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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2020

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: 001-38068

ZYMEWORKS INC.

(Exact name of registrant as specified in its charter)

British Columbia, Canada	**47-2569713**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

Suite 540—1385 West 8th Avenue
Vancouver, BC V6H 3V9
(Address of principal executive offices, including zip code)

(604) 678-1388
(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 Shares, no par value per share	ZYME	New York Stock Exchange

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

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

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

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

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

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

The number of outstanding common shares of the registrant, no par value per share, as of July 31, 2020 was 45,627,264.

ZYMEWORKS INC.

QUARTERLY REPORT ON FORM 10-Q

For the Quarter Ended June 30, 2020

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q includes “forward-looking statements” within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and “forward-looking information” within the meaning of Canadian securities laws, or collectively, forward-looking statements. Forward-looking statements 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 “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:

- 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;
- our ability to predict and manage government regulation; and
- the impact of the COVID-19 pandemic on our business and operations.

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 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 acquisitions;
- 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 set forth under “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 ability to obtain regulatory approval for our 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;
- the extent to which our business may be adversely affected by the COVID-19 pandemic;

- the Fast Track designations for any of our product candidates may not expedite regulatory review or approval;
- the U.S. Food and Drug Administration ("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;
- the competitive threat of 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 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 shareholders 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 clinical product candidate supplies and on other third parties to store, monitor and transport bulk drug substance and drug product;
- risk related to the manufacture of product candidates and difficulties in production;

- our reliance on third parties to oversee clinical trials of our product candidates and, in some cases, maintain regulatory files for those product candidates;
- our reliance on the performance of independent clinical investigators and contract research organizations ("CROs");
- our reliance on third parties for various operational and administrative aspects of our business including our reliance on third parties' cloud-based software platforms;
- the risk that natural disasters, public health crises, political crises, and other catastrophic events may damage the facilities or disrupt the operations of third parties upon which we rely;
- 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 organizational growth;
- additional costs and expenses related to no longer being considered an emerging growth company or a smaller reporting company;
- 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.

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. Azymetric, Zymeworks, ZymeCAD, EFECT, ZymeLink and the phrase "Building Better Biologics" are our registered trademarks. 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.

Except as otherwise indicated, references in this Quarterly Report on Form 10-Q to "Zymeworks," "the Company," "we," "us" and "our" refer to Zymeworks Inc. and its consolidated subsidiaries.

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 six months ended June 30, 2020

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

	June 30, 2020	December 31, 2019
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 219,569	$ 128,451
Short-term investments (note 5)	217,220	170,453
Accounts receivable	14,825	2,185
Prepaid expenses and other current assets	19,683	10,741
Total current assets	471,297	311,830
Deferred financing fees	730	650
Long-term investments (note 5)	75,978	—
Long-term prepaid assets	2,240	2,306
Deferred tax asset	1,347	1,218
Property and equipment, net	12,452	11,100
Operating lease right-of-use assets	5,673	5,400
Intangible assets, net	7,492	6,057
Acquired in-process research and development (note 6)	17,628	17,628
Goodwill (note 6)	12,016	12,016
Total assets	$ 606,853	$ 368,205
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (note 7)	$ 36,235	$ 35,691
Fair value of liability classified options (note 12)	34,621	45,569
Current portion of operating lease liability (note 11)	1,895	1,282
Other current liabilities (note 7)	29	10
Total current liabilities	72,780	82,552
Long-term portion of operating lease liability (note 11)	6,591	5,599
Long-term portion of deferred revenue (note 9)	32,941	32,941
Other long-term liabilities (note 7)	2,560	1,024
Deferred tax liability	728	408
Total liabilities	115,600	122,524
Shareholders' equity:		
Common shares, no par value; unlimited authorized shares at June 30, 2020 and December 31, 2019, respectively; 45,563,155 and 39,564,529 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively (note 8b)	708,319	450,210
Additional paid-in capital	150,399	92,839
Accumulated other comprehensive loss	(6,659)	(6,659)
Accumulated deficit	(360,806)	(290,709)
Total shareholders' equity	491,253	245,681
Total liabilities and shareholders' equity	$ 606,853	$ 368,205
Research collaboration and licensing agreements (note 9)		
Commitments and contingencies (note 13)		

The accompanying notes are an integral part of these financial statements

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue				
Research and development collaborations (note 9)	$ 12,359	$ 7,882	$ 20,628	$ 19,807
Operating expenses:				
Research and development	39,217	23,785	75,743	41,260
General and administrative	13,491	12,761	21,114	21,764
Impairment on acquired IPR&D	—	768	—	768
Total operating expenses	52,708	37,314	96,857	63,792
Loss from operations	(40,349)	(29,432)	(76,229)	(43,985)
Other income (expense):				
Interest income	1,502	1,233	3,358	2,482
Other (expenses) income, net (note 10)	(178)	(243)	3,085	(387)
Total other income, net	1,324	990	6,443	2,095
Loss before income taxes	(39,025)	(28,442)	(69,786)	(41,890)
Income tax recovery (expense)	64	(635)	(311)	(828)
Net loss and comprehensive loss	$ (38,961)	$ (29,077)	$ (70,097)	$ (42,718)
Net loss per common share (note 4):				
Basic and diluted	$ (0.77)	$ (0.89)	$ (1.41)	$ (1.32)
Weighted-average common shares outstanding (note 4):				
Basic and diluted	50,788,681	32,837,975	49,737,699	32,431,464

The accompanying notes are an integral part of these financial statements

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

	Common shares		Accumulated deficit	Accumulated other comprehensive loss	Additional paid-in capital	Total shareholders' equity
	Shares	Amount				
Balance at January 1, 2020	39,564,529	$ 450,210	$ (290,709)	$ (6,659)	$ 92,839	$ 245,681
Issuance of common shares on exercise of stock options	122,492	2,767	—	—	(754)	2,013
Issuance of common shares through employee stock purchase plan	21,451	615	—	—	—	615
Fair value adjustments upon reclassification of options to liabilities	—	—	—	—	(110)	(110)
Stock-based compensation	—	—	—	—	4,446	4,446
Issuance of common shares and pre-funded warrants in connection with public offering (Note 8)	5,824,729	254,018	—	—	46,892	300,910
Net loss	—	—	(31,136)	—	—	(31,136)
Balance at March 31, 2020	45,533,201	$ 707,610	$ (321,845)	$ (6,659)	$ 143,313	$ 522,419
Issuance of common shares on exercise of stock options	29,954	709	—	—	(152)	557
Stock-based compensation	—	—	—	—	7,238	7,238
Net loss	—	—	(38,961)	—	—	(38,961)
Balance at June 30, 2020	45,563,155	$ 708,319	$ (360,806)	$ (6,659)	$ 150,399	$ 491,253

	Common shares		Accumulated deficit	Accumulated other comprehensive loss	Additional paid-in capital	Total shareholders' equity
	Shares	Amount				
Balance at January 1, 2019	31,977,668	$ 320,074	$ (145,272)	$ (6,659)	$ 12,347	$ 180,490
Issuance of common shares on exercise of stock options	52,130	549	—	—	(130)	419
Issuance of common shares through employee stock purchase plan	18,681	325	—	—	—	325
Fair value adjustments upon reclassification of options to liabilities	—	—	—	—	(119)	(119)
Stock-based compensation	—	—	—	—	2,533	2,533
Net loss			(13,641)			(13,641)
Balance at March 31, 2019	32,048,479	$ 320,948	$ (158,913)	$ (6,659)	$ 14,631	$ 170,007
Issuance of common shares on exercise of stock options	115,298	2,285	—	—	(241)	2,044
Stock-based compensation	—	—	—	—	3,038	3,038
Issuance of common shares and pre-funded warrants in connection with public offering (Note 8)	7,013,892	117,941	—	—	70,064	188,005
Net loss	—	—	(29,077)	—	—	(29,077)
Balance at June 30, 2019	39,177,669	$ 441,174	$ (187,990)	$ (6,659)	$ 87,492	$ 334,017

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)

	Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (70,097)	$ (42,718)
Items not involving cash:		
Depreciation and amortization of property and equipment	1,539	1,001
Amortization of intangible assets	1,971	1,302
Impairment of acquired IPR&D	—	768
Stock-based compensation expense	4,257	13,866
Amortization and impairment of operating lease right-of-use assets	1,572	760
Deferred income tax expense	191	(51)
Non-cash consideration from licensing agreement	(218)	—
Change in fair value of contingent consideration	68	285
Unrealized foreign exchange (gain) loss	(2,866)	275
Changes in non-cash operating working capital:		
Accounts receivable	(12,640)	(2,351)
Prepaid expenses and other current assets	(9,284)	(6,195)
Accounts payable and accrued liabilities	(1,766)	2,796
Operating lease liabilities	(170)	(528)
Deferred revenue	—	(3,530)
Income taxes payable	—	(299)
Net cash used in operating activities	(87,443)	(34,619)
Cash flows from financing activities:		
Proceeds from public offering, net of issuance costs (note 8a)	300,910	189,035
Issuance of common shares on exercise of stock options (note 8e)	1,795	1,247
Issuance of common shares through employee stock purchase plan	419	233
Deferred financing fees	(80)	—
Finance lease payments	(7)	(11)
Net cash provided by financing activities	303,037	190,504
Cash flows from investing activities:		
Net (purchases) redemptions of short-term and long-term investments	(121,822)	86,786
Acquisition of property and equipment	(2,185)	(1,407)
Acquisition of intangible assets	(419)	—
Net cash (used in) provided by investing activities	(124,426)	85,379
Effect of exchange rate changes on cash and cash equivalents	(50)	51
Net change in cash and cash equivalents	91,118	241,315
Cash and cash equivalents, beginning of period	128,451	42,205
Cash and cash equivalents, end of period	$ 219,569	$ 283,520
Supplemental disclosure of non-cash investing and financing items:		
Leased assets obtained in exchange for operating lease liabilities	$ 1,817	$ 8,012
Acquisition of property and equipment in accounts payable and accrued liabilities	$ 706	$ 1,592

The accompanying notes are an integral part of these financial statements

ZYMEWORKS INC.
Notes to the Interim Condensed Consolidated Financial Statements
(unaudited)

1. Nature of Operations

Zymeworks Inc. (the "Company" or "Zymeworks") is a clinical-stage biopharmaceutical company dedicated to the development of next-generation multifunctional biotherapeutics. Zymeworks 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.

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 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, 2019.

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 six months ended June 30, 2020 and 2019 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, 2019, except for the new accounting guidance adopted during the period (note 3).

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 year presentation. These reclassifications had no effect on the reported results of operations.

Use of Estimates

The preparation of 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, benefits under the Scientific Research and Experimental Development ("SR&ED") Program, 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.

The full extent to which the COVID-19 pandemic may directly or indirectly impact the Company's business, results of operations and financial condition, including revenues, expenses, clinical trials, research and development costs and employee-related amounts, will depend on future developments that are evolving and highly uncertain, such as the duration and severity of the outbreak, including potential future waves or cycles, and the effectiveness of actions taken to contain and treat COVID-19. The Company considered the potential impact of COVID-19 when making certain estimates and judgments relating to the preparation of these consolidated financial statements. While there was no material impact to the Company's consolidated financial statements as of and for the three and six months ended June 30, 2020, the Company's future assessment of the magnitude and

duration of COVID-19, as well as other factors, could result in a material impact to the Company's consolidated financial statements in future reporting periods.

3. Recent Accounting Pronouncements

Initial adoption of new accounting pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, Financial Instruments—Credit Losses (Topic 326), in order to improve financial reporting of expected credit losses on financial instruments and other commitments to extend credit. ASU 2016-13 requires that an entity measure and recognize expected credit losses for financial assets held at amortized cost and replaces the incurred loss impairment methodology in prior GAAP with a methodology that requires consideration of a broader range of information to estimate credit losses. The Company adopted this accounting standard as of January 1, 2020. The adoption of this standard did not have any impact to the Company's consolidated financial statements as credit losses at the transition date were not expected to be significant, based on the evaluation of the financial condition of payment partners, and external market factors.

In August 2018, the FASB issued ASU 2018–13, Fair Value Measurement (Topic 820): Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement. The amendments in this ASU eliminate, add and modify certain disclosure requirements for fair value measurements as part of its disclosure framework project. The standard is effective for the Company in fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. The Company adopted this accounting standard as of January 1, 2020. The adoption of this new accounting standard did not have a significant impact on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU 2018–15, Intangibles — Goodwill and Other — Internal Use Software (Subtopic 350–40). This ASU addresses the accounting for implementation costs incurred by a customer in a cloud computing arrangement that is a service contract and also adds certain disclosure requirements related to implementation costs incurred for internal-use software and cloud computing arrangements. The amendment aligns the requirements for capitalizing implementation costs incurred in a cloud computing arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). This ASU is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. The Company adopted this accounting standard as of January 1, 2020 and has applied it prospectively to all implementation costs incurred after January 1, 2020. The adoption of this new accounting standard did not have a significant impact on the Company's consolidated financial statements.

Recent accounting pronouncements not yet adopted

The Company has reviewed other recent accounting pronouncements and concluded that they are either not applicable to the business, or that no material impact 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 six months ended June 30, 2020 and 2019 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Numerator:				
Net loss attributable to common shareholders:				
Basic and diluted	$ (38,961)	$ (29,077)	$ (70,097)	$ (42,718)
Denominator:				
Weighted-average common shares outstanding:				
Basic and diluted (*)	50,788,681	32,837,975	49,737,699	32,431,464
Net loss per common share — basic and diluted	$ (0.77)	$ (0.89)	$ (1.41)	$ (1.32)

(*): Weighted average number of common shares used in the basic and diluted earnings per share calculations include the pre-funded warrants issued in connection with the Company's June 2019 and January 2020 public offerings as the warrants are exercisable at any time and for nominal cash consideration.

5. Investments

Short-term Investments

Short-term investments consist of guaranteed investment certificates (“GICs”), term deposits and commercial paper acquired from financial institutions in accordance with the Company’s treasury policy. Short-term GICs, term deposits and commercial paper bear interest at rates of 0.8%-2.0% per annum with original maturities of up to 12 months, are classified as held to maturity and are accounted for at amortized cost.

Long-term Investments

Long-term investments at June 30, 2020 consist of GIC's and term deposits of $75,260 (December 31, 2019 -$nil) acquired from financial institutions in accordance with the Company’s treasury policy and other debt and equity securities of $718 (December 31, 2019 - $nil) acquired for strategic purposes or in connection with licensing and collaboration agreements. Long-term GICs and term deposits bear interest at rates of 0.9%-1.0% per annum with original maturities ranging from 12 to 24 months, are classified as held to maturity and are accounted for at amortized cost. Other long-term debt and equity securities are accounted for as available for sale financial instruments with changes in fair value recorded through other comprehensive income or at cost subject to impairment.

6. IPR&D and Goodwill

Acquired IPR&D

In-process research and development assets (“IPR&D”) acquired in the Kairos Therapeutics Inc. (“Kairos”) business combination are classified as indefinite-lived intangible assets and are not currently being amortized. The carrying value of IPR&D, net of impairment was $17,628 at both June 30, 2020 and December 31, 2019. The Company concluded that there were no impairment indicators related to IPR&D as of June 30, 2020.

Goodwill

The Company performed its most recent annual impairment test of goodwill as of December 31, 2019. 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, 2019, 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 June 30, 2020.

7. Liabilities

Accounts payable and accrued expenses consisted of the following:

	June 30, 2020	December 31, 2019
Trade payables	$ 4,735	$ 5,349
Accrued research expenses	23,821	24,262
Employee compensation and vacation accruals	4,863	5,009
Accrued legal and professional fees	598	231
Other	2,218	840
Total	$ 36,235	$ 35,691

Other current liabilities consisted of the following:

	June 30, 2020	December 31, 2019
Current portion of finance lease liability (note 11)	$ 29	$ 10
Total	$ 29	$ 10

Other long-term liabilities consisted of the following:

	June 30, 2020	December 31, 2019
Liability for contingent consideration (note 12)	$ 1,046	$ 978
Liability for in-licensing agreement	1,450	—
Finance lease liability (note 11)	64	46
Total	$ 2,560	$ 1,024

8. Shareholders' Equity

The number of shares and per share amounts are presented in actual amounts.

a. Equity Offerings

2019 Public Offering

On June 24, 2019, the Company closed an offering pursuant to which the Company sold 7,013,892 common shares including the sale of 1,458,336 common shares to the underwriters upon their full exercise of their over-allotment option at an offering price of $18.00 per common share and 4,166,690 Pre-Funded Warrants (note 8d) in lieu of common shares at $17.9999 per Pre-Funded Warrant. Net proceeds were approximately $188.0 million, after underwriting discounts, commissions and offering expenses of $13.3 million.

2020 Public Offering

On January 27, 2020, the Company closed a public offering pursuant to which the Company sold 5,824,729 common shares, including the sale of 900,000 common shares to the underwriters upon their full exercise of their over-allotment option, at $46.50 per common share and 1,075,271 Pre-Funded Warrants (note 8d) in lieu of common shares at $46.4999 per Pre-Funded Warrant. Net proceeds were approximately $300.9 million, after underwriting discounts, commissions and offering expenses of $19.9 million.

b. Authorized

The Company has an unlimited authorized number of voting Common Shares and Preferred Shares without par value.

c. Preferred Shares

As of June 30, 2020 and December 31, 2019, no preferred shares were issued or outstanding, respectively.

d. Pre-funded common share warrants

On June 24, 2019, the Company completed a public offering of 7,013,892 common shares at $18.00 per share and issued 4,166,690 Pre-Funded Warrants at a price of $17.9999 per Pre-Funded Warrant which granted holders of warrants the right to purchase up to 4,166,690 common shares of the Company, at an exercise price of $0.0001 per share (the "Exercise Price").

On January 27, 2020, the Company completed a subsequent public offering of 5,824,729 common shares at $46.50 per share and issued 1,075,271 Pre-Funded Warrants at a price of $46.4999 per Pre-Funded Warrant which granted holders of warrants the right to purchase up to 1,075,271 common shares of the Company, at an exercise price of $0.0001 per share (the "Exercise Price").

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 the Exercise Price collected from holders will be recorded in common shares.

e. Stock-Based Compensation

Original Stock Option Plan

On July 14, 2006, the shareholders of the Company approved an employee stock option plan (the “Original Plan”). The Original Plan provides for the granting of options to directors, officers, employees and consultants. Options to purchase common shares may be granted at an exercise price of each option equal to the last private issuance of common shares immediately preceding the date of the grant. The total number of options outstanding is not to exceed 20% of the issued common shares of the Company.

Options granted under the Original Plan are exercisable at various dates over their ten-year life. Common shares are issued from treasury when options are exercised.

Options issued to employees under the Original Plan vest over 4 years. Options issued to directors under the Original Plan vest over 3 years, and options issued to consultants and members of the Scientific Advisory Board under the Original Plan vest immediately upon issuance.

The exercise prices of the Company’s stock options under the Original Plan are denominated in Canadian dollars. The Canadian dollar amounts have been translated to U.S dollars using the period end rate or the average foreign exchange rate for the period, as applicable, and have been provided for information purposes. Upon the effectiveness of the Company’s New Stock Option Plan described below, no further options were issuable under the Original Plan. However, all outstanding options granted under the Original Plan remain outstanding, subject to the terms of the Original Plan and the applicable grant documents, until such outstanding options are exercised or they terminate or expire by their terms.

New Stock Option and Equity Compensation Plan

On April 10, 2017, the Company’s shareholders approved a new stock option plan, which became effective immediately prior to the consummation of the IPO. This plan allows for the grant of options to directors, officers, employees and consultants in U.S. or Canadian dollars, and also permits the Company to grant incentive stock options (“ISOs”), within the meaning of Section 422 of the Internal Revenue Code, to its employees. On June 7, 2018, the Company’s shareholders approved an amendment and restatement of this plan (this plan, as amended and restated, the “New Plan”), which was further amended on March 4, 2020, that includes an article that allows the Company to grant restricted shares, restricted share units (“RSUs”) and other share-based awards, in addition to stock options.

The maximum number of common shares reserved for issuance under the New Plan is 8,654,682, which includes 6,294,820 shares issuable upon exercise of options outstanding as of June 30, 2020. Beginning in 2020 and ending in 2028, this maximum number may be increased on the first day of each calendar year by up to 4.0% of the number of outstanding shares on the last day of the immediately preceding calendar year. ISOs may be granted with respect to a maximum fixed amount equal to 20% of the shares reserved for issuance under the New Plan as of June 7, 2018.

Restricted Stock Units ("RSUs")

During the six months ended June 30, 2020 , the Company granted 78,679 RSUs to certain employees that vest over a period of three years, in the amount of one-third each year on the anniversary of the grant date. RSUs are equity-settled on each vesting date, subject to the grantee’s continued employment with the Company on the vesting date. The fair value of RSUs granted was calculated by using the closing stock price on the grant date. The grant date fair value for the RSUs granted in the six months ended June 30, 2020 was $2,786.

Stock Options

All options granted under the New Plan will have an exercise price determined and approved by the Board on the date of the grant, which shall not be less than the market price of the common shares at such time. For the purposes of the New Plan, the market price of a common share shall be the closing sale price of a share on the grant date reported by the stock exchange with the greatest trading volume or, if such day is not a trading day, the closing sale price reported for the immediately preceding trading day. The Company may convert a market price denominated in Canadian dollars into United States dollars and vice versa and such converted amount shall be the market price.

An option shall be exercisable during a period established by the Board which shall commence on the date of the grant and shall terminate not later than ten years after the date of the granting of the option. The New Plan provides that the exercise period shall automatically be extended if the date on which it is scheduled to terminate shall fall during a black-out period. In such cases, the extended exercise period shall terminate on the tenth business day after the last day of the black-out period, provided that the exercise period shall in no case be extended beyond the tenth anniversary of the date the option was granted. All options shall vest in accordance with the terms of their grant agreements.

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, 2019	2,356,413	16.21	12.46	6.70	101,404	77,807
Granted	345,750	48.83	35.74			
Exercised	(106,982)	15.82	11.89			
Forfeited	(47,435)	27.35	20.21			
Outstanding, June 30, 2020	2,547,746	20.45	15.06	6.64	73,898	53,995

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

	Number of Options	Weighted-Average Exercise Price ($)	Weighted-Average Contractual Term (years)	Aggregate intrinsic value ($)
Outstanding, December 31, 2019	2,853,346	15.85	8.66	84,481
Granted	1,036,150	36.32		
Exercised	(45,464)	11.61		
Forfeited	(96,958)	15.84		
Outstanding, June 30, 2020	3,747,074	21.56	8.60	55,528

During the six months ended June 30, 2020, the Company received cash proceeds of $1,795 (C$2,400) from stock options exercised.

The stock options outstanding at June 30, 2020 expire at various dates from December 31, 2020 to June 9, 2030.

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, as well as the financial statement impact of the periodic revaluation of liability classified equity instruments (note 12), is recorded in research and development expense, general and administrative expense and finance expense (recovery) as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development expense (recovery):				
Stock-based compensation for equity classified instruments (*)	$ 3,346	$ 1,507	$ 5,496	$ 2,633
Change in fair value of liability classified equity instruments	(107)	1,548	(1,900)	1,968
	$ 3,239	$ 3,055	$ 3,596	$ 4,601
General and administrative expense (recovery):				
Stock-based compensation for equity classified instruments (*)	$ 4,046	$ 1,579	$ 6,497	$ 3,070
Change in fair value of liability classified equity instruments	(310)	4,800	(5,799)	6,127
	$ 3,736	$ 6,379	$ 698	$ 9,197
Finance expense (recovery):				
Change in fair value of liability classified equity instruments	(2)	—	(36)	68
	$ (2)	$ —	$ (36)	$ 68

(*) Amounts include stock-based compensation expense relating to RSUs of $411 and $503 for the three and six months ended June 30, 2020 (three and six months ended June 30, 2019: nil)

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

	Six Months Ended June 30,	
	2020	2019
Dividend yield	0 %	0 %
Expected volatility	75.5 %	73.8 %
Risk-free interest rate	0.64 %	1.46 %
Expected average life of options	6.07 years	6.05 years

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

	Six Months Ended June 30,	
	2020	2019
Dividend yield	0 %	0 %
Expected volatility	76.3 %	72.9 %
Risk-free interest rate	0.73 %	2.43 %
Expected average life of options	6.02 years	6.01 years

Expected Volatility — Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. As the Company does not yet have sufficient history of its own volatility, the Company has identified several public entities of similar complexity and stage of development and calculates historical volatility using the volatility of these companies.

Risk-Free Interest Rate — This rate is from the Government of Canada and U.S. Federal Reserve marketable bonds for the month prior to each option grant during the year, having a term that most closely resembles the expected life of the option.

Expected Term — This is the period of time that the options granted are expected to remain unexercised. Options granted have a maximum term of ten years. The Company uses the simplified method to calculate the average expected term, which represents the average of the vesting period and the contractual term.

Share Fair Value — Options granted after the Company's IPO, are issued at the fair market value of the Company's stock at the date the grant is approved by the Board. Before the IPO, the Company granted stock options at exercise prices not less than the fair value of its common shares as determined by the Board, with input from management. Management estimated the fair value

of its common shares based on a number of objective and subjective factors, including the most recently available valuation of common shares prepared by independent valuation specialists, external market considerations affecting the biotechnology industry and the historic prices at which the Company sold common shares.

The weighted-average Black-Scholes option pricing assumptions for liability classified stock options are as follows:

	June 30, 2020		June 30, 2019	
Dividend yield	0	%	0	%
Expected volatility	85.7	%	71.7	%
Risk-free interest rate	0.31	%	1.42	%
Expected average option term	3.06 years		3.43 years	
Number of liability classified stock options outstanding	1,244,204		1,375,269	

At June 30, 2020, the unamortized compensation expense related to unvested options was $34,550 (C$47,286). The remaining unamortized compensation expense as of June 30, 2020 will be recognized over a weighted-average period of 1.80 years.

f. Employee Stock Purchase Plan:

On April 10, 2017, the Company’s shareholders approved an employee stock purchase plan (“ESPP”) which became effective immediately prior to the consummation of the Company’s IPO. On June 7, 2018, certain amendments to the ESPP were approved by shareholders. Prior to these amendments, the ESPP allowed eligible employees to acquire common shares at a discounted purchase price of 85% of the market value of the Company's common shares on the purchase date. The ESPP, as amended, allows eligible employees to acquire common shares at a discounted purchase price of the lesser of (i) 85% of the market price of a common share on the first day of the applicable purchase period and (ii) 85% of the market price of a common share on the purchase date. The ESPP qualifies as an “employee stock purchase plan” within the meaning of Section 423 of the Code for employees who are United States taxpayers.

The Company currently holds offerings consisting of a single six-month purchase period commencing on January 1 and July 1 of each calendar year, with a single purchase date at the end of the purchase period on June 30 and December 31 of each calendar year.

Eligible employees are able to contribute up to 15% of their gross base earnings for purchases under the ESPP through regular payroll deductions. Purchases of shares under the ESPP are limited for each employee at $25 thousand worth of the Company’s common shares (determined using the lesser of (i) the market price of a common share on the first day of the applicable purchase period and (ii) the market price of a common share on the purchase date) for each year such purchase right is outstanding.

As this plan is considered compensatory, the Company recognizes compensation expense on these awards based on their estimated grant date fair value using the Black-Scholes option pricing model. The Company recognizes compensation expense in the consolidated statements of loss and comprehensive loss on a straight-line basis over the requisite service period. For the six months ended June 30, 2020, the Company recorded compensation expense of $311 (six months ended June 30, 2019: $131) in research and development expense and general and administrative expense accounts. As of June 30, 2020, total amount contributed by the ESPP participants and not yet settled is $701 (December 31, 2019: $435).

9. Research, Collaboration and Licensing Agreements

Revenue recognized from the Company's strategic partnerships is summarized as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Celgene Corporation and Celgene Alpine Investment Co. LLC (formerly "Celgene" and now a Bristol-Myers Squibb company, "BMS")				
Upfront fee relating to amendment	$ 12,000	$ —	$ 12,000	$ —
BeiGene, Ltd. ("BeiGene"):				
Milestone revenue	—	—	5,000	—
Recognition of deferred revenue related to upfront fee	—	—	—	3,530
Eli Lilly and Company ("Lilly"):				
Milestone revenue	—	—	—	8,000
Daiichi Sankyo, Co., Ltd ("Daiichi Sankyo"):				
Commercial license option fee	—	3,500	—	3,500
Merck Sharp & Dohme Research Ltd. ("Merck"):				
Milestone revenue	—	2,000	—	2,000
Iconic Therapeutics, Inc. ("Iconic"):				
Milestone revenue	—	1,000	—	1,000
Research support and drug supply payments	359	1,382	3,628	1,777
	$ 12,359	$ 7,882	$ 20,628	$ 19,807

During the six months ended June 30, 2020, there have not been any material changes to the key terms of our collaboration and license agreements, with the exception of the amendment to our partnership with BMS as described below. For further information on the terms and conditions of our existing collaboration and license agreements, please refer to the notes to the consolidated financial statements included in our Annual Report on Form 10-K for the year-ended December 31, 2019.

In June 2020, the Company's existing collaboration agreement with BMS was amended to expand the license grant to include the use of the Company's EFECT platform for the development of therapeutic candidates and to extend the research term. The amendment included an upfront fee of $12,000 and all other financial terms were unchanged. The Company's performance obligations in relation to the upfront fee were met on the date of amendment. Accordingly, the upfront payment was recognized as revenue during the three and six months ended June 30, 2020.

In March 2020, the Company recognized milestone revenue of $5,000 under a license and collaboration agreement with BeiGene upon BeiGene's dosing of zanidatamab (formerly known as ZW25) in the first patient in a clinical study in its territory. The Company did not have any performance obligations in relation to this milestone on the date it was achieved. Accordingly, it was recognized as revenue during the six months ended June 30, 2020.

During the six months ended June 30, 2019, the Company recognized revenue of $8,000 for achieving a development milestone under a licensing and collaboration agreement with Lilly upon Lilly's filing of an IND application for a bispecific antibody enabled by the Company's Azymetric platform; $3,500 for Daiichi Sankyo's exercise of its option to obtain a commercial license with respect to its first Azymetric lead product candidate; and $2,000 and $1,000 for development milestone payments from Merck and Iconic, respectively.

At June 30, 2020, contract assets from research, collaboration and licensing agreements were nil (December 31, 2019: nil) and contract liabilities were $32,941 (December 31, 2019: $32,941). Contract liabilities include deferred revenue relating to an upfront payment received in 2018 under the licensing and collaboration agreement with BeiGene. During the six months ended June 30, 2020, the Company did not recognize any revenue from performance obligations satisfied in relation to the deferred revenue (six months ended June 30, 2019: $3,530). Amounts not expected to be recognized as revenue in the next twelve months from June 30, 2020 have been classified as long-term deferred revenue.

10. Other income (expenses), net

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Foreign exchange (loss) gain	$ (165)	$ (178)	$ 3,058	$ (317)
Other	(13)	(65)	27	(70)
	$ (178)	$ (243)	$ 3,085	$ (387)

11. Leases

The Company leases separate office and laboratory space in Vancouver, British Columbia, with terms of each lease expiring in August 2021. On January 25, 2019, the Company entered into a lease for a new building in Vancouver to serve as the Company's future head office, including both office and laboratory space. The commencement date of this lease depends upon completion of construction of the building and is currently estimated to be no later than September 1, 2021. This lease has an initial term of ten years, with two five-year extension options. In addition, the Company leases office space in Seattle, Washington with lease terms expiring in February 2022 and September 2025. None of the optional extension periods have been included in the determination of the right-of-use asset or the lease liability for operating leases as the Company did not consider it reasonably certain that the Company would exercise any such options.

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

	June 30, 2020	December 31, 2019
Operating lease liabilities:		
Current portion	$ 1,895	$ 1,282
Long-term portion	6,591	5,599
Total operating lease liabilities	8,486	6,881
Finance lease liabilities:		
Current portion included in other current liabilities	29	10
Long-term portion included in other long-term liabilities	64	46
Total finance lease liabilities	93	56
Total lease liabilities	$ 8,579	$ 6,937

Cash paid for amounts included in the measurement of operating lease liabilities for the six months ended June 30, 2020 was $1,161 and was included in net cash used in operating activities in the consolidated statements of cash flows.

As of June 30, 2020, the maturities of the Company's operating lease liabilities were as follows:

	Operating leases
Within 1 year	$ 2,103
1 to 2 years	1,896
2 to 3 years	1,482
3 to 4 years	1,524
4 to 5 years	1,567
Thereafter	400
Total operating lease payments	8,972
Less:	
Imputed interest	(486)
Operating lease liabilities	$ 8,486

As of June 30, 2020, the weighted average remaining lease term is 4.4 years and the discount rate used to determine the operating lease liability was 4.6% for leases in Canadian dollars and 2.7% for leases in U.S. dollars.

During the six months ended June 30, 2020, the Company incurred total operating lease expenses of $1,812 (six months ended June 30, 2019: $1,263), which included lease expenses associated with fixed lease payments of $1,601 (six months ended June 30, 2019: $1,202), and variable payments associated with common area maintenance and similar expenses of $211 (six months ended June 30, 2019: $61).

During the three and six months ended June 30, 2020, the Company recognized impairment losses of $187 and $667 respectively, on the right of use asset relating to the Company's lease of office space in Seattle which has been vacated.

In addition to the operating lease liabilities included in the table above, the Company has commitments for future operating lease payments of $24,362 million under the terms of the lease for the Company’s future head office, which is expected to commence in September 2021.

The Company also leases office equipment under finance lease agreements. As of June 30, 2020, the maturities of the Company’s finance lease liabilities were as follows:

	Finance leases
Within 1 year	$ 30
1 to 2 years	14
2 to 3 years	14
3 to 4 years	11
4 to 5 years	27
Total finance lease payments	96
Less:	
Imputed interest	(3)
Finance lease liabilities	$ 93

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, amounts receivable, accounts payable and accrued liabilities, finance and operating lease obligations, liability classified stock options and other long-term liabilities.

The carrying values of cash and cash equivalents, short-term investments in marketable securities, amounts receivable and accounts payable and accrued liabilities approximate their fair values due to the near-term maturities of these financial instruments. As at June 30, 2020, the carrying value of long-term investments in debt securities also approximate their fair values which is comprised of principal investment and accrued interest to date. As quoted prices for the liability classified stock options are not readily available, the Company has uses a Black-Scholes pricing model to estimate fair value, which utilizes level 3 inputs as defined above. 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.

The following tables present information about the Company's liabilities 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:

	June 30, 2020	Level 1	Level 2	Level 3
Liabilities				
Liability classified stock options	$ 34,621	$ —	$ —	$ 34,621
Liability for contingent consideration (note 13)	1,046	—	—	1,046
Total	$ 35,667	$ —	$ —	$ 35,667

	December 31, 2019	Level 1	Level 2	Level 3
Liabilities				
Liability classified stock options	$ 45,569	$ —	$ —	$ 45,569
Liability for contingent consideration (note 13)	978			978
Total	$ 46,547	$ —	$ —	$ 46,547

The following table presents the changes in fair value of the liability classified stock options:

	Liability at beginning of the period	Reclassification to liabilities from equity	Increase (decrease) in fair value of liability classified stock options	Exercise of options	Unrealized foreign currency loss (gain)	Liability at end of the period
Three months ended June 30, 2020	$ 33,899	$ —	$ (419)	$ (209)	$ 1,350	$ 34,621
Six months ended June 30, 2020	$ 45,569	$ 110	$ (7,736)	$ (775)	$ (2,547)	$ 34,621

The change in fair value of liability classified stock options for the respective periods are presented within research and development expenses and general and administrative expenses.

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	Liability at end of the period
Three months ended June 30, 2020	$ 978	$ 68	$ 1,046
Six months ended June 30, 2020	$ 978	$ 68	$ 1,046

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 investments, long-term investments and accounts receivable. Cash and cash equivalents and investments in marketable securities are invested in accordance with the Company's treasury policy with the primary objective being the preservation of capital and maintenance of liquidity. The treasury 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, short-term investments and long-term investments with high credit quality financial institutions.

At June 30, 2020, the maximum exposure to credit risk for accounts receivable was $14,825 (December 31, 2019: $2,185) and all account receivables are due within the next 12 months. As at June 30, 2020 and December 31, 2019, the Company has not recognized a bad debt provision for 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 and short-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 due to the low volume of transactions denominated in foreign currencies.

The operating results and financial position of the Company are reported in U.S. dollars in the Company's 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 shareholders' equity in the Company's 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 consolidated financial statements.

In connection with the Kairos acquisition, the Company may be required to make future payments to CDRD Ventures Inc. ("CVI") upon the direct achievement of certain development milestones for products incorporating certain Kairos intellectual property, as well as royalty payments on the net sales of such products. For out-licensed products and technologies incorporating certain Kairos intellectual property, the Company may be required to pay CVI a mid-single digit percentage of the future revenue as a result of a revenue sharing agreement. As of June 30, 2020, the contingent consideration had an estimated fair value of approximately $1,046, which has been recorded within other long-term liabilities (December 31, 2019: $978). 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 in the statement of loss and comprehensive loss.

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, 2019 included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on March 2, 2020 and with the securities commissions in all provinces and territories of Canada on March 2, 2020. 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. Throughout this discussion, unless the context specifies or implies otherwise, the terms "Zymeworks," "we," "us," and "our" refer to Zymeworks Inc. and its subsidiary.

Overview

Zymeworks is a clinical-stage biopharmaceutical company dedicated to the development of next-generation multifunctional biotherapeutics. Our suite of complementary therapeutic platforms and our fully integrated drug development engine provide the flexibility and compatibility to precisely engineer and develop highly differentiated product candidates. These capabilities have resulted in multiple product candidates with the potential to drive positive outcomes in large underserved and unaddressed patient populations.

Our lead product candidate, zanidatamab (formerly known as ZW25), is a novel bispecific (dual-targeting) antibody that targets two distinct domains of the human epidermal growth factor receptor 2 ("HER2"). The unique mechanism of action of zanidatamab may enable it to address unmet need in patient populations with HER2-expressing cancers, including those with lower levels of expression, for which there are no approved HER2-targeted agents. In clinical trials, single-agent zanidatamab and zanidatamab in combination with chemotherapy have been well tolerated with promising anti-tumor activity in patients with heavily pretreated HER2-expressing cancers that have progressed after having received standard of care, including multiple HER2-targeted regimens. Based on these data, we initiated a number of global multicenter Phase 2 clinical trials to evaluate zanidatamab in specific indications and lines of therapy. These include (i) a registration-enabling trial in patients with previously treated HER2 gene amplified biliary tract cancer ("BTC"), (ii) the first-line treatment of HER2-positive metastatic gastroesophageal adenocarcinomas ("GEA") in combination with standard of care chemotherapy, and (iii) previously-treated locally advanced and/or metastatic HER2-positive, hormone receptor-positive breast cancer in combination with Pfizer's Ibrance® (palbociclib) and fulvestrant. Our partner, BeiGene, Ltd. ("BeiGene"), has initiated Phase 1b/2 clinical trials evaluating zanidatamab for the first-line treatment of metastatic HER2-positive breast cancer in combination with docetaxel and for the first-line treatment of metastatic HER2-positive GEA in combination with tislelizumab and chemotherapy. In addition, zanidatamab continues to be evaluated in multiple expansion cohorts in the ongoing Phase 1 trial as a single agent in several indications including colorectal, gynecological and other HER2-expressing cancers.

Our second product candidate, ZW49, combines the unique design of zanidatamab with our ZymeLink antibody-drug conjugate ("ADC") platform, comprised of our proprietary cytotoxin (cancer cell-killing compound) and cleavable linker. We designed ZW49 to be a best-in-class HER2-targeting ADC to further address unmet need across a range of HER2-expressing cancers. A Phase 1 clinical trial to establish safety and anti-tumor activity of ZW49 began in 2019.

We are also advancing a deep pipeline of preclinical product candidates and discovery-stage programs in oncology (including immuno-oncology ("I-O") agents) and other therapeutic areas.

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 core platforms include:

- ***Azymetric***, our bispecific 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 Fab regions (locations on the antibody to which epitopes bind);
- ***ZymeLink,*** our ADC platform, comprised of cytotoxins and the linker technology used to couple these cytotoxins to tumor-targeting antibodies or proteins. This platform can be used in conjunction with our other therapeutic platforms to increase safety and efficacy as compared to existing ADC technologies; and
- ***EFECT,*** which enables finely tuned modulation (both up and down) of immune cell recruitment and function.

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.

Our Azymetric, EFECT and ZymeLink therapeutic platforms have been further leveraged through multiple revenue-generating strategic partnerships with the following global pharmaceutical companies: Merck Sharp & Dohme Research GmbH ("Merck"), Eli Lilly and Company ("Lilly"), Celgene Corporation and Celgene Alpine Investment Co. LLC (formerly "Celgene" and now a Bristol-Myers Squibb company, "BMS"), GlaxoSmithKline Intellectual Property Development Limited ("GSK"), Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo"), Janssen Biotech, Inc. ("Janssen"), LEO Pharma A/S ("LEO"), BeiGene, and Iconic Therapeutics, Inc. ("Iconic").

Our goal is to leverage our next-generation therapeutic platforms and proprietary protein engineering capabilities to become a domain dominator in the discovery, development and commercialization of best-in-class multifunctional biotherapeutics for the treatment of cancer and other 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 to date 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. We have financed our operations primarily through private equity placements, an issuance of convertible debentures, payments received under license and collaboration agreements, government grants and Scientific Research and Experimental Development ("SR&ED") tax credits and a credit facility as well as our initial public offering ("IPO") in 2017 and subsequent public offerings in 2018, 2019 and 2020. From inception to June 30, 2020, we received $789.2 million, net of equity issue costs, from private equity placements, the issuance of convertible debt, which subsequently converted into equity securities, our IPO and subsequent public offerings including issuance of pre-funded warrants as well as proceeds from exercises of options and employee stock purchase plans. Payments received from our license and collaboration agreements include upfront fees and milestone payments as well as research support and reimbursement payments through our strategic partnerships and government grants. As of June 30, 2020, we had $512.0 million of cash resources consisting of cash, cash equivalents, short-term investments and certain long-term investments.

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 June 30, 2020, combined with the collaboration payments we anticipate receiving, will enable us to fund our planned operations into 2022 and potentially beyond.

We reported a net loss of $70.1 million for the six months ended June 30, 2020 and through June 30, 2020, we had an accumulated deficit of $360.8 million. We expect that over the next several years we will 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

COVID-19

The global outbreak of COVID-19 has impacted our research and development activities, but has not caused significant disruptions to our business operations to date. In March 2020, we transitioned our workforce to a remote working arrangement to protect the health and safety of our employees. In June 2020, we implemented a program to facilitate the phased return of employees to our lab and office facilities pursuant to enhanced health and safety protocols consistent with guidelines issued by local health authorities. Our preclinical research activities are being supplemented by support from external contract research organizations to offset the reduced capacity at our lab facilities. Clinical trial activities, including patient enrollment and site activation, have been delayed due to COVID-19. As of the date of this report, these clinical activities are returning to pre-COVID levels. Although the adverse impacts we have experienced to date will likely slow the pace of execution on certain of our preclinical and clinical programs, they have not had a material impact on our financial condition, liquidity or longer-term strategic development and commercialization plans.

The extent to which COVID-19 may cause more significant disruptions to our business and greater impacts to our results of operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration and severity of the outbreak, including potential future waves or cycles, and the effectiveness of actions to contain and treat COVID-19. We cannot presently predict the duration, scope and severity of any potential business shutdowns or disruptions, including to our ongoing and planned clinical studies and our regulatory approval prospects. Further prolonged shutdowns or other business interruptions could result in material and negative effects to our ability to conduct our business in the manner and on the timelines presently planned, which could have a material adverse impact on our business, results of operations, and financial condition. The COVID-19 pandemic continues to rapidly evolve, and we will continue to monitor the effects of COVID-19 on our business. See Part II - Item 1A, “Risk Factors – Risks Related to Our Business and the Development and Commercialization of Our Product Candidates – Our business may be adversely affected by the COVID-19 pandemic.”

Zanidatamab Clinical Program:

In July 2020, we initiated a global Phase 2 trial of single agent zanidatamab in patients with previously treated HER2 gene amplified BTC to support accelerated approval based on a primary endpoint of objective response rate, and secondary endpoints of duration of response and safety.

In March 2020, our partner, BeiGene, notified us that it had dosed the first patient in a two-arm Phase 1b/2 trial evaluating zanidatamab in combination with chemotherapy as a first-line treatment for patients with metastatic HER2-positive breast cancer and in combination with chemotherapy and BeiGene’s PD-1-targeted antibody tislelizumab as a first-line treatment for patients with metastatic HER2-positive GEA. This achievement triggered our receipt of a milestone payment of $5.0 million under our license and collaboration agreement with BeiGene.

In January 2020, we announced an agreement with Pfizer and the initiation of a Phase 2 clinical trial evaluating zanidatamab in combination with Pfizer’s Ibrance® (palbociclib), an oral CDK4/6 inhibitor, and the hormone therapy fulvestrant with the goal of providing a chemotherapy-free treatment option to people with advanced HER2-positive, hormone receptor-positive breast cancer. We will sponsor the study, and Pfizer will provide palbociclib. Part one of the study will evaluate the safety and tolerability of zanidatamab in combination with palbociclib and fulvestrant and identify the recommended dose of zanidatamab and palbociclib. Part two of the study will evaluate anti-tumor activity at the recommended dose level. The trial will enroll up to 76 patients at sites in the United States, Canada, and Spain.

In January 2020, we announced that the FDA has granted Fast Track and Orphan Drug Designations to zanidatamab in refractory BTC.

ZW49 Clinical Program:

In January 2020, we announced an interim update from the ongoing ZW49 Phase 1 dose-escalation study highlighting that there have been no dose-limiting toxicities observed and the maximum tolerated dose has not been reached. With over ten patients treated, the majority of treatment-related adverse events have been grade 1 or 2, and were reversible and manageable on an outpatient basis. Preliminary results from these initial dose cohorts include anti-tumor activity.

Licensing and Collaboration Agreements:

In July 2020, we entered into a new licensing agreement with Merck granting Merck a worldwide, royalty-bearing license to research, develop and commercialize up to three new multispecific antibodies toward Merck's therapeutic targets in the human health field and up to three new multispecific antibodies toward Merck's therapeutic targets in the animal health field. For the human health field, we are eligible to receive up to $411.0 million in option exercise fees and clinical development and regulatory approval milestone payments and up to $480.0 million in commercial milestone payments, as well as tiered royalties on worldwide sales. For the animal health field, we are eligible to receive additional milestone payments and tiered royalties.

In June 2020, our existing collaboration agreement with BMS was amended to expand the license grant to include the use of our EFECT platform for the development of therapeutic candidates and to extend the research term. We received an upfront expansion fee of $12.0 million and all other financial terms were unchanged.

Financing Activities:

On January 27, 2020, we announced the closing of our underwritten public offering which consisted of the issuance of 5,824,729 common shares, including the exercise in full of the underwriters' over-allotment option to purchase 900,000 additional shares, and, in lieu of common shares, to a certain investor, pre-funded warrants to purchase up to 1,075,271 common shares. The common shares were sold at a price to the public of $46.50 per common share and the pre-funded warrants were sold at a price of $46.4999 per pre-funded warrant, for aggregate gross proceeds to the Company of approximately $320.8 million, before deducting underwriting discounts and commissions and estimated offering expenses. The securities were offered in Canada pursuant to our final prospectus supplement, dated January 22, 2020 (the "Canadian Supplement"), to our Canadian final base shelf prospectus, dated November 18, 2019, and in the United States pursuant to our final prospectus supplement, dated January 22, 2020 (the "U.S. Supplement", together with the Canadian Supplement, the "Supplements"), to our U.S. automatic shelf registration statement on Form S-3ASR, including a prospectus dated November 5, 2019. The Supplements were filed in Canada and the United States on January 23, 2020.

Board of Directors Change:

In March 2020, we announced the appointment of Dr. Kelvin Neu to our Board of Directors. Dr. Neu is a partner at Baker Bros. Advisors LP, a long term life-sciences investment firm. He also serves as a director of Prelude Therapeutics, Inc. and IGM Biosciences, Inc.

Strategic Partnerships and Collaborations

Our novel therapeutic candidates, together with the unique 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, including with Merck, Lilly, BMS, GSK, Daiichi Sankyo, Janssen, LEO, BeiGene, and Iconic, provide us with the ability to accelerate clinical development of our therapeutic candidates in certain geographical regions and provide our strategic partners with access to components of our proprietary Azymetric, EFECT, and/or ZymeLink 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 increases our ability to rapidly advance our product candidates while maintaining commercial rights to our own therapeutic pipeline. To date, we have received $204.0 million in the form of non-refundable upfront payments and milestone payments and are also eligible to receive up to $2.8 billion in preclinical and development milestone payments and $5.9 billion in commercial milestone payments under our existing collaboration agreements, as well as tiered royalties on potential future product sales. 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.

Other than the updates on licensing and collaboration agreements described in the "Recent Developments" section above, there have not been any material changes to the key terms of any of our licensing and collaboration agreements since December 31, 2019. 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, 2019.

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 and research and development 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.

Research and Development Expense

Research and development expenses consist of expenses incurred in performing research and development activities. These expenses include conducting preclinical research studies, clinical trials, and other indirect expenses in support of advancing our product candidates and therapeutic platforms. The following items are included in research and development expenses:

- fees paid to third-party manufacturers to produce our clinical product candidate supplies and on other third parties to store, monitor and transport bulk drug substance and drug product;
- fees paid to consultants, subcontractors, CROs, and other third-party vendors for work performed under our clinical trials and preclinical studies, including but not limited to laboratory work and analysis, database management, statistical analysis, and other activities;
- employee-related expenses such as salaries and benefits;
- stock-based compensation expense related to employees and consultants engaged in research and development activities;
- depreciation of laboratory equipment, computers and leasehold improvements;
- amounts paid to vendors and suppliers for laboratory supplies; and
- overhead expenses such as facilities and other allocated items.

Our research and development expenditures increased to $75.7 million for the six months ended June 30, 2020, compared to $41.3 million for the six months ended June 30, 2019. This was primarily due to an increase in clinical trial activity and associated manufacturing costs for zanidatamab, as well as an increase in other research and discovery activities in 2020 as compared to the same period in 2019.

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.

General and Administrative Expense

General and administrative expenses consist of salaries and related benefit costs for employees in our executive, finance, intellectual property, business development, human resources and other support functions, as well as legal and professional fees and other expenses. We expect general and administrative expenses to increase as we expand our infrastructure to support our ongoing research and development activities.

Other Income (Expense)

Other income (expense) primarily consists of interest expense, interest income, change in fair value of warrant liabilities 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, 2019.

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates, judgments and assumptions that affect the amounts reported in the 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 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 six months ended June 30, 2020 as compared to what has been described in our most recent annual consolidated financial statements.

The full extent to which the COVID-19 pandemic may directly or indirectly impact our business, results of operations and financial condition, including revenues, expenses, clinical trials, research and development costs and employee-related amounts, will depend on future developments that are evolving and highly uncertain, such as the duration and severity of the outbreak, including potential future waves or cycles, and the effectiveness of actions taken to contain and treat COVID-19. We considered the potential impact of COVID-19 when making certain estimates and judgments relating to the preparation of our condensed consolidated financial statements. While there was no material impact to our consolidated financial statements as of and for the three and six months ended June 30, 2020, our future assessment of the magnitude and duration of COVID-19, as well as other factors, could result in a material impact to our consolidated financial statements in future reporting periods.

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 June 30, 2020 within this Quarterly Report on Form 10-Q.

Results of Operations for the Three and Six Months Ended June 30, 2020 and 2019

Revenue

(dollars in millions)	Three Months Ended June 30,		Increase / (Decrease)		Six Months Ended June 30,		Increase / (Decrease)	
	2020	2019	$	%	2020	2019	$	%
Revenue from research and collaborations	$ 12.4	$ 7.9	$ 4.5	57 %	$ 20.6	$ 19.8	$ 0.8	4 %

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

Total revenue increased by $4.5 million in the three months ended June 30, 2020 compared to the same period in 2019. Revenue for the three months ended June 30, 2020 included recognition of a $12.0 million expansion fee resulting from the BMS collaboration agreement amendment, as well as $0.4 million in research support and other payments from our partners. Revenue for the same period in 2019 included $3.5 million for a commercial license option exercise fee received from Daiichi Sankyo, $3.0 million in development milestone payments from our partners, as well as $1.4 million in research support and other payments from our partners.

Total revenue increased by $0.8 million in the six months ended June 30, 2020 compared to the same period in 2019. Revenue for the six months ended June 30, 2020 included recognition of a $12.0 million expansion fee resulting from the BMS collaboration agreement amendment, recognition of a $5.0 million development milestone and $3.6 million in research support and other payments from our partners. Revenue for the same period in 2019 included $8.0 million received from Lilly for achievement of a development milestone upon Lilly's submission of an IND application, recognition of $3.5 million from deferred revenue relating to the upfront fee received in 2018 from BeiGene under our licensing and collaboration agreement for development of zanidatamab, $3.5 million for a commercial license option exercise fee received from Daiichi Sankyo, $3.0 million for development milestone payments from our partners , as well as $1.8 million in research support and other payments from our partners.

Research and Development Expense

(dollars in millions)	Three Months Ended June 30, 2020	2019	Increase / (Decrease) $	%	Six Months Ended June 30, 2020	2019	Increase / (Decrease) $	%
Research and development expense	$ 39.2	$ 23.8	$ 15.4	65 %	$ 75.7	$ 41.3	$ 34.4	83 %

Research and development expense increased by $15.4 million and $34.4 million in the three and six months ended June 30, 2020, respectively, compared to the same periods in 2019. This was primarily due to an increase in clinical trial activity and associated drug manufacturing costs for zanidatamab, an increase in development activity for ZW49, increase in licensing fee expenses as well as an increase in salaries and benefits expense from additional research and development headcount in 2020 as compared to the same periods in 2019. Research and development expense in the three months ended June 30, 2020 included non-cash stock-based compensation expense of $3.2 million comprised of $3.3 million from equity classified equity awards (three months ended June 30, 2019 – expense of $1.5 million) and a $0.1 million recovery related to the non-cash mark-to-market revaluation of certain historical liability classified equity awards (three months ended June 30, 2019 – expense of $1.6 million). Research and development expense in the six months ended June 30, 2020 included non-cash stock-based compensation expense of $3.6 million comprised of $5.5 million from equity classified equity awards (six months ended June 30, 2019 – expense of $2.6 million) and a $1.9 million recovery related to the non-cash mark-to-market revaluation of certain historical liability classified equity awards (six months ended June 30, 2019 – expense of $2.0 million).

General and Administrative Expense

(dollars in millions)	Three Months Ended June 30, 2020	2019	Increase / (Decrease) $	%	Six Months Ended June 30, 2020	2019	Increase / (Decrease) $	%
General and administrative expense	$ 13.5	$ 12.8	$ 0.7	5 %	$ 21.1	$ 21.8	$ (0.7)	(3) %

General and administrative expense increased by $0.7 million in the three months ended June 30, 2020 and decreased by $0.7 million in the six months ended June 30, 2020 compared to the same periods in 2019. The variances were primarily due to an increase in salaries and benefits expense resulting from an increase in headcount to support our expanding research and development activities and higher insurance expenses offset by lower non-cash stock-based compensation expense in 2020, compared to 2019. General and administrative expense for the three months ended June 30, 2020 includes non-cash stock-based compensation expense of $3.7 million comprised of $4.0 million from equity classified equity awards (three months ended June 30, 2019 – expense of $1.6 million) and a $0.3 million recovery related to the non-cash mark-to-market revaluation of certain historical liability classified equity awards (three months ended June 30, 2019 – expense of $4.8 million). General and administrative expense for the six months ended June 30, 2020 includes non-cash stock-based compensation expense of $0.7 million comprised of $6.5 million from equity classified equity awards (six months ended June 30, 2019 – $3.1 million) and a $5.8 million recovery related to the non-cash mark-to-market revaluation of certain historical liability classified equity awards (six months ended June 30, 2019 – expense of $6.1 million).

Other Income (Expense), net

(dollars in millions)	Three Months Ended June 30, 2020	2019	Increase / (Decrease) $	%	Six Months Ended June 30, 2020	2019	Increase / (Decrease) $	%
Other income (expense), net	$ 1.3	$ 1.0	$ 0.3	30 %	$ 6.4	$ 2.1	$ 4.3	205 %

Other income increased by $0.3 million for the three months ended June 30, 2020 compared to the same period in 2019. Net other income for the three months ended June 30, 2020 included $1.5 million of interest income, which was partially offset by a $0.2 million net foreign exchange loss. Net other income for the three months ended June 30, 2019 primarily included $1.2 million of net interest income, which was partially offset by a $0.2 million net foreign exchange loss.

Other income increased by $4.3 million for the six months ended June 30, 2020 compared to the same period in 2019. Net other income for 2020 included $3.4 million of interest income and a $3.1 million net foreign exchange gain primarily due to revaluation of stock option liabilities denominated in Canadian dollars. Other income for the six months ended June 30, 2019 primarily included $2.5 million of net interest income, which was partially offset by a $0.3 million net foreign exchange loss.

Liquidity and Capital Resources

Sources of Liquidity

Prior to the completion of our IPO, we had financed our operations primarily through private equity placements of our common shares, the issuance of convertible debentures that subsequently converted into equity securities, a private placement of preferred shares and a credit facility.

We closed our IPO on May 3, 2017, pursuant to which we sold 4,894,467 common shares (including the sale of 394,467 common shares to the underwriters upon their partial exercise of their over-allotment option to purchase additional shares on May 31, 2017) for gross proceeds of $63.6 million. We received net cash proceeds of $54.2 million, after underwriting discounts, commissions and offering expenses.

We completed a subsequent public offering on June 11, 2018, pursuant to which we sold 6,210,000 common shares (including the sale of 810,000 common shares to the underwriters upon their full exercise of their over-allotment option) for gross proceeds of $97.8 million. We received net proceeds of approximately $90.8 million, after underwriting discounts, commissions and offering expenses.

We completed a subsequent public offering on June 24, 2019 pursuant to which we sold (i) 7,013,892 common shares (including the sale of 1,458,336 common shares to the underwriters upon their full exercise of their over-allotment option) and (ii) 4,166,690 pre-funded warrants in lieu of common shares. We received gross proceeds of approximately $201.3 million and net cash proceeds of approximately $188.0 million, after underwriting discounts, commissions and offering expenses.

We completed a subsequent public offering on January 27, 2020 pursuant to which we sold (i) 5,824,729 common shares (including the sale of 900,000 common shares to the underwriters upon their full exercise of their over-allotment option) and (ii) 1,075,271 pre-funded warrants in lieu of common shares. We received gross proceeds of approximately $320.8 million and net cash proceeds of approximately $300.9 million, after underwriting discounts, commissions and estimated offering expenses.

In addition to equity offerings, our operations have been funded through upfront fees, milestone payments, and research support payments generated from our strategic collaborations and licensing agreements, government grants and SR&ED credits.

Funding Requirements

We have not generated any revenue from approved product sales to date 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. We expect to continue our strategic partnerships and will look for additional collaborations as well as expanded collaboration opportunities. Although it is difficult to predict our funding requirements, based on our current operating plan, we anticipate that our existing cash and cash equivalents, short-term investments and certain long-term investments combined with certain anticipated milestone payments from our collaborations will enable us to fund our operating expenses and capital expenditure requirements into 2022 and potentially beyond. 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. These estimates include future milestone payments which are dependent upon the successful completion of specified research and development activities by us and our collaborators and are therefore uncertain at this time. The successful development of our product candidates and the achievement of milestones by our strategic partners is uncertain, and therefore we are unable to estimate 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 Dependence on Third Parties – We may not realize the anticipated benefits of our strategic partnerships”.

As of June 30, 2020, we had $512.0 million in cash resources consisting of cash, cash equivalents, short-term investments and certain long-term investments.

Cash Flows

The following table represents a summary of our cash flows for the six months ended June 30, 2020 and 2019:

(dollars in millions)	Six Months Ended June 30, 2020	2019
Net cash provided by (used in):		
Operating activities	$ (87.4)	$ (34.6)
Investing activities	(124.4)	85.4
Financing activities	303.0	190.5
Effect of exchange rate changes on cash and cash equivalents	(0.1)	0.1
Net change in cash and cash equivalents	$ 91.1	$ 241.4

Operating Activities

During the six months ended June 30, 2020, cash used in operating activities was $87.4 million compared to $34.6 million for the same period in the prior year. The increase in net cash used in operating activities was primarily due to higher expenditures for expansion of our clinical programs and other research and development activities as well as lower receipts from collaboration partners in the form of milestones and research support payments in the six months ended June 30, 2020 compared to the same period in 2019.

Investing Activities

Net cash used in investing activities for the six month period ended June 30, 2020 is primarily related to purchases of short and long-term investments in marketable securities. A significant portion of the proceeds from our January 2020 public offering was invested in guaranteed investment certificates (“GICs”), term deposits and commercial paper resulting in a net change in short-term and long-term investments of $121.8 million. The remaining change was due to acquisition of property and equipment and intangible assets. Net cash provided by investing activities for the six months ended June 30, 2019 related primarily to net redemptions of short-term investments.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2020 included net proceeds of $300.9 million from our January 2020 public offering of equity securities, $1.8 million from stock option exercises, and $0.4 million from the issuance of common shares in relation to our employee stock purchase plan. Net cash provided by investing activities for the six months ended June 30, 2019 primarily included net proceeds of $189.0 million from our recent public offering of equity securities, $1.2 million from stock option exercises and $0.2 million from the issuance of common shares in relation to our employee stock purchase plan.

Contractual Obligations and Contingent Liabilities

Lease Commitments

We lease separate office and laboratory space in Vancouver, British Columbia, with terms of each lease expiring in August 2021. We entered into a lease on January 25, 2019 to serve as our new Vancouver, British Columbia headquarters, including both office and laboratory space. The commencement date of this lease depends upon completion of construction of the building and is currently estimated to be no later than September 1, 2021. This lease has an initial term of ten years, with two five-year extension options.

In addition, we lease office space in Seattle, Washington for which the lease term expires in February 2022. On February 25, 2019, we entered into a new lease for office space in Seattle and vacated the previous space. The commencement date of this new lease was July 30, 2019 for a portion of the space and June 23, 2020 for the remaining portion of the space. The expiration date of the lease is September 30, 2025.

We also lease office equipment under capital lease agreements. Future minimum lease payments under the non-cancellable operating leases and capital leases at June 30, 2020 are as follows:

	Payments due by period					
	Less Than 1 Year	1 to 2 Years	2 to 3 Years	3 to 4 Years	Thereafter	Total
	(dollars in thousands)					
Capital lease obligations	$ 30	$ 14	$ 14	$ 11	$ 27	$ 96
Operating lease obligations	2,103	3,815	3,785	3,827	19,804	33,334
Total contractual obligations	$ 2,133	$ 3,829	$ 3,799	$ 3,838	$ 19,831	$ 33,430

Other Commitments

We have 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, we are 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, we currently hold commercial and product liability insurance. This insurance limits our liability and may enable us to recover a portion of any future amounts paid. Historically, we have not made any indemnification payments under such agreements and we believe that the fair value of these indemnification obligations is minimal. Accordingly, we have not recognized any liabilities relating to these obligations for any period presented.

In connection with our acquisition of Kairos Therapeutics Inc. (“Kairos”), we may be required to make future payments to CDRD Ventures Inc. (“CVI”) upon the direct achievement of certain development milestones for products incorporating certain Kairos intellectual property, as well as royalty payments on the net sales of such products. For out-licensed products and technologies incorporating certain Kairos intellectual property, we may be required to pay CVI a mid-single-digit percentage of the future revenue as a result of a revenue sharing agreement. As of June 30, 2020, the development milestone payments had an estimated fair value of $1.05 million, which has been recorded as contingent consideration within other long-term liabilities (December 31, 2019: $0.98 million). The contingent consideration was calculated using a probability weighted assessment of the likelihood the milestones would be 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 in the statement of operations and comprehensive loss.

Contingencies

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

Off-Balance Sheet Arrangements

We have no material undisclosed off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our results of operations or financial condition.

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

As of July 31, 2020, our authorized share capital consisted of an unlimited number of common shares, each without par value, of which 45,627,264 were issued and outstanding, and an unlimited number of preferred shares, each without par value, none of which were issued and outstanding. As of July 31, 2020, we had 5,241,961 common shares issuable pursuant to 5,241,961 pre-funded warrants, 3,015,804 common shares issuable pursuant to 3,015,804 exercisable outstanding stock options, 3,272,012 common shares issuable pursuant to 3,272,012 outstanding options that were not exercisable at that date, and 78,679 outstanding restricted stock units.

Jumpstart Our Business Startups Act (the "JOBS Act") Accounting Election

Prior to December 31, 2019, the Company was an "emerging growth company" under the JOBS Act. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we irrevocably elected not to avail ourselves of this extended transition period and, as a result, adopted new or revised accounting standards on the relevant dates on which adoption of such standards was required for other public companies.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business that may affect our results of operations, cash flows and fair values of assets and liabilities, including interest rate movements, volatility in foreign currency exchange rates, and changes in economic conditions as a result of the COVID-19 pandemic. The primary market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates and exchange rates.

Interest Rate Risk

Our exposure to interest rate risk relates primarily to our cash, cash equivalent, short-term investment and long-term investment portfolio. At June 30, 2020 and December 31, 2019, we had cash, cash equivalents, short-term investments and long-term investments of $512.0 million and $298.9 million, respectively, consisting primarily of funds in cash, guaranteed investment certificates and term deposits. The primary objective of our investment activities is to preserve principal while also maintaining liquidity and maximizing investment returns without significantly increasing risk. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio, we do not believe that a hypothetical 10% increase in interest rates or in investment returns would have a material effect on the fair market value of our portfolio or investment income as our investment portfolio is primarily composed of short term investments and our long term investments in debt securities are held to maturity, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

Foreign Currency Exchange Risk

Our functional currency is the U.S. dollar as most of our revenues and operating expenses are denominated in U.S. dollars. We incur certain operating expenses in Canadian dollars and accordingly, are subject to foreign currency transaction risk. We do not use derivative instruments to hedge exposure to foreign transaction risk due to the low volume of transactions denominated in Canadian dollars and other foreign currencies. We do not anticipate that foreign currency transaction gains or losses will be significant at our current level of operations.

At June 30, 2020, our net monetary assets denominated in Canadian dollars were $30.5 million (C$41.7 million). We are subject to foreign currency translation risk when translating these foreign currency denominated net monetary assets to U.S. dollars for period end financial statement preparation. The fluctuation of the Canadian dollar relative to the U.S. dollar will have an impact on the reported balances for net assets, net loss and shareholders' equity in our consolidated financial statements. A hypothetical 10% increase (decrease) in the value of the Canadian dollar relative to the U.S. dollar would result in a foreign exchange gain (loss) of $3.1 million in our Condensed Consolidated Statement of Loss and Comprehensive Loss for the six month period ended June 30, 2020.

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 U.S. Securities Exchange Act of 1934, as amended (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 June 30, 2020, 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 June 30, 2020 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 June 30, 2020, 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 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.

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

We have a limited number of product candidates, all which are still in preclinical or early 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 regulatory authorities outside the United States. Our product candidates are in early stages of development and we have not submitted an application, or received marketing approval, for any of our product candidates. Furthermore, the fact that our core competencies have been recognized through strategic partnerships does not improve our product candidates' outlook for regulatory approval. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the

FDA. Obtaining regulatory approval of our product candidates will depend on many factors, including, but not limited to, the following:

- successfully completing preclinical studies, including product chemistry, toxicity and formulation studies;
- 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 commercial manufacturing capabilities;
- a potential pre-approval audit of the nonclinical and clinical trial sites that generated the data 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 very expensive, time consuming and 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 non-U.S. regulatory authorities.

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 foreign regulatory authorities. 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 planned 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. Success in preclinical studies or early-stage clinical trials does not mean that future clinical trials or registration 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 non-U.S. regulatory authorities, despite having progressed through preclinical studies and initial clinical trials. Product candidates that have shown promising results in early clinical trials may still suffer significant setbacks in subsequent clinical trials or registration clinical trials. For example, a number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials. Similarly, preclinical interim results of a clinical trial do not necessarily predict final results.

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 are currently evaluating zanidatamab in Phase 1 and 2 clinical trials and ZW49 in a Phase 1 clinical trial in patients with recurrent or metastatic HER2-expressing solid tumors. 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. 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;
- 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 an 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 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;
- the need to repeat or terminate clinical trials as a result of inconclusive or negative results or unforeseen complications in testing; and
- 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.

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.

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.

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 products 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 clinical tests for our product candidates pursuant to the relevant partnership agreement, 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, on May 30, 2018, the federal Right to Try Act was signed into law. The law, 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 future 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.

Our business has been and may continue to be adversely affected by the COVID-19 pandemic.

COVID-19 has had a broad adverse impact on the global economy across many industries and has 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. Although COVID-19 has had an impact on our research and development activities, it has not caused a significant disruption to our business operations to date. In March 2020, we transitioned our workforce to a remote working arrangement to protect the health and safety of our employees. In June 2020, we implemented a program to facilitate the phased return of employees to our lab and office facilities pursuant to enhanced health and safety protocols consistent with guidelines issued by local health authorities. Our preclinical research activities are being supplemented by support from external contract research organizations to offset the reduced capacity at our lab facilities. Clinical trial activities, including patient enrollment and site activation, have been delayed due to COVID-19. As of the date of this report, these clinical activities are returning to pre-COVID levels. Although the adverse impacts we have experienced to date will likely slow the pace of execution on certain of our preclinical and clinical programs, they have not had a material impact on our financial condition, liquidity or longer-term strategic development and commercialization plans.

The extent to which COVID-19 may cause more significant disruptions to our business and greater impacts to our results of operations will depend on future developments, which are highly uncertain and cannot be predicted, such as the duration of the outbreak (including future potential waves or cycles), travel restrictions and social distancing, business closures or business disruptions and the effectiveness of actions taken to contain and treat the disease and to address its impact, including on financial markets.

If the COVID-19 pandemic worsens or continues for a prolonged period of time, 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 an 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 difficulties in recruiting clinical site investigators and clinical site staff;

- disruptions in supply, logistics or other activities related to the procurement of materials, 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 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;
- 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 the COVID-19 pandemic 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 preclinical research, clinical, regulatory and other professional staff on the timeframe required to support our research and development programs.

In addition, COVID-19 could result in the continued significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. Financial volatility has adversely affected, and may continue to adversely affect, the value of our common shares.

The COVID-19 pandemic continues to rapidly evolve, and we will continue to monitor the effects of COVID-19 on our business. While the extent of the impact of the COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on our business, financial condition and operating results.

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

If a product candidate is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet needs for this condition, the sponsor may apply for FDA Fast Track designation. If Fast Track designation is obtained, the FDA may prioritize interactions with the sponsor concerning the designated development program and conduct a rolling review of sections of a New Drug Application before the application is complete. The FDA has granted two 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 refractory BTC. These Fast Track designations do not ensure that we will experience a faster development, regulatory review or approval process compared to conventional FDA procedures or that we 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 our clinical development program.

We have conducted, and may in the future conduct, clinical trials for existing or future product candidates in sites outside the United States and the FDA may not accept data from trials conducted in such locations.

We have conducted, and may in the future choose to conduct, clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all

applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside the United States. If the FDA does not accept the data from any clinical trials we may 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 permanently halt our development of any future 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. Average review times at the agency have fluctuated in recent years as a result. 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 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. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Separately, in response to the global COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most domestic and foreign inspections of manufacturing facilities, and regulatory authorities outside the United States have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. Although the FDA has indicated that it intends to resume domestic inspections if health circumstances permit, if a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

Before obtaining regulatory approval for the commercial distribution of our product candidates, we must conduct, at our own expense, extensive preclinical tests and clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Additionally, the results from nonclinical testing or early clinical trials of a product candidate may not predict the results that will be obtained in subsequent subjects or in subsequent human clinical trials of that product candidate or any other 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 product candidates under development or reprioritize our focus on other product candidates at any time and at our discretion.

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 such 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 early clinical development. Additionally, all of our product candidates are required to undergo ongoing safety testing in humans as part of clinical trials. Consequently, not all adverse effects of drugs can be predicted or anticipated. 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. We believe zanidatamab has been well tolerated in human clinical trials and zanidatamab and ZW49 have demonstrated favorable safety profiles in animals; however, zanidatamab and ZW49 continue to be evaluated in clinical trials. The results of these and future clinical trials may show that zanidatamab, ZW49 or our other 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 and autoimmune disorders, including many major pharmaceutical and biotechnology companies. These treatments consist both of small-molecule drug products, as well as biologics that work by using next-generation antibody therapeutic platforms to address specific cancer targets. These companies include Macrogenics, Inc., AstraZeneca PLC/Daiichi Sankyo, Roche AG, Seattle Genetics, Inc. and others.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, and are more convenient or are 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.

Our product candidates, for which we intend to seek approval, may face competition sooner than anticipated.

Our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of biosimilar products. Biosimilar products are expected to become available over the coming years. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive biosimilar products, if any have been approved by then. The Biologics Price Competition and Innovation Act of 2009, which is included in the 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 Biologics License Application ("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;
- the degree of cost-effectiveness of our product candidates;
- availability of alternative therapies at similar or lower cost, including generic 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 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.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. The FDA has granted Orphan Drug Designation to zanidatamab for the treatment of BTC, GEA and ovarian cancer and we may seek Orphan Drug Designation 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 European Medicines Agency ("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 we obtain orphan drug exclusivity for zanidatamab, or 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.

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.

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.

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.

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 presently 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 expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

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 forego or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs, therapeutic platforms and product candidates for specific indications may not yield any commercially viable products. 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.

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

A key element of our strategy is to use and expand 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 to date 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 a steady stream of 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 share 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 current good manufacturing practices ("cGMP") and current good clinical practice ("cGCP"), 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. 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.

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.

If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our financial condition or results of operations.

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.

Changes 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.

Acquisitions or joint ventures could disrupt our business, cause dilution to our shareholders and otherwise harm our business.

We actively evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures or investments in complementary businesses. 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;
- 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.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Also, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize or such strategic alliance, joint venture or acquisition 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 future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.

In most foreign countries, particularly in 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 foreign 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, or 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, 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 collect and store petabytes of sensitive data, including legally protected health information, personally identifiable 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, including 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.

The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure and that of any third-party billing and collections provider we may utilize, may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or 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. Although we have implemented security measures and a formal enterprise security program to prevent unauthorized access to patient data, there is no guarantee that we can continue to protect our systems from breach. Unauthorized access, loss or dissemination could also disrupt our operations (including our ability to conduct our analyses, provide test results, bill payors or providers, process claims and appeals, 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 that perform services for them that involve individually identifiable health information. Mandatory penalties for HIPAA violations can be significant. A single breach incident can result in violations of multiple standards. If a person knowingly or intentionally obtains or discloses personal health information in violation of HIPAA requirements, criminal penalties may also be imposed. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. Although drug manufacturers are not directly subject to HIPAA, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Furthermore, in the event of a breach as defined by HIPAA, HIPAA regulations impose specific reporting requirements to regulators, individuals impacted by the breach and 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, U.S. states have enacted and are considering enacting laws relating to the protection of patient health and other data, which may be more rigorous than, or impose additional requirements beyond those required by, HIPAA. For example, the California Consumer Privacy Act ("CCPA") became effective on January 1, 2020. The CCPA gives California residents 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 by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations as well as a private right of action for data breaches that is expected to increase data breach litigation. Although there are limited exemptions for clinical trial data and the CCPA's implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, the CCPA may increase our compliance costs and potential liability. Many similar privacy laws have been proposed at the federal level and in other states.

We may also become subject to laws and regulations in non-U.S. countries covering data privacy and the protection of health-related and other personal information. In particular, the European Economic Area ("EEA") has adopted data protection laws and regulations, which impose significant compliance obligations. Laws and regulations in these jurisdictions apply broadly to the collection, use, storage, disclosure, processing and security of personal information that identifies or may be used to identify an individual, such as names, contact information, and sensitive personal data such as health data. These laws and regulations are subject to frequent revisions and differing interpretations, and have generally become more stringent over time.

As of May 25, 2018, the General Data Protection Regulation 2016/676 ("GDPR") replaced the Data Protection Directive (Directive 95/46/EC) with respect to the processing of personal data in the EEA. The GDPR imposes many requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, 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 data. 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 data protection 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.

Separate from, and in addition to, the GDPR requirements, certification requirements for the hosting of health data will vary by jurisdiction (and may or may not apply to hosts of health data). To the extent we begin to operate in various EEA countries, 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 data protection laws in the United States, the EEA, 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 data privacy or data protection may result in claims, warnings, communication, requests or investigations from individuals, supervisory authorities or other legal or regulatory authorities in relation to our processing of personal data. 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.

Furthermore, the loss 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 could also have a material adverse effect on our business.

In addition, as a result of the COVID-19 pandemic, we may face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities.

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. There have been judicial, Congressional and executive branch challenges to certain aspects of the PPACA and we expect there will be additional challenges and amendments to the PPACA in the future. For example, the Tax Cuts and Jobs Act, signed into law in 2017, repealed the individual health insurance mandate, which is considered a key component of the PPACA. In addition, there is currently litigation pending in federal court in the United States regarding the constitutionality of the PPACA and the individual mandate. This and other ongoing challenges to the PPACA and new legislative proposals have resulted in uncertainty regarding the PPACA's future viability and destabilization of the health insurance market.

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 began in 2013 and will remain in effect through 2027 unless additional Congressional action is taken, calls for aggregate reductions to Medicare payments to providers of up to 2% per fiscal year. 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. In addition, President Trump and the Secretary of the U.S. Department of Health and Human Services ("HHS") released the "American Patients First Blueprint" and have begun implementing certain portions. The initiative includes proposals to increase generic drug and biosimilar competition, enable the Medicare program to negotiate drug prices more directly and improve transparency regarding drug prices and ways to lower consumers' out-of-pocket costs. Further, many states have proposed or enacted legislation that seeks 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. Both the U.S. Congress and state legislatures are considering and have proposed various bills that would reform drug purchasing and price negotiations, allow greater use of utilization management tools to limit Medicare Part D coverage, facilitate the import of lower-priced drugs from outside the United States and encourage the use of generic drugs. Such initiatives and legislation may 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.

Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. It is unclear whether any of these proposed bills will be signed into law, and if enacted, what effect these or other legislative measures would have on our business.

In the EU similar political, economic and regulatory developments may affect our ability to profitably commercialize our current or 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.

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. 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 weakness, including inflation, or political 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 United Kingdom'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;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- differing reimbursement regimes, including price controls;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing foreign operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- 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.

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, without limitation, 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, but are not limited to, 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, 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;
- the federal Open Payments program under the Physician Payments Sunshine Act, created under Section 6002 of the PPACA and its implementing regulations, requires certain 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 to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors and, effective in 2022, advanced practice nurses and physician assistants) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to HHS ownership and investment interests held by physicians (as defined above) and their immediate family members; and
- analogous state and foreign laws and regulations, including: state anti-kickback and false claims laws that may apply to our business practices (including, but not limited to, 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. 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, without limitation, 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.

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 abroad 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.

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 to date 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 years ended December 31, 2018 and 2019 and for the six months ended June 30, 2020 was $36.6 million, $145.4 million and $70.1 million, respectively. As of June 30, 2020, our accumulated deficit was $360.8 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase 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 and personnel to support our product development efforts and operations as a public company. The net losses and negative cash flows incurred to date, together with expected future losses, have had, and likely will continue to have, an adverse effect on our shareholders' 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. For example, our expenses could increase if we are required by the FDA to perform trials in addition to those that we currently expect to perform, or if there are any delays in completing our currently planned clinical trials or in the development of any of our product candidates.

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 shareholders 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 in the early stages of developing our product candidates, and we have not completed development of any products. Our revenue to date 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 for the foreseeable future.

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 are currently advancing two of our product candidates through clinical development as well as other potential product candidates through discovery and preclinical development. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. In order to obtain such regulatory approval, we will be required to conduct clinical trials for each indication for each of our product candidates. We will continue to require additional funding to complete the development and commercialization of our product candidates and to continue to advance the development of our other product candidates, and such funding may not be available on acceptable terms or at all.

Although it is difficult to predict our liquidity requirements, based upon our current operating plan, we believe that our existing cash and cash equivalents and short-term investments and projected revenue from our existing strategic partnerships and licensing agreements will enable us to fund our operating expenses and capital expenditure requirement into 2022 and potentially beyond. We may also be eligible to receive certain research, development and commercial milestone payments in the future, as described under “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Strategic Partnerships and Collaborations” under Item 2 of Part I above. However, because successful development of our product candidates and the achievement of milestones by our strategic partners is uncertain, we are unable to estimate the actual funds we will require to complete research and development and to commercialize our product candidates.

Our future funding requirements will depend on many factors, including but not limited to:

- 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 need and ability to hire 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, 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, strategic partnerships and grant funding.

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.

Raising additional capital may cause dilution to our shareholders, 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 shareholders' ownership interest will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect our shareholders' rights as common shareholders. 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.

Unstable market and economic conditions may have serious adverse consequences on our business and financial condition.

Global credit and financial markets experienced extreme disruptions at various points over in the past several years, including most recently in connection with the COVID-19 pandemic, characterized by diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the disruption in credit and financial markets and deterioration of confidence in economic conditions in connection with COVID-19 continues, of it another such disruption occurs, our business may be adversely affected. If the equity and credit markets were to deteriorate significantly in the future, it may make any necessary debt or equity financing more difficult to complete, costlier, 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 share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our current strategic partners, service providers, manufacturers and other partners would not survive or be able to meet their commitments to us under such circumstances, which could directly affect our ability to attain our operating goals on schedule and on budget.

We are subject to risks associated with currency fluctuations, and changes in foreign currency exchange rates could impact our results of operations.

Management assesses its functional currency to be the U.S. dollar based on management's analysis of the primary economic environment in which we operate. Our cash, cash equivalents and short term investments are primarily denominated in U.S. dollars. As of June 30, 2020, 6% of our cash and cash equivalents and short-term investments was denominated in Canadian dollars. However, if our Canadian-dollar-denominated holdings substantially increase in the future, fluctuations in U.S. dollar and Canadian dollar exchange rates could result in a material increase in reported expenses relative to revenue, and therefore could cause our operating income (expense) to appear to decline materially. Fluctuations in foreign currency exchange rates also impact the reporting of our receivables and payables in non-Canadian currencies. As a result of such foreign currency fluctuations, it could be more difficult to detect underlying trends in our business and results of operations. In addition, to the extent that fluctuations in currency exchange rates cause our results of operations to differ from our expectations or the expectations of our investors, the trading price of our common shares could be adversely affected.

Although we do not currently do so, from time to time, we may engage in exchange rate hedging activities in an effort to mitigate the impact of exchange rate fluctuations. However, any hedging technique we implement may fail to be effective. If our hedging activities are not effective, changes in currency exchange rates may have a more significant impact on the trading price of our common shares.

Risks Related to Our Dependence on Third Parties

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 do not yet have any capability for sales, marketing or distribution. Accordingly, we have entered into strategic partnerships with other companies that we believe can provide such capabilities, including our collaboration and license agreements with Merck, Lilly, BMS, GSK, Daiichi Sankyo, Janssen, LEO, BeiGene and Iconic. 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;
- 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 Merck, Lilly, BMS, GSK, Daiichi Sankyo, Janssen, LEO, BeiGene and Iconic 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 the COVID-19 pandemic on our strategic partners' operations or business.

We may not realize the anticipated benefits of our strategic partnerships.

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. Moreover, our estimates of the potential revenue we are eligible to receive under our strategic partnerships may include potential payments in respect of therapeutic programs for which our partners have discontinued development or may discontinue development in the future. Furthermore, our strategic partners may not keep us informed as to the status of their in-house research activities and they may fail to exercise options embedded within certain agreements. Any discontinuation of product development by our strategic partners could reduce the amounts receivable under our strategic partnerships below the stated amounts we are eligible to receive under those agreements. If we do not receive the funding we expect under these 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. All of the risks relating to product development, regulatory approval and commercialization described in our Quarterly Report on Form 10-Q also apply to the activities of our program strategic partners.

Additionally, subject to its contractual obligations to us, if one of our strategic partners is involved in a business combination, the partner might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our strategic partners terminates its agreement with us, we may find it more difficult to attract new partners.

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 clinical product candidates and on other third parties to 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 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 extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, contamination and 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 by starting cells that are stored in a cell bank. We have one master cell bank for each antibody manufactured in accordance with cGMP. While we believe we would have adequate back up should any cell bank be lost in a catastrophic event, it is possible that we could lose multiple cell banks and have our manufacturing severely impacted by the need to replace the cell banks. 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 synthesize and 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.

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. 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 cGCP 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 cGCP 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 cGCP 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 cGCP 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 but not limited to external financial, legal, 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.

Natural disasters, public health crises, political crises, and other catastrophic events or other events outside of our control may damage the facilities or disrupt the operations of our strategic partners, third-party manufacturers, suppliers or other third parties upon which we rely, and could delay or impair our ability to initiate or complete our clinical trials or commercialize approved products.

Our strategic partners, third-party manufacturers, suppliers and other third parties upon which we rely have operations around the world and are exposed to a number of global and regional risks outside of our control. These include, but are not limited to, natural disasters, such as earthquakes, tsunamis, power shortages or outages, floods or monsoons, public health crises, such as the current COVID-19 pandemic, political crises, such as terrorism, war, political instability or other conflict, or other events outside of our control.

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 we are unable to invalidate those patents, or if licenses for them are not available on commercially reasonable terms or at all, our business could be materially harmed.

We are also aware of third-party patents and patent applications containing claims directed to compositions and methods for treating various forms of cancer with antibodies targeting HER2, alone or in combination with other anti-cancer agents, which patents and applications could potentially be construed to cover our product candidates and the use thereof to treat cancer. If our products or our strategic partners' products were to be found to infringe any such patents, and we were unable to invalidate those patents, or if licenses for them are not available on commercially reasonable terms, or at all, our business could be materially harmed. These patents may not expire before we receive marketing authorization for our product candidates, and could delay the commercial launch of one or more future products. There is also 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 technology that we require may materially harm our business, financial condition and results of operations. Moreover, our failure to maintain a license to 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 have become commonplace. The types of situations in which we may become a party to such litigation or proceedings include:

- we or our strategic partners may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties, to obtain a judgment that our products or processes do not infringe those third parties' patents or to obtain a judgement that those parties' patents are unenforceable;
- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference, derivation or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;
- if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights or initiating other proceedings, including post-grant proceedings and *inter partes* reviews, we and our strategic partners will need to defend against such proceedings; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our strategic partners would need to defend against such proceedings.

These lawsuits would 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 the third party's patents and would order us or our strategic partners to stop the activities 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 will 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 foreign countries.

Moreover, the patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years 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 foreign 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 foreign 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 foreign 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, particularly in a foreign jurisdiction, 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, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the 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 foreign 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 and 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 owned by or licensed 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 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, 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 shares.

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 natural 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.

If we do not obtain protection under the Hatch-Waxman amendments and similar foreign legislation 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 Drug Price Competition and Patent Term Restoration Act of 1984, referred to as 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 proprietary computational technologies, including unpatented know-how and other proprietary information, as trade secrets. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, strategic partners and others upon the commencement of their relationships with us. These agreements require 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. Thus, despite such agreement, such inventions may become assigned to third parties. 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 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.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming and the outcome is unpredictable. 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 in the future 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. Recent 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.

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 foreign countries do not protect intellectual property rights to the same extent as federal and state 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. Recent 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 foreign jurisdictions. The legal systems of certain countries, particularly certain developing 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, particularly developing countries. For example, unlike other countries, 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.

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 and insider trading.

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.

If we market products in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting 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 in recent years to restrict certain marketing practices in the pharmaceutical industry, and include, but are not limited to, anti-kickback, false claims, data privacy and security and transparency statutes and regulations.

Federal false claims laws prohibit 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. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. 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.

Over the past few years, a number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as:

- providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers;
- reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates;
- engaging in off-label promotion;
- submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates; and
- providing funding to third-party charitable foundations in order to offset patient co-payment obligations.

The 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 certain 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 or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to comply with required reporting requirements could subject applicable manufacturers and others to substantial civil money 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 Washington State and the Province of British Columbia 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.

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 the research and development, clinical and business expertise of Dr. Ali Tehrani, Ph.D., our President and Chief Executive Officer, Dr. Diana Hausman, our Chief Medical Officer, and other 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 executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. In addition, we will need to expand and 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 executive officers and key 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 may limit our ability to retain and motivate these 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 growth strategy will be limited.

We will need to grow our organization, and we may experience difficulty in managing this growth, which could disrupt our operations.

As of June 30, 2020, we had 295 full-time employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, financial and other resources. Additionally, as our product candidates enter and advance through preclinical studies and any clinical trials, we will need to expand our development, manufacturing, regulatory sales and marketing capabilities or contract with other organizations to provide these capabilities for us. 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 these growth activities. We may not be able to effectively manage the 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. Our expected 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 our expected 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 Shares

Our share price is likely to be volatile and the market price of our common shares may drop below the price paid by shareholders.

Investors should consider an investment in our common shares as risky and invest only if they can withstand a significant loss and wide fluctuations in the market value of their investment. In addition, the stock market has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. Some of the factors that may cause the market price of our common shares 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;
- 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 shares;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- public concern over our product candidates or any future approved products;
- litigation;
- future sales of our common shares;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key personnel;
- changes in the structure of health care payment systems in the United States or overseas;
- failure of any of our product candidates, if approved, to achieve commercial success;
- economic and other external factors or other disasters or crises, such as the COVID-19 pandemic;
- 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;
- overall fluctuations in U.S. equity markets; 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, including recently in connection with the ongoing COVID-19 pandemic, 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 relating to the ongoing COVID-19 pandemic, 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.

In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our shareholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit and divert the time and attention of our management, which could seriously harm our business.

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

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

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

A large volume of sales of our common shares could decrease the prevailing market price of our common shares 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 shares does not occur, the mere perception of the possibility of these sales could depress the market price of our common shares and have a negative effect on our ability to raise capital in the future.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to corporate governance standards.

As a public company, we incur significant legal, accounting and other expenses. In addition, our administrative staff are required to perform additional tasks not required for a private company. For example, as a public company, we have adopted additional internal controls and disclosure controls and procedures, retained a transfer agent and adopted an insider trading policy. As a public company, we bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under securities laws.

In addition, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and the related rules and regulations implemented by the SEC, the applicable Canadian securities regulators and the New York Stock Exchange ("NYSE") have legal and financial compliance costs and make some compliance activities time consuming. We intend to invest resources to comply with evolving laws, regulations and standards, and such investment will result in increased general and administrative expenses and may divert management's time and attention from our other business activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Additionally, as a public company, we maintain our directors' and officers' liability insurance coverage, which results in higher insurance costs. In the future, it may be more expensive or more difficult for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

Under the corporate governance standards of the NYSE, a majority of our board of directors and each member of our audit committee must be an independent director. Canadian securities laws require each member of the audit committee to be independent within the meaning of Canadian securities laws. As of the date of this Quarterly Report on Form 10-Q, we meet these requirements, but we may in the future encounter difficulty in attracting and retaining qualified persons to serve on our board of directors and the audit committee, and our board of directors and management may be required to divert significant time and attention and resources away from our business to identify qualified directors. If we fail to attract and retain the required number of independent directors, we may be subject to the delisting of our common shares from the NYSE.

Effective December 31, 2019, we no longer qualify as an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies no longer apply, which will increase our costs and demands on management.

As a result of our public float (the market value of our common shares held by non-affiliates) as of June 28, 2019, we became a large accelerated filer as of December 31, 2019 and therefore no longer qualify as an "emerging growth company" as defined in the JOBS Act. Additionally, due to our public float as of June 28, 2019, we no longer qualify as a "smaller reporting company" as defined under the Exchange Act.

As an emerging growth company and a smaller reporting company, we previously had the option to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies, including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions related to certain "Say-on-Pay" rules under Section 14A of the Exchange Act, including requirements to hold a nonbinding advisory vote on named executive officer compensation, the frequency of such votes and arrangements with named executive officers regarding compensation based on or related to an acquisition, merger, or similar transaction.

Further, as an emerging growth company, we had not been subject to Section 404(b) of the Sarbanes Oxley Act ("Section 404"), which requires that our independent registered public accounting firm provide an attestation report of our internal controls over financial reporting. Preparing such attestation report and the cost of compliance with reporting requirements that we have not previously implemented has increased our expenses and requires significant management time. Investors may find our common shares less attractive because of the additional compliance costs. In addition, 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 or significant deficiencies 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. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common shares.

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, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common shares.

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. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. Pursuant to Section 404, and related rules adopted by the SEC and the U.S. Public Company Accounting Oversight Board (the "PCAOB"), our management is required to disclose changes made in our internal control over financial reporting on a quarterly basis and assess the effectiveness of our internal control over financial reporting annually. In connection with previous financial reports, we elected to take advantage of certain exceptions from reporting requirements available to emerging growth companies under the JOBS Act and therefore had not, prior to the filing of our Annual Report on Form 10-K for our fiscal year ended December 31, 2019, delivered an auditor's attestation report on the effectiveness of our internal control over financial reporting pursuant to Section 404.

As of December 31, 2019, we no longer qualified as an emerging growth company. As a result, our independent registered public accounting firm is required to issue an attestation report on the effectiveness of our internal control over financial reporting, pursuant to Section 404. Going forward, 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 or significant deficiencies 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. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common shares.

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.

We do not anticipate paying cash dividends, and accordingly, shareholders must rely on share appreciation for any return on their investment.

We have never paid any dividends on our common shares. 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 shares in the foreseeable future. As a result, capital appreciation, if any, of our common shares will be the sole source of gain on investment in our common shares for the foreseeable future. Investors seeking cash dividends should not invest in our common shares.

The NYSE may delist our securities from its exchange, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.

Our securities may fail to meet the continued listing requirements to be listed on the NYSE. If the NYSE delists our common shares from trading on its exchange, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- a determination that our common shares is a "penny stock", which will require brokers trading in our common shares to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our common shares;
- 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.

We are governed by the corporate laws of Canada, which in some cases have a different effect on shareholders than the corporate laws of the United States.

We are governed by the Business Corporations Act (British Columbia) ("BCBCA") and other relevant Canadian laws, which may affect the rights of shareholders differently than those of a company governed by the laws of a U.S. jurisdiction, and may, together with our charter documents, have the effect of delaying, deferring or discouraging another party from acquiring control of our company by means of a tender offer, a proxy contest or otherwise, or may affect the price an acquiring party would be willing to offer in such an instance. The material differences between the BCBCA and Delaware General Corporation Law ("DGCL") that may have the greatest such effect include, but are not limited to, the following: (i) for certain corporate transactions (such as mergers and amalgamations or amendments to our articles) the BCBCA generally requires the voting threshold to be a special resolution approved by 66 2/3% of shareholders, or as set out in the articles, as applicable, whereas DGCL generally only requires a majority vote; and (ii) under the BCBCA a holder of 5% or more of our common shares can requisition a special meeting of shareholders, whereas such right does not exist under the DGCL. We cannot predict whether investors will find our company and our common shares less attractive because we are governed by foreign laws.

U.S. civil liabilities may not be enforceable against us, our directors, our officers or certain experts named in our Annual Report on Form 10-K.

We are governed by the BCBCA and our principal place of business is in Canada. One of our directors and certain of our officers, as well as certain experts named herein, reside outside of the United States, and all or a substantial portion of their assets as well as all or a substantial portion of our assets are located outside the United States. As a result, it may be difficult for investors to effect service of process within the United States upon us and such director, officers and experts or to enforce judgments obtained against us or such persons, in U.S. courts, in any action, including actions predicated upon the civil liability provisions of U.S. federal securities laws or any other laws of the United States. Additionally, rights predicated solely upon civil liability provisions of U.S. federal securities laws or any other laws of the United States may not be enforceable in original actions, or actions to enforce judgments obtained in U.S. courts, brought in Canadian courts, including courts in the Province of British Columbia. Furthermore, provisions in our articles provide that, unless we consent in writing to the selection of an alternative forum, the Supreme Court of British Columbia and the appellate courts therefrom, to the fullest extent permitted by law, will be the sole and exclusive forum for certain actions or proceedings brought against us, our directors and/or our officers. These provisions may limit our shareholders' ability to bring a claim against us in a judicial forum that our shareholders consider favorable or convenient for such disputes and may discourage lawsuits with respect to such claims.

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.

The trading market for our common shares 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 shares negatively, our share 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 share price or trading volume to decline. Moreover, the research and reports that analysts publish may suggest a price for our common shares 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.

U.S. holders of the company's shares may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

We believe that we were not classified as a passive foreign investment company ("PFIC") for the taxable year ended December 31, 2019. However, the determination as to whether we are a PFIC for any taxable year is based on the application of complex U.S. federal income tax rules that are subject to differing interpretations. If we are a PFIC for any taxable year during which a U.S. Holder (as defined under Item 5 of our Annual Report on Form 10-K, "Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities – Certain U.S. Income Tax Considerations For U.S. Holders") holds the common shares, it would likely result in adverse U.S. federal income tax consequences for such U.S. Holder. U.S. Holders should carefully read Item 5 of our Annual Report on Form 10-K, "Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities – Certain U.S. Income Tax Considerations For U.S. Holders" for more information and consult their own tax advisors regarding the likelihood and consequences if we are treated as a PFIC for U.S. federal income tax purposes, including the advisability of making a "qualified electing fund" election (including a protective election), which may mitigate certain possible adverse U.S. federal income tax consequences but may result in an inclusion in gross income without receipt of such income.

Our principal shareholders, in aggregate, could exert substantial control 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 shareholders, together with their affiliates and related persons, in aggregate, own or could acquire (contingent upon the exercise of convertible securities they own) approximately 37.5% of our outstanding common shares as of June 30, 2020 (27.5% excluding the exercise of convertible securities). Our directors and named executive officers beneficially own, in the aggregate, approximately 4.4% of our outstanding common shares as of June 30, 2020. Our principal shareholders, if acting together (with or without our directors and named executive officers), may have the ability to exert substantial control over the outcome of matters submitted to our shareholders for approval, including but not limited to the election and removal of directors and any merger or sale of all or substantially all of our assets. In addition, our principal shareholders, if acting together (with or without our directors and named executive officers), may have the ability to exert substantial control over the management and affairs of our company. Accordingly, this concentration of ownership could harm the market price of our common shares 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.

Provisions in our corporate charter documents and Canadian law could make an acquisition of us, which may be beneficial to our shareholders, more difficult and may prevent attempts by our shareholders to replace or remove our current management and/or limit the market price of our common shares.

Provisions in our notice of articles and articles, as well as certain provisions under the BCBCA, and applicable Canadian securities laws, may discourage, delay or prevent a merger, acquisition or other change in control of us that shareholders may consider favorable, including transactions in which they might otherwise receive a premium for their common shares. These provisions include the establishment of a staggered board of directors, which divides the board into three groups, with directors in each group serving a three-year term. The existence of a staggered board can make it more difficult for shareholders to replace or remove incumbent members of our board of directors. As such, these provisions could also limit the price that investors might be willing to pay in the future for our common shares, thereby depressing the market price of our common shares. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our board of directors. Among other things, these provisions include the following:

- shareholders cannot amend our articles unless such amendment is approved by shareholders holding at least a majority of the shares entitled to vote on such approval;
- our board of directors may, without shareholder approval, issue preferred shares having any terms, conditions, rights, preferences and privileges as the board of directors may determine; and
- shareholders must give advance notice to nominate directors or to submit proposals for consideration at shareholders' meetings.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

During the six months ended June 30, 2020, we (i) granted our Canadian employees, consultants and advisors options to purchase an aggregate of 670,425 common shares under our equity compensation plan at exercise prices ranging from C$47.87 to C$63.59 and ranging from $35.20 to $44.92 per share, (ii) made an aggregate of 21,451 common shares available to eligible Canadian employees for purchase under our employee stock purchase plan at purchase price of $19.54 per share, and (iii) granted certain Canadian employees 44,377 restricted stock units under our equity compensation plan. Such options, shares and restricted stock units were issued and sold in offshore transactions pursuant to Regulation S under the Securities Act.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit No.	Description
3.1	Form of Notice of Articles of the Registrant (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form F-1 (File No. 333-217100), originally filed with the SEC on April 17, 2017).
3.2	Form of Articles of the Registrant (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form F-1 (File No. 333-217100), originally filed with the SEC on April 17, 2017).
4.1	Specimen common share certificate (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form F-1 (File No. 333-217100), originally filed with the SEC on April 24, 2017).
10.1*	First Amendment to Collaboration Agreement, dated May 25, 2020, by and between Zymeworks Inc. and BeiGene, Ltd.
10.2*	Third Amendment to Collaboration Agreement, dated June 22, 2020, by and between Zymeworks Inc., Celgene Corporation and Celgene Alpine Investment Co. LLC.
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 June 30, 2020, formatted in Inline XBRL (Inline eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at June 30, 2020 (unaudited) and December 31, 2019 (audited), (ii) Condensed Consolidated Statements of Loss and Comprehensive Loss for the three and six month periods ended June 30, 2020 and 2019 (unaudited), (iii) Condensed Consolidated Statements of Changes in Shareholders' Equity for the three and six month periods ended June 30, 2020 and 2019 (unaudited), (v) Condensed Consolidated Statements of Cash Flows for the six month periods ended June 30, 2020 and 2019 (unaudited) and (vi) Notes to the Interim Condensed Consolidated Financial Statements (unaudited).
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).
*	Certain portions of this exhibit (indicated by "[…***…]") have been omitted as Zymeworks has determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to Zymeworks if publicly disclosed.

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/ Ali Tehrani

Name: Ali Tehrani

Title: President and Chief Executive Officer and Director (Principal Executive Officer)

Date: August 5, 2020

By: /s/ Neil Klompas

Name: Neil Klompas

Title: Executive Vice President, Business Operations and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

Date: August 5, 2020

Exhibit 10.1

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO ZYMEWORKS INC. IF PUBLICLY DISCLOSED. INFORMATION THAT HAS BEEN OMITTED HAS BEEN NOTED IN THIS DOCUMENT WITH A PLACEHOLDER IDENTIFIED BY THE MARK "[…*…]".**

CONFIDENTIAL

FIRST AMENDMENT TO COLLABORATION AGREEMENT

This First Amendment (the "**Amendment**") to the Agreement (as defined below), is entered into as of May 25, 2020 (the "**Amendment Effective Date**"), by and between **Zymeworks Inc.**, a corporation organized and existing under the laws of British Columbia ("**Zymeworks**"), having a place of business at 540-1385 West 8th Avenue, Vancouver, BC, Canada V6H 3V9, and **BeiGene, Ltd.**, a Cayman Island exempted company incorporated with limited liability ("**BeiGene**"), having a place of business at c/o Mourant Ozannes Corporate Services (Cayman) Limited, 94 Solaris Avenue, Camana Bay, PO Box 1348, Grand Cayman KY1-1108, Cayman Islands. Zymeworks and BeiGene are each referred to individually as a "**Party**" and together as the "**Parties**".

BACKGROUND

A. Zymeworks and BeiGene entered into that certain License and Collaboration Agreement dated November 26, 2018 pursuant to which BeiGene obtained an exclusive license under certain patents and know-how controlled by Zymeworks to develop and commercialize Zymeworks' proprietary bispecific HER2 antibody-drug conjugate known as ZW49 in the Field in the Territory (the "**Agreement**").

B. Zymeworks is conducting clinical development of the Licensed Product outside the Territory and wishes to expand the scope of its clinical development of Licensed Product to certain countries in the Territory (as further described below).

C. BeiGene wishes for Zymeworks to conduct such clinical development in such countries in the Territory.

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

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

AGREEMENT

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

2. **Article 1. Definitions.** Article 1 of the Agreement is hereby amended as follows:

   a. Section 1.18 of the Agreement is hereby deleted in its entirety and replaced with the following:

"**1.18** "**Completion**" means, (a) with respect to Dose Escalation Studies, the date on which […***…] and (b) with respect to the Phase 1 Clinical Trial, the date on which […***…].[1]"

b. The following definitions are hereby added as Sections 1.70 and 1.71, respectively, of the Agreement, and the current Section 1.70 (Additional Definitions) of the Agreement is hereby renumbered as Section 1.72:

"**1.70** "**Dose Escalation Studies**" means a Phase 1 Clinical Trial, or portion thereof, in which subjects are dosed with increasing doses of Licensed Product to establish (a) the maximum tolerated dose of such Licensed Product and (b) one or more recommended doses of such Licensed Product for use in further clinical development of Licensed Product."

"1.71 "**Zymeworks Territory Studies**" means any and all Clinical Trials set forth in the Global Development Plan, other than the ZW49 Multi-Regional Registrational Studies, to the extent such Clinical Trials are to be conducted by Zymeworks in South Korea, New Zealand, Australia or […***…].[2]"

3. **Section 4.1 Technology Transfer.** Section 4.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

"**4.1 Technology Transfer**. The Parties acknowledge that as of the Amendment Effective Date, Zymeworks has transferred to BeiGene certain Zymeworks Know-How existing as of the Effective Date (the "**Initial Technology Transfer**"). Upon Completion of the Phase 1 Clinical Trial for the Licensed Product, Zymeworks shall promptly notify BeiGene in writing, including a copy of the results and other existing information relevant thereto (the "**Clinical Trial Results**") (collectively, the "**Trial Completion Notice**"). Upon Completion of the Dose Escalation Study Zymeworks will promptly notify BeiGene in writing of Completion of the Dose Escalation Study, including a copy of the results and the recommended dose for the Licensed Product (collectively, the "**Dose Identification Notice**"). Within […***…] of the earlier of BeiGene's receipt of (a) the Trial Completion Notice or (b) Dose Identification Notice, Zymeworks will provide and transfer to BeiGene, […***…], the Zymeworks Know-How that exists as of the date of such Trial Completion Notice or Dose Identification Notice and was not previously provided to BeiGene by providing copies or samples of relevant documentation, materials and other embodiments of such Zymeworks Know-How, including data within reports, and electronic files, that exists on the Effective Date (the "**Secondary Technology Transfer**"). During the Term, Zymeworks shall (i) at each meeting of the JSC (and, in any event, on […***…] if any JSC meeting is not held in a particular […***…]), provide BeiGene with a summary of additional Zymeworks Know-How, if any, developed since the last meeting of the JSC, (ii) transfer any such Zymeworks Know-How to BeiGene promptly following BeiGene's reasonable request, (iii) transfer a copy of the results of the Zymeworks Territory Studies to BeiGene, promptly after completion of each such study; and (iv) provide BeiGene with reasonable access to Zymeworks personnel involved in the research and Development of Licensed Products, either in-person at Zymeworks' facility or by teleconference (the "**Continuing Technology Transfer**," and together with the Initial Technology Transfer and the Secondary Technology Transfer, the "**Technology Transfer**"). For the avoidance of doubt, Zymeworks' personnel shall not be obligated to travel to BeiGene's facilities, and Zymeworks' transfer obligations under this Section 4.1 shall apply solely to the extent the Zymeworks Know-How is reasonably necessary to support BeiGene's Development and

[1] Competitive Information – Commercially Sensitive Terms.
[2] Competitive Information – Commercially Sensitive Terms.

Commercialization of the Licensed Product in the Field in the Territory in accordance with this Agreement. Notwithstanding the foregoing, Zymeworks' technology transfer obligations hereunder shall not include the obligation to transfer manufacturing-related Know-How, except as set forth in Section 7.2 or unless otherwise mutually agreed by the Parties in writing. [3]"

4. **Section 5.1 Diligence and Responsibilities.** Section 5.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

"**5.1 Diligence and Responsibilities**. […***…], BeiGene shall be responsible for the Development of the Licensed Products in the Field in the Territory in accordance with this Article 5. […***…], BeiGene shall use Commercially Reasonable Efforts to (i) […***…], and (ii) […***…]. BeiGene shall conduct such tasks in a timely, professional manner and in compliance with the Territory Development Plan and Global Development Plan, as applicable, and all Applicable Laws, including GLP, GCP and cGMP. […***…].[4]"

5. **Section 5.2 Global Development Plan.** Section 5.2 of the Agreement is hereby amended as follows:

a. The first sentence of Section 5.2(b) of the Agreement is hereby deleted in its entirety and replaced with the following:

"[…***…], BeiGene shall use Commercially Reasonable Efforts to perform the Development activities assigned to BeiGene under the Global Development Plan to support the global Development and registration of Licensed Products, […***…].[5]"

b. The following new Section 5.2(c) is hereby appended to Section 5.2 of the Agreement to the end thereof:

"(c) Notwithstanding anything to the contrary herein (including Sections 5.1, 5.2(b) and 6.1), (i) Zymeworks will have the sole right, and shall use Commercially Reasonable Efforts, […***…]; (ii) […***…]; and (iii) Zymeworks, or its designee, will hold all Regulatory Submissions for the Zymeworks Territory Studies, and will control all correspondence and interactions with Regulatory Authorities with respect thereto, unless and until such Regulatory Submissions are assigned to BeiGene pursuant to Section 6.1.[6]"

6. **Section 5.7 Development Reports.** Section 5.7 of the Agreement is hereby amended to append the following new Section 5.7(b) to the end thereof and the current language in Section 5.7 of the Agreement is hereby renumbered as Section 5.7(a):

"(b) Zymeworks shall provide BeiGene with […***…] written reports, […***…], summarizing its conduct of (and Manufacture of Licensed Product for) the Zymeworks Territory Studies, including a summary of the results of such Zymeworks Territory Studies, which reports shall be in English. Subject to BeiGene's right to use and disclose data and results in accordance with Section 5.8 and the licenses and rights to Zymeworks IP granted to BeiGene in Section 2.1, such reports shall be

[3] Competitive Information – Commercially Sensitive Terms.
[4] Competitive Information – Commercially Sensitive Terms.
[5] Competitive Information – Commercially Sensitive Terms.
[6] Competitive Information – Commercially Sensitive Terms.

Confidential Information of Zymeworks pursuant to Article 10. The Parties shall discuss the status, progress and results of Zymeworks Territory Studies at JSC meetings.[7]"

7. **Section 5.8 Data Exchange and Use.** The first sentence of Section 5.8 of the Agreement is hereby deleted in its entirety and replaced with the following:

"In addition to its adverse event and safety data reporting obligations pursuant to Section 6.4, each Party shall promptly (but in any event no later than […***…] from the other Party's request) provide the other Party with copies of all data and results, including all Clinical Data, and all supporting documentation (e.g. protocols, CRFs, analysis plans) Controlled by such Party or its Affiliates that are generated by or on behalf of such Party or its Affiliates or sublicensees, if applicable, in the Development of Licensed Products, including, with respect to Zymeworks, in the conduct of the Zymeworks Territory Studies; provided that Zymeworks shall only be required to provide BeiGene such data, results and documentation to the extent it comprises Zymeworks Know-How and is reasonably necessary or useful for BeiGene's Development or Commercialization of the Licensed Products in the Field in the Territory, including any such data, results and documentation that are reasonably requested by BeiGene or that are necessary to support filings for Regulatory Approval for the Licensed Product in the Territory.[8]"

8. **Section 6.1 Holder of Regulatory Approvals and Regulatory Submissions.** Section 6.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

"**6.1 Holder of Regulatory Approvals and Regulatory Submissions**. BeiGene shall be the holder of Regulatory Approvals and Regulatory Submission for Licensed Products in the Field in the Territory, except as expressly set forth in Section 5.2(c) with respect to the Zymeworks Territory Studies. Zymeworks shall reasonably cooperate with BeiGene, at BeiGene's request and expense, to enable BeiGene to obtain any or all such Regulatory Approvals and Regulatory Submissions. Such cooperation may include transferring the Regulatory Submissions for the Zymeworks Territory Studies to BeiGene, if necessary to enable BeiGene to fulfill its obligations to enroll patients in South Korea, Australia, New Zealand and […***…] in the ZW49 Multi-Regional Registrational Studies in accordance with the Global Development Plan.[9]"

9. **Section 6.4 Adverse Event Reporting.** Section 6.4 of the Agreement is hereby deleted in its entirety and replaced with the following:

"**6.4 Adverse Events Reporting**. Promptly following BeiGene's receipt of (x) the Trial Completion Notice or (y) the Dose Identification Notice, whichever occurs first, but in no event later than […***…] thereafter, BeiGene and Zymeworks shall develop and agree in a written agreement to worldwide safety and pharmacovigilance procedures for the Parties with respect to Licensed Products, such as safety data sharing and exchange, adverse events reporting and prescription events monitoring (the "**Pharmacovigilance Agreement**"). Such Pharmacovigilance Agreement shall (a) describe the obligations of both Parties with respect to the coordination of collection, investigation, reporting and exchange of information between the Parties concerning adverse events or any other safety issue of any significance and product quality and product complaints involving adverse events, in each case with respect to Licensed Products and sufficient to permit each Party and its Affiliates, licensees or

[7] Competitive Information – Commercially Sensitive Terms.
[8] Competitive Information – Commercially Sensitive Terms.
[9] Competitive Information – Commercially Sensitive Terms.

sublicensees to comply with its legal obligations with respect thereto; (b) be promptly updated if required by changes in Applicable Law; (c) provide that (i) BeiGene shall maintain an adverse event database for Clinical Trials conducted in the Territory under the Territory Development Plan and the Global Development Plan, […***…]; (ii) BeiGene shall be responsible for (A) reporting to the applicable Regulatory Authorities in the Territory, all quality complaints, adverse events and safety data related to Licensed Products for all Clinical Trials conducted in the Territory under the Territory Development Plan or the Global Development Plan, (B) responding, to safety issues and to all requests of Regulatory Authorities related to such safety issues with respect to the Licensed Products in the Field in the Territory, in each case ((i) and (ii)), other than the Zymeworks Territory Studies, with respect to which Zymeworks will retain such responsibilities and will keep BeiGene reasonably informed until such time as the Regulatory Submissions for the Zymeworks Territory Studies are assigned to BeiGene pursuant to Section 6.1, at which time BeiGene will assume such responsibilities; (iii) BeiGene shall provide to Zymeworks access to BeiGene's adverse event database for the Licensed Product in the Territory; (iv) Zymeworks shall maintain a global adverse event database for the Licensed Products, including with respect to Clinical Trials conducted under the Global Development Plan, at Zymeworks' cost and expense, except for any costs allocated to BeiGene pursuant to Section 5.4; and (v) Zymeworks will provide BeiGene with adverse event information regarding the Licensed Products in accordance with the PV Agreement; and (d) include the following definition of "adverse event": any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment; an adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not related to the medicinal product.[10]"

10. **Section 7.2.** The first sentence of Section 7.2 of the Agreement is hereby deleted in its entirety and replaced with the following:

"7.2 **Manufacturing Technology Transfer**. In addition to the Zymeworks Know-How provided to BeiGene pursuant to the Initial Technology Transfer and any Secondary Technology Transfer, upon BeiGene's written request, after the earlier of: (a) […***…], and (b) […***…], Zymeworks will promptly prepare and submit to the JSC, for its review, a plan ("**Manufacturing Technology Transfer Plan**") for the transfer to BeiGene of all Know-How Controlled by Zymeworks with respect to the Manufacture of Licensed Product ("**Zymeworks Manufacturing IP**"), and the conduct by Zymeworks of such consultation activities, as are necessary to enable BeiGene or any Third Party contract manufacturing organization (the "**CMO**") designated by BeiGene and agreed by the Parties in writing to manufacture for the Territory (a) the Licensed Antibody-Drug Conjugate as the Active Ingredient of the applicable Licensed Product and/or (b) the applicable Licensed Product (such actions, "**Manufacturing Technology Transfer**").[11]"

11. **Section 7.3(a) Supply by Zymeworks.** The first paragraph of Section 7.3(a) of the Agreement (but not, for clarity, Sections 7.3(a)(i) and 7.3(a)(ii) of the Agreement) is hereby deleted in its entirety and replaced with the following:

"(a) **Development Supply**. Subject to Sections 7.2 and 7.3(b), Zymeworks shall have the right, either by itself or through a Third Party contract manufacturer, to manufacture and supply to

[10] Competitive Information – Commercially Sensitive Terms.
[11] Competitive Information – Commercially Sensitive Terms.

BeiGene all Licensed Products required by BeiGene for Development use in the Territory under the Territory Development Plan and for BeiGene's Development-related responsibilities under the Global Development Plan, including the conduct of any ZW49 Multi-Regional Clinical Study. Subject to Section 7.2, the Parties shall use Commercially Reasonable Efforts to enter into an agreement governing the supply by Zymeworks of such Licensed Products for such Development use by BeiGene ("**Clinical Supply Agreement**") within […***…] following BeiGene's receipt of (x) the Trial Completion Notice or (y) the Dose Identification Notice, whichever occurs first, pursuant to which:[12]"

12. **Section 9.2 Development Milestones.** Section 9.2 of the Agreement is hereby amended to append the following to the end thereof after the table setting forth Development Milestones Events:

"For clarity, any activities conducted by or on behalf of Zymeworks with respect to the […***…] will not trigger a Development Milestone Event. For further clarity, neither BeiGene nor its Affiliates shall be deemed to be acting "on behalf of" Zymeworks for purposes of the foregoing sentence.[13]"

13. **Section 11.1(c) Publications.** The second sentence of Section 11.1(c) of the Agreement is hereby deleted in its entirety and replaced with the following:

"In the event Zymeworks desires to publicly present or publish a Zymeworks Publication that includes data from a Clinical Trial site in the Territory in accordance with the foregoing sentence, including any Zymeworks Publication with respect to Clinical Trial Results or Clinical Data generated in conduct of the Zymeworks Territory Studies, Zymeworks shall provide BeiGene (including the Alliance Manager and all BeiGene members of the JSC) with a copy of such proposed Zymeworks Publication consistent with the applicable Review Period."

14. **Sections 12.5(b) and 12.5(c) Covenants of Zymeworks.** Sections 12.5(b) and 12.5(c) of the Agreement are hereby deleted in its entirety and replaced with the following:

"(b) Zymeworks will conduct its obligations with respect to the Zymeworks Territory Studies and the ZW49 Multi-Regional Registrational Study under the Global Development Plan in strict adherence with the study design set forth in the protocol for such Zymeworks Territory Study or ZW49 Multi-Regional Registrational Study, as applicable, and as set forth in the Global Development Plan, each as may be amended from time to time, and will comply with the statistical analysis plan implemented by Zymeworks in connection therewith;

(c) Zymeworks will only engage Clinical Trial sites under the Global Development Plan, including for the Zymeworks Territory Studies, that conduct all Clinical Trials in compliance with Applicable Laws, including GCP and the ICH Guidelines, and are approved by the applicable Regulatory Authority;"

15. **Exhibit 5.2 ZW Global Development Plan.** Exhibit 5.2 of the Agreement is hereby deleted in its entirety and replaced with Exhibit 5.2 attached to this Amendment.

16. **No Other Modifications.** Except as specifically set forth in this Amendment, the terms and conditions of the Amendment shall remain in full force and effect. No waiver of any obligation under this Amendment shall be effective unless it has been given in writing and signed by the Party giving such waiver. No

[12] Competitive Information – Commercially Sensitive Terms.
[13] Competitive Information – Commercially Sensitive Terms.

provision of this Amendment may be amended or modified other than by a written document signed by authorized representatives of each Party.

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

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

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

ZYMEWORKS INC.

By: /s/ Ali Tehrani
Name: Ali Tehrani, Ph.D.
Title: President & Chief Executive Officer

BEIGENE, LTD.

By: /s/ Guillaume Vignon
Name: Guillaume Vignon
Title: SVP, Business Development

Exhibit 5.2

ZW49

GLOBAL DEVELOPMENT PLAN

[…***…][14]

[14] Competitive Information – Discovery Information and Technical Information.

Exhibit 10.2

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO ZYMEWORKS INC. IF PUBLICLY DISCLOSED. INFORMATION THAT HAS BEEN OMITTED HAS BEEN NOTED IN THIS DOCUMENT WITH A PLACEHOLDER IDENTIFIED BY THE MARK "[…*…]".**

CONFIDENTIAL

THIRD AMENDMENT TO COLLABORATION AGREEMENT

This Third Amendment (the "**Amendment**") to the Agreement (as defined below), is entered into as of June 22, 2020 (the "**Amendment Effective Date**"), by and between **CELGENE CORPORATION**, a corporation organized and existing under the laws of Delaware, with its principal business office located at 86 Morris Avenue, Summit, NJ 07901, USA ("**Celgene Corp.**"), **CELGENE ALPINE INVESTMENT CO. LLC** ("**Celgene Alpine**" and, together with Celgene Corp., "**Celgene**") and **ZYMEWORKS INC.**, a corporation organized and existing under the laws of British Columbia, having an address at 540-1385 West 8th Avenue, Vancouver, BC, Canada V6H 3V9 ("**Zymeworks**"). Zymeworks and Celgene are each referred to individually as a "**Party**" and together as the "**Parties**".

BACKGROUND

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

B. Prior to the Amendment Effective Date, Celgene extended the Research Program Term (as defined in the Agreement) by an additional twenty-four (24) months to April 23, 2020 by providing notice and a non-refundable payment of [**…*****…**][1] dollars ($[**…*****…**][2] USD) to Zymeworks, and further extended the Research Program Term to [**…*****…**][3].

C. Celgene wishes to make an additional payment to Zymeworks to further extend the Research Program Term and make such other changes to the Agreement as set forth herein and Zymeworks is willing to provide such extension and make such other changes to the Agreement in exchange for such additional payment.

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

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

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[1] Competitive Information – Financial Provisions.
[2] Competitive Information – Financial Provisions.
[3] Competetive Information – Commercially Sensitive Terms.

AGREEMENT

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

2. **Amendment Upfront Payment.** In consideration of this Amendment, Celgene shall pay to Zymeworks a one-time, non-refundable upfront payment of […***…][4] US Dollars (USD $[…***…][5]), paid 50% by Celgene Corp. and 50% by Celgene Alpine, within […***…][6] following the Amendment Effective Date.

3. **Zymeworks Platform Definition.** Section 1.61 of the Agreement is hereby deleted in its entirety and replaced with the following:

   "**1.61 "Zymeworks Platform"** means (a) Zymeworks' proprietary […***…][7] mutations which enable the efficient formation of […***…][8], alone or in conjunction with (b) Zymeworks' proprietary […***…][9] platform solely for the following […***…][10] mutations: […***…][11]. For clarity, references to the Zymeworks Platform with respect to the […***…][12] platform shall only include the […***…][13] mutations […***…][14]."

4. **Section 2.1.2. Option.** The reference to eight (8) Collaboration Sequence Pairs in Section 2.1.2 is hereby replaced with a reference to […***…][15] Collaboration Sequence Pairs. The last sentence of the first paragraph of Section 2.1.2 is hereby deleted in its entirety.

5. **Section 3.1.2. Research Program Term.** Section 3.1.2 of the Agreement is hereby deleted in its entirety and replaced with the following:

   "**3.1.2 Research Program Term**. The Research Program shall commence on the Effective Date and shall conclude on […***…][16] (such period, the **"Research Program Term"**).

6. **Section 3.4. Collaboration Sequence Pairs; Definitions. Section 3.4 of the Agreement is hereby deleted in its entirety and replaced with the following:**

   "Subject to gatekeeping pursuant to Section 3.5, the Parties (through the JRC) may select, in accordance with this Article 3 and during the Research Program Term, up to [**…***…**][17] Collaboration Sequence Pairs for incorporation into Antibodies pursuant to the Workplan. To designate a Sequence Pair as a Collaboration Sequence Pair, Celgene shall provide Zymeworks with written notice of such

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[4] Competitive Information – Financial Provisions.
[5] Competitive Information – Financial Provisions.
[6] Competetive Information – Commercially Sensitive Terms.
[7] Competitive Information – Commercially Sensitive Terms.
[8] Competitive Information – Commercially Sensitive Terms.
[9] Competitive Information – Commercially Sensitive Terms.
[10] Competitive Information – Commercially Sensitive Terms.
[11] Competitive Information – Commercially Sensitive Terms.
[12] Competitive Information – Commercially Sensitive Terms.
[13] Competitive Information – Commercially Sensitive Terms.
[14] Competitive Information – Commercially Sensitive Terms.
[15] Competitive Information – Commercially Sensitive Terms.
[16] Competitive Information – Commercially Sensitive Terms.
[17] Competitive Information – Commercially Sensitive Terms.

Sequence Pair, setting forth the Sequences included in such Sequence Pair and the Target(s) To which they are Directed, and requesting that such Sequence Pair be submitted to gatekeeping (each, a "**Designation Notice**"). Each designated Sequence Pair shall then be subject to gatekeeping pursuant to Section 3.5 below, and if a designated Sequence Pair is available in accordance with such gatekeeping, and is further approved by the JRC, it then becomes a "**Collaboration Sequence Pair,**" and Celgene shall have [**…***…**][18] with respect to such Collaboration Sequence Pair, meaning that Zymeworks will not (alone or in collaboration with a Third Party) apply the Zymeworks Platform to such Collaboration Sequence Pair or Sequence Pairs that are [**…***…**][19] to both [**…***…**][20], other than pursuant to the Research Program; provided that, for so long as a Collaboration Sequence Pair is the Confidential Information of Celgene, Zymeworks shall not, for the purpose of avoiding [**…***…**][21], reverse engineer such Collaboration Sequence Pair, or otherwise start with such Collaboration Sequence Pair and [**…***…**][22] to create a Sequence Pair which is [**…***…**][23]. For clarity, the foregoing shall not limit Zymeworks' ability to apply the Zymeworks Platform (alone or in collaboration with a Third Party) to any Sequence Pair that is [**…***…**][24], which Sequence Pair is generated and provided to it by a Third Party without access to the Collaboration Sequence Pair through Zymeworks. For clarity, the Parties (through the JRC) may submit more than [**…***…**][25] Sequence Pairs for consideration as potential Collaboration Sequence Pairs during the Research Program Term, but [**…***…**][26] shall not arise until any given Sequence Pair is actually designated as a Collaboration Sequence Pair pursuant to this Section 3.4 and Section 3.5. Accordingly, Zymeworks acknowledges that Celgene may be investigating Sequence Pairs as potential Collaboration Sequence Pairs, which investigation may include use of the Zymeworks Platform. Subject to gatekeeping pursuant to Section 3.5, the Parties (through the JRC) may freely change Collaboration Sequence Pairs during the Research Program Term (e.g. by proposing another Sequence Pair in a new Designation Notice and if such Sequence Pair passes gatekeeping, by then removing a previously-designated Collaboration Sequence Pair); provided that such changes shall not occur so frequently as to be unduly burdensome to Zymeworks and that in no event shall Celgene have more than [**…***…**][27] Collaboration Sequence Pairs at any given time."

7. **Section 5.3. Upfront License Fee.** The penultimate sentence of Section 5.3 is hereby deleted in its entirety and replaced with the following:

   "For clarity, if Celgene exercises the Option with respect to all [**…***…**][28] for which it has the right to exercise the Option, Celgene shall pay to Zymeworks a total of [**…***…**][29] U.S. Dollars (USD $[**…***…**][30]), paid 50% by Celgene Corp. and 50% by Celgene Alpine."

8. **No Other Modifications.** Except as specifically set forth in this Amendment, the terms and conditions of the Amendment shall remain in full force and effect. No waiver of any obligation under this Amendment

[18] Competitive Information – Commercially Sensitive Terms.
[19] Competitive Information – Commercially Sensitive Terms.
[20] Competitive Information – Commercially Sensitive Terms.
[21] Competitive Information – Commercially Sensitive Terms.
[22] Competitive Information – Commercially Sensitive Terms.
[23] Competitive Information – Commercially Sensitive Terms.
[24] Competitive Information – Commercially Sensitive Terms.
[25] Competitive Information – Commercially Sensitive Terms.
[26] Competitive Information – Commercially Sensitive Terms.
[27] Competitive Information – Commercially Sensitive Terms.
[28] Competitive Information – Commercially Sensitive Terms.
[29] Competitive Information – Financial Provisions.
[30] Competitive Information – Financial Provisions.

shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Amendment may be amended or modified other than by a written document signed by authorized representatives of each Party.

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

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

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

ZYMEWORKS INC.

By: /s/ Ali Tehrani
Name: Ali Tehrani, Ph.D.
Title: President & Chief Executive Officer

CELGENE CORPORATION

By: /s/ Ho Cho
Name: Ho Cho
Title: SVP, Discovery Biotherapeutics

CELGENE ALPINE INVESTMENT CO. LLC

By: /s/ Kevin Mello
Name: Kevin Mello
Title: Manager

Exhibit 31.1

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

I, Ali Tehrani, 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: August 5, 2020

/s/ Ali Tehrani

Chief Executive Officer

Exhibit 31.2

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

I, Neil Klompas, 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: August 5, 2020

/s/ Neil Klompas

Chief Financial Officer

Exhibit 32.1

SECTION 906 CERTIFICATION

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code) in connection with the Quarterly Report on Form 10-Q of Zymeworks Inc. for the quarterly period ended June 30, 2020 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/ Ali Tehrani

Name:	Ali Tehrani
Title:	Chief Executive Officer
Date:	August 5, 2020

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

Exhibit 32.2

SECTION 906 CERTIFICATION

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code) in connection with the Quarterly Report on Form 10-Q of Zymeworks Inc. for the quarterly period ended June 30, 2020 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/ Neil Klompas

Name: Neil Klompas

Title: Chief Financial Officer

Date: August 5, 2020

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.