

**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 September 30, 2024

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
(State or other jurisdiction of
incorporation or organization)

88-3099146
(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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 October 30, 2024 was 68,877,526.

ZYMEWORKS INC.
QUARTERLY REPORT ON FORM 10-Q
For the Quarter Ended September 30, 2024
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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,” “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 or equity 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 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 Gaza Strip 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 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 (the “FDA”) may not accept data from trials we conduct outside the United States;
- disruptions at the FDA and other government agencies caused by funding shortages or global health concerns;
- 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;
- 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 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;
- we may become involved 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;
- we may be unable 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 intellectual property rights for some of our product candidates are dependent on the abilities of third parties to assert and defend such rights;
- patent reform legislation and court decisions can diminish the value of patents in general, thereby impairing our ability to protect our products;
- we may not be able to protect our intellectual property rights throughout the world;
- we will require FDA approval for any proposed product candidate names and any failure or delay associated with such approval may adversely affect our business;
- 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;
- 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 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
- if securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

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 and nine months ended September 30, 2024

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

	September 30, 2024	December 31, 2023
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 122,356	\$ 157,557
Short-term marketable securities (note 5)	174,844	216,770
Accounts receivable	23,704	19,477
Prepaid expenses and other current assets	22,865	19,122
Total current assets	343,769	412,926
Long-term marketable securities (note 5)	77,667	81,930
Long-term prepaids and other assets	7,228	7,566
Deferred tax asset	4,206	3,615
Property and equipment, net	18,333	19,847
Operating lease right-of-use assets	17,355	17,696
Intangible assets, net	6,407	7,656
Acquired in-process research and development (note 6)	171	17,628
Goodwill (note 6)	12,016	12,016
Total assets	\$ 487,152	\$ 580,880
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (note 7)	\$ 51,707	\$ 45,992
Income tax payable	2,071	1,811
Current portion of operating lease liability (note 11)	2,943	4,261
Deferred revenue (note 9)	27,188	3,699
Total current liabilities	83,909	55,763
Long-term portion of operating lease liability (note 11)	17,274	22,369
Deferred revenue (note 9)	14,607	32,941
Other long-term liabilities (note 7)	929	1,701
Deferred tax liability	3,455	3,300
Total liabilities	120,174	116,074
Stockholders' equity:		
Common stock, \$0.00001 par value; 900,000,000 authorized shares at September 30, 2024 and December 31, 2023, respectively; 69,584,882 and 70,115,997 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively (note 8b)	1,014,327	997,227
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 September 30, 2024 and December 31, 2023 (note 8b).	—	—
Exchangeable shares, no par value, 570,637 and 651,219 issued and outstanding shares at September 30, 2024 and December 31, 2023, respectively (note 8b)	8,188	9,345
Additional paid-in capital	148,296	142,274
Accumulated other comprehensive loss	(5,999)	(6,603)
Accumulated deficit	(797,834)	(677,437)
Total stockholders' equity	366,978	464,806
Total liabilities and stockholders' equity	\$ 487,152	\$ 580,880
Research collaboration and licensing agreements (note 9)		
Commitments and contingencies (note 13)		
Subsequent event (note 8c)		

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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue				
Research and development collaborations (note 9)	\$ 16,000	\$ 16,506	\$ 45,273	\$ 59,086
Operating expenses:				
Research and development	36,353	32,775	97,558	118,095
General and administrative	13,852	16,968	45,321	55,623
Impairment on acquired in-process research and development assets ("IPR&D") (note 6)	—	—	17,287	—
Total operating expenses	<u>50,205</u>	<u>49,743</u>	<u>160,166</u>	<u>173,718</u>
Loss from operations	<u>(34,205)</u>	<u>(33,237)</u>	<u>(114,893)</u>	<u>(114,632)</u>
Other income:				
Interest income	4,785	5,026	15,859	14,656
Other (expense) income, net (note 10)	(204)	634	214	(62)
Total other income, net	<u>4,581</u>	<u>5,660</u>	<u>16,073</u>	<u>14,594</u>
Loss before income taxes	<u>(29,624)</u>	<u>(27,577)</u>	<u>(98,820)</u>	<u>(100,038)</u>
Income tax expense	(226)	(1,110)	(369)	(4,154)
Net loss	<u>(29,850)</u>	<u>(28,687)</u>	<u>(99,189)</u>	<u>(104,192)</u>
Other comprehensive income (loss):				
Unrealized income (loss) on available for sale securities, net of tax of nil (note 5)	1,905	(485)	604	(1,639)
Total other comprehensive income (loss)	<u>1,905</u>	<u>(485)</u>	<u>604</u>	<u>(1,639)</u>
Comprehensive loss	<u>\$ (27,945)</u>	<u>\$ (29,172)</u>	<u>\$ (98,585)</u>	<u>\$ (105,831)</u>
Net loss per common share (note 4):				
Basic	\$ (0.39)	\$ (0.41)	\$ (1.30)	\$ (1.53)
Diluted	\$ (0.39)	\$ (0.41)	\$ (1.30)	\$ (1.53)
Weighted-average common stock outstanding (note 4):				
Basic	76,128,531	70,575,773	76,244,893	68,212,756
Diluted	76,157,101	70,575,773	76,266,177	68,214,482

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, 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 restricted stock units ("RSUs")	—	—	—	—	224,104	1,939	—	—	(1,939)	—
Issuance of common stock for retracted exchangeable shares (note 8b)	—	—	(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
Issuance of common stock on exercise of options	—	—	—	—	154,439	1,829	—	—	(692)	1,137
Stock-based compensation	—	—	—	—	—	—	—	—	4,891	4,891
Net loss	—	—	—	—	—	—	(37,686)	—	—	(37,686)
Other comprehensive loss	—	—	—	—	—	—	—	(180)	—	(180)
Balance at June 30, 2024	1	\$ —	570,637	\$ 8,188	70,831,545	\$ 1,005,310	\$ (746,776)	\$ (7,904)	\$ 147,343	\$ 406,161
Issuance of common stock on exercise of options	—	—	—	—	495,640	8,251	—	—	(3,043)	5,208
Issuance of common stock through employee stock purchase plan	—	—	—	—	75,327	734	—	—	—	734
Issuance of common stock upon vesting of RSUs	—	—	—	—	900	32	—	—	(32)	—
Stock-based compensation	—	—	—	—	—	—	—	—	4,028	4,028
Repurchase and retirement of common stock (note 8c)	—	—	—	—	(1,818,530)	—	(21,124)	—	—	(21,124)
Excise tax on repurchase of common stock (note 8c)	—	—	—	—	—	—	(84)	—	—	(84)
Net loss	—	—	—	—	—	—	(29,850)	—	—	(29,850)
Other comprehensive income	—	—	—	—	—	—	—	1,905	—	1,905
Balance at September 30, 2024	1	\$ —	570,637	\$ 8,188	69,584,882	\$ 1,014,327	\$ (797,834)	\$ (5,999)	\$ 148,296	\$ 366,978

The accompanying notes are an integral part of these financial statements

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	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, 2023	1	\$ —	1,424,533	\$ 20,442	63,059,501	\$ 886,322	\$ (558,763)	\$ (6,659)	\$ 151,614	\$ 492,956
Issuance of common stock on exercise of options	—	—	—	—	203,239	2,649	—	—	(1,001)	1,648
Issuance of common stock through employee stock purchase plan	—	—	—	—	50,420	371	—	—	—	371
Issuance of common stock upon vesting of RSUs	—	—	—	—	2,965	132	—	—	(132)	—
Issuance of common stock for retracted exchangeable shares (note 8b)	—	—	(767,645)	(11,016)	767,645	11,016	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	2,196	2,196
Net loss	—	—	—	—	—	—	(24,353)	—	—	(24,353)
Other comprehensive income	—	—	—	—	—	—	—	720	—	720
Balance at March 31, 2023	1	\$ —	656,888	\$ 9,426	64,083,770	\$ 900,490	\$ (583,116)	\$ (5,939)	\$ 152,677	\$ 473,538
Issuance of common stock on exercise of options	—	—	—	—	202,048	2,129	—	—	(697)	1,432
Issuance of common stock upon vesting of RSUs	—	—	—	—	46,066	465	—	—	(465)	—
Issuance of common stock for retracted exchangeable shares (note 8b)	—	—	(5,500)	(79)	5,500	79	—	—	—	—
Issuance of common stock in connection with at-the-market ("ATM") program, net of issue costs (note 8a)	—	—	—	—	3,350,000	26,233	—	—	—	26,233
Stock-based compensation	—	—	—	—	—	—	—	—	742	742
Net loss	—	—	—	—	—	—	(51,152)	—	—	(51,152)
Other comprehensive loss	—	—	—	—	—	—	—	(1,874)	—	(1,874)
Balance at June 30, 2023	1	\$ —	651,388	\$ 9,347	67,687,384	\$ 929,396	\$ (634,268)	\$ (7,813)	\$ 152,257	\$ 448,919
Issuance of common stock on exercise of options	—	—	—	—	172,615	2,124	—	—	(796)	1,328
Issuance of common stock through employee stock purchase plan	—	—	—	—	61,491	584	—	—	—	584
Issuance of common stock upon vesting of RSUs	—	—	—	—	900	32	—	—	(32)	—
Issuance of common stock for retracted exchangeable shares (note 8b)	—	—	(169)	(2)	169	2	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	2,685	2,685
Net loss	—	—	—	—	—	—	(28,687)	—	—	(28,687)
Other comprehensive loss	—	—	—	—	—	—	—	(485)	—	(485)
Balance at September 30, 2023	1	\$ —	651,219	\$ 9,345	67,922,559	\$ 932,138	\$ (662,955)	\$ (8,298)	\$ 154,114	\$ 424,344

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)

	Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (99,189)	\$ (104,192)
Items not involving cash:		
Depreciation of property and equipment	3,191	5,926
Amortization of intangible assets	2,494	2,029
Stock-based compensation expense	12,771	4,732
Amortization of operating lease right-of-use assets	1,819	6,002
Impairment of acquired IPR&D (note 6)	17,287	—
Deferred income tax (recovery) expense	(436)	210
Change in fair value of contingent consideration liability	(1,878)	331
Unrealized foreign exchange gain	(588)	(384)
Changes in non-cash operating working capital:		
Accounts receivable	(4,729)	(33,873)
Prepaid expenses and other current assets	(4,159)	11,976
Accounts payable and accrued liabilities	6,997	(22,468)
Operating lease liabilities	(7,531)	(2,630)
Deferred revenue and other consideration	5,154	93
Income taxes payable	261	(9)
Net cash used in operating activities	<u>(68,536)</u>	<u>(132,257)</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock under at-the-market program and from public offerings, net of issuance costs (notes 8a)	—	26,233
Issuance of common stock on exercise of stock options	8,072	4,236
Issuance of common stock through employee stock purchase plan	930	820
Purchases of common stock for retirement	(20,624)	—
Deferred financing fees	(174)	(39)
Finance lease payments	(12)	(14)
Net cash (used in) provided by financing activities	<u>(11,808)</u>	<u>31,236</u>
Cash flows from investing activities:		
Purchases of marketable securities	(229,923)	(491,340)
Proceeds from marketable securities	277,645	287,747
Acquisition of property and equipment	(1,677)	(2,118)
Acquisition of intangible assets	(1,075)	(205)
Net cash provided by (used in) investing activities	<u>44,970</u>	<u>(205,916)</u>
Effect of exchange rate changes on cash and cash equivalents	173	357
Net change in cash and cash equivalents	<u>(35,201)</u>	<u>(306,580)</u>
Cash and cash equivalents, beginning of period	157,557	400,912
Cash and cash equivalents, end of period	<u>\$ 122,356</u>	<u>\$ 94,332</u>
<i>Supplemental disclosure of non-cash investing and financing items:</i>		
Leased assets obtained in exchange for operating lease liabilities	\$ 644	\$ 922
Acquisition of property and equipment and intangible assets in accounts payable and accrued liabilities	—	1,073
Purchases of common stock not settled	500	—

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 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, 2023.

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 and nine months ended September 30, 2024 and 2023 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, 2023.

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

The Company has reviewed recent accounting pronouncements and concluded that they are either not applicable to the business, or that no material effect is expected on the consolidated financial statements as a result of future adoption.

4. Net loss per share

Net loss per share for the three and nine months ended September 30, 2024 and 2023 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net loss attributable to common stockholders:				
Basic	\$ (29,850)	\$ (28,687)	\$ (99,189)	\$ (104,192)
Adjustment for change in fair value of liability classified stock options	(56)	—	(198)	(12)
Diluted	\$ (29,906)	\$ (28,687)	\$ (99,387)	\$ (104,204)
Denominator:				
Weighted-average common stock outstanding:				
Basic	76,128,531	70,575,773	76,244,893	68,212,756
Adjustment for dilutive effect of liability classified stock options	28,570	—	21,284	1,726
Diluted	76,157,101	70,575,773	76,266,177	68,214,482
Net loss per common share – basic	\$ (0.39)	\$ (0.41)	\$ (1.30)	\$ (1.53)
Net loss per common share – diluted	\$ (0.39)	\$ (0.41)	\$ (1.30)	\$ (1.53)

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 June 2019 and January 2020 offerings and 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 and nine months ended September 30, 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 September 30, 2024:

	Amortized Cost	September 30, 2024 Unrealized Gain (Loss)	Fair Value
Short-term marketable securities:			
Contractual maturity of one year or less:			
Guaranteed investment certificates ("GICs") and mutual funds	\$ 36,868	\$ —	\$ 36,868
U.S. Treasury notes	65,960	134	66,094
Corporate debt securities	71,932	(50)	71,882
	<u>174,760</u>	<u>84</u>	<u>174,844</u>
Long-term marketable securities:			
Contractual maturity of one to three years:			
U.S. Treasury notes	11,947	117	12,064
Corporate debt securities	65,144	459	65,603
	<u>77,091</u>	<u>576</u>	<u>77,667</u>
	<u>\$ 251,851</u>	<u>\$ 660</u>	<u>\$ 252,511</u>

The following table summarizes the Company's marketable securities as of December 31, 2023:

	Amortized Cost	December 31, 2023 Unrealized Gain (Loss)	Fair Value
Short-term marketable securities:			
Contractual maturity of one year or less:			
GICs	\$ 75,066	\$ —	\$ 75,066
U.S. Treasury notes	46,416	136	46,552
Corporate debt securities	94,900	252	95,152
	<u>216,382</u>	<u>388</u>	<u>216,770</u>
Long-term marketable securities:			
Contractual maturity of one to three years:			
Corporate debt securities	70,181	(321)	69,860
Contractual maturity of three to four years:			
Corporate debt securities	12,081	(11)	12,070
	<u>82,262</u>	<u>(332)</u>	<u>81,930</u>
	<u>\$ 298,644</u>	<u>\$ 56</u>	<u>\$ 298,700</u>

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:

	September 30, 2024				December 31, 2023			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Cash and cash equivalents:								
Cash				\$ 40,992				\$ 23,126
Cash equivalents:								
Money market funds	\$ 24,746	\$ —	\$ —	\$ 24,746	\$ 64,247	\$ —	\$ —	\$ 64,247
GICs	56,618	—	—	56,618	70,184	—	—	70,184
	<u>\$ 81,364</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 122,356</u>	<u>\$ 134,431</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 157,557</u>
Marketable securities:								
GICs and mutual funds	\$ 36,868	\$ —	\$ —	\$ 36,868	\$ 75,066	\$ —	\$ —	\$ 75,066
U.S. Treasury notes	78,158	—	—	78,158	46,552	—	—	46,552
Corporate debt securities	—	137,485	—	137,485	—	177,082	—	177,082
	<u>\$ 115,026</u>	<u>\$ 137,485</u>	<u>\$ —</u>	<u>\$ 252,511</u>	<u>\$ 121,618</u>	<u>\$ 177,082</u>	<u>\$ —</u>	<u>\$ 298,700</u>
	<u>\$ 196,390</u>	<u>\$ 137,485</u>	<u>\$ —</u>	<u>\$ 374,867</u>	<u>\$ 256,049</u>	<u>\$ 177,082</u>	<u>\$ —</u>	<u>\$ 456,257</u>

6. IPR&D and Goodwill

Acquired IPR&D

In-process research and development assets ("IPR&D") acquired in the 2016 Kairos Therapeutics Inc. ("Kairos") business combination are classified as indefinite-lived intangible assets and were not amortized until their classification as definite-lived assets. During the nine months ended September 30, 2024, the Company determined that the fair value of IPR&D, which was estimated using an income approach, was less than its carrying value. Accordingly, the Company recorded an impairment charge of \$17,287. The impairment was a result of the Company's decision to discontinue the zanidatamab zovodotin clinical development program which utilized the acquired technology represented by the IPR&D assets. As of July 1, 2024, the Company classified these assets as definite-lived and commenced amortization. The carrying value of IPR&D, net of impairment and amortization, was \$171 at September 30, 2024 (December 31, 2023: \$17,628).

Goodwill

The Company performed its most recent annual impairment test of goodwill as of December 31, 2023. 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, 2023, 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 September 30, 2024.

7. Liabilities

Accounts payable and accrued liabilities consisted of the following:

	September 30, 2024	December 31, 2023
Trade payables	\$ 3,423	\$ 6,212
Accrued research and development expenses	38,705	26,661
Employee compensation and related accruals	5,071	6,153
Fair value of liability classified stock options	833	960
Accrued legal, professional fees and other	3,675	4,436
Liability for contingent consideration (note 13)	—	1,570
	<u>\$ 51,707</u>	<u>\$ 45,992</u>

Other long-term liabilities consisted of the following:

	September 30, 2024	December 31, 2023
Liability for contingent consideration (note 13)	\$ —	\$ 308
Liability from in-licensing agreements	747	747
Finance lease liability (note 11)	33	92
Other	149	554
	<u>\$ 929</u>	<u>\$ 1,701</u>

8. Stockholders' Equity

a. Equity Offerings

2023 Private Placement

On December 28, 2023, the Company completed a private placement pursuant to which the Company sold 5,086,521 pre-funded warrants to purchase 5,086,521 shares of common stock at \$9.8299 per pre-funded warrant. The Company received gross proceeds of \$50,000 and net proceeds were \$49,862, after expenses.

2023 ATM financing

On June 16, 2023, the Company sold 3,350,000 shares of common stock pursuant to the Company's at-the-market sale program, at \$8.12 per common share. Net proceeds were \$26,233 after underwriting commissions and offering expenses.

b. 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 September 30, 2024, there were 570,637 Exchangeable Shares held by former Zymeworks BC shareholders (December 31, 2023: 651,219). 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.

c. 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 three months ended September 30, 2024, the Company repurchased 1,818,530 shares of its common stock for a cost of \$20,587, incurred an obligation to purchase common stock for a cost of \$500 which had not been settled by September 30, 2024 and incurred commission expense of \$37, 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 \$84. During the three months ended September 30, 2024, the Company retired all 1,818,530 shares repurchased. These shares were returned to the status of authorized and unissued shares.

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

	<u>Total number of shares purchased</u>	<u>Average price paid per share</u>	<u>Approximate value of shares purchased</u>
Three Months Ended September 30, 2024	1,818,530	\$ 11.32	\$ 20,587

As of October 31, 2024 the Company has completed the initial \$30,000 of the Repurchase Program for 2,545,402 shares of its common stock at an average price per share of \$11.79 (exclusive of commission expense and estimated excise tax).

d. Pre-Funded Common Share Warrants

In connection with the public offerings completed on June 24, 2019, January 27, 2020, January 31, 2022 and private placement completed on December 28, 2023 (note 8a), the Company issued a total of 13,668,482 pre-funded warrants which granted holders of warrants the right to purchase up to 13,668,482 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.

On August 23, 2022, October 25, 2022, October 27, 2022 and October 19, 2023, a total of 8,581,961 pre-funded warrants were exercised in exchange for issuance of 8,581,868 common shares. As a result of the December 28, 2023 private placement, as of September 30, 2024, there were 5,086,521 pre-funded warrants outstanding (December 31, 2023: 5,086,521).

e. Stock-Based Compensation

As of September 30, 2024, 5,516,837 shares of common stock were available for future award grants under the New Plan (December 31, 2023: 4,594,639 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 September 30, 2024, 390,000 shares of common stock were available for future award grants under this plan (December 31, 2023: 50,000).

RSUs

The following table summarizes the Company's RSU activity under the New Plan since December 31, 2023:

	Number of RSUs	Weighted-average grant date fair value (\$)
Outstanding, December 31, 2023	771,413	8.63
Granted	957,750	10.56
Vested and settled	(225,004)	8.76
Forfeited	(167,887)	10.98
Outstanding, September 30, 2024	<u>1,336,272</u>	<u>9.70</u>

As of September 30, 2024, there was \$4,984 of unamortized RSU expense that will be recognized over a weighted average period of 1.38 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, 2023	1,489,478	19.59	14.39	5.50	2,987	2,255
Granted	—	—	—			
Exercised	(174,613)	10.98	8.11			
Forfeited	(173,908)	24.76	18.15			
Outstanding, September 30, 2024	<u>1,140,957</u>	<u>20.12</u>	<u>14.78</u>	<u>4.91</u>	<u>4,251</u>	<u>3,143</u>

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, 2023	6,069,242	12.97	7.67	9,213
Granted	2,647,075	10.63		
Exercised	(678,984)	9.70		
Forfeited	(1,020,571)	17.18		
Outstanding, September 30, 2024	<u>7,016,762</u>	<u>11.80</u>	<u>8.10</u>	<u>19,081</u>

During the nine months ended September 30, 2024, the Company received cash proceeds of \$8,072 from stock options exercised.

The stock options outstanding at September 30, 2024 expire at various dates from January 1, 2025 to September 9, 2034.

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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development expense	\$ 2,171	\$ 1,317	\$ 6,477	\$ 677
General and administrative expense	2,381	647	6,022	3,790

The amounts above include stock-based compensation expense relating to RSUs of \$1,602 and \$4,260 for the three and nine months ended September 30, 2024 (2023: \$795 and \$2,538).

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:

	Nine Months Ended September 30,	
	2024	2023
Dividend yield	0 %	0 %
Expected volatility	64.7 %	68.9 %
Risk-free interest rate	4.03 %	3.86 %
Expected average life of options	6.04 years	5.92 years

The weighted-average Black-Scholes option pricing assumptions for liability classified stock options outstanding at September 30, 2024 and 2023 are as follows:

	September 30, 2024	September 30, 2023
Dividend yield	0 %	0 %
Expected volatility	41.7 %	72.6 %
Risk-free interest rate	2.90 %	4.80 %
Expected average option term	0.97 years	1.52 years
Number of liability classified stock options outstanding	295,794	503,166

At September 30, 2024, the unamortized compensation expense related to unvested options was \$12,030. The remaining unamortized compensation expense as of September 30, 2024 will be recognized over a weighted-average period of 1.73 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Jazz:				
Development support payments	\$ 764	\$ 2,478	\$ 3,939	\$ 50,544
Drug supply for ongoing studies	5,266	7,559	15,467	16,952
Other drug supply	6,032	5,391	13,356	8,919
Credit for program amendments	—	—	—	(20,100)
BeiGene, Ltd. ("BeiGene"):				
Milestone revenue	—	—	8,000	—
Drug supply	1,438	632	1,843	819
Development support payments	—	267	—	487
GlaxoSmithKline Intellectual Property Development Ltd. ("GSK")				
Milestone revenue	2,500	—	2,500	—
Research support and other payments from other partners	—	179	168	1,465
	<u>\$ 16,000</u>	<u>\$ 16,506</u>	<u>\$ 45,273</u>	<u>\$ 59,086</u>

Since December 31, 2023, there have not been any material changes to the key terms of our collaboration and license agreements.

In July 2024, the Company recognized \$2,500 of milestone revenue from GSK in relation to the sequence pair nomination by GSK under the 2016 licensing agreement between the Company and GSK.

In June 2024, the Company recognized \$8,000 of milestone revenue from BeiGene in relation to the acceptance by the CDE of the NMPA in China of the BLA for zanidatamab for second-line treatment of HER2-positive BTC.

Contract Assets and Liabilities

As at September 30, 2024, contract assets from research, collaboration and licensing agreements were nil (December 31, 2023: nil) and contract liabilities were \$41,795 (December 31, 2023: \$36,640). As at September 30, 2024 and December 31, 2023, \$27,188 and \$3,699 respectively, of the contract liabilities is classified as short-term. Contract liabilities relate to deferred revenue from the BeiGene and Jazz agreements.

10. Other (expense) income, net

Other (expense) income, net, consists of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Foreign exchange (loss) gain, net	\$ (167)	\$ 264	\$ 179	\$ (631)
Other	(37)	370	35	569
	<u>\$ (204)</u>	<u>\$ 634</u>	<u>\$ 214</u>	<u>\$ (62)</u>

11. Leases

The lease for our Vancouver location, 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 December 2024 and August 2027. In addition, the Company has commitments for future operating lease payments of \$804 under a lease agreement for office space which will commence on January 1, 2025, with an expiry date of June 30, 2026, that is not included in the table below. 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:

	September 30, 2024	December 31, 2023
Operating lease liabilities:		
Current portion	\$ 2,943	\$ 4,261
Long-term portion	17,274	22,369
Total operating lease liabilities	20,217	\$ 26,630
Finance lease liabilities:		
Current portion included in other current liabilities	28	30
Long-term portion included in other long-term liabilities	33	92
Total finance lease liabilities	61	122
Total lease liabilities	\$ 20,278	\$ 26,752
Weighted average remaining lease term:		
Operating leases	6.6 years	6.7 years
Weighted average discount rate:		
Operating leases in U.S. dollars	5.4 %	3.6 %
Operating leases in Canadian dollars	4.8 %	4.8 %

Cash paid for amounts included in the measurement of operating lease liabilities for the three and nine months ended September 30, 2024 was \$973 and \$3,195, respectively, and were included in net cash used in operating activities in the consolidated statement of cash flows. In addition, on April 4, 2024, the Company terminated its long-term facility lease in Seattle, pursuant to which the Company paid \$6,075 as a termination fee.

As of September 30, 2024, the maturities of the Company's operating lease liabilities were as follows:

	Operating leases
Within 1 year	\$ 3,818
1 to 2 years	3,658
2 to 3 years	3,637
3 to 4 years	3,117
4 to 5 years	2,926
Thereafter	6,408
Total operating lease payments	<u>23,564</u>
Less:	
Imputed interest	<u>(3,347)</u>
Operating lease liabilities	<u>\$ 20,217</u>

The cost components of the operating leases were as follows for the three and nine months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Lease expenses:				
Operating lease expense	\$ 749	\$ 4,675	\$ 1,723	\$ 6,010
Variable lease expense	463	358	1,484	1,193
Termination of long-term facility lease in Seattle, net	—	—	1,033	—
	<u>\$ 1,212</u>	<u>\$ 5,033</u>	<u>\$ 4,240</u>	<u>\$ 7,203</u>

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 September 30, 2024, 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 September 30, 2024, the maximum exposure to credit risk for accounts receivable was \$23,704, 80% of which was from Jazz (December 31, 2023: \$19,477) and all accounts receivable are due within the next 12 months. As at September 30, 2024 and December 31, 2023, 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 September 30, 2024, the Company's net monetary liabilities denominated in Canadian dollars were \$3,189 (C\$4,313).

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.

In connection with the Company's 2016 Kairos acquisition, the Company may be required to make future payments of up to an aggregate of C\$8,500, consisting of (i) a C\$2,500 payment when the first patient is dosed in the first Phase 2 trial and (ii) a C\$6,000 payment when the first patient is dosed in the first Phase 3 trial, to CDRD Ventures Inc. ("CVI") upon the direct achievement of certain development milestones for products incorporating certain Kairos intellectual property (such as zanidatamab zovodotin or other product candidates using our ZymeLink technology). In addition, CVI is eligible to receive low single-digit royalty payments from the Company on the net sales of such products. For out-licensed products and technologies incorporating certain Kairos intellectual property, the Company may also be required to pay CVI a mid-single digit percentage of certain future revenue. As of September 30, 2024, the contingent consideration had an estimated fair value of nil, which has been recorded within liabilities (note 7) on the Company's consolidated balance sheet (December 31, 2023: \$1,878). The contingent consideration was calculated using a probability weighted assessment of the likelihood of the milestones being met, a probability adjusted discount rate that reflects the stage of the development and time to complete the development. Contingent consideration is a financial liability and measured at its fair value at each reporting period, with any changes in fair value from the previous reporting period recorded within research and development expenses in the statement of loss and comprehensive loss.

The following table presents the changes in fair value of the Company's liability for contingent consideration:

	Liability at the beginning of the period	Increase / (decrease) in fair value of liability for contingent consideration	Amounts paid or transferred to payables	Liability at end of the period
Three months ended September 30, 2024	\$ —	\$ —	\$ —	\$ —
Nine months ended September 30, 2024	\$ 1,878	\$ (1,878)	\$ —	\$ —

The following tables present information about the Company's liability for contingent consideration measured at fair value on a recurring basis, and indicate the fair value hierarchy of the valuation technique used to determine such fair value:

	December 31, 2023	Level 1	Level 2	Level 3
Liability for contingent consideration	\$ 1,878	\$ —	\$ —	\$ 1,878
	<u>\$ 1,878</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,878</u>

The Company used the following assumptions to estimate fair value of contingent consideration liability as of September 30, 2024 and December 31, 2023:

	September 30, 2024	December 31, 2023
Weighted assessment of the likelihood of the milestones	0.0 %	33.5 %
Weighted average estimated period for achievement of milestones	0.00 years	0.92 years
Discount rate	17.0 %	17.0 %

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.

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, 2023 included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the “SEC”) on March 6, 2024 and with the securities commissions in all provinces and territories of Canada on March 6, 2024. 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. 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.

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 synergistic activity, which we believe will result in improved patient outcomes. Our platforms include:

- **Azymmetric**, 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 antibody-drug conjugate (“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;
- **EFFECT**, 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.

Zanidatamab is a novel bispecific antibody that targets two distinct domains of the human epidermal growth factor receptor 2 (“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, granting to each of them exclusive rights to develop and commercialize zanidatamab in different territories. Jazz Pharmaceuticals Ireland Limited and Jazz Pharmaceuticals, Inc. (“Jazz Inc.”) are both subsidiaries of Jazz Pharmaceuticals plc. Jazz Pharmaceuticals Ireland Limited, Jazz Inc. and Jazz Pharmaceuticals plc are referred to herein collectively as “Jazz”. For additional information regarding these agreements with BeiGene and Jazz, see the section titled “Strategic Partnerships and Collaborations” below. In May 2024, our partner Jazz announced that the FDA accepted and granted Priority Review of the Biologics License Application (“BLA”) for zanidatamab for the treatment of previously treated, unresectable, locally advanced, or metastatic HER2-positive (“HER2+”) biliary tract cancers (“BTC”). Under the Prescription Drug User Fee Act (“PDUFA”), the FDA has set a target action date of November 29, 2024. Jazz has also confirmed that the European Medicines Agency (“EMA”) has validated the Marketing Authorization Application (“MAA”) for zanidatamab in second-line (2L) BTC. Jazz has initiated a Phase 3 confirmatory trial for zanidatamab as first-line treatment in BTC. Based on the expected timeline and subject to approval, Jazz expects to launch zanidatamab for 2L BTC in the United States in the fourth quarter of 2024. Similarly, our partner BeiGene announced that the Center for Drug Evaluation (“CDE”) of the National Medical

Products Administration (“NMPA”) in China accepted the BLA for zanidatamab for second-line treatment of HER2+ BTC. Jazz is also evaluating zanidatamab for the first-line treatment of HER2+ unresectable locally advanced or metastatic gastroesophageal adenocarcinomas (“GEA”). The pivotal HERIZON-GEA-01 trial is ongoing and Jazz has estimated top-line progression-free survival (“PFS”) data will be available in the second quarter of 2025. In July 2024, Jazz announced that it had initiated the Phase 3 EmpowHER-BC-303 trial to evaluate zanidatamab plus chemotherapy or trastuzumab plus chemotherapy in patients with HER2+ breast cancer whose disease has progressed on previous trastuzumab deruxtecan (T-DXd) treatment.

Our early-stage programs include novel ADC and multispecific antibody therapeutics (“MSAT”) candidates focusing on validated 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) T cell engager 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.

Our early-stage pipeline currently includes four candidates which have been nominated for development:

- **ZW191**, a clinical-stage ADC that targets folate receptor alpha (“FR α ”)-expressing tumors including ovarian, other gynecological, and non-small cell lung cancer (“NSCLC”), is built using our drug conjugate platforms, including our novel bystander active TOPO1i-based payload technology. A drug-antibody-ratio (“DAR”) of eight was selected, as well as a moderate stability antibody-linker, to balance tolerability and efficacy. The FR α monoclonal antibody (“mAb”) incorporated in ZW191 was generated in-house and selected based on enhanced internalization characteristics to enable targeting of high, mid, and low levels of FR α expression. FR α is a clinically validated target, and data supports its expression in approximately 75% of high-grade serous ovarian carcinomas and in 70% of NSCLC. Preclinical data is encouraging, demonstrating strong activity across a range of FR α -expressing patient-derived xenografts and superior internalization, payload delivery and tissue penetration compared to multiple FR α mAbs from other ADCs. ZW191 has achieved a highest non-severely toxic dose in non-human primates of 60 mg/kg, which presents a compelling profile and enables the expectation of achieving an efficacious dose level in the Phase 1 clinical trial. The IND application for ZW191 has been cleared by the FDA. The Company is actively recruiting patients in the 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 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.
- **ZW171**, a clinical-stage multispecific antibody built using our Azymetric platform, is a novel 2 + 1 format T cell engaging multispecific antibody 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 T cell engager technology. In preclinical studies, ZW171 has demonstrated in vivo potent preferential killing of MSLN-overexpressing target cells and stimulation MSLN-dependent T cell activation, mitigating the risk of on-target-off tumor toxicity and 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. In October 2024, we announced the first patient dosed in the Phase 1 clinical trial for ZW171. The global Phase 1, open-label, multicenter study of ZW171, registered under NCT06523803 on [clinicaltrials.gov](#), is expected to enroll approximately 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.
- **ZW220**, an ADC that targets sodium-dependent phosphate transporter 2b (“NaPi2b”)-expressing NSCLC and ovarian cancer, and is built, like ZW191, using our proprietary TOPO1i-based payload technology. The NaPi2b-targeting monospecific antibody incorporated in ZW220 was developed in-house and selected based on a favorable binding profile and enhanced internalization properties to enable targeting of both high- and low-expressing NaPi2b-expressing tumors. A DAR of four was selected, as well as a moderate stability antibody-linker, to balance tolerability and efficacy, with the fragment crystallizable (“Fc”) gamma receptor being silenced with the goal to minimize potential toxicities associated with this target. NaPi2b is expressed in approximately 96% of ovarian and 87% of NSCLC, with anti-tumor activity being demonstrated in patient-derived cell lines and growth inhibition in 3D spheroid NSCLC models (data generated using ZW220 that had a wildtype Fc region of the antibody). The bystander effect of the TOPO1i payload may help

address NaPi2b heterogeneity across different cancers. Preclinical data demonstrate high tolerability in animal studies with MTD ≥ 90 mg/kg in non-human primates and ≥ 200 mg/kg in rats, suggesting potential for high doses in humans.

- **ZW251**, a potential first-in-class ADC molecule designed for the treatment of glypican 3 (“GPC3”)-expressing hepatocellular carcinoma (“HCC”), which incorporates the same Zymeworks proprietary bystander-active TOPO1i payload utilized in ZW191 (anti-FR α) and ZW220 (anti-NaPi2b). A DAR of four was selected, as well as a moderate stability antibody-linker, to balance tolerability and efficacy. 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. 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 non-human primate studies, ZW251 displayed significant tolerability at doses up to 120 mg/kg, suggesting the possibility of high initial dosing in human trials. We are encouraged by published research demonstrating the potential of GPC3-targeting antibody in HCC patients as evidenced by tumor localization of iodine radiolabeled condrituzumab, a prior clinical-stage anti-GPC3 mAb, and believe that ADC-based targeting of GPC3 could enable a novel and effective approach to treatment of HCC.

We have received FDA clearance for our IND applications for ZW171 and ZW191, and Phase 1 studies for both candidates are now actively recruiting. Similarly, we expect to submit INDs and non-U.S. applications for ZW220 in the first half of 2025, and ZW251 in the second half of 2025. Beyond this, we aim to nominate the preclinical candidate for our fifth development program during 2024, and intend to submit an IND and non-U.S. applications for this candidate in the first half of 2026.

We maintain ongoing discovery efforts to identify and test new target combinations, product candidates and platform technologies that have the potential to address unmet medical needs. We have developed multiple early-stage product candidates targeting a combination of known and novel tumor antigens based on our platform technologies. All of these candidates remain unencumbered. We continue to focus on advancing multiple well-differentiated product candidates into clinical trials to build our pipeline portfolio as well as exploiting our protein engineering and ADC expertise to develop innovative product candidates.

Our goal is to use our experience and in-house capabilities of developing multifunctional therapeutics platforms, along with our proprietary protein engineering capabilities, to improve the standard of care for people living with difficult-to-treat cancers and other serious diseases with high unmet medical need.

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. We have not generated any revenue from the sale of approved products as of September 30, 2024, and 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 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 September 30, 2024, we received \$1,002.2 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 September 30, 2024, we had \$374.9 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 short-term investments as of September 30, 2024 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 \$99.2 million for the nine months ended September 30, 2024 and through September 30, 2024, we had an accumulated deficit of \$797.8 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.

Recent Developments

Zanidatamab Clinical Program

In September 2024, our partner Jazz announced new and updated presentations at ESMO 2024 on zanidatamab highlighting its potential for the first-line treatment of multiple HER2+ indications. The presentations included:

- Efficacy and tolerability findings from an ongoing, open-label Phase 2 study (NCT03929666) evaluating zanidatamab in combination with chemotherapy as first-line treatment for patients with HER2-expressing metastatic GEA, which comprises gastric, esophageal and gastroesophageal junction adenocarcinomas. Data from 41 patients with HER2+ metastatic GEA who were treated with zanidatamab in combination with physician's choice of chemotherapy treatment demonstrated a median progression-free survival (mPFS) of 15.2 [95% CI: 9.5, 33.4] months. After a median duration of follow-up of 41.5 (range, 23.0-52.7) months, the median overall survival was not mature, a Kaplan-Meier-estimated 24-month overall survival was 65% [95% CI: 48.0, 78.0] and the 30-month overall survival was 59% [95% CI: 41.0, 73.0].
- A mini-oral presentation from another arm of the Phase 2, open-label trial (NCT03929666) that includes a cohort of patients with metastatic colorectal cancer treated with first-line zanidatamab plus chemotherapy ± bevacizumab ("bev"). In 11 response-evaluable patients, there were 10 confirmed partial responses and one patient with stable disease as a best response. The confirmed objective response rate ("cORR") was 91% (95% CI: 58.7, 99.8) and median duration of response was not reached (2.9+, 16.7+ months). All patients experienced treatment related adverse events ("TRAEs") – Grade 3-4 TRAEs occurred in five (38%) patients, three (23%) of whom experienced diarrhea. No patients discontinued zanidatamab due to a TRAE and there were no treatment-related deaths. Zanidatamab plus chemotherapy ± bev demonstrated encouraging anti-tumor activity with a generally manageable safety profile as first-line treatment for patients with HER2+ metastatic colorectal cancer.
- A poster presentation on the trial design for the ongoing, global, Phase 3, randomized, open-label trial (NCT06282575) investigating the efficacy and safety of zanidatamab with cisplatin and gemcitabine ("CisGem") versus CisGem alone ± a programmed cell death protein-1/ligand 1 (PD-1/L1) inhibitor (pembrolizumab or durvalumab at physician's discretion if locally approved) as first-line treatment for patients with advanced HER2+ BTC. The primary endpoint is PFS in patients with immunohistochemistry ("IHC") 3+ tumors. Secondary/exploratory endpoints include: overall survival (IHC 3+ subgroup; overall population), PFS (overall population), cORR, incidence and severity of adverse events and patient-reported outcomes. The study is currently recruiting patients.

Early-Stage Programs

In October 2024, we announced that the first patient has been dosed in the first-in-human Phase 1 trial (NCT06523803) to evaluate the safety and tolerability of the investigational therapy ZW171 in the treatment of advanced or metastatic ovarian cancer, NSCLC, and other MSLN-expressing cancers. The Phase 1 study is a two-part, open-label, multi-center study that is expected to enroll approximately 160 adult patients with advanced MSLN-expressing cancers. Part 1 of the study will evaluate the safety and tolerability of ZW171 and involve dose escalation in patients with advanced ovarian and NSCLC, with secondary endpoints assessing pharmacokinetics and confirmed objective response rate. Part 2 of the study will involve dose expansion in three cohorts (ovarian cancer, NSCLC, and a basket cohort enrolling patients with any MSLN-expression) and will evaluate the anti-tumor activity of ZW171, with primary endpoints focused on safety and tolerability and secondary endpoints assessing PFS, duration of response rates, and overall survival. The Company expects to conduct the Phase 1 study at investigator sites in North America, Europe, and the Asia-Pacific region.

In October 2024, Zymeworks presented preclinical data at the European Organisation for Research and Treatment of Cancer-National Cancer Institute-American Association for Cancer Research Conference on two ADC product candidates, ZW220 and ZW251, both of which are scheduled for IND filings in 2025. Presentations included:

- An oral presentation titled "ZW220, a NaPi2b-directed topoisomerase I inhibitor Antibody-Drug Conjugate, demonstrates compelling preclinical activity in NSCLC, ovarian and uterine cancer models, with a favorable toxicology profile in non-human primates"; and
- A poster presentation titled "ZW251, a novel glypican-3-targeting antibody-drug conjugate bearing a topoisomerase I inhibitor payload, demonstrates compelling preclinical activity in hepatocellular carcinoma models".

Other Matters

- As of September 30, 2024, we have completed the repurchase of 1,818,530 shares of our common stock under the Repurchase Program announced in August 2024 at an average price per share of \$11.32 (exclusive of commission expense and estimated excise tax) for a cost of \$20.6 million. As of October 31, 2024 we have completed the initial

\$30.0 million of the Repurchase Program for 2,545,402 shares of common stock at an average price per share of \$11.79 (exclusive of commission expense and estimated excise tax).

- On October 15, 2024, Hollings C. Renton submitted his resignation from our board of directors, including as chair and member of the board of directors' compensation committee, effective December 10, 2024 (the date of our 2024 Annual General Meeting of Stockholders). Mr. Renton's resignation was not the result of any disagreement with the Company on any matter relating to the Company's operations, policies or practices.
- We will host an in-person and virtual R&D day in New York, NY on December 12, 2024. A live webcast of the event will be available via the Investor section of our company website and will begin at 8:30 am Eastern Time. As part of the event, we will feature in-depth presentations including:
 - Updates on our portfolio of solid tumor targeting antibody-drug conjugates and T-cell engager molecules, featuring key opinion leaders from these therapeutic areas who will join our management team to discuss ongoing R&D and clinical activities;
 - Candidate nomination from our Trispesific TCE platform as the last product candidate selected in our '5 by 5' R&D strategy with a projected IND application filing in the first half of 2026; and
 - Strategy and rationale for expansion into new therapeutic areas in hematological cancers and autoimmune and inflammatory diseases and preclinical development progress on potential IND applications for new product candidates in 2026 and beyond.

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 lead programs for zanidatamab and zanidatamab zovodotin, we have received \$446.0 million through September 30, 2024 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 September 30, 2024, we remain eligible to receive up to \$1.55 billion in potential regulatory, development and commercial milestone payments, as well as tiered royalties on potential future product sales, pending receipt of regulatory approval. 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 described above, as of September 30, 2024, we have received \$181.0 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 and Celgene Alpine Investment Co. LLC (now a Bristol-Myers Squibb company, "BMS"), GlaxoSmithKline Intellectual Property Development Limited ("GSK"), Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo"), Janssen Biotech, Inc. ("Janssen"), Iconic Therapeutics, Inc. ("Iconic"), and Merck Sharp & Dohme Research GmbH ("Merck"). As of September 30, 2024, 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 utilizing our platforms.

There have not been any material changes to the key terms of any of our licensing and collaboration agreements since December 31, 2023. 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, 2023.

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 and milestone payments 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 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 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. 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 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, 2023.

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 and nine months ended September 30, 2024 as compared to what has been described in our most recent annual consolidated financial statements except as disclosed in note 8c to the interim 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 September 30, 2024 within this Quarterly Report on Form 10-Q.

Results of Operations for the Three and Nine Months Ended September 30, 2024 and 2023

Revenue

(dollars in millions)	Three Months Ended September 30,		Increase/ (Decrease)	Nine Months Ended September 30,		Increase/ (Decrease)		
	2024	2023		2024	2023			
Revenue from research and collaborations	\$ 16.0	\$ 16.5	\$ (0.5)	(3)%	\$ 45.3	\$ 59.1	\$ (13.8)	(23)%

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

Total revenue decreased by \$0.5 million in the three months ended September 30, 2024 compared to the same period in 2023. Revenue for the three months ended September 30, 2024 included \$12.1 million for development support and drug supply revenue from Jazz and \$2.5 million of milestone revenue from GSK in relation to the sequence pair nomination under the 2016 licensing agreement, and \$1.4 million of drug supply revenue from BeiGene. Revenue for the same period in 2023 included \$15.4 million for development support and drug supply revenue from Jazz, \$0.9 million of development support and drug supply revenue from BeiGene and \$0.2 million from our partners for research support and other payments.

Total revenue decreased by \$13.8 million in the nine months ended September 30, 2024 compared to the same period in 2023. Revenue for the nine months ended September 30, 2024 included \$32.8 million for development support and drug supply revenue from Jazz, \$8.0 million of milestone revenue from BeiGene in relation to the acceptance by the CDE of the NMPA in China of the BLA for zanidatamab for second-line treatment of HER2+ BTC, \$2.5 million of milestone revenue from GSK in relation to the sequence pair nomination under the 2016 licensing agreement, \$1.8 million from BeiGene for research support payments and \$0.2 million from our partners for research support and other payments. Revenue for the same period in 2023 included \$76.4 million for development support and drug supply revenue from Jazz, which was partially offset by a \$20.1 million credit, issued to Jazz

for contractual amendments to our partnership arrangement, and \$2.8 million from BeiGene and our other partners for research support and other payments. The decrease in revenue from Jazz reflects the transfer of responsibility for certain clinical trials regarding zanidatamab to Jazz pursuant to the Transfer Agreement (as defined below) and the Amended Jazz Collaboration Agreement, with such future costs to be borne by Jazz instead of being incurred by us and reimbursed by Jazz.

Research and Development Expense

(dollars in millions)	Three Months Ended September 30,		Increase/ (Decrease)	Nine Months Ended September 30,		Increase/ (Decrease)		
	2024	2023		2024	2023			
Third-party research and development program expenses:								
Zanidatamab	\$ 2.0	\$ 1.7	\$ 0.3	18 %	\$ 7.4	\$ 43.2	\$ (35.8)	(83)%
Zanidatamab zovodotin	1.1	1.7	(0.6)	(35)%	5.4	4.8	0.6	13 %
ZW171	1.9	7.2	(5.3)	(74)%	5.3	9.6	(4.3)	(45)%
ZW191	1.9	4.9	(3.0)	(61)%	5.5	8.9	(3.4)	(38)%
ZW220	4.9	0.1	4.8	4,800 %	11.7	0.6	11.1	1,850 %
ZW251	3.5	0.1	3.4	3,400 %	6.1	0.6	5.5	917 %
Other preclinical and research programs	4.9	2.8	2.1	75 %	11.0	6.8	4.2	62 %
	20.2	18.5	1.7	9 %	52.4	74.5	(22.1)	(30)%
Unallocated departmental research and development expenses:								
Salaries and benefits	8.6	6.7	1.9	28 %	25.3	26.7	(1.4)	(5)%
Stock-based compensation expense	2.2	1.3	0.9	69 %	6.7	0.7	6.0	857 %
Other unallocated expenses	5.4	6.3	(0.9)	(14)%	13.2	16.2	(3.0)	(19)%
Research and development expense ⁽¹⁾	\$ 36.4	\$ 32.8	\$ 3.6	11 %	\$ 97.6	\$ 118.1	\$ (20.5)	(17)%

⁽¹⁾ Excluding zanidatamab and zanidatamab zovodotin, we expect research and development expenditures to increase over time, subject to periodic fluctuations, in line with the advancement, expansion and completion of the clinical development of our product candidates, support of our ongoing collaborations, and our ongoing clinical and preclinical research activities.

Research and development expense increased by \$3.6 million for the three months ended September 30, 2024 compared to the same period in 2023. The increase in research and development expense was primarily due to an increase in expenses for ZW220 and ZW251 and other preclinical and research activities, which were partially offset by a decrease in expenses for ZW171 and ZW191. Salaries and benefits and stock-based compensation expense in 2024 increased primarily due to an increase in headcount in 2024 compared to same period in 2023.

Research and development expense decreased by \$20.5 million for the nine months ended September 30, 2024 compared to the same period in 2023. The decrease in research and development expense was primarily due to a decrease in expenses for zanidatamab, as a result of transfer of responsibility for this program to Jazz per our Transfer Agreement and the Amended Jazz Collaboration Agreement, and a decrease in expenses for ZW171 and ZW191. This decrease, compared to the same period in 2023, was partially offset by an increase in expenses for ZW220 and ZW251 and other preclinical and research activities. Stock-based compensation expense increased primarily due to a lower expense in 2023 as a result of the cancellation and modification of awards in respect of employees transferred to Jazz per the Transfer Agreement.

Our research and development expenses relating to zanidatamab, following the May 2023 transfer of responsibility for the zanidatamab development program to Jazz, have decreased compared to the three and nine months ended September 30, 2023. We expect to continue incurring research and development expenses for activities over which we maintain responsibility under the Amended Jazz Collaboration Agreement and for costs of third party services and other expenses under certain contracts being transferred to Jazz pursuant to the Transfer Agreement. We are eligible for reimbursement of these expenses from Jazz and expect to recognize these reimbursements as revenue from research and collaborations. We similarly expect that research and development expenses relating to zanidatamab zovodotin will decrease in future periods following our decision to discontinue the zanidatamab zovodotin clinical development program.

General and Administrative Expense

(dollars in millions)	Three Months Ended September 30,		Increase/ (Decrease)	Nine Months Ended September 30,		Increase/ (Decrease)		
	2024	2023		2024	2023			
Salaries and benefits	\$ 3.7	\$ 3.9	\$ (0.2)	(5)%	\$ 12.5	\$ 13.1	\$ (0.6)	(5)%
Stock-based compensation expense	2.4	0.6	1.8	300 %	6.1	3.8	2.3	61 %
Professional fees, consulting and business insurance	4.4	6.0	(1.6)	(27)%	14.9	22.2	(7.3)	(33)%
Other general and administrative expenses	3.4	6.5	(3.1)	(48)%	11.8	16.5	(4.7)	(28)%
General and administrative expense	<u>\$ 13.9</u>	<u>\$ 17.0</u>	<u>\$ (3.1)</u>	<u>(18)%</u>	<u>\$ 45.3</u>	<u>\$ 55.6</u>	<u>\$ (10.3)</u>	<u>(19)%</u>

General and administrative expense decreased by \$3.1 million for the three months ended September 30, 2024 compared to the same period in 2023. The decrease in general and administrative expense was primarily due to a decrease in external consulting expenses for information technology, legal fees and insurance, as well as depreciation and amortization expenses compared to the same period in 2023. This was partially offset by an increase in stock-based compensation expenses compared to the same period in 2023, primarily due to the reversal of compensation expense due to options cancellations in 2023.

General and administrative expense decreased by \$10.3 million for the nine months ended September 30, 2024 compared to the same period in 2023. The decrease in general and administrative expense was primarily due to a decrease in external consulting expenses for information technology, legal fees, and other expenses for advisory services, insurance and depreciation and amortization expenses compared to the same period in 2023. This was partially offset by costs incurred due to the termination of our long-term facility lease in Seattle in 2024 and an increase in stock-based compensation expense over 2023, primarily due to reversal of compensation expense for options cancellations and modifications in 2023.

Impairment on Acquired IPR&D

(dollars in millions)	Three Months Ended September 30,		Increase/ (Decrease)	Nine Months Ended September 30,		Increase/ (Decrease)		
	2024	2023		2024	2023			
Impairment on acquired IPR&D	\$ —	\$ —	\$ —	—%	\$ 17.3	\$ —	\$ 17.3	100 %

During the nine months ended September 30, 2024, we recorded an impairment charge of \$17.3 million as a result of our decision to discontinue the zanidatamab zovodotin clinical development program which utilized the technology represented by acquired IPR&D assets.

Other Income, net

(dollars in millions)	Three Months Ended September 30,		Increase/ (Decrease)	Nine Months Ended September 30,		Increase/ (Decrease)		
	2024	2023		2024	2023			
Other income, net	\$ 4.6	\$ 5.7	\$ (1.1)	(19)%	\$ 16.1	\$ 14.6	\$ 1.5	10 %

Other income, net decreased by \$1.1 million for the three months ended September 30, 2024 compared to the same period in 2023. Other income, net for 2024 included \$4.8 million in interest income partially offset by \$0.2 million in net foreign exchange loss and other miscellaneous expense. Other income, net for the three months ended September 30, 2023 included \$5.0 million in interest income and a \$0.6 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 2023.

Other income, net increased by \$1.5 million for the nine months ended September 30, 2024 compared to the same period in 2023. Other income, net for 2024 included \$15.9 million in interest income and \$0.2 million in net foreign exchange gain and other miscellaneous income. Other income, net for the nine months ended September 30, 2023 included \$14.7 million in interest income partially offset by a \$0.1 million in net loss which includes foreign exchange loss and other miscellaneous income. The increase in interest income was primarily driven by an increase in the average interest yields of these investments during the period.

Income Tax

	Three Months Ended September 30,		Increase/ (Decrease)	Nine Months Ended September 30,		Increase/ (Decrease)		
	2024	2023		2024	2023			
(dollars in millions)								
Income tax expense	\$ 0.2	\$ 1.1	\$ (0.9)	(82)%	\$ 0.4	\$ 4.2	\$ (3.8)	(90)%

Income tax expense decreased by \$0.9 million and \$3.8 million for the three and nine months ended September 30, 2024, respectively, compared to the same periods in 2023, primarily due to a reduction in U.S. taxes under the global intangible low-taxed income rules and Subpart F income rules.

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 November, 2022, we entered into a sales agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co. (“Cantor”) 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 Cantor would act as our sales agent. In June 2023, we sold an aggregate of 3,350,000 shares of common stock at \$8.12 per share under the Sales Agreement. We received gross proceeds of \$27.2 million and net cash proceeds of \$26.2 million, after underwriting commissions and offering expenses. On July 29, 2024, we notified Cantor of our decision to terminate the Sales Agreement effective July 31, 2024.

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.

On December 28, 2023, we completed a private placement pursuant to which we sold 5,086,521 pre-funded warrants at a price of \$9.8299 per pre-funded warrant. We received gross proceeds of \$50.0 million, and net proceeds of \$49.9 million, after expenses. Each pre-funded warrant is exercisable for one share of common stock at an exercise price of \$0.0001 per share, subject to adjustments as provided under the terms of the pre-funded warrants.

As of September 30, 2024, we had \$374.9 million of cash, cash equivalents, and marketable securities, comprised of \$122.4 million in cash and cash equivalents and \$252.5 million in marketable securities.

Cash Flows

The following table represents a summary of our cash flows for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,	
	2024	2023
(dollars in millions)		
Net cash (used in) provided by:		
Operating activities	\$ (68.5)	\$ (132.3)
Investing activities	45.0	(205.9)
Financing activities	(11.8)	31.2
Effect of exchange rate changes on cash and cash equivalents	0.2	0.4
Net change in cash and cash equivalents	\$ (35.2)	\$ (306.6)

Operating Activities

During the nine months ended September 30, 2024, cash used in operating activities was \$68.5 million compared to \$132.3 million for the same period in the prior year. The decrease in net cash used in operating activities was primarily due to a decrease in cash expenditures for operations as a result of transfer of responsibility over the zanidatamab program to Jazz and favorable movements in working capital compared to the same period in the prior year. This was partly offset by an increase in payments for our other preclinical and clinical product candidates.

Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2024 primarily related to net proceeds from marketable securities of \$47.7 million and cash outflows of \$2.8 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. Net cash used in investing activities for the nine month period ended September 30, 2023 primarily related to net purchases of marketable securities of \$203.6 million and cash outflows of \$2.3 million for the acquisition of property and equipment in relation to our office and lab spaces in Canada.

Financing Activities

Net cash used in financing activities for the nine months ended September 30, 2024 included \$20.6 million used for the Repurchase Program partially offset by net proceeds of \$8.1 million from stock option exercises and \$0.9 million from the issuance of shares of common stock under our employee stock purchase plan. Net cash provided by financing activities for the nine months ended September 30, 2023 included net proceeds of \$26.2 million from our share issuance pursuant to the Sales Agreement, net proceeds of \$4.2 million from stock option exercises and \$0.8 million from the issuance of shares of common stock in relation to our employee stock purchase plan.

Funding Requirements

We have not generated any revenue from approved product sales as of September 30, 2024 and do not expect to do so until such time as we obtain regulatory approval and commercialize one or more of our 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 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 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. 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. The timing, number of shares repurchased, and prices paid for the shares 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 amount 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, should any of such drug candidates 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 October 30, 2024, 68,877,526 shares of common stock were issued and outstanding. In addition, as of October 30, 2024, we had 5,086,521 shares of common stock issuable pursuant to 5,086,521 pre-funded warrants, 3,770,708 shares of common stock issuable pursuant to

3,770,708 exercisable outstanding stock options, 4,281,673 shares of common stock issuable pursuant to 4,281,673 outstanding options that were not exercisable at that date, and 1,303,708 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 note 1 of our interim condensed consolidated financial statements as of and for the quarter ended September 30, 2024, within this Quarterly Report on Form 10-Q.

As of October 30, 2024, 853,896 Exchangeable Shares have been exchanged on a one-to-one basis for 853,896 shares of our common stock and 570,637 Exchangeable Shares are held by former Zymeworks BC shareholders and are exchangeable on a one-to-one basis, subject to adjustment, for up to 570,637 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 September 30, 2024, 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 September 30, 2024 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 September 30, 2024, 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 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, all of which are still in preclinical or clinical development. If we do not obtain regulatory approval of one or more 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; no regulatory agency has made any determination that any of our product candidates are safe or effective for use by the general public for any indication.
- We face significant competition, and if our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.
- If any of our product candidates receive regulatory approval, the approved products may not achieve broad market acceptance among physicians, patients, the medical community and third-party payors, in which case revenue generated from their 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 may be required to limit commercialization of our product candidates.

- 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 to commercialize any products that we or our strategic partners develop and affect the prices we may obtain.
- We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We have no products approved for commercial sale, and, as of September 30, 2024, we have not generated any revenue or profit from product sales. 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.
- 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 approved 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 effective tax rate may change in the future.
- 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, all of which are still in preclinical or clinical development. If we do not obtain regulatory approval of one or more of our product candidates, or experience significant delays in doing so, our business will be materially adversely affected.

We currently have no products approved for sale or marketing in any country, and may never be able to obtain regulatory approval for any of our product candidates. As a result, we are not currently permitted to market any of our product candidates in the United States or in any other country until we obtain regulatory approval from the FDA or comparable regulatory authorities outside the United States. Our product candidates are in preclinical or clinical development and we have not submitted an

application, or received marketing approval, for any of our product candidates. Obtaining regulatory approval of our product candidates will depend on many factors, including:

- completing clinical trials that demonstrate the efficacy and safety of our product candidates;
- 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 and maintaining adequate commercial manufacturing arrangements 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.

We have not previously submitted a BLA to the FDA or similar marketing applications to foreign health authorities. 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. Positive or timely results from preclinical or early-stage trials do not ensure positive or timely results in late-stage clinical trials or product approval by the FDA or comparable regulatory authorities outside the United States. 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. 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. For example, a number of companies in the pharmaceutical industry have suffered significant setbacks in late-stage clinical trials, even after obtaining promising results in earlier-stage clinical trials. Similarly, interim results of a clinical trial do not necessarily predict final results.

There is a high failure rate for biopharmaceutical products proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical trials even after achieving promising results in earlier stage clinical trials. 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 during the period of product development. For example, the FDA's Oncology Center of Excellence initiated Project Optimus to reform the dose optimization and dose selection paradigm in oncology drug development and Project FrontRunner to help develop and implement strategies to support approvals in the early clinical setting, among other goals. How the FDA plans to implement those goals and their impact on specific clinical programs and the industry are unclear.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA or foreign health authorities may disagree with the design, implementation or data analyses of our clinical trials;
- the FDA or foreign health authorities may determine that our product candidate(s) do not have adequate risk-benefit ratio or have undesirable or unintended side effects, toxicities or other characteristics that preclude our 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 we seek approval;
- the FDA or foreign health authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our 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 with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or foreign health authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Additionally, 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 also complied with all applicable U.S. laws and regulations. If the FDA does not accept the data from any clinical trials we conduct 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 our development of any future product candidates.

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

We currently have three clinical-stage product candidates, including zanidatamab, ZW171 and ZW191. Our partner Jazz has been responsible for the conduct of ongoing and future zanidatamab trials since May 2023, and is currently evaluating this product candidate in Phase 1, Phase 2, and Phase 3 clinical trials, including certain ongoing pivotal clinical trials. In May 2024, Jazz announced that the FDA accepted and granted Priority Review of the BLA for zanidatamab for the treatment of previously treated, unresectable, locally advanced, or metastatic HER2+ biliary tract cancer. Under the PDUFA, the FDA has set a target action date of November 29, 2024. Following a strategic review of our emerging wholly-owned pipeline, we decided to discontinue the zanidatamab zovodotin clinical development program.

Following the transfer of the zanidatamab development program to Jazz and the discontinuation of our zanidatamab zovodotin clinical development program, we have been 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 are actively progressing with additional submissions in selected non-U.S. countries in relation to our Phase 1 study sites in North America, Europe, and the Asia-Pacific region.

We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during clinical development, and, because our product candidates are in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, particularly because early trials have smaller numbers of subjects tested. In addition, it is not uncommon for product candidates to exhibit unforeseen safety or efficacy issues, such as immunogenicity, when tested in humans despite promising results in preclinical animal models.

Any clinical trials that we may conduct may not demonstrate the safety and efficacy profiles necessary to obtain regulatory approval to market our product candidates. As we continue developing our product candidates, serious adverse events, undesirable side effects, or unexpected characteristics may emerge, causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the risk-benefit ratio is more acceptable.

Patients treated with our product candidates 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. In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to a variety of factors, including, but not limited to, changes in 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.

The commencement or completion of these planned clinical trials could be substantially delayed or prevented 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 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;
- 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 current good manufacturing practices (“cGMP”) regulations or other applicable requirements, or cross-contaminations of product candidates in the manufacturing process;

- the need to repeat or terminate clinical trials as a result of inconclusive or negative results or unforeseen complications in testing;
- our clinical trials may be suspended or terminated upon a breach or 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; 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.

We could also experience delays in physicians enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments or other clinical trials. Furthermore, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted, the Data Monitoring Committee for such trial, or by the FDA or foreign health authorities due to a number of factors, including failure to conduct the clinical trial 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. 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.

Securing regulatory approval also requires the submission of information about the manufacturing processes and inspection of manufacturing facilities by the relevant regulatory authority. The FDA or foreign health authorities may fail to approve our manufacturing processes or facilities, whether run by us or our contract manufacturing organizations. In addition, if we make manufacturing changes to our product candidates in the future, we may need to conduct additional preclinical and/or clinical studies to bridge our modified product candidates to earlier versions.

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 for our product candidates would adversely affect our ability to obtain regulatory approval, and our commercial prospects and ability to generate product revenue will be diminished.

In addition, even if the 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 that 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 those 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 the following:

- generating sufficient data to support the initiation or continuation of clinical trials;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- the timely manufacture of sufficient quantities of the product candidate for use in clinical trials; and
- adverse events in the clinical trials.

Even if we successfully advance any other product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this “Risk Factors” section. Accordingly, 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 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.

In addition, the U.S. federal Right to Try Act, among other things, provides a federal 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 also 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.

In addition, 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 we have 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. 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. Additionally, 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. Although Jazz and we have met with the FDA to discuss the data readout from the HERIZON-BTC-01 study in support of submitting a BLA for zanidatamab in patients with previously treated HER2 gene-amplified BTC, the receipt of a Breakthrough Therapy designation for a product candidate may not ultimately result in a faster development process or review, and it does not in any way assure approval of a product candidate by the FDA. In addition, 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 the zanidatamab 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 designation 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 Center for Drug Evaluation 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.

In May 2024, Jazz announced that the FDA accepted and granted Priority Review of the BLA for zanidatamab for the treatment of previously treated, unresectable, locally advanced, or metastatic HER2+ biliary tract cancer. Under the PDUFA, the FDA has set a target action date of November 29, 2024. The FDA may not approve the BLA by the PDUFA date or may raise issues or deficiencies during its review of the BLA.

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

Even if any of our product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, the EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own 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 cancer 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 cancer 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 used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the cost of combination therapies are 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, 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 diagnostic marketing clearance or approval could delay the drug approval.

In particular, on April 13, 2020, the FDA issued new guidance on developing and labeling companion diagnostics for a specific group of oncology therapeutic products, including recommendations to support a broader labeling claim rather than individual therapeutic products. In June 2023, the FDA announced a new voluntary pilot program through which drug manufacturers can provide to the FDA the diagnostic test performance information used to enroll patients into clinical trials for drug approval. Based on assessment of the performance information, the FDA will publish the minimum performance characteristics recommended for similar tests that may be used to select patients for treatment with the approved drug to help laboratories identify specific biomarkers for their development of laboratory-developed tests (“LDTs”), and to ensure more consistent performance of these tests for drug selection and improved cancer patient care. In May 2024, FDA issued a final rule that phases out its enforcement discretion for most LDTs and amends the FDA’s regulations to make explicit that in vitro diagnostics are medical devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the diagnostic product is a laboratory. We will continue to evaluate the impact of this rule on our companion diagnostic development and strategy. Any future issuances from the FDA and other regulatory authorities, including changes in the FDA’s regulation of diagnostic tests and LDTs, may impact our development of a companion diagnostic for our product candidates and result in delays in regulatory approval. We may be required to conduct additional studies to support a broader claim. Also, to the extent other approved diagnostics are able to broaden their labeling claims to include our approved drug products, we may be forced to abandon any of our companion diagnostic development plans, or we may not be able to compete effectively upon approval, which could adversely impact our ability to generate revenue from the sale of our approved products and our business operations.

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 caused by funding shortages or global health concerns 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. Disruptions at the FDA and other agencies, including delays or disruptions due to pandemics or other health crises, travel restrictions, staffing shortages, government shutdowns and furloughs, may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect 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. For example, following a strategic review of our emerging wholly-owned pipeline, we decided to discontinue the clinical development program of zanidatamab zovodotin, our HER2-targeted antibody-drug conjugate, to focus on the development of our early-stage programs, which we believe have the potential to be best-in-class and/or first-in-class drugs. While we continue to explore partnering and other alternatives for zanidatamab zovodotin, we cannot be certain that we will be successful in these efforts.

Additionally, 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; no regulatory agency has made any determination that any of our product candidates are safe or effective for use by the general public for any indication.

All of our product candidates are still in preclinical or clinical development. Consequently, all of our product candidates are required to undergo ongoing safety testing in humans as part of clinical trials. 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. No regulatory agency has made any such determination that any of our product candidates are safe or effective for use by the general public for any indication.

If any of our product candidates receive marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require us to take our approved product 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 may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we 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 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 currently 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 both 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 all 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, 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 cancer 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.

In addition, we expect to compete with biosimilar versions of already approved products, and even if our 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 any of our product candidates receive regulatory approval, the approved products may not achieve broad market acceptance among physicians, patients, the medical community and third-party payors, in which case revenue generated from their sales would be limited.

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

- limitations or warnings contained in the approved labeling for a product candidate;
- changes in the standard of care for the targeted indications for any of our product candidates;
- limitations in the approved clinical indications for our product candidates;
- demonstrated clinical safety and efficacy compared to other products;
- sales, marketing and distribution support;
- availability of coverage and extent of 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, including generic, biosimilar and over-the-counter products;
- the extent to which the product candidate 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 our product candidates or favorable publicity about competitive products;
- convenience and ease of administration of our products; and
- potential product liability claims.

If any of our product candidates are approved, but 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 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 has granted Orphan Drug Designation to zanidatamab for the treatment of BTC and gastric cancer, including cancer of the gastroesophageal junction, the EMA has 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 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.

Even if orphan drug exclusivity for zanidatamab is obtained, or is obtained for any 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. On January 24, 2023, the FDA published a notice in the Federal Register to clarify that while the agency 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. 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 products 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 for us 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 region to region 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. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in 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, whether internally or with third parties, 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.

We cannot be certain that our clinical trials will be initiated and completed on time, if at all, or whether our planned clinical strategy will be acceptable to the FDA or foreign health authorities. To become and remain profitable, we must develop, obtain approval for and eventually commercialize products, if approved, that generate significant revenue. In addition, it is not uncommon for product candidates to exhibit unforeseen safety issues or inadequate efficacy when tested in humans despite promising results in preclinical animal models or earlier trials, and we may ultimately be unable to demonstrate adequate safety and efficacy of our product candidates to obtain marketing approval. 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.

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. In many jurisdictions, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. 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. Additionally, 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 of our approved products.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act (“MMA”), changed the way Medicare covers and pays for pharmaceutical products. The legislation established Medicare Part D, which expanded Medicare coverage for outpatient prescription drug purchases by the elderly but provided authority for limiting the number of drugs that will be covered in any therapeutic class. The MMA also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. 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. Various industry stakeholders, including pharmaceutical companies, the U.S. Chamber of Commerce, the National Infusion Center Association, the Global Colon Cancer Association, and the Pharmaceutical Research and Manufacturers of America, 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, 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.

If the market opportunities for any product that we or our strategic partners develop are smaller than we believe they are, our revenue may be adversely affected and our business may suffer.

We intend to initially focus our independent product candidate development on treatments for oncology. Our projections of addressable patient populations that have the potential to benefit from treatment with our product candidates are based on estimates. If our projections are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business.

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 as of the date of this report have resulted in a pipeline of product candidates directed at various cancers, we may not be able to develop product candidates that are safe and effective. In addition, 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 that 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 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. 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. In June 2024, the U.S. Supreme Court overruled the *Chevron* doctrine, which gives deference to regulatory agencies’ statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This landmark Supreme Court decision may invite more companies and other stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, including the FDA’s statutory interpretations of market exclusivities and the “substantial evidence” requirements for drug approvals, which could undermine the FDA’s authority, lead to uncertainties in the industry, and disrupt the FDA’s normal operations, any of which could delay the FDA’s review of our regulatory submissions. We cannot predict the full impact of this decision, 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 the FDA-approved labeling, although healthcare professionals are permitted to use drug products for off-label uses. The FDA, the Department of Justice, the Inspector General of the Department of Health and Human Services, among other government agencies, actively enforce 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 our 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 may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability lawsuits related to the testing of our product candidates in seriously ill patients, and will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. 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 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 future approved products;
- injury to our reputation;
- 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 our product candidates.

We may need to have in place increased product liability coverage when we begin the commercialization of our product candidates. Insurance coverage is becoming increasingly expensive. As a result, 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 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 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 our opportunity to receive or maintain regulatory approval to market our product candidates, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our product candidates, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals 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 or any of our third-party manufacturers encounter manufacturing difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, 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. If contaminants are discovered in our supply of our 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 product candidates will not occur in the future. 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 for using, handling, storing and disposing of these materials 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.

Material modifications in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through preclinical to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize 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. Additionally, future acquisitions or dispositions could result in potentially 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.

Many governments impose strict price controls, which may adversely affect our future profitability.

In many countries, particularly those in the European Union ("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.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we or our strategic partners might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenue that is generated from the sale of the product in that country. If reimbursement of such product candidates is unavailable or limited in scope or amount, if pricing is set at unsatisfactory levels, or if there is competition from lower priced cross-border sales, our profitability will be negatively affected.

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 utilizing 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 utilize 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, or other breaches, incidents, outages, interruptions, compromises or vulnerabilities due to 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 such as the conflict between Russia and Ukraine. Any such breach, incident, outage, interruption, compromise or vulnerability 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, prevention of access to, disclosure, or dissemination of, or 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 processed or maintained 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 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, outages, interruptions, compromise or vulnerabilities. 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, prevention of access to, disclosure, or dissemination of, or 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 upon entities subject to the law, such as health plans, healthcare clearinghouses and healthcare providers and their respective business associates and subcontractors that perform services for them that involve individually identifiable health information. Mandatory penalties for HIPAA violations can be significant, and criminal and monetary penalties, as well as injunctive relief, may be imposed for HIPAA violations. Although most drug manufacturers are not directly subject to HIPAA, prosecutors are increasingly using HIPAA-related theories of liability against drug manufacturers and their agents and we also 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, in the event of a breach as defined by HIPAA, HIPAA regulations impose specific reporting requirements to regulators, individuals impacted by the breach and, in some cases, the media. Issuing such notifications can be costly, time and resource intensive, and can generate significant negative publicity. Breaches of HIPAA may also constitute contractual violations that could lead to contractual damages or terminations. In addition to HIPAA, other applicable data privacy and security obligations, including U.S. state data breach notification laws, 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.

In addition, we may face increased cybersecurity risks due to our reliance on internet technology given that we have employees at five office locations (Vancouver, British Columbia; Bellevue, Washington; Dublin, Ireland; Singapore; and Redwood City, California) and at a co-working space in Cambridge, UK, as well as a significant number of employees who work remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities.

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 on January 1, 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 for data breaches, which may increase the volume of data breach litigation. In addition, the California Privacy Rights Act of 2020, which went into effect on January 1, 2023, expanded the CCPA by, among other things, giving California residents the ability to limit use of certain sensitive personal information, establishing restrictions on personal information retention, expanding the types of data breaches subject to the CCPA’s private right of action, and establishing a new California Privacy Protection Agency to implement and enforce the new 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, including such laws in Colorado, Connecticut, Delaware, Florida, Indiana, Iowa, Kentucky, Maryland, Minnesota, Montana, Nebraska, New Hampshire, New Jersey, Oregon, Rhode Island, Tennessee, Texas, Utah, and Virginia. Further, Washington also has enacted the My Health, My Data Act, which, among other things, provides for a private right of action. While limited exemptions to some of these laws may apply to portions of our business, the recency of these laws’ enactment and evolving interpretations of these laws 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 United Kingdom (“UK”), and Switzerland have adopted privacy and security protection laws and regulations that impose significant compliance obligations. Laws and regulations in these jurisdictions apply broadly to the collection, use, storage, disclosure, processing, and security of information that identifies or may be used to identify an individual, such as names, contact information, and sensitive personal information such as health data. 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 many requirements for controllers and processors of personal information, including, for example, higher standards for obtaining consent from individuals to process their personal information, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for 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 processors in connection with the processing of the personal information. The GDPR allows EEA countries to make additional laws and regulations further limiting the processing of genetic, biometric or health data. Failure to comply with the requirements of the GDPR and the applicable national privacy and security laws of EEA countries may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties; we may also be liable should any individual who has suffered financial or non-financial damage arising from our infringement of the GDPR exercise their right to receive compensation against us. Furthermore, adverse publicity relating to our failure to comply with the GDPR could cause a loss of goodwill, which could have an adverse effect on our reputation, brand, business and financial condition. Additionally, 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 data localization laws and cross-border personal information transfer laws. 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. On July 10, 2023, the European Commission adopted its adequacy decision for the EU-U.S. Data Privacy Framework. The decision concludes that the United States ensures an adequate level of protection – comparable to that of the European Union – for

personal information transferred from the EU to U.S. companies under the framework. Based on this new adequacy decision, personal information can flow from the EU to U.S. companies participating in the EU-U.S. Data Privacy Framework, without having to put in place additional data protection safeguards. While we are not certified under the EU-U.S. Data Privacy Framework, we 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 the enhanced due diligence obligations on data exporters and importers to ensure that the laws of the country to which the personal information is transferred offer a level of data protection that is essentially equivalent to the EEA and the UK. 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 international transfers of data. Additionally, 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 and the UK, 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 and cybersecurity requirements that may apply to our business. For instance, we are taking steps to assess our exposure to the EU NIS2 Directive 2022/2555. The NIS2 Directive requires organizations of a certain size providing certain services, including in the health sector, to adopt appropriate cybersecurity risk-management measures and to report certain cybersecurity incidents. EU countries must apply the requirements of the NIS2 Directive as of October 18, 2024. Failure to comply with the requirements of the NIS2 Directive may result in sanctions, including administrative fines of up to €10,000,000 or 2% of worldwide annual turnover, whichever is greater, for large organizations.

Separate from, and in addition to, requirements under the GDPR and UK GDPR, certification requirements for the hosting of health data will vary by jurisdiction. To the extent we operate in various EEA countries or the UK, there might be other national healthcare regulations or regulatory requirements with which we will be required to comply. 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 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. In addition, 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 to commercialize any products that we or our strategic partners develop and affect the prices we may obtain.

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 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 1, 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 United States 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 Biden 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 1, 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, with the exception of a temporary suspension implemented under various COVID-19 relief legislation. 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 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 will 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. Additionally, in July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to Biden’s executive order, on September 9, 2021, the Department of Health and Human Services (“HHS”) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. 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, 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. 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 as well as future actions and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. 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, in January 2024 the FDA authorized the state of Florida to import certain prescription drugs from Canada for a period of two years 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 our 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 to what extent 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. In addition, increased scrutiny by Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as 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.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the 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. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-approval testing and other requirements.

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, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Unstable or unfavorable global market and economic conditions may have adverse consequences on our business, financial condition and stock price.

Global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in the rate of inflation and uncertainty about economic stability. We cannot assure you that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our business, financial condition, and stock price may be adversely affected by any such economic downturn, volatile business environment, or large-scale unpredictable or unstable market conditions, including a prolonged government shutdown, geopolitical events such as the conflict between Russia and Ukraine and the conflicts in Israel and the Gaza Strip and the broader Middle East, or a global pandemic such as the COVID-19 pandemic.

If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

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

Our business is subject to risks associated with conducting business internationally. We have physical operations and personnel in Canada, the United States, Ireland and Singapore, and maintain offices in these four countries. We also have personnel in the UK, who have access to a co-working space in the UK. In addition, 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 Gaza Strip 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 non-U.S. regulations and customs, tariffs and trade barriers, including any changes that China may impose as a result of political tensions between Canada and China or the United States and China;
- regulatory changes and economic conditions following the UK's withdrawal from the EU and uncertainty related to the terms of the withdrawal;

- changes in non-U.S. currency exchange rates and currency controls;
- 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, including the COVID-19 pandemic, 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, 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, legislative proposals have been passed by the House of Representatives and have been referred to the Senate 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. Further, 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. In addition, we cannot predict what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

Our business has been and may continue to be adversely affected by public health outbreaks and pandemics.

Our business has been and may in the future be adversely affected by public health outbreaks and pandemics, such as the COVID-19 pandemic. The COVID-19 pandemic had a broad adverse impact on the global economy across many industries and resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions and business shutdowns, as well as significant volatility in global financial markets. In May 2023, the federal government ended the COVID-19 public health emergency, which ended a number of temporary changes made to federally funded programs while some continue to be in effect.

If a public health outbreak, pandemic, or a resurgence of COVID-19 cases and related disruptions were to occur, 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;
- further delays or difficulties in enrolling patients in our ongoing and planned clinical trials;
- patients discontinuing their treatment or follow-up visits;
- further 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. In addition, public health outbreaks, pandemics, or a resurgence of COVID-19 cases 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 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 products for which we obtain marketing approval. 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 (as defined above) 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. Additionally, 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 United Kingdom 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 no products approved for commercial sale, and, as of September 30, 2024, we have not generated any revenue or profit from product sales. We may never achieve or sustain profitability.

We are a clinical-stage biopharmaceutical company. We have incurred significant losses since our inception. Our net loss for the year ended December 31, 2023 was \$118.7 million, while our net income for the year ended December 31, 2022 was \$124.3 million, which was driven in large part by our entry into the Original Jazz Collaboration Agreement (as defined below) and the receipt of certain payments thereunder, and we do not anticipate being net income positive on a regular basis for the foreseeable future. Our net loss for the nine months ended September 30, 2024 was \$99.2 million. As of September 30, 2024, our accumulated deficit was \$797.8 million. 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 September 30, 2024, 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.

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.

To become and remain profitable, we 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 that is significant enough to achieve profitability. 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.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty. We have never generated any revenue from product sales and may never be profitable.

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. We and our partners are still developing our product candidates, and we have not completed development of any products. Our revenue as of September 30, 2024 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. Our ability to generate revenue and achieve profitability depends in large part on our ability, alone or with our strategic partners, to achieve milestones and to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize, product candidates. We do not anticipate generating revenue from sales of products in the near term.

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 three clinical-stage product candidates, including zanidatamab, ZW171 and ZW191. Our partner Jazz has been responsible for the conduct of ongoing and future zanidatamab trials since May 2023, and is currently evaluating this product candidate in Phase 1, Phase 2, and Phase 3 clinical trials, including certain ongoing pivotal clinical trials. Following a strategic review of our emerging wholly-owned pipeline, we decided to discontinue the zanidatamab zovodotin clinical development program. Following the transfer of the zanidatamab development program to Jazz and the discontinuation of the zanidatamab zovodotin clinical development program, we have been focused on the development of our early-stage product candidates and general discovery efforts. 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. In November 2022, we entered into the Sales Agreement with Cantor 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 Cantor would act as our sales agent. On June 16, 2023, we sold an aggregate of 3,350,000 shares of common stock under the Sales Agreement for net proceeds of \$26.2 million, after underwriting commissions and offering expenses. On July 29, 2024, we notified Cantor of our decision to terminate the Sales Agreement effective July 31, 2024. In August 2024, we entered into the Cowen Sales Agreement with 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. 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. In addition, on December 23, 2023, we entered into a securities purchase agreement for a private placement with certain institutional accredited investors affiliated with EcoR1 Capital, LLC of 5,086,521 pre-funded warrants to purchase 5,086,521 shares of our common stock for an aggregate purchase price of \$50.0 million. 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 may have to include additional amounts in income under the so-called "global intangible low-taxed income" regime or as a result of the application of "controlled foreign corporation" rules. In addition, 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. 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. Pursuant to the terms of the agreement, we received a \$50 million upfront payment following receipt of HSR Clearance and delivery of licenses and technology transfer to Jazz and a further payment of \$325 million following Jazz's decision to continue the collaboration after readout of the top-line clinical data from HERIZON-BTC-01. We were also eligible to receive additional milestone payments upon achievement of certain regulatory and commercial milestones, as well as tiered royalties on Jazz's net sales of licensed products.

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 (the “Closing”), 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, are 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 are directly borne by Jazz instead of being incurred by us and charged back to Jazz for reimbursement, though Zymeworks BC will remain 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;
- 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.

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, Janssen, Iconic 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, Janssen, Iconic 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.

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 a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future 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, as were experienced during the COVID-19 pandemic, 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 did not suffer any direct, material negative impacts from these supply chain disruptions, we cannot be certain that we will not be impacted by similar 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. In addition, 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.

In addition, 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. If our products or our strategic partners’ products incorporate any Fab or Fc region mutations 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, and we are unable to invalidate or render unenforceable those patents, 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 that is 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.

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. 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. 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 U.S. Patent and Trademark Office (“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 then 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 U.S. 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. In addition, 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.

For our U.S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, also known as the America Invents Act (“AIA”), was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation.

The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business. 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.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

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.

Additionally, the requirements for patentability may differ in certain countries. For example, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United

States, there is no link between regulatory approval of a drug and its patent status. In addition to 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, the United States, Canadian, and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have a predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. 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. While we monitor our use of open source software and try to ensure that none is used in a manner that would require us to disclose our proprietary source code or that would otherwise breach the terms of an open source agreement, such use could inadvertently occur, or could be claimed to have occurred, in part because open source license terms are often ambiguous. 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. In addition, 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 could, if not properly addressed, negatively affect our business. We have established processes to help alleviate these risks, including a review process for the use of open source software, but we cannot be sure that all of our use of open source software is in a manner that is consistent with our current policies and procedures, or will not subject

us to liability. Any of these risks could be difficult to eliminate or manage and, if not 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. Although we currently do not have any products on the market, we may be subject, and if our product candidates are approved and we begin commercialization 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.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by HITECH, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates-independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, and newly empowered state attorneys general with the authority to enforce HIPAA. In January 2013, the Office for Civil Rights of the U.S. Department of Health and Human Services issued the Final Omnibus Rule under HIPAA pursuant to HITECH that makes significant changes to the privacy, security and breach notification requirements and penalties. The Final Omnibus Rule generally took effect in September 2013 and enhances certain privacy and security protections, and strengthens the government's ability to enforce HIPAA. The Final Omnibus Rule also enhanced requirements for both covered entities and business associates regarding notification of breaches of unsecured protected health 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.

Additionally, the PPACA also included the federal Physician Payments Sunshine Act, which 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 information related to certain payments or other transfers of value made in the previous year to covered recipients, including physicians, as defined by law, and teaching hospitals and, effective for data reported in 2022, expanded to include nurse practitioners, physician assistants, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives, 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.

Also, 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.

As a result of the Redomicile Transactions, we became a Delaware corporation on October 13, 2022 following the completion of an arrangement under the Business Corporations Act (British Columbia). 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.

In addition, we incurred a number of non-recurring costs associated with the Redomicile Transactions, including legal fees, accountants' fees, proxy solicitor fees, filing fees, mailing expenses and financial printing expenses. The completion of 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. The success of the Redomicile Transactions will depend, in part, on our ability to realize the anticipated benefits associated with the Redomicile Transactions and associated reorganization of our corporate structure, and we may not be able to realize such benefits on a timely basis or at all.

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. In connection with the transactions contemplated by the Transfer Agreement in May 2023, certain of our clinical operations personnel and other personnel with later-stage development experience were transferred to Jazz. 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. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. 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 September 30, 2024, we had 294 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. Additionally, as our product candidates enter and advance through preclinical studies and any clinical trials, we may need to expand 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 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 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 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, 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.

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. Some of the factors that may cause the market price of our common stock to fluctuate or decrease 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, including our and Jazz's ability and efforts to collaborate to develop and commercialize zanidatamab in the territories covered by the Amended Jazz Collaboration Agreement;
- our ability to achieve milestones and receive associated milestone payments pursuant to the terms of our collaboration agreements;
- 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;
- changes in estimates or recommendations by securities analysts that cover our common stock;
- 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;
- 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 any of our product candidates, if approved, to achieve commercial success;
- economic and other external factors or other disasters or crises, including pandemics;
- 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;
- overall fluctuations in U.S. equity markets;
- purchases under our Repurchase Program; and
- other factors that may be unanticipated or out of our control.

In addition, 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. 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.

Our common stock was first listed on the New York Stock Exchange (the “NYSE”) in connection with the completion of the Redomicile Transactions on October 13, 2022. In December 2022, we moved our listing to The Nasdaq Stock Market LLC (“Nasdaq”). 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 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 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 decreased ability to issue additional securities or obtain additional financing in the future.

Substantial future sales of our common stock, or the perception that these sales could occur, may cause the price of our common stock to drop significantly, even if our business is performing well.

A large volume of sales of our common stock could decrease the prevailing market price of our common stock and could impair our ability to raise additional capital through the sale of equity securities in the future. Even if a substantial number of sales of our common stock does not occur, the mere perception of the possibility of these sales could depress the market price of our common stock and have a negative effect on our ability to raise capital 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, including proceeds received from our strategic collaboration with Jazz and pursuant to any “at-the-market” equity offering programs we may use from time to time, 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. However, 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 to be received from our fundraising efforts or for the funds received from time to time pursuant to our strategic collaborations. In addition, the amount, allocation and timing of our actual expenditures will depend upon numerous factors, including additional milestone payments received from our strategic partnerships and royalties received on sale of any future approved product. Accordingly, we will have broad discretion in using these proceeds. 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, including our results of operations, financial position, capital requirements, distributable reserves, credit terms, general economic conditions and other factors as our board of directors may deem relevant from time to time. Consequently, 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, beneficially own approximately 49.3% of our outstanding common stock as of September 30, 2024. Our current directors and executive officers beneficially own, in the aggregate, approximately 1.6% of our outstanding common stock as of September 30, 2024. 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 have recently qualified 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 shares less attractive to investors.

As a result of our public float (the market value of our shares of common stock held by non-affiliates) as of June 30, 2024 and our revenue for 2023, we qualify as a “smaller reporting company,” as defined under the Exchange Act. For as long as we continue to be a smaller reporting company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies that are not smaller reporting companies.

In addition, beginning with our Annual Report on Form 10-K for the year ending December 31, 2024, we will be a “non-accelerated filer” as defined under the Exchange Act. For as long as we continue to be a non-accelerated filer, we are eligible to take advantage of 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. For our Annual Report on Form 10-K for the year ending December 31, 2024, we expect to rely on this exemption and not obtain an attestation from our independent registered public accounting firm. Our decision to rely on this exemption 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.

If we choose to rely on any of these disclosure exemptions, the information we provide shareholders will be different than the information that is available with respect to other public companies. Moreover, if some investors find our common shares less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common shares and the market price of our common shares 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.

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 in the capital of our subsidiary 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.

In addition, 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 provides 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 its 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 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 October 31, 2024, 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 the stock 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 amount 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.

General Risk Factors

We are at risk of securities class action litigation.

Securities class action litigation has often been brought against companies following a decline in the market price of their securities. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. 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.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We cannot assure that analysts will cover us or provide accurate or favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion of our common stock negatively, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline. Moreover, the research and reports that analysts publish may suggest a price for our common stock that does not fully or accurately reflect the true value of our company. Furthermore, even if such analyst publications are favorable, these reports could have negative consequences for us.

The increasing focus on environmental, social, and governance ("ESG") initiatives could impact our business and reputation.

There has been increasing public focus by investors, environmental activists, the media and governmental and nongovernmental organizations on a variety of environmental, social, and governance and other sustainability matters, such as climate change and diversity, equity, and inclusion. A variety of organizations measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. If we are not effective in addressing environmental, social, and governance matters affecting our business, or setting and meeting relevant sustainability goals, our reputation may suffer. In addition, even if we are effective at addressing such concerns, we may experience increased costs related to execution and monitoring, which could have an adverse impact on our business.

In addition, emphasis on environmental, social and other sustainability matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements with the SEC and applicable Canadian securities regulators. If additional rules regarding ESG matters are adopted or if investors continue to increase their focus on ESG matters, we could incur substantially higher costs in our efforts to comply and cannot be certain that our efforts will be viewed as adequate.

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. In the third quarter of 2024, shares of common stock purchased under the authorization consisted of the following:

Period	Total number of shares purchased	Average price paid per share ⁽¹⁾	Total number of shares purchased as part of publicly announced plans or programs	Approximate dollar value of shares that may yet be purchased under publicly announced plans or programs (in millions)
July 1, 2024 - July 31, 2024	—	\$ —	—	\$ —
August 1, 2024 - August 31, 2024	1,024,005	10.60	1,024,005	49.1
September 1, 2024 - September 30, 2024	794,525	12.25	794,525	39.4
	<u>1,818,530</u>	<u>\$ 11.32</u>	<u>1,818,530</u>	<u>\$ 39.4</u>

(1) Average price paid per share excludes commission expense and estimated excise tax.

As of October 31, 2024, we have completed the initial \$30.0 million of the Repurchase Program for 2,545,402 shares of our common stock at an average price per share of \$11.79 (exclusive of commission expense and estimated excise tax).

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 #	Employment Agreement between Zymeworks Biopharmaceuticals Inc. and Leone Patterson, dated July 19, 2024 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 25, 2024).
10.2#	Amended and Restated Inducement Stock Option and Equity Compensation Plan (and forms of award agreements thereunder) (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on July 25, 2024).
10.3	Sales Agreement, dated August 2, 2024, by and between the Company and TD Securities (USA) LLC (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on August 2, 2024).
10.4	Direction to Tenants, dated July 9, 2024, from 130 E 4th(2) Partnership, 130 E 4th Property Inc., and 114 East 4th Avenue, LLC to Tenants of 114 East 4th Avenue, Vancouver, BC
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 September 30, 2024, formatted in Inline XBRL (Inline eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of September 30, 2024 (unaudited) and December 31, 2023 (audited), (ii) Condensed Consolidated Statements of Loss and Comprehensive Loss for the three and nine month periods ended September 30, 2024 and 2023 (unaudited), (iii) Condensed Consolidated Statement of Changes in Stockholders' Equity for the three and nine month periods ended September 30, 2024 and 2023 (unaudited), (iv) Condensed Consolidated Statements of Cash Flows for the nine month period ended September 30, 2024 and 2023 (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.

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: October 31, 2024

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: October 31, 2024

DIRECTION TO TENANTS

FROM: 130 E 4th(2) Partnership (the “**Vendor**”)

AND FROM: 130 E 4th Property Inc. (the “**Nominee**”)

AND FROM: 114 East 4th Avenue, LLC (the “**Purchaser**”)

TO: Tenants of 114 East 4th Avenue, Vancouver, BC (commonly known as “**M2**”)

RE: Sale of 114 East 4th Avenue, Vancouver, BC, and legally described as Parcel Identifier: 030-712-181, Lot A Block 24 District Lot 200A Group 1 New Westminster District Plan EPP83574 (the “**Property**”)

Please be advised as follows:

1. Effective **July 9, 2024**, the Property was conveyed by the Vendor to the Purchaser and your lease was assigned to 1000937483 Ontario Inc.
2. You are hereby directed to pay all rent and other payments that become payable after, as of, from and including July 9, 2024 to the Purchaser or as the Purchaser may direct.
3. Until otherwise notified by the Purchaser, cheques should be made payable to:

Westbank Pacific Realty Corp.
6th Floor-1067 West Cordova Street
Vancouver, BC V6C 1C7

Attention: Property Management

Telephone: 604-416-3929

This Direction may be signed in counterparts and may be signed by facsimile or other means of electronic communications producing a printed copy, each of which so signed shall be deemed to be an original, and such counterparts together shall constitute one and the same instrument.

[Signature page follows]

Executed by the Vendor, the Nominee and the Purchaser as of the date first written above.

130 E 4th(2) PARTNERSHIP, by its partners
2000 MAIN HOLDINGS INC.

Per: /s/ Judy Leung
Authorized Signatory

**MOUNT PIXEL PROJECTS LIMITED
PARTNERSHIP**, by its general partner,
1038324 B.C. LTD.

Per: /s/ Ryan Holmes
Authorized Signatory

114 EAST 4th AVENUE, LLC

Per: /s/ John S. Grassi
Authorized Signatory

130 E 4th PROPERTY INC.

Per: /s/ Judy Leung
Authorized Signatory

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: October 31, 2024

/s/ Kenneth Galbraith

Chief Executive Officer

**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: October 31, 2024

/s/ Leone Patterson

Chief Financial Officer

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 September 30, 2024 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: October 31, 2024

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.

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 September 30, 2024 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: October 31, 2024

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.