for, or payments to, individual medical or health professionals and/or require pharmaceutical companies to track and report gifts and other payments made to physicians and other healthcare providers.

If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal, civil or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion of products from reimbursement under government programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products will be sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research and development involves, and may in the future involve, the use of potentially hazardous materials and chemicals. Our operations may produce hazardous waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by local, state and federal laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations and fire and building codes, including those governing laboratory procedures, exposure to blood-borne pathogens, use and storage of flammable agents and the handling of biohazardous materials. Although we maintain workers' compensation insurance as prescribed by certain jurisdictions in which we operate to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

We may be subject to certain costs and inefficiencies as a result of our 2022 Redomicile Transactions.

We became a Delaware corporation in October 2022 as a result of the Redomicile Transactions. Pursuant to the agreements governing the Redomicile Transactions, we agreed to use reasonable efforts to take certain corporate steps and actions, as may be necessary or desirable, to effect and implement certain post-arrangement transactions, including the internal reorganization of certain subsidiaries (the "Post-Arrangement Transactions"). Following the entry into the Original Jazz Collaboration Agreement subsequent to the Redomicile Transactions, we determined that completing the Post-Arrangement Transactions as originally contemplated would result in negative tax consequences. As a result, we do not currently intend to complete the Post-Arrangement Transactions. While we expect to manage any tax and operational inefficiencies that may result under our current organizational structure, and we may pursue additional internal reorganizations in the future, certain tax and operational inefficiencies may persist notwithstanding our management and/or additional reorganization that could adversely affect our business, financial condition and results of operations (including, for example, the requirement to recognize certain income (such as interest income) under the "global intangible low-taxed income" regime).

We incurred a number of non-recurring costs associated with the Redomicile Transactions, and the associated reorganization of our corporate structure may result in additional and unforeseen expenses in the future. While it is expected that benefits of the Redomicile Transactions will offset these transaction costs over time, this net benefit may not be achieved in the short-term or at all. These combined factors could adversely affect our business and overall financial condition.

Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on key members of our senior management team, including Kenneth Galbraith, the Chair of our board of directors, President, and Chief Executive Officer, Leone Patterson, our Chief Business Officer and Chief Financial Officer, Paul Moore, our Chief Scientific Officer, Jeffrey Smith, our Chief Medical Officer, and other key members of our senior management, scientific and clinical teams. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. The loss of the services of our key senior managers and employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

Retention and any future recruitment of qualified scientific, technical, clinical, manufacturing and sales and marketing personnel will also be critical to our success. If we are successful in advancing the development of our early-stage candidates, we will need to evaluate any organizational hiring needs. In addition, we will need to effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our research, development and commercialization efforts for our existing and future product candidates. Furthermore, replacing key senior managers and employees may be difficult and may take an extended period of time because of the limited talent pool in our industry due to the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Intense competition for attracting key skill-sets and the impact of inflationary pressure on wages may limit our ability to attract, retain and motivate key personnel on acceptable terms. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our business strategy will be limited.

As we advance our development and commercialization plans and strategies, we may need to grow or modify our organization, and we may experience difficulty in managing such change, which could disrupt our operations.

As of March 31, 2025, we had 299 full-time employees. As we advance our development and commercialization plans and strategies in the future, we anticipate that we may need to expand or modify our employee base. As our product candidates enter and advance through preclinical studies and any clinical trials, we may need to expand or modify our development, manufacturing, regulatory sales and marketing capabilities or contract with other organizations to provide these capabilities for us. We believe the need for future expansion or modification in these areas will increase as our product candidates reach later stages of preclinical and clinical development. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of their attention away from our day-to-day activities and devote a substantial amount of time to managing any necessary growth activities. We may not be able to effectively manage an expansion or modification of our operations, which may result in weaknesses in our infrastructure, give rise to operational errors, loss of business opportunities, loss of employees and reduced productivity amongst remaining employees. Any growth or organizational modification could require significant capital expenditures and may divert financial resources from other projects, such as the development of existing and additional product candidates. If our management is unable to effectively manage any needed growth or organizational modifications, our expenses may increase more than expected, our ability to generate or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively with others in our industry will depend on our ability to effectively manage any future growth or organizational modification.

Risks Related to Our Common Stock

Our stock price is likely to be volatile and the market price of our common stock may drop below the price paid by stockholders.

Investors should consider an investment in our common stock as risky and invest only if they can withstand a significant loss and wide fluctuations in the market value of their investment. Investors may be unable to sell their common stock at or above the price they paid for such stock due to fluctuations in the market price of our common stock arising from changes in our operating performance or prospects. Factors that may cause the market price of our common stock to fluctuate include:

- results and timing of our clinical trials and clinical trials of our competitors' products;
- failure or discontinuation of any of our development programs;
- the success of our partnerships;
- our ability to achieve milestones and receive associated milestone payments pursuant to the terms of our partnerships;
- issues in manufacturing our product candidates or future approved products;
- regulatory developments or enforcement in the United States and foreign countries with respect to our product candidates or our competitors' products;
- competition from existing products or new products that may emerge;
- developments or disputes concerning patents or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- announcements by us, our strategic partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;
- actions taken by industry or securities analysts that cover our company or common stock, including changes in estimates or recommendations, inaccurate or unfavorable research or a decision to drop coverage;
- fluctuations in the valuation of companies in the biotechnology industry or otherwise perceived by investors to be comparable to us;
- additional instances of stockholder activism, including unsolicited takeover proposals or proxy contests;
- public concern over our product candidates or any future approved products;
- litigation;
- future sales of our common stock or the perception that such sales could occur;
- stock price and volume fluctuations attributable to inconsistent trading volume levels of our common stock;
- additions or departures of key personnel;
- our ability to execute on our key strategic priorities;
- changes in the structure of health care payment systems in the United States or other countries;
- failure of zanidatamab or our product candidates, if approved, to achieve commercial success;
- economic and other external factors or other disasters or crises, including pandemics;
- changes in regulations and customs, tariffs and trade barriers, or the perception that any of them could occur;
- period-to-period fluctuations in our financial condition and results of operations, including the timing of receipt of any milestone or other payments under commercialization or licensing agreements;
- general market conditions and market conditions for biopharmaceutical stocks;
- potential disagreements or disputes with certain of our stockholders;
- our ability to effectively address environmental, social, and governance matters affecting our business that are a focus of certain investors, environmental activists, the media, and governmental and nongovernmental organizations;
- overall fluctuations in U.S. equity markets;

- purchases under our Repurchase Program; and
- other factors that may be unanticipated or out of our control.

The stock market in general, and the stock of biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the relevant companies, which has resulted in increased volatility and decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments, may negatively affect the market price of our common stock, regardless of our actual operating performance. Securities class action litigation has often been brought against companies following a decline in the market price of their securities. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could materially harm our business. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a material adverse effect on the market price of our common stock.

An active trading market for our common stock may not be sustained.

If an active market for our common stock does not continue, it may be difficult for our stockholders to sell their stock without depressing the market price for the common stock or sell their common stock at or above the prices at which they acquired their common stock or sell their common stock at the time they would like to sell. Any inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling common stock and may impair our ability to acquire other companies or technologies by using our common stock as consideration.

We may fail to meet the continued listing requirements of the Nasdaq Stock Market LLC ("Nasdaq"). If Nasdaq delists our shares of common stock from trading on its exchange, we could face significant material adverse consequences, including:

- significant impairment of the liquidity for and visibility of our common stock, which may substantially decrease the market price of our common stock;
- a limited availability of market quotations for our securities;
- a determination that our common stock qualifies as a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly resulting in a reduced level of trading activity in the secondary trading market for our common stock;
- a limited amount of news and analyst coverage for our company; and
- a loss of confidence of potential industry partners, lenders and employees, which may harm our ability to pursue our business strategy, issue additional securities or obtain additional financing in the future.

Our management team has broad discretion to use the net proceeds from our financing activities as well as funds received pursuant to our strategic collaborations, and its investment of these proceeds may not yield a favorable return. They may invest the proceeds in ways with which our stockholders disagree.

Our management team has broad discretion in the application of the proceeds we receive from our financing activities and from our strategic collaborations, and we could spend or invest the proceeds in ways with which our stockholders disagree. Accordingly, stockholders will need to rely on our management team's judgment with respect to the use of these proceeds. The failure by management to apply these funds effectively could negatively affect our ability to operate and grow our business. We cannot specify with certainty all of the particular uses for the net proceeds received from our fundraising efforts or for funds received pursuant to our strategic collaborations and our actual expenditures will depend upon numerous factors. Until the net proceeds are used, they may be placed in investments that do not produce significant income or that may lose value.

We do not anticipate paying cash dividends for the foreseeable future, and accordingly, stockholders must rely on stock appreciation for any return on their investment.

We have never paid any dividends on our common stock. We currently intend to retain our future earnings, if any, to fund the development and growth of our business and do not anticipate that we will declare or pay any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be the sole source of gain on investment in our common stock for the foreseeable future. Investors seeking cash dividends should not invest in our common

stock. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon many factors, and, as a result, future dividends payable to investors are not guaranteed.

Our principal stockholders, in aggregate, could exert substantial influence over us which could delay or prevent a change in corporate control or result in the entrenchment of management or the board of directors.

Our principal stockholders, being our stockholders that beneficially own 5% or more of our common stock, together with their affiliates and related persons, in aggregate, owned approximately 56.6% of our outstanding common stock as of March 31, 2025. Our directors and executive officers together with their respective affiliates owned, in the aggregate, approximately 25.0% of our outstanding common stock as of March 31, 2025. Our principal stockholders, if acting together (with or without our directors and executive officers), may have the ability to exert substantial influence over the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger or sale of all or substantially all of our assets. In addition, our principal stockholders, if acting together (with or without our directors and executive officers), may have the ability to exert substantial influence over the management and affairs of our company. Accordingly, this concentration of ownership could harm the market price of our common stock by:

- delaying, deferring, or preventing a change in control;
- entrenching our management or the board of directors;
- impeding a merger, takeover, or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

We qualify as a smaller reporting company, and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to such companies could make our common stock less attractive to investors.

We qualify as a "smaller reporting company," as defined under the Exchange Act. In addition, we are a "non-accelerated filer" as defined under the Exchange Act. For as long as we continue to be a smaller reporting company or a non-accelerated filer, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies that are not smaller reporting companies or non-accelerated filers, as applicable, including, but not limited to, an exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404.

Opting to forego an attestation to the effectiveness of our internal control over financial reporting from our independent registered public accounting firm may have a detrimental impact on our ability to maintain the adequacy of our internal control over financial reporting, and any failure to maintain adequacy, or inability to produce accurate financial statements or other reports on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. As a result of our decision to rely on certain of these disclosure exemptions, the information we provide stockholders will be different than the information that is available with respect to other public companies and some investors may find our shares of common stock less attractive, which may result in a less active trading market for our common stock and the market price of our common stock may be more volatile.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Under the Sarbanes-Oxley Act of 2002, we are required to establish and maintain effective internal control over financial reporting and adequate disclosure controls and procedures. Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

We plan to transition to a new enterprise resource planning system in 2025, which we believe will lead to improvements in our internal control over financial reporting; however, the full impact of this transition is not yet known. If, during the evaluation and testing process of our internal controls, we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there

will not be material weaknesses in our internal controls over financial reporting in the future. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. Furthermore, if we cannot provide reliable financial reports or prevent fraud, including as a result of remote working by our employees, our business and results of operations would likely be materially and adversely affected.

Holders of our Exchangeable Shares are subject to additional risks.

Pursuant to the Redomicile Transactions, certain holders of common shares of our predecessor company exchanged their common shares for exchangeable shares ("Exchangeable Shares") in the capital of our subsidiary Zymeworks ExchangeCo Ltd. ("ExchangeCo"). Exchangeable Shares are exchangeable at the option of the holder for shares of our common stock.

Exchangeable Shares are subject to additional risks, including:

- The Exchangeable Shares are not and will not be listed on any stock exchange. There is no market through which the Exchangeable Shares may be sold, and holders may not be able to sell their Exchangeable Shares.
- Holders of Exchangeable Shares who request an exchange may not receive shares of our common stock until a period of time after the applicable request is received. During this period, the market price of our common stock may increase or decrease. Any such increase or decrease would affect the value of the consideration to be received by such a holder of Exchangeable Shares upon a subsequent sale of shares of our common stock received in the exchange.
- Exchangeable Shares may be subject to different tax consequences under Canadian law depending on whether the exchangeable shares are disposed of in a redemption or an acquisition by one of our subsidiaries, and such transaction may not be within the control of the holder.
- The tax treatment of Exchangeable Shares for non-Canadian tax purposes, including U.S. federal income tax purposes, is uncertain.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws might delay, discourage or prevent a change in control of Zymeworks or changes in our management, thereby depressing the market price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of Zymeworks more difficult or delay or prevent changes in control of its management. Among other things, these provisions:

- authorize our board of directors to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- permit only the board of directors to establish the number of directors and fill vacancies and newly created directorships on the board, provided that the board of directors' ability to increase the size of the board and fill vacancies and newly created directorships will be subject to the restrictions in our amended and restated certificate of incorporation and amended and restated bylaws;
- establish that members of our board of directors serve in one of three staggered terms of three years each;
- provide that our directors may only be removed by the affirmative vote of at least 66 2/3% of the voting power of the shares cast on such proposal;
- permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- not provide for cumulative voting rights in the election of directors;
- provide that special meetings of Zymeworks' stockholders may be called only by the board of directors, the chairperson of the board of directors, Zymeworks' chief executive officer, president or the secretary upon request from holders of no

less than 20% of our outstanding voting stock, subject to the limitations and requirements set forth in our amended and restated bylaws; and

- require a super-majority vote of stockholders to amend some of the provisions described above.

Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested stockholder" for a period of three years following the date on which the stockholder became an "interested stockholder" unless certain conditions are met.

These provisions, alone or together, could delay, discourage or prevent a transaction involving a change in control of Zymeworks. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors of their choosing and to cause Zymeworks to take other corporate actions they desire, any of which, under certain circumstances, could limit the opportunity for our stockholders to receive a premium for their shares of common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated bylaws designate a state or federal court located within the State of Delaware as the exclusive forum for substantially all disputes between Zymeworks and its stockholders, and also provide that the federal district courts are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, each of which could limit our stockholders' ability to choose the judicial forum for disputes with Zymeworks or its directors, officers, stockholders or employees.

Our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, stockholders, officers or other employees to Zymeworks or our stockholders, (3) any action arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws or (4) any other action asserting a claim that is governed by the internal affairs doctrine shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware), except for any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction. This provision does not apply to any action brought to enforce a duty or liability created by the Exchange Act and the rules and regulations thereunder.

Section 22 of the Securities Act establishes concurrent jurisdiction for federal and state courts over Securities Act claims. Accordingly, both state and federal courts have jurisdiction to hear such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

Any person or entity purchasing or otherwise acquiring or holding or owning (or continuing to hold or own) any interest in any of our securities shall be deemed to have notice of and consented to the foregoing bylaw provisions. Although we believe these exclusive forum provisions benefit us by providing increased consistency in the application of Delaware law and federal securities laws in the types of lawsuits to which each applies, the exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or our current or former directors, officers, stockholders or other employees, which may discourage such lawsuits against us and our current and former directors, officers, stockholders and other employees. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder as a result of our exclusive forum provisions.

The enforceability of similar exclusive forum provisions in other companies' organizational documents have been challenged in legal proceedings, and, while certain courts have determined these provisions are enforceable, it is possible that a court of law could rule that these types of provisions are inapplicable or unenforceable if they are challenged in a proceeding or otherwise. If a court were to find either exclusive forum provision contained in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur significant additional costs associated with resolving such action in other jurisdictions, which could harm our financial condition and results of operations.

There can be no assurance that we will repurchase additional shares of our common stock or that we will repurchase shares at favorable prices.

In August 2024, our board of directors approved the Repurchase Program, pursuant to which we are authorized to repurchase up to $60.0 million of our common stock from time to time through open market transactions, or other means in accordance with Rule 10b5-1 and Rule 10b-18 under the Exchange Act. As of March 31, 2025, we have repurchased 2,545,402 shares of our common stock under the Repurchase Program. The timing, number of shares repurchased, and prices paid for any additional shares of stock repurchased under this program will depend on general business and market conditions as well as corporate and regulatory limitations, prevailing stock prices, and other considerations. Our Repurchase Program may be suspended or discontinued at any time, and does not obligate us to acquire any additional shares of common stock.

Our ability to make share repurchases will depend upon market conditions, cash balances and future capital requirements, results of operations, financial condition, compliance with applicable legal requirements and other factors that we may deem relevant and which may be beyond our control. In addition, we can provide no assurance that we will repurchase stock at favorable prices. As a result, there can be no guarantee around the timing of our share repurchases. Any failure to repurchase additional shares of stock, a reduction in the frequency of repurchases, or the completion of our Repurchase Program could have a negative effect on our reputation, investor confidence in us and our stock price.

The existence of our Repurchase Program could cause our stock price to be higher than it otherwise would be and could potentially reduce the market liquidity for our stock. Although our Repurchase Program is intended to enhance long-term stockholder value, there is no assurance that it will do so because the market price of our common stock may decline below the levels at which we repurchase shares, and short-term stock price fluctuations could reduce the effectiveness of the program.

Repurchasing our common stock reduces the amount of cash we have available, and we may fail to realize the anticipated long-term stockholder value of any share repurchase program.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities.

On August 1, 2024, our board of directors authorized the Repurchase Program, whereby we may repurchase up to $60.0 million of our outstanding common stock, par value $0.00001 per share. No shares were repurchased under this program during the three months ended March 31, 2025. As of March 31, 2025, $30.0 million remained authorized for repurchase under the Repurchase Program.

Item 3. Defaults upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

During our last fiscal quarter, no director or officer, as defined in Rule 16a-1(f) of the Exchange Act, adopted or terminated a “Rule 10b5-1 trading arrangement” or any “non-Rule 10b5-1 trading arrangement,” each as defined in Item 408 of Regulation S-K.

Item 6. Exhibits.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K12B filed with the SEC on October 13, 2022).
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on March 15, 2023).
3.3	Certificate of Elimination of Series B Participating Preferred Stock of Zymeworks Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on June 12, 2023).
3.4	Certificate of Designations of Special Voting Stock of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K12B filed with the SEC on October 13, 2022).
10.1*	Fifth Amendment to Collaboration Agreement, effective March 3, 2025, by and between Zymeworks BC Inc. and Celgene Corporation.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the period ended March 31, 2025, formatted in Inline XBRL (Inline eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of March 31, 2025 (unaudited) and December 31, 2024 (audited), (ii) Condensed Consolidated Statements of Loss and Comprehensive Loss for the three month period ended March 31, 2025 and 2024 (unaudited), (iii) Condensed Consolidated Statement of Changes in Stockholders' Equity for the three month periods ended March 31, 2025 and 2024 (unaudited), (iv) Condensed Consolidated Statements of Cash Flows for the three month period ended March 31, 2025 and 2024 (unaudited) and (v) Notes to the Interim Condensed Consolidated Financial Statements (unaudited).
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).
#	Indicates management contract or compensatory plan.
*	Certain portions of this exhibit (indicated by "[***]") have been omitted in accordance with Item 601(b)(10) of Regulation S-K because the omitted information is not material and the Company customarily and actually treats such omitted information as private or confidential.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ZYMEWORKS INC.

By: /s/ Kenneth Galbraith

Name:	Kenneth Galbraith
Title:	Chair of the Board of Directors, President and Chief Executive Officer (Principal Executive Officer)
Date:	May 8, 2025

By: /s/ Leone Patterson

Name:	Leone Patterson
Title:	Executive Vice President, Chief Business Officer and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
Date:	May 8, 2025

Exhibit 10.1

CERTAIN PORTIONS OF THIS EXHIBIT (INDICATED BY [***]) HAVE BEEN EXCLUDED PURSUANT TO ITEM 601(B)(10) OF REGULATION S-K BECAUSE THEY ARE BOTH NOT MATERIAL AND ARE THE TYPE THAT THE COMPANY TREATS AS PRIVATE AND CONFIDENTIAL.

CONFIDENTIAL

FIFTH AMENDMENT TO COLLABORATION AGREEMENT

This Fifth Amendment (the "**Amendment**") to the Agreement (as defined below), dated effective on March 3, 2025 (the "**Amendment Effective Date**") regardless of the dates of the signatures below, by and between **CELGENE CORPORATION**, a corporation organized and existing under the laws of Delaware, with its principal business office located at 86 Morris Avenue, Summit, NJ 07901, USA ("**Celgene"**), and **ZYMEWORKS BC INC.**, formerly named Zymeworks Inc., a corporation organized and existing under the laws of British Columbia, having an address at114 East 4th Avenue, Suite 800, Vancouver, BC, Canada V5T 1G4 ("**Zymeworks**"). Zymeworks and Celgene are each referred to individually as a "**Party**" and together as the "**Parties**".

BACKGROUND

A. Celgene and Zymeworks entered into that certain Collaboration Agreement dated December 23, 2014, as amended on May 29, 2017, March 31, 2020, June 22, 2020 and August 4, 2021 (the "**Agreement**") pursuant to which the Parties conducted the Research Program (as defined in the Agreement) and Zymeworks granted certain licenses to Celgene under the Zymeworks Intellectual Property (as defined in the Agreement).

B. Celgene Alpine Investment Co., LLC, was merged into Celgene Corporation on November 9, 2022, and the Agreement was assigned to Celgene Corporation so that Celgene Alpine Investment Co., LLC is no longer a party to the Agreement.

C. Celgene wishes to extend the Option Term (as defined in the Agreement), and Zymeworks is willing to provide such extension.

D. The Parties now desire to amend the Agreement as set forth herein.

NOW THEREFORE, in consideration of the mutual covenants and agreements contained herein below, the sufficiency of which is acknowledged by both Parties, the Parties agree as follows as of the Amendment Effective Date:

AGREEMENT

1. **Definitions**. Unless otherwise defined in this Amendment, initially capitalized terms used herein shall have the meanings given to them in the Agreement.

2. **Option Term Definition**. Section 1.37 of the Agreement is hereby deleted in its entirety and replaced with the following:

"**1.37** "**Option Term**" means, with respect to each Collaboration Sequence Group, the period commencing on the initiation of the Research Program and expiring on the earlier of: [***].

3. **No Other Modifications**. Except as specifically set forth in this Amendment, the terms and conditions of the Agreement shall remain in full force and effect. No waiver of any obligation under this Amendment shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Amendment may be amended or modified other than by a written document signed by authorized representatives of each Party.

4. **Miscellaneous**. This Amendment, together with the Agreement, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other communications between the Parties with respect to such subject matter. This Amendment may be executed by electronic signature and in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Amendment shall be governed by and construed in accordance with the laws of the State of New York and the patent laws of the United States without reference to any rules of conflict of laws.

[Remainder of page left blank intentionally; signature page to follow.]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Amendment to be executed by their duly authorized representatives.

ZYMEWORKS BC INC.

By: /s/ Daniel Dex
Name: Daniel Dex
Title: General Counsel
Date: March 21, 2025

CELGENE CORPORATION

By: /s/ Christopher Mussari
Name: Christopher Mussari
Title: Senior Manager
Date: March 25, 2025

Exhibit 31.1

CERTIFICATION
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kenneth Galbraith, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Zymeworks Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2025

/s/ Kenneth Galbraith

Chief Executive Officer

Exhibit 31.2

CERTIFICATION
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Leone Patterson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Zymeworks Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2025

/s/ Leone Patterson

Chief Financial Officer

Exhibit 32.1

SECTION 906 CERTIFICATION

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code) in connection with the Quarterly Report on Form 10-Q of Zymeworks Inc. for the quarterly period ended March 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer hereby certifies, to such officer's knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Zymeworks Inc.

/s/ Kenneth Galbraith

Name: Kenneth Galbraith

Title: Chief Executive Officer

Date: May 8, 2025

This certification accompanies the Report pursuant to § 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed "filed" by the Company for purposes of §18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section.

Exhibit 32.2

SECTION 906 CERTIFICATION

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code) in connection with the Quarterly Report on Form 10-Q of Zymeworks Inc. for the quarterly period ended March 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer hereby certifies, to such officer's knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Zymeworks Inc.

/s/ Leone Patterson

Name: Leone Patterson
Title: Chief Financial Officer
Date: May 8, 2025

This certification accompanies the Report pursuant to § 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed "filed" by the Company for purposes of §18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section.